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Intra-operative Waste in Spine Surgery: Incidence, Cost, and Effectiveness of an Educational Program

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Introduction: Each year, over 600 000 surgical interventions are performed on the spine in the USA. Spine procedures are known for their associated high cost, particularly in cases where instrumentation is employed. Intra-operative waste—defined by previous authors as products that were prepared but not used during the surgery, and could not be reused for a different patient—can contribute to the high cost of spine surgery. Prior studies have demonstrated that surgical implant waste is a factor influencing cost in arthroplasty and orthopaedic trauma. However, the role of intra-operative waste has not yet been studied in the context of spine surgery. This study aims to quantify the incidence of intra-operative waste in spine surgery, and to examine the efficiency of an educational program directed at surgeons in inducing a decrease in the intra-operative waste.

Methods: Data was collected during a 25-month period (October 2007 to November 2009) from one academic center. The total number of spine procedures, and the incidence of intra-operative waste were recorded prospectively. Other variable recorded included the type of product wasted, cost associated with the product or implant wasted, and reason for the waste. After an initial observation period of 15 months, an educational program was put in place. Surgeons were made aware of the definition of intra-operative waste, and data on total cost incurred was presented. Data was collected for an additional 10 months after the intervention. Statistical analysis was performed with STATA (v11.0), using X², t-tests, and regression analysis as deemed appropriate. A p-value of less than 0.05 was considered significant.

Results: Intra-operative waste occurred in 20.2% of the procedures prior to the educational program and in 10.3% of the procedures after the implementation of the program (p<0.001). Monthly costs associated with surgical waste were, on average 17680.29$ prior to the awareness intervention, and 5876.87$ afterwards (p=0.0006). Further analysis of our data revealed that implant waste was associated with a higher cost than other types of waste (662.5$/item, p<0.001). In cases where the reason of wastage was the surgeon’s change of mind, a higher cost per item wasted was observed (532.9$/item, p<0.001). Our educational program allowed us to decrease the number of implants wasted (OR 0.434 p<0.001), and the incidence of surgeons’ change of mind (OR 0.41, p<0.001).

Discussion: To our knowledge, this is the first study looking at the incidence of intra-operative waste in spine surgery, and evaluating the effectiveness of an awareness program. According to our results, the incidence of surgical waste related to spine surgery is considerably higher than that published in the trauma and arthroplasty literature. Prior to the educational intervention, the annualized cost related to surgical waste was 212 000$ at our institution. Extrapolation of our data to the national level leads to an annual estimate of 127 200 000 $ attributable to intra-operative waste. A program that made surgeons aware of costs related to surgical waste allowed us to reduce that value by 66%. This study demonstrates that surgical waste is an important cost in spine surgery, and that surgeon awareness may help contribute to decrease the cost burden.
Metanalysis of Class I Results of Anterior Cervical Discectomy and Fusion with Allograft and Plating

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Purpose: What are the clinical results of anterior cervical discectomy and fusion (ACDF) with plating? Most spine surgeons would answer a one-level ACDF has a 95% fusion rate and 95% excellent clinical results. This perception is based on class III or class IV data, retrospective reviews typically performed by a spine fellow or resident on a senior author’s surgical series.

Materials and methods: Class I data from six FDA IDE studies involving ACDF allograft with plating were reviewed. The studies include: The Prestige (265 patients), ProDisc (103 patients), Bryan (221 patients), PCM (185 patients), Kineflex-C (133 patients), and Secure-C (144 patients) artificial discs versus intervertebral allograft with plating. Total number of patients included in this metanalysis was 1,051. FDA clinical success was very similar in all studies and defined as a 15 point or 20% improvement in NDI, no reoperation, and no neurologic deterioration.

Results: The average re-operation rate for a pseudoarthrosis, adjacent level degeneration, or index level revision at two year follow-up was 9.8% (table one illustrates individual study results). Clinical success rates at two year follow up averaged 68% (table two illustrates individual study results).

Conclusions: Based on a metanalysis of class I data, the results of ACDF with allograft and plating are a 9.8% reoperation rate at two-year follow-up due to pseudoarthrosis, adjacent level degeneration or revision of the index surgical site and a 68% clinical success. These results emphasize the importance in differentiating the validity of information gained from class I versus class III and IV data.

Clinical Outcomes after Cervical Disc Arthroplasty for Workers’ Compensation Patients

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Introduction: The evidence-based literature offers little support for surgical treatment of spine patients with workers’ compensation claims. Low back pain patients treated surgically in the SPORT study, for example, were generally found to have significantly greater improvement after two years than nonoperative patients, while claimants saw no added benefit with surgery. Cervical disc arthroplasty (CDA) in workers’ compensation patients, however, has been reported to provide significant improvement in pain and disability outcomes, and significantly earlier return to work than anterior cervical discectomy and fusion in recent IDE studies. In this study with up to 3-year follow up (ongoing) we compare clinical outcomes of CDA patients at a single site with a large workers’ compensation population.

Methods: This is a review of prospectively collected data for 223 consecutive patients treated with CDA for symptomatic cervical degenerative disease unresponsive to nonoperative measures. A total of 157 workers’ compensation claimants (WC) and 66 patients without claims (NC) underwent CDA at one to four levels, with over 90% in each group treated at 1 or 2 levels. Patient demographics, intraoperative measures including operative time and blood loss, postoperative outcomes including Neck Disability Index (NDI), neck and arm pain numerical questionnaires, and work status were analyzed preoperatively and at 1.5, 3, 6, 12, 24 and 36 months.

Results: Demographics were similar between groups; in total 58% were male, with an overall average age of 45.3 years (range 25–71) and average weight of 195.1 pounds. More WC were smokers (p=0.04). Preoperative disability and pain scores were statistically equivalent. Mean operative time was 82.6 minutes (avg. 58.6 per treated level), and estimated mean blood loss was 49.3 cc, with no significant differences between groups. Mean improvements vs. baseline in NDI, neck and arm pain were all significant for both WC and NC patients at all intervals. At 12, 24, and 36 months, NDI mean improvements for WC/NC were: 29.5/34.9, 29.7/32.9, and 42.1/34.9 points, with no significant differences between groups. Substantial neck and arm pain score improvement was similarly achieved in both groups. Medical release to work had been given to over 90% of patients in both groups who were beyond their 6-week follow up.

Conclusions: In this large cohort of single and multilevel CDA patients at a single site, mean disability and pain score improvements up to three years postoperatively were significant and indicative of substantial clinical benefit from surgery. There was no significant difference for patients in

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the WC and NC groups. Appropriately selected worker’s compensation claimants with cervical degenerative disease at one or more levels may be effectively treated and released to return to work with CDA.

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A Prospective, Randomized, Pivotal Study of the SECURE®-C Cervical Artificial Disc: Two Year Outcomes  

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Purpose: Clinical outcomes from a pivotal 380 patient Investigational Device Exemption (IDE) study to evaluate the safety and effectiveness of the SECURE®-C Cervical Artificial Disc are presented.  

Methods: A prospective, randomized pivotal study of the SECURE®-C device (Globus Medical, Audubon, PA) compared to control fusion was conducted at eighteen centers across the U.S. Enrolled patients were randomized 1:1 to either the investigational SECURE®-C disc or the control anterior cervical discectomy and fusion (ACDF), with the exception of the first five non-randomized patients from each site who received the disc. Indications for study participation included symptomatic cervical disc disease (SCDD) in one vertebral level between C3 and C7 defined by neck and/or arm pain, herniated nucleus pulposus, radiculopathy or myelopathy. Outcome measures and radiographic evaluations were collected pre-operatively and at 6 weeks, 3 and 6 months, and 1 and 2 years post-operatively. An individual patient was considered to be a success by meeting the following criteria: pain/disability improvement of at least 25% in Neck Disability Index (NDI); no device failures requiring revision, re-operation or removal; absence of major complications; and radiographic fusion (control patients only). Alternative definitions of overall success included improvement of NDI in points rather than percentage, maintenance or improvement in neurologic status, absence of device-related events, and intraoperative changes in treatment as failures. Secondary outcome measurements included Visual Analog Scale (VAS) neck and arm pain, SF-36 Health Status survey, and patient satisfaction.  

Results summary: Three hundred eighty (380) patients were treated in this study. Data is presented from randomized patients only: 151 patients received the investigational SECURE®-C device and 140 received the control ACDF. There were no differences in gender, age, race, height, weight or BMI between the two randomized groups. Eighty nine percent (89.2%) of SECURE®-C patients demonstrated NDI improvement vs. 84.3% of control patients. Ninety six percent (96.0%) of SECURE®-C and 94.9% of ACDF patients were neurological successes. Two percent (2.1%) of SECURE®-C patients required a removal, revision or reoperation at the index level as compared to 6.9% for the control group. There were no device-related adverse events reported in 96.6% of the investigational cohort vs. 91.6% of the control. Ninety eight percent (98.0%) of those treated with the investigational device experienced no intraoperative change in treatment and 89.1% of control patients demonstrated radiographic fusion. Both groups also showed statistically significant improvement in VAS neck and arm pain at 2 years compared to preoperative values. At 24 months post-op, patient satisfaction was 95.7% for the SECURE®-C group and 85.2% for the ACDF group. Overall success rates were 90.1% for the SECURE®-C group and 71.7% for the control group, using the original protocol definition. Superiority of the SECURE®-C group to the control was established for overall success, with a posterior probability of 100% for the protocol-specified overall success and 98%-99% for alternative definitions of overall success.  

Conclusion: Study results indicate that the SECURE®-C Cervical Artificial Disc is a safe and effective treatment for symptomatic cervical disc disease, as an alternative to anterior discectomy and fusion.

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Cost-effectiveness of Single-level Cervical Disc Arthroplasty  
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Background context: Regulators and payers increasingly look at cost-effectiveness analysis, aimed at demonstrating value for money when considering the introduction of technology such as cervical disc arthroplasty (CDA).  

Purpose: Formal economic evaluation of CDA with either the Bryan® or Prestige® (Medtronic, Memphis, TN) disc versus ACDF in the Australian context.  

Study design: Clinical data from two IDE RCT’s were combined with cost data to produce an economic model assessing the cost-effectiveness of CDA compared to cervical disectomy and fusion (ACDF).  

Patient sample: 1004 patients from US IDE randomized trials comparing either Bryan or Prestige disc with ACDF.  

Methods: Outcome measures for each technique were used to estimate quality adjusted life years (QALYs), by transforming unpublished SF-36 data into preference based SF-6D utility weights. A Markov process, with a cohort expected value analysis was performed. The model used monthly cycles and a duration of five years. There were six possible health states: surgery; success; failure; index re-operation; adjacent re-operation and multilevel reoperation, with transition probabilities determined by trial outcome frequency. Billing codes for medical procedures and ancillary services were determined through expert opinion and for ACDF, after averaging across various ACDF techniques using cost weights derived from sales figures for fusion implants provided by Medtronic. The costs of each service, prosthesis, hospital stay and for lost productivity costs due to work absence were sourced from various Australian government databases. Expected per-patient costs were calculated for five years. This data was used in conjunction with the QALY estimate to calculate the incremental cost-effectiveness ratio (ICER) of CDA versus ACDF.  

Results: Accounting for all downstream costs, including productivity loss by work absence, CDA was estimated to cost AU$803 less than ACDF per treated individual over a five year period. Further, the CDA group accrued 0.13 QALYs more than the ACDF group (3.43 QALYs for CDA versus 3.31 QALYs for ACDF). Removal of the impact of re-operations reduced the cost saving offered by CDA but the intervention remained cost-saving overall. Removal of the productivity losses (adopting a health care perspective only), increased the incremental cost of CDA to AU$1200, with an ICER of AU$10,395 per QALY gained. The model also demonstrated that the cost-effectiveness of CDA is sensitive to prosthesis price and overall success rate. Increasing the prosthesis price by 20% leads to an incremental cost of AU$554, with an ICER per QALY of AU$4795, while lowering the probability of overall success in the CDA arm of the model to its lower 95%
confidence interval leads to an incremental cost of AUS322, with an ICER of per QALY of AUS4425. Two-way sensitivity analysis assessing the impact of reducing the overall success rate to its lower 95% confidence interval and simultaneously removing the productivity losses resulted in an ICER of AUS27352 per QALY.

Conclusions: From the perspective of a reimbursement authority, there is a clear argument for use of CDA over ACDF in single-level surgery, with CDA being associated with a lower overall cost and improved quality of life. Worst case assumptions suggest that any incremental cost of CDA is offset by an acceptable incremental increase in quality of life.

134 Does Sagittal Position of the CTDR Related Center of Rotation Influence Functional Outcome? Prospective 1 Year Follow-up Analysis


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Aims: Segmental range of motion (ROM) and restoration of cervical spine balance in the sagittal profile are currently considered to be essential aspects for CTDR success, influencing the risk for future adjacent segment degenerations. But what is the role of implant related center of rotation positioning in this coherence?

Methods: We analyzed the interim results of 111 patients (47m, 64f), who were treated with single-level (2xC3/4, 7xC4/5, 56xC5/6, 46xC6/7) CTDR (activ C™) at 11 European sites. 81 of them received a standard and 30 a flat implant version. One major difference between both types is the sagittal position of the center of rotation, which is more anterior in flat components, depending on the implant size. Examinations took place pre-operatively, 6 weeks, 6 months and 1 year postoperatively. Computerized radiographic measures and statistical analysis were performed independently.

Results: Mean NDI changed from 40.1 preoperatively to 22.2 at 6 weeks, 19.8 at 6 months and 19.9 at 1 year follow-up, mean VAS for neck pain severity from 52.0 to 23.1, 22.6, and 21.8 respectively. This substantial postoperative improvement was statistically significant (p<0.001) for all outcome measures, but there were no significant differences by implant type apart from NDI after 6 weeks (p=0.037). For standard components the mean preoperative segmental angle increased from -2.3° lordosis to -5.4° after 6 weeks and remained at -5.2 after 6 months and -5.3° after 1 year and for flat components from -1.0° lordosis to -5.9° after 6 weeks and remained at -6.1 after 6 months and -6.0° after 1 year (no significant differences by implant version). However, correction of disc angle achieved (preop vs. 1 year) differed between standard and flat implants (3° vs. 5° lordotic correction, p=0.008). Correlation analyses showed a medium effect (Pearson Rho -0.322, p<0.001) between the COR of the implant relative to the midpoint of the inferior endplate (CORi) and correction achieved.

ROM was for standard components 9.6° preoperatively, 7.6° after 6 weeks and 7.8° after 6 months. For flat components these measures were 9.0°, 9.4° and 8.7°. Significant differences between both groups were detected after 6 weeks (p=0.049), but there was no statistically significant correlation between CORi and ROM after 6 months.

Lateral device placement was considered to be ideal for all cases (111/111) just as all devices (111/111) were intact. No device subsidence (>3mm), migration (>3mm) or expulsion occurred (0/111) and 3/111 cases showed signs of osteolysis.

Conclusions: Our results demonstrate a relationship between the sagittal position of the COR of cervical disc prostheses and mid-term correction of cervical lordosis: the more anterior the CORi, the higher the lordotic correction achieved. As proper sagittal profil seems to be essential for good rotational movement in the long term, future analysis should investigate the development of segmental motion. For clinical practice we suggest to consider COR positioning for specific CTDR devices accordingly.

347 Clinical Outcomes of Prestige LP Cervical Disc Arthroplasty: A Prospective, Controlled, Single Site Trial with 24-month Follow-up

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Study design: A prospective, controlled, one center study of surgical treatment of cervical disc disease.

Objective: To report safety and efficacy of cervical disc arthroplasty using Prestige LP cervical disc device at 24 months follow-up.

Methods: A total of 78 patients were enrolled at our site as study investigating ACDF versus Prestige LP cervical disc prosthesi. 40 patients received the investigational device and 38 patients underwent a single-level anterior cervical disectomy and decompression and fusion as the control group. Clinical outcomes are now reported at 24 months follow-up for our cohort of participants. Japanese Orthopedics Association score (JOA), neck/arm pain VAS scores, Neck disability index score (NDI) and SF-36 both physical and mental as well as complications are reported.

Results: Demographic and surgical data were generally similar in two groups. Clinical outcome data collected at routine postoperative intervals for 24 months demonstrated that the both group has favorably demonstrated improved functional outcomes for JOA, neck/arm pain VAS scores, NDI and the SF-36 physical and mental health component scores. Compared the groups, the improvement in the JOA score was equivalent at 24 months (P=0.553). Pain relief for both neck and arm was similar between groups (P=0.561, P=0.611). Investigational group had statistically significant (P<0.05) improvements as assessed by the Neck Disability Index, the SF-36 both Physical and Mental component scores compared with the control group at some follow-up points. During the course of the 2-years follow-up, in control group, 3 patients (7.9%) received surgical intervention and 4 patients(10.5%) complained paraesthesia of bone-harvesting skin, while 3 patients(7.5%) in the investigational group were observed less than 3mm anterior device migrations in the early follow-up.

Conclusions: At 24 months, cervical arthroplasty with the...
Prestige LP cervical disc prosthesis compares favorably to ACDF at our study. The results indicate that Prestige LP cervical disc arthroplasty is a feasible alternative to the patients with persistently symptomatic cervical disc disease. Keywords: Prestige LP cervical disc, cervical arthroplasty, prospective, ACDF.

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Radiographic Outcomes Following Cervical Disc Arthroplasty Compared to Anterior Cervical Disciscectomy and Fusion in a Prospective Randomized Study
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Purpose: The intent of cervical disc arthroplasty is to maintain normal physiologic motion of the cervical spine rather than traditional fusion which immobilizes the diseased segment. Radiographic outcomes of cervical arthroplasty as compared to anterior discectomy and fusion were assessed in a prospective, randomized clinical trial of the SECURE®-C Artificial Disc (Globus Medical, Audubon, PA).

Methods: A prospective randomized IDE study of the SECURE®-C device compared to control ACDF was conducted at eighteen participating sites in the USA. Enrolled patients were randomized 1:1 to either the investigational SECURE®-C disc or the control ACDF, with the exception of the first five non-randomized patients from each site who received the investigational treatment. The dual articulating device allows for a range of motion of up to 30° (±15°) during flexion-extension, 20° (±10°) lateral bending, unlimited axial rotation, and 1.25mm of translation in the sagittal plane. Indications for study participation included symptomatic cervical disc disease (SCDD) in one vertebral level between C3 and C7 defined by neck and/or arm pain, herniated nucleus pulposus, radiculopathy or myelopathy. Anterior-posterior and lateral films were obtained preoperatively and at 6 weeks, 3 months, 6 months, 1 year and 2 years post-operatively. Flexion/extension radiographs were obtained preoperatively and at 6, 12 and 24 months post-op. Measurement of disc height and range of motion (flexion-extension and AP translation) on flexion/extension films was conducted by Medical Metrics, Houston, TX. Data from IDE sites having received approval by their respective Institutional Review Boards are presented.

Results summary: Three hundred eighty (380) patients were treated in this IDE. Data is presented from randomized patients only: 151 patients received the investigational SECURE®-C device and 140 received the control ACDF. Flexion-extension range of motion increased for SECURE®-C patients, with 8.5° (±4.80) at preop and 9.3° (±5.91) at 2 years, as compared to ACDF patients who had 7.2° (±4.31) of motion preop, that decreased to 0.70° (±0.72). AP translation during flexion-extension also increased for SECURE®-C patients, with 0.9mm (±0.62) at preop and 1.2mm (±0.81) at 2 years, which compares to ACDF patients who had 0.8mm (±0.59) of motion preop that decreased to 0.1mm (±0.08).

Disc height increased significantly for patients treated in the SECURE®-C cohort; the pre-op average was 3.8mm (±0.75) and increased to 5.7mm (±0.99) at 2 years. In the ACDF group the average pre-op disc height was measured at 3.7mm (±0.71) and grew to 4.3mm (±1.24) for those reaching 2 years. No device migrations or displacements, including superior and inferior subsidence, were observed in any patients treated with the SECURE®-C device. Radiolucencies of more than 25% were evaluated; none of the SEC patients and 3.8% of the control demonstrated radiolucencies at 24 months post-operative.

Conclusion: The SECURE®-C group had greater range of motion and increased disc heights as compared to the ACDF group, as expected. The unique dual articulating design of the SECURE®-C implant allows for AP translation during motion. The SECURE®-C device may help restore and maintain normal physiologic motion and increase disc height in the cervical spine.

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Spinal Kinetics M6®-C German Registry: 24 Month Clinical and Radiographic Outcomes
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Introduction: The M6-C artificial cervical disc (Spinal Kinetics, Sunnyvale, CA) is an advanced generation artificial disc developed to treat degenerative cervical radiculopathy. It is designed to replicate the anatomic structure of a natural disc by incorporating an artificial nucleus and annulus. The compressible polymer nucleus of the M6-C is designed to simulate the function of the native nucleus, while the surrounding multi-layer high tensile strength fiber annulus is intended to provide a controlled range of motion. This unique design allows the M6-C prosthesis to have all 6 degrees of freedom to include angular motion in flexion-extension, lateral bending and axial rotation as well as allowing independent translations along the 3 anatomic planes (anterior/posterior, side to side and axial compression).

Methods: The M6-C German Registry is a single arm, prospective registry intended to evaluate the safety and clinical performance of the M6-C artificial cervical disc for the treatment of symptomatic cervical radiculopathy at one or more levels. Ethics Committee approval was attained prior to initiation. Patients enrolled in the registry signed a study specific informed consent, met the requirements of the Instructions for Use for the device and underwent unsuccessful conservative care prior to surgery. Patients were evaluated pre-operatively and post-operatively at 3 months, 12 months and 24 months. Evaluations at each visit included a routine neurological examination, the Neck Disability Index (NDI), arm and neck pain assessments (VAS) and Quality of Life (SF-36v2). In addition, AP, Lateral and Flexion/Extension x-rays were obtained for both quantitative and qualitative assessment (Medical Metrics, Inc., Houston, TX). Adverse events were monitored to evaluate safety.

Results: Fifty patients (24 males and 26 females) have been followed for up to 24 months with a mean age of 44 yrs for the males and 43 yrs for the females. Forty-six patients were treated at 1 level and 4 at 2 levels for a total of 54 implanted discs. Thirty discs were implanted at C5/C6, 23 at C6/C7 and 1 at C4/C5. The mean duration of surgery was 78 minutes. The mean NDI decreased significantly from baseline to 24 months and on 10-point scales, both the neck and arm pain VAS also decreased significantly through 24 months. Both the Physical Component Summary (PCS) and Mental Component Summary (MCS) of the SF-36 increased significantly from...
baseline and have been maintained through 24 months. Surgeon assessment indicated excellent or good results for 88% of the patients, and 88% of the patients reported improvement to complete recovery. Index Level ROM, Global ROM and Disc Angle increased significantly after surgery and have been maintained over time. Device position has been maintained with no evidence of device migration or expulsion. The incidence of Heterotopic Ossification (HO) was somewhat higher than anticipated at 24 months. One patient had the disc removed at 3 months due to subsidence. There have been no additional serious device related adverse events.

**Conclusion:** Clinical and radiographic data from the M6-C German Registry indicates acceptable clinical and radiographic outcomes at 24 months post procedure.

### 542 Does CTDR Have a Lower Risk of Device Subsidence Compared to ACDF? 1 Year Results of a Prospective Multicenter Study


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Although ACDF is an effective procedure for the treatment of DDD, loss of segmental disc height and cage subsidence, possibly resulting in kyphotic deformity, pseudarthrosis and worsening of clinical outcome, are common concerns. Various factors may influence subsidence, but certainly the biomechanical situation at the bone-implant interface is an important one, influenced by the devices’ operative technique, primary stability, geometry and contact area. While the preservation of segmental motion and a lower risk for adjacent segment degeneration are the main pros for CTDR, this technology may also contribute to a reduced risk of subsidence.

Therefore we investigated the one year interim results (n=111) of a prospective, multicenter study, performed at 11 European sites. All patients (mean age 43.3 years; male = 47; female = 64) underwent single-level total disc replacement (activ™ C disc prosthesis) between C3/4 and C6/7 (C3/4=7, C4/5=6.5, C5/6=4.6) and were followed-up 6 wk, 6 mo and 1 y postoperatively. Radiographic measures were performed independently by using computer-aided image processing. Disc height is calculated as the average anterior and posterior disc height (distance between anterior (posterior) edge of the inferior endplate of the superior vertebra, and the corresponding edge of the inferior vertebra). Mean disc heights were as follows: preop 3.7 mm, postop 6.4 mm, 6wk 5.8 mm, 6mo 5.7 mm, 1y 5.6 mm. Statistically significant differences were detected between preop/postop, postop/6wk and 6wk/6mo (p<0.001), and after 1 year (p=0.009 Linear Contrasts, ANOVA). Mean loss of disc height by level was 1.1 mm for C3/4, 1.2 mm for C4/5, 0.8 mm for C5/6 and 0.7 mm for C6/7 (overall loss of disc height 0.8 mm). The subsidence rate (loss of height >3 mm) in our study is 0% (0/111) or, based on a subsidence definition of >2 mm, 6.3% (7/111).

Mean segmental lوردosis increased significantly from 1.9° preop to 5.5° after 1 year (p>0.001, Paired Samples T-Test). Also clinical outcome (NDI, VAS neck pain, VAS arm pain) improved significantly from preop to 1 year postop as follows: 40.1 to 19.9, 52.0 to 24.0, and 53.6 to 20.0, respectively (p<.001 Wilcoxon Signed Ranks Test). There is no correlation between loss of disc height after 1y and clinical outcome (p>0.05 Spearman’s Correlation).

### Breakout 1: Cervical TDR

### 116 Cervical Disc Prosthesis versus Arthrodesis Using One-level, Hybrid and Two-level Constructs. An in vitro Investigation

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**Study design:** Biomechanical In Vitro evaluation using human cadaveric cervical spines.

**Objectives:** To analyse cervical spine kinematics after 1-level and 2-level total disc replacement (TDR) and compare them with those after anterior cervical arthrodesis (ACA) and hybrid construct. Kinematics and intradiscal pressures were also investigated at adjacent levels.

**Methods:** Twelve human cadaveric spines from C2 to T2 were divided in two groups. In group A, six specimens were evaluated intact, after TDR (Discocerv™, Scient’x/Alphatec Spine Inc., Carlsbad, CA) at C5–C6, after TDR at C5–C6 and C4–C5, and after ACA at C4–C5 and C5–C6. In group B, the six specimens were evaluated intact, after ACA at C5–C6 and after additional TDR at C4–C5 (hybrid construct). All tests were performed under load control by applying pure moments loading of 2 N.m in FE, AR and LB. Three-dimensional ranges of motion (ROM) were measured from C3 to C7 using optoelectronic system and intradiscal pressure (IDP) was measured at upper adjacent level for 2-level constructs.

**Results:** Group A. Implantation of TDR at C5–C6 decreased ROM in FE, AR and LB (only significant in LB). Additional TDR at C4–C5 resulted in decrease of ROM at the two instrumented levels in FE, AR and LB; however reduction of mobility was only significant at C5–C6 in AR and at C4–C5 in LB. A second TDR did not affect kinematics of the previously implanted TDR. Two-level arthrodesis caused significant decrease of ROM at the two instrumented levels (p<0.05).

Group B. One-level arthrodesis at C5–C6 was associated with significant reduction of ROM. Implantation of additional TDR at C4–C5 (hybrid construct) did not affect ROM at C5–C6 but decreased ROM at C4–C5 in FE (not significant), AR (p=0.046) and LB (p=0.028). One- and two-level arthrodesis increased adjacent levels contribution to global ROM during FE. Significant changes in contribution were noted for 2-level TDR at lower level and for 1-level TDR at upper level. Concerning IDP during FE, we found no significant differences between intact spines and those instrumented with 2-level TDR whereas IDP increased by a factor of 6.7 (p<0.05) and 2.3 (p<0.05) for 2-level arthrodesis and hybrid constructs, respectively.

**Conclusions:** Implantation of TDR at 1 or 2 levels restored...
Cervical Total Disc Replacement vs. Anterior Cervical Fusion: Data from Four Prospective, Randomized, Multicenter Trials

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Texas Back Institute, Plano, TX, USA, 2Texas Back Institute Research Foundation, Plano, TX, USA

Introduction: Cervical total disc replacement (TDR) has emerged as an alternative to fusion in patients with radiculopathy or myelopathy with disc involvement. Food and Drug Administration (FDA) investigational device exemption (IDE) studies have been performed to compare arthroplasty devices to fusion. The purpose of this study was to perform a meta-analysis of the FDA IDE studies of four different cervical TDRs.

Methods: The inclusion and exclusion criteria were similar in the IDE studies for the Bryan Cervical Disc, Prestige, ProDisc-C, and KineflexC, and all used the same version of the Neck Disability Index (NDI) as an outcome instrument. Each study used a multi-component definition of overall success, although there were differences in the components used. However, all studies used a minimum of a 15 point improvement in NDI score as a success criterion, and three of the four studies included the criterion of maintained or improved neurological status. In addition to combining these factors across the four studies, the mean NDI score at each time period and across each study was evaluated.

Results: NDI scores through 24-month follow-up followed the same pattern of change in all 8 treatment groups (the TDR and ACF groups from each of the four studies; Figure 1). With respect to success criteria, NDI success (greater than 15 point improvement) was achieved in 84.1% (417/496) of patients in the pooled arthroplasty group compared with 80.5% (364/452) of patients in the pooled fusion group. In three of the four studies, neurological success was defined as maintenance or improvement in neurological function. In the arthroplasty group, 93.0% (357/384) of patients were classified as having neurological success compared to 89.0% (306/344) of the fusion group.

Conclusions: This study found that the results of the four TDR vs. ACF trials produced very consistent results with respect to the mean NDI scores during 24-month follow-up. The percentage of patients achieving at least a 15 point improvement in the NDI score as well as the percentage of patients achieving neurological success were both approximately 4% greater in the TDR group.
Meta-analysis of Four Prospective Randomized Cervical Arthroplasty FDA Trials - Superiority of Neurologic Outcomes

**Introduction:** The following analysis was derived from four prospective FDA studies comparing cervical arthroplasty vs. ACDF—compiled by three different sponsors, a total of 99 investigative sites and 1,399 patients. The four studies were designed and performed independently but the criteria for neurologic success vs. failure were consistent. Each of these studies tracked a similar measure of neurologic success for all patients over a two-year span. Deterioration of neurological function was considered a failure, while maintenance or improvement was considered a success.

**Methods:** Journal publications for three trials (Prestige, Bryan, ProDisc-C) were evaluated for the reported rate of neurological success. For the fourth trial (PCM), the authors had access to the sponsor company’s (NuVasive Inc, San Diego, CA) trial database. A random-effects meta-analysis was performed on the neurological outcomes data to evaluate the overall effect. This type of analysis weighs trials that had greater precision more heavily than those with lesser precision, and makes provisions for the possibility of random outside influences on trial outcomes.

**Results:** Table 1 shows the success and failure data that were reported by the different studies, while Table 2 shows the odds ratios for each study individually, as well as the percentage weights each was assigned for the final analysis. Combined, the studies encompassed 1,399 patients. In the disc replacement investigational groups, 704/754 (93.4%) of patients were neurological successes, while in the control groups, 576/645 (89.3%) were successes. This is a difference of 4.1 percentage points. The lowest success percentage in any of the disc replacement groups was 91.3% (ProDisc-C), while the highest success percentage in any of the fusion groups was 90.2% (Bryan Control). The random-effects meta-analysis model yielded an odds ratio of 0.598 in favor of arthroplasty over fusion, with a 95% confidence interval of 0.409 to 0.875, and a two-tailed p-value of 0.008.

Patients undergoing cervical fusion were seen to be 67% more likely to suffer neurologic deterioration over the two years following surgery than patients undergoing cervical arthroplasty. The PCM study further analyzed contributing factors and found a statistically significant maintenance of disk space height at two year follow up in the arthroplasty group vs. the control group (p = 0.0002).

**Conclusions:** Cervical arthroplasty demonstrated an as-yet unappreciated strong protective effect against progressive neurological deterioration compared to cervical fusion. The findings were conclusive and statistically powerful in this large, well-controlled, and well-monitored data set of 1,399 patients. Given these findings, we suggest that cervical arthroplasty, not cervical fusion, ought to be considered the standard of care treatment for cervical degenerative disc conditions.

**Table 1: Neurological Outcomes Reported in IDE Studies**

<table>
<thead>
<tr>
<th>Study</th>
<th>Failure</th>
<th>Success</th>
<th>Success %</th>
<th>Control (Post and Adjacent Fusion)</th>
<th>Failure</th>
<th>Success</th>
<th>Success %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prestige</td>
<td>18</td>
<td>287</td>
<td>95.4%</td>
<td>17</td>
<td>287</td>
<td>95.4%</td>
<td></td>
</tr>
<tr>
<td>Bryan</td>
<td>14</td>
<td>213</td>
<td>90.9%</td>
<td>19</td>
<td>273</td>
<td>90.2%</td>
<td></td>
</tr>
<tr>
<td>ProDisc-C</td>
<td>8</td>
<td>94</td>
<td>91.7%</td>
<td>13</td>
<td>93</td>
<td>90.7%</td>
<td></td>
</tr>
<tr>
<td>PCM</td>
<td>11</td>
<td>189</td>
<td>94.6%</td>
<td>14</td>
<td>157</td>
<td>98.0%</td>
<td></td>
</tr>
<tr>
<td>Mobi-C</td>
<td>36</td>
<td>784</td>
<td>95.4%</td>
<td>69</td>
<td>276</td>
<td>95.3%</td>
<td></td>
</tr>
</tbody>
</table>

**Table 2: Odds Ratios and Assigned Weights of Each Study**

<table>
<thead>
<tr>
<th>Study</th>
<th>Odds Ratio</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prestige</td>
<td>0.52</td>
<td>31.2%</td>
</tr>
<tr>
<td>Bryan</td>
<td>0.60</td>
<td>20.1%</td>
</tr>
<tr>
<td>ProDisc-C</td>
<td>0.69</td>
<td>10.3%</td>
</tr>
<tr>
<td>PCM</td>
<td>0.52</td>
<td>22.7%</td>
</tr>
</tbody>
</table>

**Background context:** The Mobi-C Cervical Artificial Disc (Mobi-C) is designed to preserve motion and disc height at the affected cervical vertebral level. Comparing Mobi-C to the current standard of care, interbody allograft with a rigid anterior cervical plate, provided an excellent evaluation benchmark.

**Study objective:** Compare the overall effectiveness of the Mobi-C to anterior cervical discectomy and fusion (ACDF) for the treatment of degenerative disc disease (DDD) with radiculopathy or myeloradiculopathy at one level between C3 and C7.

**Study design:** The study was conducted by 26 investigators at 24 study sites; 245 one-level subjects were analyzed for effectiveness. A non-inferiority design with a 2:1 randomization (Mobi-C: control) was used. 24 month follow-up data is available for this analysis.

**Outcome measures:** The primary endpoint of individual subject success was defined as a composite of Neck Disability Index (NDI) improvement, no subsequent surgical intervention, and the absence of major complications. Secondary endpoints included radiographic outcomes (Range of Motion (ROM), adjacent segment degeneration), neck and arm pain, subject satisfaction, significant neurological deterioration, quality of life (SF12), dysphagia, gait, blood loss, operative time, duration of hospitalization, and time to return to work.

**Methods:** The Investigation Device Exemption (IDE) study
was a prospective, randomized, multi-center, controlled investigation. Patient evaluations were performed pre- and post-operatively at 6 weeks, 3, 6, 12, 18, and 24 months.

Results: The individual subject composite success rate for Mobi-C was 73.6% at 24 months compared to a 65.3% success rate observed in the ACDF subjects (p=.002), establishing non-inferiority between the two groups. Improvement in the Mobi-C group was achieved earlier, with a higher subject success rate by 6 months than ACDF achieved by 24 months. This early improvement was also noted in many of the secondary endpoints, with subjects in the Mobi-C group generally achieving positive results earlier than the subjects in the ACDF group.

Conclusions: Mobi-C is an excellent alternative to anterior cervical discectomy and fusion for symptomatic cervical degenerative disc disease with radiculopathy or myeloradiculopathy at one level between C3 and C7. Mobi-C has the advantage of earlier achievement of overall success as well as earlier improvement in many of the secondary endpoints.

537 ProDisc-C Total Disc Replacement - 7 Years Follow up
R. Bertagnoli

Introduction: Cervical total disc replacement (TDR) for the treatment of cervical disc disease between C3-C7. Cervical TDR has potential benefits of providing immediate stability, reducing adjacent level disc degeneration and restoring/preserving range of motion between vertebral bodies. The purpose of this study was to evaluate the 7 year clinical results of ProDisc-C TDR.

Material and methods: A prospective, controlled, consecutive case series of 288 patients who received TDR was conducted (total number of implants 458). Patients were assessed pre- and post-operatively at up to 84 months using the Neck Disability Index (NDI), Visual Analog Scale (VAS) Pain Intensity and SF-36.

Results: Of the 288 patients (136 male mean age 47.7 yrs. range 30 - 68 / 152 females mean age 48 yrs. range 18 - 69). 146 underwent single level, 142 underwent multi-level surgery. The most frequent single level treated was C5-C6 (49.3%) followed by C6/C7 (31.5%), C4/C5 (15.7%) and C3/C4 (3.5%). Of multi-level cases, two levels were most common (82.3%), with C4-C6 and C5-C7 being equally as frequent as in three level cases (10.6%). 4 levels are 6.3% and 5 levels are 0.7%. The scores decreased at 3 month postoperative and were maintained throughout the follow up.

VAS scores decreased from a mean score of 7.1 ± 6.7 baseline to 3.8 ± 2.4 at 3 months; 4.3 ± 2.5 at 6 months; 4.2 ± 2.7 at 1 yr; 4.0 ± 2.9 at 2 yrs; 3.8 ± 2.7 at 3 yrs; 4.2 ± 2.9 at 4 yrs; 4.5 ± 2.9 at 5 yrs; 4.4 ± 2.3 at 6 yrs and 3.9 ± 3.4 at 7 yrs. NDI scores (in %) were reduced from 49.7 ± 18.4 baseline to 32.6 ± 18.0 at 3 months, 33.6 ± 19.4 at 6 months; 33.2 ± 21.7 at 1 yr; 32.8 ± 20.3 at 2yrs; 32.3 ± 20.1 at 3 yrs. 36.7 ± 19.2 at 4 yrs; 36.7 ± 22.2 at 5 yrs; 31.0 ± 21.6 at 6 yrs and 31.1 ± 24.1 at 7 yrs. The SF 36 physical / mental component and total was baseline P 35.4 ± 9.4 M 27.4 ± 12.2 T 76.0 ± 16.5 and improved at 3 month P 40.2 ± 8.9 M 29.0 ± 9.4 T 85.1 ± 16.6; 6 month P 40.7 ± 9.9 M 28.8 ± 9.4 T 85.8 ± 18.1; 1 yr P 41.6 ± 11.2 M 29.2 ± 8.8 T 87.6 ± 18.3; 2 yrs P 41.7 ± 11.7 M 28.1 ± 8.8 T 86.2 ± 18.8; 3 yrs P 40.1 ± 10.9 M 29.4 ± 8.9 T 84.3 ± 21.8; 4 yrs P 39.2 ± 10.6 M 28.8 ± 7.3 T 84.3 ± 19.9; 5 yrs P 39.3 ± 9.3 M 29.0 ± 10.3 T 83.9 ± 19.6; 6 yrs P 40.1 ± 10.8 M 30.3 ± 9.0 T 87.1 ± 19.0 and 7 yrs P 39.7 ± 15.2 M 28.7,4 ± 8.5 T 83.9 ± 24.11.

Conclusions: Cervical TDR using ProDisc-C demonstrates significant clinical improvement and provides long-term patient satisfaction. This data suggests that patients who receive multi-level TDR surgery using ProDisc-C experience similar clinical outcomes to single level patients.

331 2-level Cervical Disc Arthroplasty: 3-year Clinical Results from 6 Centers in a Prospective Randomized IDE Trial


Introduction: With the introduction of cervical arthroplasty in the USA, appropriate indications for these devices must be carefully studied. We report clinical outcomes from six centers participating in the ongoing prospective randomized PRESTIGE® LP Disc investigational device exemption (IDE) clinical study comparing arthroplasty with anterior fusion in patients with two-level cervical disc disease.

Methods: To date at these six sites, 180 patients with two adjacent levels of cervical disc disease have undergone surgery and received either the PRESTIGE LP devices (n = 97) or a two-level anterior cervical discectomy and fusion utilizing allograft spacers and the Atlantis anterior cervical plate (n = 83). At the time of this report, 51% of patients have been evaluated at the three-year follow up interval. Entrance criteria included symptomatic two-level cervical disc disease documented neurological deficit and confirmatory preoperative imaging studies. Demographic variables including age, sex race, and work status are similar between the two study groups. Operative variables including operative time, blood loss and levels treated were also similar. All patients were evaluated according to the standardized IDE protocol preoperatively and at defined postoperative intervals: 6 weeks and 3, 6, 12, 24, and 36 months. Outcomes measures include neck and arm pain numerical rating scale (NRS) for both intensity and frequency, neck disability index (NDI), and the Short-Form 36 (SF-36). Cervical flexion/extension, A/P, and neutral lateral x-rays were obtained at all data points. Additionally, all adverse events are recorded.

Results: Preoperative values for the NRS, NDI and SF-36 scores were similar. At 36 months, there was a 35.3 point mean improvement in the NDI in the PRESTIGE LP group as compared to a 30.0 point improvement in the fusion group. In the SF-36 PCS, a 15.9 point mean improvement is seen in the PRESTIGE LP group as compared to a 13.2 point improvement in the fusion group. The neck pain score improved 11.4 points in the PRESTIGE LP group compared to a 13.2 point improvement in the fusion group. In theSF-36, a 15.9 point mean improvement is seen in the PRESTIGE LP group compared to a 13.2 point improvement in the fusion group. The neck pain score improved 11.4 points in the PRESTIGE LP group as compared to a 13.2 point improvement in the fusion group. In the NDI, the Short-Form 36 (SF-36).

Conclusion: Analysis of three-year data from 6 sites participating in the PRESTIGE LP 2-level IDE study suggest that cervical disc arthroplasty appears to achieve favorable outcomes at three-year postoperative for patients with 2-level cervical disc disease. Longer term-follow-up is required.
Sagittal Alignment and Kinematics at Instrumented and Adjacent Levels after Total Disc Replacement in the Cervical Spine

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1Hospices Civils de Lyon, Neurosurgery and Spine Surgery, Lyon, France, 2Claude Bernard University Lyon, Neurosurgery, Lyon, France, 3Arts et Metiers ParisTech, Laboratory of Biomechanics, Paris, France, 4Clinique Beausoleil, Neurosurgery, Geneva, Switzerland

Study design: Prospective 2-center clinical and radiological study with 24-month follow-up.

Objective: To report clinical and radiological outcomes after implantation of cervical disc arthroplasty with a special focus on sagittal alignment, mobility and centers of rotation at instrumented and adjacent levels.

Methods: 32 patients were consecutively included in the study with a mean age of 42.3 ± 8.9. All patients sustained 1-level cervical disc prosthesis with the Discocerv™ implant (Scient’x/Alphatec Spine, Carlsbad, USA) for radiculopathy due to soft disc herniation. Clinical (cervical VAS, radicular VAS and NDI) and radiological data were obtained preoperatively and postoperatively at 3/6-months, 1-year and 2-year follow-up. Sagittal alignment, ranges of motion (ROM) and centres of rotation (COR) were analysed using specific quantitative motion analysis software (Spineview™, Arts et Metiers PARISTECH, France). The location of COR was calculated using X,Y coordinates system (which the origin was defined as the postero-superior corner of the lower vertebra) and then compared with data previously obtained from a control group of 39 normal and asymptomatic subjects.

Results: All patients had a minimum 24 months follow-up with a mean of 37.6 ± 10.2.

The cervical disc prosthesis was implanted most frequently at C5-C6 (n=24/32). The VAS neck pain, the VAS arm pain and the Neck Disability Index demonstrated significant postoperative improvement. Local and C3-C7 lordosis significantly increased from -2 ± 4° and 1 ± 7.5° preoperatively to 7 ± 5° and 14 ± 10° at M24, respectively. ROM in flexion-extension was measured to 10.2 ± 6.5° preoperatively versus 7.5 ± 4° at M12 (p>0.05) and 6.1 ± 4° (p<0.05) at M24. No differences were found in sagittal ROM at upper neither lower adjacent levels between pre and postoperative assessments. Compared to control group and preoperative values, we noted postoperative cranial shift of the mean COR (p>0.05). In addition, compared with control group, the dispersion of COR around the mean location was greater for the patients group. No differences were found in COR location at adjacent levels between pre and postoperative assessments neither between control and patients groups.

Conclusions: Through this prospective study, cervical TDR demonstrated to be safe and efficient in improving pain and functional status. Radiological analysis found that both local and global lordoses were restored. In addition, although TDR restored only partially segmental ROM in flexion-extension and significantly affected the quality of motion, we did not observed significant changes in kinematics at both lower and upper adjacent levels.
S.M. Golembeski¹, E.M. Lindley¹, A.M. Sophocles¹, E.L. Burger¹, V.V. Patel¹
¹University of Colorado Denver, Aurora, CO, USA

Introduction: The use of anterior plating systems in cervical spine stabilization has been well studied and proven effective in increasing fusion rates and improving clinical outcomes since their introduction in the 1980’s. Initially these plates were all static in nature and served to restrict movement between adjacent vertebral levels. More recently, several plates have been designed to allow for movement between fused vertebrae to increase load sharing across the interbody graft. Biomechanical studies show that load sharing is much greater for dynamic plates, especially after simulation of 10% subsidence. Translating plates, which allow longitudinal motion, are the newest type of plate to reach the market. To date there have been no clinical studies to evaluate this latest version of the dynamic plate. The primary purpose of this study was to investigate whether the use of dynamic translating plates results in improved clinical and radiographic outcomes, including higher fusion rates and fewer hardware complications, than variable angle screw plates in patients undergoing anterior cervical discectomy and fusion (ACDF). Theoretically, both types of plates allow settling and load sharing, but for this to happen with variable angle screw plates, bone remodeling around the screws is required.

Methods: In this retrospective study we reviewed medical records and postoperative radiographic films of patients who underwent single and multilevel ACDF using either dynamic translating or variable angle plates. Radiographs were analyzed immediately postoperative and at 3, 6, and 12 months postoperative. Data were analyzed relative to mean displacement of vertebrae (subsidence), number of vertebrae fused, fusion status, and Cobb angle.

Results: A total of 24 patients with translating and 26 patients with variable angle plates were reviewed. There were no significant differences between the two plate types in mean displacement of vertebrae, number of vertebrae fused, or fusion status. We observed a significantly higher rate of Cobb angle change greater than 3° at all time points in patients with translating plates as compared to those with variable angle plates. Overall, we observed a trend towards decreased Cobb angle in the translating plate group and increased Cobb angle in the variable angle plate group.

Conclusions: Our study failed to confirm our hypothesis that translating plates allow more load sharing and would confer a higher fusion rate than variable angle plates. Although not significant different, there was a higher percentage of patients whose films were read as completely fused at 6 and 12 months in the variable angle versus the translating plate group (85% vs. 67% and 96% vs. 83%, respectively). This finding may suggest that the increase in dynamic motion provided by the translating plates could be excessive when accounting for the stability needed for fusion. Patients given translating plates also had a higher tendency towards postoperative loss of lordosis while variable angle plates were typically associated with increases in lordosis. The loss of lordosis in the translating group may suggest the potential for greater breakdown, stress, and disease at adjacent levels with these plates. Further prospective studies are needed to confirm the clinical and radiographic outcomes associated with these cervical plate designs.
Breakout 2: Biologics

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Reduced Dose of rhBMP-2 with Demineralized Bone Matrix Product for Spinal Fusion
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Each year there are more demineralized bone matrix-based products (DBMs) commercially available as allograft bone graft extenders for fusion procedures. DBM-based products are most commonly used with autograft, allografts, and possibly BMPs. Very few of these DBM-based products have been systematically evaluated in vivo. Even fewer of these DBM-based products have been evaluated when combined with, autografts, allografts, or BMPs. Previously we have reported fusion variability across different production lots of these DBM-based products. Recent studies have shown both intra product variability (lot-to-lot variability due to production lots) and inter product variability (product formulations). The purpose of this study was to assess the benefit of a sub efficacious dose of rhBMP-2, or autogenous bone added to a DBM-based product.

Methods. A L4-5 posterolateral lumbar spinal fusion was performed on athymic rats with implantation of 3 unique Lots of DBM-based product (EquivBone ™, Etex Co., Cambridge, MA) with and without sub efficacious dose of 0.006 mg/ml rhBMP2 + DBM-based product. Each combination was tested on 4 rats total. Fusion success was determined at eight weeks (short-term endpoint) and 6 months (long-term endpoint) with use of radiographs and manual palpation of the vertebral segments. Fisher’s exact tests and Logistic regression were used to determine the differences and predictive abilities of assayed and added BMPs.

Results. All segments implanted with 0.006 mg/ml rhBMP2/ACS only were not fused; however, all segments implanted with the same dose of 0.006 mg/ml rhBMP2/ACS combined with DBM-based product were fused. Also, when 25% DBM and 25%CP was used with 50% ICBG fusion was also seen in all the animals after 6 months.

Discussion and Conclusion. Fusion was not observed with the low dose of rhBMP-2/ACS only. The higher the quantity of DBM to CP base in the product, the more rapid the bone formation. The optimal ratio between DBM and CP was 75% DBM to 25% CP. Very low doses of rhBMP-2 added to DBM-based product enhanced remodeling and rapid bone formation at all ratios of DBM to base. As is clinically practiced, autogeneous bone added to the DBM-based product also enhanced rapid bone formation.

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The Degradation of Bioactive Bone Cement for Vertebroplasty and Kyphoplasty in vivo
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Purpose: To observe the degradation process of calcium phosphate cements (CPC) and calcium sulfate cement (CSC) in vertebrae, and explore the ideal filler for vertebroplasty and kyphoplasty.

Methods: Bone voids were created in L2- L5 vertebrae of twenty-four female mature sheep. CPC, CSC and polymethylmethacrylate (PMMA) were injected into one bone voids randomly, the remaining void was served as the blank control, and L6 vertebra served as the normal control. Eight sheep were sacrificed at 2w, 12w and 24w after operation randomly. Gross observation, biomechanical test and undecalcified bone histology analyses were used to determine the performance of the three cements.

Results: Gross observation showed that fibro-like scar was seen around the vertebrae with bone voids at 2w, some callus was seen covering the bone voids at 12w and 24w. Biomechanical analysis showed that the vertebrae could be augmented by CPC and CSC. The mechanical properties of vertebrae augmented with CSC decreased from 2w to 12w, however, increased from 12w to 24w after operation. The mechanical properties of vertebrae augmented with CPC increased from 2w to 24w, however, lower than the vertebrae with PMMA. Histology analysis showed CSC was mostly absorbed at 12w, however, the bone voids were repaired only in large part at 24w. CPC was absorbed partly at 24w, and new bone was formed in contact with the surface of the CPC. Fibrous membrane was observed in the interface between the PMMA and bone trabeculae.

Conclusion: The vertebrae can be augmented instantly by CPC and CSC. As time went on, the evaluation process was different in two cements, CSC was absorbed fast and CPC was absorbed very slowly.

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Novel Nano-technology Platform for Covalently Bonding Antimicrobials to Orthopaedic Biomaterials Reduces Bacterial Numbers on Numerous Substrates
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Aim: Approximately 0.01% to 0.3% of all orthopaedic surgeries result in nosocomial infections, and spinal surgery infection rates are up to 3% are commonly reported. These infections are extremely costly and devastating to the patient. We have developed methods to covalently bond molecules, including antibiotics, to biomaterial surfaces. Surface-bound drugs can deliver a locally high concentration of antibiotic that is non-elutive and systemically non-toxic. We tested the antibacterial efficacy of covalently bound gentamicin using three novel chemical processes on metal, collagen, and glass substrates against S. aureus.

Methods: Three different methods were developed to immobilize gentamicin. Each method was chosen in response to the specific chemical nature of the substrate glass, steel, or collagen. In all cases, gentamicin was permanently bound and demonstrated efficacy without elution.

Surfaces were inoculated with S. aureus (ATCC 25923) using a spray method which was adopted from a previously published study (Tillier et al, PNAS 98:5981, 2001). Percent reduction of colony formation on treated vs. untreated surfaces was the gauge of treatment efficacy. A Kirby-Bauer zone-of-inhibition assay confirmed that treated surfaces were anti-microbial in the absence of elution.

Results: Each surface was amenable to one or more of the treatment methodologies. Substantial reductions were obtained on all substrates as shown in Table 1. In some instances, 100% reduction was observed (Fig. 1).
Table 1

<table>
<thead>
<tr>
<th>Surface</th>
<th>Avg % Colony Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glass(^a)</td>
<td>91%</td>
</tr>
<tr>
<td>Steel (^b)</td>
<td>92%</td>
</tr>
<tr>
<td>Collagen(^a)</td>
<td>96%</td>
</tr>
</tbody>
</table>

\(^a\) Method 1  \(^b\) Method 2  \(^c\) Method 3

Figure 1 illustrates the bactericidal efficacy of gentamicin covalently bound to a surface (collagen coated glass). On the left is shown a treated collagen surface which had been inoculated, then overlain with agar to promote colony growth. On the right is the untreated control. It can be seen that after an 18 h incubation, a substantial number of colonies formed on the untreated collagen while there were none on the treated sample.

**Conclusion:** This study demonstrates that gentamicin can be covalently bound to a biomaterial surface and act in a bactericidal fashion in vitro. As gentamicin is permanently immobilized, the typical mechanism of action for the drug is blocked. We postulate that when bound, gentamicin acts like a contact antibacterial. We believe that this effect will prevent bacterial colonization on orthopaedic implants in vivo. By tethering the antibiotic to the surface, gentamicin levels are locally high enough to achieve efficacy against the gram positive organism, *S. aureus*.

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**Novel Nanocoating Promotes Bone Growth and Apposition on Stainless Steel**

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**Background:** Appositional bone growth to spine and orthopedic implants is a desirable quality especially if a surface treatment does not adversely affect implant size or biomechanics. It becomes even more important with motion-preserving implants of the spine. A novel chemically stable coating of self-assembled-monolayer of phosphonates (SAMP) that covalently bonds to metallic oxide surfaces, has been developed. In-vitro results have shown the SAMP coating to be osteoconductive, enhancing osteoblast attachment to and spreading on metallic surfaces. We report bone growth in a rabbit model comparing SAMP-treated stainless steel (SS) implants versus untreated controls.

**Methods:** Forty-four male, skeletally mature New Zealand White rabbits were implanted bilaterally in the femoral intramedullary canals where each animal received a treated and untreated cylindrical 316L SS implants. The rabbits were randomized to one of four time points (n = 11 animals): 4, 8, 12 and 16 weeks. In-vivo plain radiographs were performed immediately post-operatively and at all time points until sacrifice. Specimens designated either for histology (n = 3 femurs) or mechanical evaluation (n = 8 femurs). In-vitro images of cancellous and cortical sections were taken using a scanning electron microscope (SEM) (FEI, Peabody, MA) to identify new bone around the implants. The sections were embedded in PMMA in order to prepare undecalcified slides for histomorphometry.

**Results:** Bone formation was observed in the epiphysial cancellous bone in the area surrounding the distal end of the implant and the trabeculae in that area had grown thicker in treated than untreated implants. Moreover, newly formed bone was found in intimate contact with the surface of the proximal end of the treated implant that was not in contact with the femoral cortex as early as 4 weeks. Histological evaluation showed cell types associated with new bone formation in both the cortical and cancellous regions in higher numbers in treated than untreated implants.

**Conclusion:** We have shown that for early implant fixation, the SAMP treatment of SS rods in this rabbit model provides a promising improvement of bony integration onto metal components of orthopaedic implants.

**Figure 1A:**

Figure 1B:

Figure 1: Backscatter SEM images of distal epiphyseal regions of two rabbit femurs.
A: implanted with an uncoated implant at 4 weeks.
B: implanted with SAMP-coated implant at 4 weeks. The metal is indicated by higher density (white). Postoperatively formed trabeculae is more evident in the epiphyseal region surrounding the coated implant than that in surrounding the uncoated one.

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Immunolocalization of Human Bone Morphogenetic Protein 13 in the Developing Human Spine; Further Rationale for its Use for Disc Regeneration
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Introduction and aim: Bone Morphogenetic Protein 13 (BMP-13) is a member of the TGF-β protein superfamily. We have demonstrated that mutations in BMP-13 cause congenital vertebral fusions seen in Klippel Feil Syndrome. As molecular processes occurring in development are reiterated in tissue repair, we postulated that BMP-13 could be used for disc regeneration. In fact recently, BMP-13 was found to stimulate cells from endplate in the intervertebral disc and prevent the effects of annular injury in an animal model. We further postulate that BMP-13 has a role in regulating spinal column endochondral ossification in its early development. This study aimed to examine the tissue-localised expression of BMP-13, its’ receptors, and key IVD extracellular matrix proteins in the developing human spine in an attempt to better understand its role amongst the myriad of regulators in the developing human spine.

Methods: Twelve human foetal spine specimens with a total of 172 discs, aged 8-19 weeks, were collected fresh and immediately fixed in 10% neutral buffered formalin for 24 hours. Paraffin embedded tissues were cut in medal sagitally, and sliced into 4µm serial sections. Histological examination on haematoxylin-eosin (H&E) and Alcian Blue staining were performed. Immuno-histochemical staining was conducted to detect BMP-13 either pro or active domain, BMP Receptor-1A&1B, collagen I, collagen II and aggrecan protein expression.

Results: The protein expression of BMP-13 (both pro and active domain) was found to locate in the nucleus pulposus, inner annulus and hypertrophic chondrocytes of the developing vertebral bodies in all age groups examined. Expression of BMP13 protein was detected in the cell cytoplasm and in the extracellular matrix. The expression of BMP-13 correlated with that of BMPR1B, collagen II and aggrecan. There was a trend towards reduced expression of BMP-13 with increasing enchondral ossification of the foetal column with age and reduced expression in the ossified areas.

Discussion and conclusion: To the best of our knowledge this is the first study in human foetus spine demonstrates that BMP-13 is expressed more in the early developing human intervertebral disc and vertebral bodies. As the expression is consistent with its proposed role in cartilage-like tissue formation, the observed trends strengthen the hypothesis that BMP-13 has a role in preventing the intervertebral disc from ossifying, and may offer a stronger therapeutic rationale for its use as a disc tissue regenerator.

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Osteogenic and Chondrogenic Differentiation of Umbilical Cord Blood-derived Mesenchymal Stem Cells
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Introduction: Mesenchymal stem cells (MSCs) found in many adult tissues are an attractive stem cell source for the regeneration of damaged tissues in clinical applications because they are characterized as undifferentiated cells, able to self-renew with a high proliferative capacity, and possess a mesodermal differentiation potential. Although bone marrow has been the main source for the isolation of multipotent MSCs, the harvest of bone marrow is a highly invasive procedure and the number, differentiation potential, and maximal life span of MSCs from BM decline with increasing age. Therefore, alternative sources from which to isolate MSCs are subject to intensive investigation. A recently reported potential alternative tissue source of MSCs is the connective tissue (Wharton’s Jelly) of human umbilical cord. Umbilical cord blood -derived MSCs (UCBMSCs) are ontogenically primitive, less exposed to immunologic challenges, abundantly available, and can be harvested without risk to the donor. Our study is to study the ability of UCBMSCs to differentiate into osteogenic and chondrogenic cells.

Methods: UCBMSCs were isolated from umbilical cords (n=4) from consenting patients after extensive washing with phosphate derived saline and digesting with collagenase. After primary culture in basic medium and expanded to two passages, the cells were incubated in the osteogenic and the chondrogenic medium for 2-4 weeks to induce osteogenesis and chondrogenesis. Osteogenic differentiation was confirmed using the ALP and Von-Kossa Staining. Expressions of osteoblast-specific genes (ALP, Osteopontin, and Osteocalcin) were confirmed by RT-PCR. Chondrogenic differentiation was confirmed using the Alcian Blue Staining. Expressions of chondrocyte-specific genes (Collagen II, X, and Aggrecan) were confirmed by RT-PCR.

Results: UCBMSCs were able to be isolated from umbilical cords and expanded rapidly. They showed the highest proliferation capacity. UCBMSCs induced to osteogenesis were stained positively for alkaline phosphatase activity after 2 weeks and formed mineralized nodular structures, as confirmed by Von Kossa staining. Expression of osteoblast specific genes, such as ALP, Osteopontin, Osteocalcin, were detected. ALP and Osteopontin, were expressed constitutively in osteogenic medium after 2 and 4 weeks of culture. Expression of Osteocalcin, was induced by osteogenic growth factors at 4 weeks. UCBMSCs induced to chondrogenesis were positive of Alcian blue staining under acidic conditions and expression of Aggrecan and Collagen II and X genes. Aggrecan and collagen X genes were abundant after 2 weeks in chondrogenic medium. Collagen X was detected at 4 weeks.

Discussion: UCBMSCs can be isolated from umbilical cords. Their biological characteristics are similar with bone marrow mesenchymal stem cells, and have the potential to differentiate into osteogenic and chondrogenic lineage. Interestingly, they showed the high proliferation capacity. This may prove to be an attractive strategy for bone formation and spinal fusion in humans. From the therapeutic indication, the clinical applications may be based on differentiation capacity, but more likely on the abundance, frequency, and expansion potential of the cells. Since alternative sources are intensely investigated, one day the new source may replace bone marrow.
Comparative Neuroprotective Effects of Methylprednisolone and Rosiglitazone, a Peroxisome Proliferator-activated Receptor -γ Following Spinal Cord Injury

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Introduction: Spinal cord injury (SCI) results in the loss of function below the lesion. Secondary injury following the primary impact includes a number of biochemical and cellular alterations leading to tissue necrosis and cell death. Peroxisome proliferator-activated receptor (PPAR) is a ligand-activated transcription factor of nuclear hormone receptor superfamily and plays a significant role in glucose and lipid homeostasis. PPARγ agonists have been reported to be applied in several models of central nervous system injury and disease. Presently, to explore the possibility of PPARγ agonists applying in SCI, we compared the neuroprotective effects of methylprednisolone (MPSS) and PPARγ agonist rosiglitazone (ROSG) following spinal cord injury.

Materials and methods: Spinal cord injury was induced by the application of vascular clips (force of 24 g) to the dura via a four-level T5-T8 laminectomy in adult male Sprague-Dawley rats. To gain a better insight into the mechanism of action of the anti-inflammatory effects of rosiglitazone, rosiglitazone was administrated following SCI and the following end points of the inflammatory process were evaluated:

1. Motor function recovery was studied with the Basso-Beattie-Bresnahan (BBB) scoring system;
2. Spinal cord inflammation and tissue injury were scored histopathologically and apoptosis were determined by TUNEL staining;
3. Neutrophil infiltration was assayed by measuring myeloperoxidase (MPO) activity
4. The expressoins of the inflammatory markers TNF-α, IL-1β were investigated by immunohistochemistry.
5. Tissue bax, bcl-2 and HSP70 expression were semi-quantitated by western blotting. The SCI induced rats were delivered with MPSS as control.

Results: Locomotor function progressively improved from day 3 to day 28 in rats suffering from SCI, while a significant improvement was shown in ROSG- or MPSS-treated groups (P< 0.05). Histopathologically, treatment with ROSG or MPSS resulted in a significantly smaller damage, less apoptosis and neutrophil infiltration, compared to vehicle control after SCI insults (P< 0.05, respectively). TNF-α and IL-1β were expressed higher in vehicle control rats than in ones with ROSG or MPSS administration (P< 0.05). Correspondingly, the ratio of Bax:Bcl-2 and the expression of HSP 70 were higher significantly in vehicle control group than ones in drug delivered groups (P< 0.05, respectively). All results showed ROSG significantly decreased spine cord damage, apoptosis and cytokine expression. There showed no significantly difference between MPSS- and ROSG-treated groups (P>0.05).

Conclusion: Taken together, our results clearly demonstrate that administration of ROSG induces significant neuroprotection after SCI insults. Since PPARγ agonists currently are approved for type-2 diabetes treatment by the USA Food and Drug Administration (FDA), they may be considered as a novel target of therapeutic applications in the treatment of spinal cord injury. However, based on the complexity and redundancy of the inflammatory response associated with SCI, it is unlikely that a single target could achieve complete inhibition of inflammation. Thus, it should be point out combined treatment modalities could promise better therapeutic effects.

Comparison of Osteogenesis of an Early Lineage Stem Cell to Bone Marrow Aspirate and Pure Mesenchymal Stem Cells within a Demineralized Bone Scaffold in an Athymic Rat Model

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Purpose: Previous in vitro testing of early lineage adult (ELA) stem cells demonstrated superior bone marker expression compared to pure mesenchymal stem cells (MSCs), indicative of cell maturation and mineralization. The purpose of the current study was to evaluate the osteogenic capability of an ELA stem cell compared to pure MSCs in an athymic rat muscle pouch model.

Methods: Nine athymic mature Sprague Dawley rats were randomized to three treatment groups (n=3/group). Each treatment group utilized 0.3cc of the same demineralized bone (DB) scaffold as a carrier matrix. Cellular component of the study groups were one of the following: human bone marrow aspirate (BMA) (1.5 million cells / implantation), human MSCs identified by CD-105 surface marker (1.5 million cells/implantation), and human ELA stem cells (1.5 million cells/implantation) (PureGen™, Alphatec Spine, Carlsbad, CA). Implantations were done bilaterally in the biceps femoris muscle (6 limbs/group).

Radiographs were taken at 2, 4 and 6 weeks and reviewed by a blinded third party radiography specialist for radiodensity evaluation (Syncare, San Francisco, CA). Density was ranked 0-3 with 0 representing no calcification present, 1 representing hypodense bone relative to the proximal femur in each limb, 2 representing isodense bone and 3 representing hyperdense bone. Radiographic scores at the six week time point were analyzed with a one-way ANOVA (p< 0.05) comparing the ELA group to both BMA and MSC groups. Tissue samples were allocated to: one of five sections for H&E stain, 3 sections for immunohistochemistry (IHC) and one section for human class I MHC for bone producing markers and human class I HMC markers.

Results: None of the implantation sites demonstrated bone formation at the 2 week time point (all scores = 0). All animals showed bone growth at 4 weeks (BMA = 0.67±0.52, MSC = 0.42±0.49, ELA =1±0). All animals showed bone growth at six weeks (BMA = 1.08±0.2, MSC = 0.67±0.68, ELA = 1.58±0.38) (Figure 1). All of the DB scaffolds with bone marrow aspirate (6/6) and ELA cells (6/6) were visible at 6 weeks, but only half (3/6) of the DB scaffolds with MSCs were visible at six weeks. The six week data showed statistically greater radiographic bone formation for the ELA group as compared to either BMA or MSC groups (p< 0.017).

In examination of the histology, osteocalcin, osteopontin, and alkaline phosphatase indicated that osteogenesis was occurring in all animals with the DB scaffold. B2M staining indicated that viable ELA stem cells were present in all implants.

Conclusion: Improved bone formation was found when using an early lineage adult (ELA) stem cell as compared to either BMA or MSC with a demineralized bone scaffold in an athymic rat muscle pouch model. Histologic analyses found
Activated using 0.1 ug/ml of phorbol-12-myristate-13-acetate (PMA). Co-culturing of ADSCs with PBMCs yielded no PBMC expansion after 3 days in culture. Proliferation of PBMCs is observed after 3 days when stimulated with 0.1 ug/ml of PMA, but the PMA-induced proliferation is reduced when PBMC is co-cultured with ADSCs.

Discussion and conclusion: ADSCs have surface expressions of MHC class I molecules but not MHC class II or its co-stimulator molecule CD80. Co-culture of ADSCs together with PBMCs have demonstrated ADSCs alone will not cause the proliferation of the T-cell population within PBMCs. This suggests that implantation of ADSCs will not cause rejection by the host. More surprisingly, ADSCs were able to modulate the stimulation of T-cell proliferation by PMA. This suggests an immunomodulatory role for ADSCs, and that they may be a potential therapeutic agent with autoimmune disease. In vivo experiments are needed and are ongoing to confirm the in vitro findings in this abstract. Allografts of ADSCs may be particularly interesting in cell-based treatment of intervertebral disc disease.

Immunomodulatory Actions of Adipose-derived Stem Cells

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In stem cell-based strategies for disc regeneration, the potential rejection of the implanted cells into the host's body remains a concern. Adipose tissue represents an abundant and easily accessible source of adult stem cells with the ability to differentiate along multiple lineage pathways and potentially to facilitate treatment of an early degenerating disc. Rejection of implanted stem cells by host immune system has been a major concern in the field of stem cell-based therapies and is the focus of this study. The specific purpose of this study was to determine if ADHSC express major histocompatibility complexes (MHC 1 and 2) and if so whether ADHSC show an immune response after co-culture with T-cells.

Methods: Adipose-derived stem cells (ADSCs) were obtained from a commercial source (ZenBio, Research Triangle Park, NC). ADSCs were characterized for both stem cell and immune surface markers using flow cytometry. Briefly, ADSCs were incubated with fluorochrome conjugated antibodies for 15 minutes, washed 3 times, and fixed with 1% paraformaldehyde. Peripheral blood mononuclear cells (PBMCs) were isolated from heparinized whole blood using Lymphocyte Separation Medium (Mediatech, Manassas, VA). ADSCs were plated 4 hours prior to the plating of PBMCs to allow for adherence. PBMCs are counted prior to plating and after 3 days in culture using hemocytometer. PBMCs are activated using 0.1ug/ml of phorbol-12-myristate-13-acetate (PMA) (Sigma-Aldrich, St. Louis, MO).

Results: The ADSCs were determined by flow to be CD11c-, CD29+, CD44+, CD49+, CD90+, MHC I+, MHC II-, CD80-. Co-culturing of ADSCs with PBMCs yielded no PBMC expansion after 3 days in culture. Proliferation of PBMCs is observed after 3 days when stimulated with 0.1 ug/ml of PMA, but the PMA-induced proliferation is reduced when PBMC is co-cultured with ADSCs.

[Graph 1]
in 5 cases). Statistically NCOG group showed lower incidence of misplacement of screw (P < 0.05, \( \chi^2 \) test) and a less degree of cortex violation (P < 0.05, Spearman correlation) than CFG group.

The time required for inserting a screw was 1.2 to 10.4 minutes (average 3.6 minutes) in CFG and 2.3 to 6.7 minutes (average 4.2 minutes) in NCOG (P < 0.05, T-test). Mean time required for preparation of screw placement was about 4 minutes in CFG, and 15 minutes in NCOG (P < 0.05, T-test). Mean times of X-ray shot for each screw placement in CFG was 6.5, while none in the NCOG.

Postoperatively, 2 patients with misplacement of a screw under CFG presented ipsilateral leg paresthesia possibly related to the screw position. Among them, one patients required reoperation for reposition of the screw. The other patient improved the leg symptom spontaneously.

**Conclusion:** The present study demonstrates that pedicle placement in the thoracic and lumbar spines under the NCOG is significantly more efficient compared with that under the CFG in terms of accuracy and safety, although the time required for the preparation and the screw placement procedure is rather long in surgery under the NCOG. In addition, the NCOG surgery can be considered as a preventive measure against radiation hazards for medical personnel and as an intraoperative CT scan for in situ verification of the screw position.

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**O-arm and Stealth System Navigation for Pedicle Screw Placement in Thoracolumbar Spine Surgery**

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**Introduction:** Pedicle screws are commonly used for posterior stabilization in the thoracolumbar spine. Various navigation systems have been introduced to improve the accuracy of screw placement and prevent vascular and neurological injury. The O-Arm generates a 3-D image of the spine, similar to CT scanning, that is downloaded to the Stealth Station. This gives real time transverse, coronal, and sagittal images of the spine and replaces the need for fluoroscopy and thus reduces radiation exposure. While various studies have reported on the use of CT-based and Isocentric 3D fluoroscopy-based navigation, there is a paucity of data on the use of O-Arm and Stealth. The objectives of this study were to (1) evaluate the accuracy of pedicle screw placement using O-Arm and Stealth, (2) assess the time required for draping, positioning of the O-Arm, and screw placement, (3) evaluate whether tapping improves the accuracy of pedicle screw trajectory, and (4) compare the results of intraoperative neuromonitoring with the actual number of screws that breached the medial cortex on CT.

**Methods:** In this prospective study, we evaluated pedicle screw placement in patients that underwent surgery using O-Arm and Stealth at our institution. The times required for draping, positioning of the O-Arm, and screw placement were recorded. The number of tapped screws and neuromonitoring results were noted. “Snap-shot” navigation images with the awl in the pedicles and O-Arm-CT scan confirmation images were analyzed to assess accuracy.

**Results:** Between February and August 2010, 188 screws were placed in 25 patients (16-75 years old) using O-Arm and Stealth; 116 screws were evaluated, the remaining screws were excluded from analysis due to either poor image quality or missing images. The average time required for O-Arm draping was 3.5 minutes, initial O-Arm positioning was 6.1 minutes, and final positioning was 4.9 minutes. The overall mean time required between attachment of the array and screw placement was 8.1 minutes/screw. The mean time required for screw placement alone was 5.9 minutes/screw. Measurements on O-Arm snap-shot images of the distance from the awl tip to the anterior and lateral cortex were on average 3.14 mm shorter than that of screws on final CT images; thus the screws were actually deeper than the position shown on snap-shot images of awls. Three screws (2.5%) breached the medial cortex (by less than 2 mm) and three screws were misaligned by an average of 13.76°. All misaligned screws had been tapped. Intraoperative stimulations of all screws were normal despite the fact that three screws breached the medial cortex, resulting in a false negative rate of 1.59% for neuromonitoring.

**Conclusions:** The use of O-Arm and Stealth led to a low rate of pedicle screw misalignment in the present study. The mean time to place the screws was less than previously reported times for CT navigation, but longer than those for screw placement using conventional technique. It is important to be aware of the potential discrepancy between the position of the awl on snap-shot images and actual screw placement on CT-O-Arm. Our findings suggest that the final screw position may be deeper than awl positions appear on the navigation image.

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**Robotic-assisted Pedicle Screw Placement in Complex Spinal Surgery Cases: What Was Learned from Our First 23 Patients**

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**Introduction:** Surgeons’ interest is increasing in the use of image guidance and or robotics for the placement of spinal implants. The technology used in these systems is continually improving and may be particularly useful for patients with challenging anatomy. Only through careful clinical evaluation can its successful applications, limitations, and areas for improvement be defined. The purpose of this study was to prospectively review one clinic’s experience in a series of initial consecutive cases scheduled for surgery using robotic-assisted pedicle screw placement.

**Methods:** Data were collected for the consecutive series of the first 23 patients scheduled for posterior pedicle screw placement using robotic guidance at a single hospital. Notes from each case were reviewed by an independent researcher to identify the diagnosis, number of levels operated, number of screws placed, and any complications or unanticipated events that occurred during attempted screw placement. The majority of the patients had idiopathic or degenerative scoliosis. Other diagnoses included kyphosis, Scheuermann’s kyphosis, ankylosing spondylitis, adjacent segment degeneration with stenosis, spondylolisthesis, and L5 spondylolysis.

**Results:** The robotic guidance was scheduled for use in 23 patients. In one patient with kyphosis and a body mass index of 45.0, an adequate fluoroscopic image used for registration
could not be obtained in the operating room. In this case all screws were placed manually. In another patient with severe scoliosis and cerebral palsy, only two screws were placed using robotic guidance again due to inadequate fluoroscopic images used for registration. In the remaining 21 patients, placement of 232 screws was attempted using robotic assistance. Screws were successfully implanted in 86.2% (200 of 232) of attempts. Three screws (1.5%) placed using the robotic system were misplaced. All three presumably due to “skiving” of the drill bit or trocar off the side of the facet joint. One was repositioned using robotic guidance. Another had deviated superiorly into L4-5 disc space and was redirected manually through the same drill hole. In one patient a misplaced L4 screw was removed 4 days post implantation due to nerve irritation. The remaining 32 screws (13.8%) were converted to manual placement for a variety of reasons. In one patient with a severely rotated spine, 10 screws were placed manually due to poor registration. Twenty additional screw placements were converted to manual placement due to problems with registration and/or suitable trajectory for placement. The remaining two screws converted to manual implantation were in a patient with an L5 spondylolysis in whom all attempts to seat the drill bit for “pars screws” failed due to mobility of the lytic segment. Of note, among the 32 manually placed screws, one screw (3.1%) was redirected due to mal-positioning.

Conclusions: Robot-assisted screw placement was successfully accomplished in approximately 86% of attempts, with only 1% being misplaced despite the majority of patients in this series having significant spinal deformities. Intraoperative fluoroscopic imaging for registration is critical and was the limiting issue for some cases. “Tool skiving” was felt to be the inciting issue with the misplaced screws.

Method: 100 consecutive Patients undergoing Lumbar Transforaminal Endoscopic Discectomy were monitored pre-op, intra-op, and post-operatively by SEP (somatosensory evoked potentials) and EMG (electromyography) activity. A comparable group without neuromonitoring served as the control. Live free-running EMG was recorded during surgery, on the affected leg. Responses were graded as: mechanical irritation, neurotonic discharges, and no response. Surface electrodes monitored the Quadriceps muscle for L3/4, Tibialis Anterior for L5, and Gastrocnemius for S1. Each patient was anesthesized with 1% lidocaine, Versed and sedation. The patient providing intra-operative feedback is as, if not more valuable than neuromonitoring.

Results:
SEP: The SEP on the affected leg was averaged, and compared with the asymptomatic unaffected leg pre-operative and post-operatively. Post-operative dysesthesia, if moderate or severe, was treated by a transforaminal block and sympathetic block or gabapentin until the usually temporary dysesthesia resolved. The painful affected leg sometimes, but not always demonstrated latency delays or depressed amplitudes in the SEP waveform. The recorded pathway may show, but not always, asymmetries between affected and control limbs.

EMG: Mechanical elicitation of evoked discharges occurred in 33% of the cases intra-operatively. Discharges correlated with the action of tapping a dilator and cannula past the exiting and/or traversing nerve. EMG neurotonic irritation patterns was also exhibited when the peripheral nerve was stimulated either during extraction of a sequestered disc fragment or during foraminoplasty. The patient was able to simultaneously feel nerve irritation. Immediately after decompression, the EMG returned to baseline, correlating well with lack of symptoms. While EMG provided feed back to the surgeon, warning him of the vicinity of a peripheral nerve, it was not critical to the performance of endoscopic decompression or the use of thermal ablation, but provided feedback on the pain source. The patient may report pain even when there was no EMG activity, but continuous EMG monitoring warned the surgeon that the nerve was in the vicinity. There was no correlation of EMG irritation patterns experienced intra-operately with post-operative dysesthesia. Dysesthesia occurred in 5% of patients even when no EMG activity intraoperatively. Some patients exhibiting EMG activity (33%) during surgery had no dysesthesia post-op. SEP monitoring documented improved changes in latency of the involved nerve when there was significant radiculopathy pre-operatively, but this was not consistent. Some amplitudes increased and others decreased, with post-operative decrease in amplitude was expected, due to the effects of the local anesthetic. Overall, these latency and amplitude changes nevertheless reflect measurable changes of the central and peripheral nervous system, and generally provided additional information to the surgeon regarding nerve decompression and the position and irritability of the nerves in the operative area. EMG stimulation could be correlated with physician visualization of the involved nerve in the operative field.

Conclusion: Monitoring EMG and SEP may be useful in avoiding complications in general Lumbar surgery under general anesthesia, but its expense appears to be unnecessary when the surgery is under local anesthesia and sedation. The patient providing intra-operative feedback to the surgeon is as, if not more valuable than neuromonitoring.
to abnormal loading of the facets and capsular ligaments. Our goal was to develop a tool to assess the effect of motion preservation devices on the facet joint motions without making any assumptions regarding the host anatomy, tissue properties, or the performance of the prosthesis implanted in a motion segment.

**Methods:** Cervical spine specimens (C3-T1) were instrumented with a minimum of 3 radiopaque markers per vertebral body. A 3-dimensional (3-D) specimen-specific anatomical model of the specimen was reconstructed using fine-slice axial CT scans. Therefore, the anatomy of each vertebra was defined in relation to the markers attached to that vertebra. The next step was to establish a digital link between the radiopaque markers in the CT reconstruction and the motion sensors attached to each vertebra by digitizing the location of the markers on each body relative to the motion sensors on that body. Next, the specimen's kinematic response was measured in response to flexion-extension, lateral bending, and axial rotation moments. Three-dimensional motion of each vertebral body was tracked using an optoelectronic motion measurement system. The 3-D motion data obtained during the flexibility test was then used to drive the 3-D CT anatomical model. As a result, 3-D motion of any anatomical landmark on the specimen could be assessed in response to the loads applied to the specimen during flexibility testing.

**Results:** The model was used to visualize and quantify the facet motions at all motion segments for all loading modes. An illustrative application is shown for calculation of facet overlap area at the C4-C5 segment undergoes motion in flexion-extension (Figures 1 & 2).

**Conclusions:** This model couples an individual specimen's 3D CT reconstruction with its own kinematic data collected in the laboratory. In this fashion, there are no assumptions made regarding material properties, host anatomy or implant motion as with a finite element model. In addition to assessing the motion of facet joints, the specimen-specific model can be also used to make quantitative measurements of facet joint gapping, area of intervertebral foramen and spinal canal, and ligament stretch in the specimen's intact state and after TDR.

**Figure 1:** Facet Overlap Area at C4-C5

**Figure 2:** Facet Overlap Area Change (mm²)

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**Segmental Kinematics before and after Lumbar TDR: A Prospective Randomized Study Comparing Unconstrained, Semi-constrained, and Constrained Implants**

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**Introduction:** Segmental motion is quite variable among symptomatic individuals. While some patients with symptomatic discogenic pain demonstrate relative immobility at the affected segment, others demonstrate hypermobility/instability. Appropriate selection of lumbar TDR may be related to proper matching to the patients' segmental motion. Implant design may affect in-vivo motion following lumbar TDR, and post-operative motion may be related to implant design and not to patients' variables.

**Purpose:** The purpose of this study was to demonstrate the segmental motion characteristics of 3 different implant designs (ie unconstrained, semi-constrained, and constrained).

**Methods:** All patients enrolled in a FDA IDE study comparing 3 different lumbar TDR implants were included in the study. All data was collected prospectively. All patients met inclusion criteria, including single level symptomatic disc disease at either L4/5 or L5/S1. Patients were randomized to either the investigational group (semi-constrained), or to the control group (unconstrained or constrained). All patients had a retroperitoneal approach by an approach surgeon, and disc replacement by an orthopedic spine surgeon.

**Results:** 162 patients were included in this study. Motion was measured in degrees. Overall the average ROM was 6.5 pre-operatively and 5.7 at 12 months.
The average ROM at 12 months was: 6.1 for unconstrained, 5.9 for semi-constrained, and 4.5 for constrained. Overall the average ROM at 12 months at L4/5 was 6.1, while at L5/S1 was 5.5. The average ROM at 12 months at L4/5 was 5.8 for unconstrained, 6.6 for unconstrained, and 4.5 for constrained. The average ROM at 12 months at L5/S1 was 6.3 for unconstrained, 5.6 for semi-constrained, and 4.5 for constrained. The average ROM of the adjacent level was 6.7 preoperatively and 7.3 at 12 months for all 3 groups combined. The average ROM of the adjacent level at 12 months for the 3 groups were 8.7 for the unconstrained, 7.4 for the semi-constrained, and 5.7 for the constrained.

Conclusions: The results of our study demonstrate that in general lumbar TDR restores preoperative ROM regardless of implant design. However, our results also suggest that implant design does tend to affect adjacent level kinematics with unconstrained implants associated with increased adjacent level motion, and constrained implants associated with decreased adjacent level motion.

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Cervical Disc Replacement Augmented by an Anterior Polyester Mesh: Biomechanical Evaluation with Two Disc Replacement Devices
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Purpose: Removal of the anterior longitudinal ligament and anterior annulus during cervical total disc replacement (TDR) surgery may lead to hypermobility and instability in some motion planes; potentially contributing to altered facet loading and subsequent degeneration. In this study the effect on spinal kinematics of augmenting cervical TDR with an embroidered polyester mesh (Embrace, NuVasive, Inc., San Diego, CA), in place of the removed soft tissues, was investigated with two ball-and-socket TDRs: (1) CerPass (NuVasive, Inc.) - smaller diameter, ceramic-on-ceramic articulation; (2) PCM (NuVasive, Inc.) - larger diameter, metal-on-UHMWPE articulation.

Methods: Six fresh-frozen cadaveric osteo-ligamentous cervical spines were potted at C2 and T1 (average age 37.8, range 24-52 yrs; 3 male, 3 female). Infra-red motion-tracking markers arrays were mounted at C2, C4, C5, C6, C7 and T1. Specimens were tested using a multi-directional, hybrid protocol. The intact spines were tested in load-control at ±1.5 Nm in flexion-extension, lateral bending and axial rotation. The global ROM (C2-T1) was measured in each direction and applied to all further test conditions, applied at C5-6, which were: (i) CerPass, (ii) CerPass + Embrace mesh, (iii) PCM, and (iv) PCM + Embrace mesh. Intervertebral motion was recorded using an optoelectronic system (Optotrak Certus). Range-of-motion (ROM) and neutral zone (NZ) were determined at the index and adjacent levels.

Results: Flexion-extension ROM at the index level was not significantly altered (p > 0.05) from the intact spine (11.9°) with either CerPass (11.6°) or PCM (10.1°). The primary impact of adding the mesh was seen in sagittal plane motion, with a significant reduction in extension ROM for both TDRs (CerPass + mesh: 2.5° decrease; PCM + mesh: 3.0°). Extension NZ (Figure 1) increased with respect to intact for both discs (2.5-3 times greater), however the difference only reached significance with CerPass. Adding the mesh noticeably reduced extension NZ for both discs, returning it closer to intact. In lateral bending and axial rotation, there were no significant differences between the TDRs with or without the mesh, and average ROM and NZ were less than intact in all cases.

Conclusion: While total intact flexion-extension ROM was maintained with both anterior cervical TDRs, extension ROM and extension NZ both increased with respect to intact. ROM and NZ were less than intact in lateral bending and axial rotation. The addition of the Embrace anterior polyester mesh had the predominant effect of decreasing extension ROM and extension NZ. Preventing hyperextension with the mesh may protect the facets from overloading, while reducing extension NZ provides more stable and controlled motion. Similar biomechanical behavior has previously been reported when this mesh was applied over anterior lumbar TDRs (Cunningham, Cappuccino, et al., SAS9, 2009).
Results: The ROM results are shown in Fig 2. Decompression produced more flexible segment, while instrumentation of either titanium or PEEK rod systems stabilized the segment equally.

Load Sharing - Under 400N upper thoracic load, 335 N was transferred through the anterior column support and 68 N through the semi-rigid rod. The corresponding load sharing for the rigid rod was 300 N and 104 N respectively. The semi-rigid rod shifted 10% of the upper thoracic load from the posterior to anterior, thus reducing loading on the posterior instrumentation by approximately 34% compared to the rigid rod.

Bone-Screw Loading - The screw bending moment for the semi-rigid rod construct was 0.3 Nm for both flexion and extension. The corresponding load for rigid rod construct were 1.0 Nm and 0.4 Nm. The bending moment acting on the bone-screw interface is reduced by 70% and 25% in flexion and extension respectively when compared to titanium rod.

Conclusions: These results show that there is no difference between rigid and semi-rigid rods for stabilization in spine in fusion construct. However, the semi-rigid has an advantage by shifting the load from posterior instrumentation to anterior column support thus promoting fusion in accordance to Wolff's law, while reducing loads on the bone screw interface. Thereby may be ideal for fusion in the aging spine and poor osteoporotic bone quality.

Introduction: A key design parameter for a constrained ball and socket TDR device is its fixed center of rotation (CoR). Malalignment between the implant CoR and the inherent rotational axis of the MSU may lead to an overloaded, over-constrained condition. Different paradigms exist for the surgical placement of TDR devices however conventional in-vitro testing methodologies lack the sensitivity to discern the effects of changes in implant placement.

Objective: The objective was to evaluate in-vitro changes in MSU mechanics and ROM due to variations in surgical placement of a simulated ball and socket TDR device, like the ProDisc-L, within a human cadaveric lumbar model.

Methods: A custom designed Spine Robot was programmed to prescribe pure rotation of an MSU about any desired CoR location. Six fresh human cadaveric lumbar spines, L4-L5, were implanted with the ProDisc-L (Synthes Spine). Lateral radiographs and Image-J software (NIH) were used to determine the surgical placement of the implant’s CoR. Each specimen was mounted in the Spine Robot and rotated in flexion and extension about the implanted CoR. Subsequently, with the MSU held rigid in the robot, the implant was removed and rotation about the implant’s CoR was repeated. Thereafter, simulated CoRs were tested as defined by a customized grid pattern of 8 CoRs simulating different possible placements of a medium and large size ProDisc-L implant with a 10mm inlay height and 6º lordosis (Figure 1). The pattern was based on surgeon preference for posterior placement of the implant with the largest size footprint and the smallest inlay height (i.e. point LP Figure 1). All subsequent points were offset from this point (mean distance 2.5mm). Specimens were rotated to an end limit of 8Nm or 15º rotation. Resultant shear forces, axial forces and global rotation were compared at each CoR using a RM ANOVA with SNK tests (p=0.05).

Results: During flexion, an increased net anterior shear force and net tensile axial force occurred as the simulated implant was positioned more posterior with significant differences occurring within and between the medium (6mm) and large (8mm) CoR planes. In extension net axial loads were compressive and significantly increased at midline-anterior placements in both planes. In extension ROM was significantly increased with posterior CoR placements in both planes. Simulated medium and large size implants performed in a similar manner.

Discussion: This study demonstrates the net posterior tissue response to varying simulated placements of the ProDisc-L which was sensitive in terms of loading mechanics and ROM. For both implant footprints, posterior positioning of the simulated implant during flexion created a stiffer MSU construct with higher loading, while in extension posterior positioning promoted reduced loading and greater rotation. These data suggest that flexion and extension may have
different initial CoRs. A study limitation is that a fully constrained ball and socket TDR may not always function as intended in-vivo.

**Breakout 1: Cervical Complications**

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**Transitional Appearance of Advanced Heterotopic Ossification in Cervical Artificial Disc Replacement**

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**Background and Aims:** Reported heterotopic ossification occurrence rate in cervical artificial disc replacement was unexpectedly high and varied. This study was designed to investigate the transitional appearance of heterotopic ossification from the mid-term observational study of heterotopic ossification and to understand natural course of heterotopic ossification.

**Methods:** The total of 67 patients undergoing cervical arthroplasty with the Bryan Cervical Disc Prosthesis (Medtronic Sofamor Danek, Memphis, TN, USA), Mobi-C disc prosthesis (LDR medical, Troyes, France) and ProDisc-C (Synthes, Inc., West Chester, PA, USA) were included. The investigation of heterotopic ossification was already made in the mid-term observational study at 19.9 months after operation. Cervical lateral radiographs and computed tomography obtained after the last observation were used to identify the change in the heterotopic ossification. The change in the grade of heterotopic ossification and the characteristics were investigated according to the preexisting ossification and different prosthesis.

**Results:** Each prosthesis group included patients as follows; Bryan disc 21 patients, Mobi-C 29 patients, and ProDisc-C 17 patients. Overall heterotopic ossification rate was 46.3% (31 of 67 patients; Bryan disc 28.6%, Mobi-C 45.2%, ProDisc-C 64.7%) at 18.6 months follow up period in the midterm observation and final heterotopic ossification rate was 64.2% (43 of 67 patients; Bryan disc 28.6%, Mobi-C 83.9%, ProDisc-C 76.5%) at 36.9 months in the present study. The time interval of observation was 18.3 months in average and increased heterotopic ossification rate was 17.9%. The rate of relative increase was overall 39.4% compared with preexisting status. Each preexisting heterotopic ossification showed the different rate of relative increase as below; grade 1 (33.3%), grade 2 (66.2%), grade 3 (47.4%) and grade 4 (0.0%, no change possible by definition). The rates of relative increase by the prosthesis were the Bryan disc group 5.0%, Mobi-C group 58.6% and the ProDisc-C group 47.1%. The overall new occurrence rate of heterotopic ossification was 33.3%; by prosthesis were the Bryan disc group 0.0%, Mobi-C group 70.6% and the ProDisc-C group 33.3%.

**Conclusions:** Occurrence of heterotopic ossification is inevitable postoperative complication after cervical artificial disc replacement. The occurrence rate of heterotopic ossification was higher than our expectation. Moreover, the progressive ossification pattern after initial occurrence was revealed in this study. But the lower grade of preexisting heterotopic ossification showed the slow or no progression in the ossification and advanced preexisting heterotopic ossification showed more progression.

**References:**


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**Analysis of the Formation and Grade of Heterotopic Ossification that May Influence the Postoperative Segmental Range of Motion after Bryan Cervical Artificial Disc Replacement**

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**Objectives:** To evaluate the influence of the formation and grading of heterotopic ossification (HO) on the postoperative segmental range of motion (ROM) after Bryan cervical artificial disc replacement (CADR).

**Methods:** A total of 40 patients undergoing single level Bryan disc replacement from December 2003 to August 2009 were reviewed retrospectively. There were 18 men and 22 women with a mean age of 42.6 years (range, 20-54 years). All cases were followed up for more than 1 year (range, 12-69 months; average, 38.8 months). The occurrence of HO was defined by the McAfee classification, and segmental ROM (full flexion angle-full extension angle) was measured in Picture Archiving and Communication System (PACS). Correlations between the occurrence and grading of HO and segmental ROM at last follow-up were analyzed.

**Results:** The occurrence rate of HO in this study was 37.5% (15/40), and the classification of HO by McAfee’s criteria distributed as follows: grade I 2cases, grade II 3cases, grade III 8cases, grade IV 2cases. For all the patients, the mean segmental ROM changed from 8.82°preoperatively to 8.52°at last follow-up. ROM of the patients with or without HO was 9.77°±2.74°and 6.43°±3.23° respectively at last follow-up (p < 0.05). ROM of the HO patients identified McAfee grade I, II, and grade III, IV, was 8.76°±3.40°and 5.26°±2.64° respectively at last follow-up (p < 0.05).

**Conclusions:** The occurrence of HO after CADR with Bryan disc prosthesis may reduce the segmental ROM, especially for the McAfee grade III and IV.
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**Adjacent Level Ossification Development Following Anterior Cervical Fusion: How does it Affect the Next Level Disc?**


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**Introduction:** Anterior adjacent level ossification development (ALOD) is a form of heterotopic ossification that occurs commonly after anterior cervical arthrodesis. In severe form, it might lead to near or complete auto fusion, thus resulting in restriction of the range of motion (ROM) at the affected segment. However, to date, there have been no reports regarding its clinical significance. The purpose of this study was to investigate how ALOD influences the affected and the next level discs in terms of ROM and degenerative changes including disc height decrease, osteophyte formation, and anteroposterior displacement.

**Methods:** This is a retrospective, single institution, matched-pair study of anterior cervical fusions with minimum 2-year follow-up. The severity of ossification was classified as grade 0 (no ossification), grade 1 (< 50% of disc space), grade 2 (≥50% of disc space), and grade 3 (complete bridging). Twelve patients who presented with grade 3 ALOD were first selected. To these patients, 12 patients with grade 2 disease, 12 with grade 1, and 12 with grade 0 were matched using criteria of age, gender, and number of fusion levels.

Three lateral radiographic views of the cervical spine were taken in neutral, extension, and flexion preoperatively and at the final follow up. On the neutral films, disc height and the length of osteophytes were measured at the segments which were 1 (adjacent segment) and 2-level cranial (the next segment) to the uppermost fused disc. On the lateral films in extension/flexion position, the ROM of each segment and the degree of maximal listhesis (antero- or retro-) were investigated. The patients were classified into two groups according to the degree of ALOD: group 1 (grade 0-1, N=24) vs. group 2 (grade 2-3, N=24). The changes of all variables were compared between two groups.

**Results:** There were no significant differences between two groups based on age, gender, the number of fusion levels, and follow-up period (p>0.05). The mean ROM of adjacent segment increased by 3.6° in group 1; meanwhile, decreased by 2.8° in group 2 (p=0.002). The mean ROM of the next segment increased in both groups and the increasing amount was significantly greater in group 2 than in group 1 (4.5° vs. 1.2°, p=0.016). The osteophyte growth and the aggravation of listhesis at the next segment were significantly greater in group 2 (p<0.05); however, at the adjacent segment, the degree of listhesis was not aggravated. Neither at the adjacent level nor at the next level, was the disc height changed significantly (p>0.05).

**Conclusions:** Moderate to severe ALOD (grade 2-3) following anterior cervical fusion significantly reduced ROM at the affected segment; meanwhile it increased the motion at the next segment. This suggests that ALOD affects not only the adjacent segment, but also 2 levels cranial to the fusion site by increasing osteophyte growth and the aggravation of listhesis. On the basis of these results, ALOD could be considered as a type of complication related with anterior cervical arthrodesis. Therefore, surgeons need to apply the possible techniques to avoid or mitigate this problem.

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**Analysis of Adjacent Segment Degeneration: Results of a Prospective, Randomized Study Comparing Cervical Total Disc Replacement vs. Anterior Cervical Fusion**


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**Introduction:** Clinical results of anterior cervical fusion (ACF) are generally good, but there is support for potential accelerated degenerative changes at the adjacent level(s). One potential benefit of cervical total disc replacement (TDR) is motion of the operated segment which may protect adjacent levels from accelerated deterioration. The purpose of this prospective, randomized study was to evaluate a new cervical TDR implant by analyzing radiographic findings of range of motion and deterioration of the adjacent segment and compare those data to ACF.

**Methods:** The study was a prospective, randomized trial conducted at 21 centers across the USA participating in an FDA-regulated trial. A total of 269 patients, all treated for single-level cervical disc problems, were enrolled and randomly assigned to either cervical TDR using the Kineflex|C (Spinal Motion) (n=136) or to ACF (n=133). Anteroposterior, neutral lateral, and flexion/extension radiographs were made at each study visit. After patients were enrolled in the study they were assigned to undergo cervical TDR or ACF using autograft and an anterior plate. Patients were evaluated radiographically pre-operatively and at 3, 6, 12, and 24 months after surgery. All radiographs were evaluated by a center specializing in spinal radiographic assessment. Range of motion (ROM) was determined by measuring the rotation from flexion/extension images. The extent of adjacent segment degeneration was classified by an independent radiologist as: none, mild, moderate, or severe.

**Results:** Segmental ROM in the TDR group significantly decreased at 3 months, but was significantly greater than the pre-operative mean at 12- and 24-month follow-up (Figure 1). The ROM in the ACF group was significantly reduced by 3 months and remained so throughout the follow-up.

![Figure 1. Operated segment range of motion.](image-url)

**Figure 1. Operated segment range of motion.**

Pre-operatively, there was no significant difference in the proportions of patients in the disc degeneration categories, when comparing TDR to ACF (Figure 2). However, at 24-month follow-up there was a significant difference (p<0.01), indicating that more patients in the ACF group had greater grades of adjacent segment disc degeneration than the TDR group.
Introduction: Anterior cervical disectomy and fusion (ACDF) remains the surgical standard of care for cervical radiculopathy and/or myelopathy unresponsive to nonoperative treatment. With reported reoperation rates of 5-10% two years after single-level ACDF, cervical disc arthroplasty (CDA) is gaining interest as an alternative for up to 40% of ACDF candidates. Multilevel CDA patient outcomes at least equivalent to single-level CDA have also been reported. This study reports secondary surgery rates for a large consecutive series of CDA patients.

Methods: In this study at a single site, 237 patients with similar preoperative diagnoses including cervical degenerative disease at one or more cervical levels—but no prior surgery—were treated by two fellowship-trained spine surgeons in a hospital setting (99) or an outpatient center (138) with CDA through a standard anterior approach between April 2003 and October 2010. Patient demographics, intraoperative measures including operative time and blood loss, and postoperative observations including complications, readmissions, and secondary surgical procedures were reviewed.

Results: Patients (138 male/99 female) with average age of 45.0 years and average weight of 194.3 pounds (male 215, female 166) were treated at one (142), two (76), three (18), or four (1) levels. Median time since surgery was 27.9 months. Workers’ compensation claims totaled 70.5% of patients, and 46% were smokers. Mean operative time was 81.7 minutes (mean 58.8 minutes per device implanted), and mean estimated blood loss (EBL) was 49.4 cc. No infections, delayed intubations or other postoperative complications were reported; there were no unplanned readmissions or transfers to hospital. One patient died in an accident 5 months after surgery. Eight (3.4%) patients underwent cervical revision or reoperation at an outpatient center, a median 603 days (range 104-918) after their index surgery. Four (4.0%) were originally hospital procedures, and four (2.9%) were outpatient center surgeries (p = 0.72). Six of 142 (4.4%) single-level patients underwent secondary surgical procedures. The one revision was a device removal revised to an anterior fusion. There were 5 single-level reoperation surgeries as follows: one decompression, three CDA at another level, and one hybrid ACDF/CDA at the two superior adjacent levels. Two of 95 (2.1%) multilevel patients (both 2-level) had secondary surgeries: one was a decompression, and one a removal of the inferior level prosthesis revised to an anterior fusion. Differences in second surgery rates for single and multilevel CDA were not significant (p = 0.48). Mean operative time for these eight secondary surgeries was 82.9 minutes with average 50cc EBL.

Conclusion: Cervical disc arthroplasty at a single level was shown to be safe and effective compared to ACDF in three recent large FDA prospective randomized controlled trials, and multilevel trials are in progress. In this large case series, reported rates of secondary surgical procedure after CDA at one to four levels were equivalent to or better than rates reported in the evidence-based literature for ACDF. CDA may be a safe and effective alternative to ACDF for appropriately selected patients, and long-term studies currently underway will answer important questions about adjacent level disease and the incidence of additional surgery.
of the 50 point total) and are between 18 and 60 years of age. Data from all participating IDE sites having received appropriate approval by their respective Institutional Review Boards are presented.

**Results Summary:** Three hundred eighty (380) patients were treated in the approved IDE Study (the first five patients at each site were non-randomized to the SECURE-C implant). Data is presented from randomized patients only: 151 patients were treated with the investigational SECURE-C device and 140 received the control ACDF. Two of the patients treated with the SECURE-C device received additional anterior surgery at adjacent levels; one patient underwent a two-level fusion at 16.9 months post-op; the other received another cervical disc replacement at an adjacent level at 17.3 months post-op. Seven of the patients in the control ACDF cohort experienced adjacent level treatments, six of these patients received a two level anterior fusion between 7 weeks post-op and 35 months post-op; one underwent a three level anterior fusion at 20.8 months post-op. Adjacent levels requiring treatment occurred at both above and below the index level, with no evident trends in the data. The rate of anterior adjacent level surgery was 4.9% for the control group, and 1.3% for the cervical disc arthroplasty group.

**Conclusion:** The incidence of anterior surgical treatment for adjacent level disc disease was higher in the control ACDF group as compared to the incidence among those patients who were treated with the investigational SECURE-C device. These results suggest that devices such as SECURE-C that utilize motion preservation technology may help reduce the risk of developing adjacent level disease in the cervical spine.

**470 Treating Cervical Pseudoarthrosis with Cervical Artificial Disc Replacement**

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**Introduction:** The standard surgical correction for pseudoarthrosis following anterior cervical decompression and fusion (ACDF) is a posterior fusion with various types of instrumentation versus anterior revision. The purpose of this abstract is to ascertain the safety and efficacy of treating an ACDF pseudoarthrosis by conversion to cervical artificial disc replacement. The Prestige ST implant was selected due to its anterior phalanges allowing immediate secure screw fixation into the vertebral bodies. The phalanges also prevent heterotopic bone formation.

**Methods:** Clinical data from every patient undergoing removal of an anterior cervical plate and fibrous pseudoarthrosis with redo decompression followed by implantation of a Prestige ST cervical artificial disc (CADR) were evaluated. Pseudoarthrosis was diagnosed on flexion/extension x-rays.

**Results:** Eight patients with previous multi-level cervical fusion and single-level pseudoarthrosis elected to proceed with conversion of pseudoarthrosis to CADR. The surgical technique will be described. There were no surgical complications in terms of neurologic deficits, hematoma or implant complications.

**448 Lessons Learned on Cervical Total Disc Replacement after 7 Years Follow-up**

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**Introduction:** Degeneration of the spine is a very common phenomenon. The morphological changes have been described macroscopically, histologically, and using many different imaging techniques such as plain radiography, discography, magnetic resonance imaging, or computed tomography. Indications can range from conservative care, anterior or posterior surgical techniques. Cervical spine fusion was well adopted since the 1950s to stabilize, treat degenerative changes and reduce deformity. Various studies demonstrate that single-level ACDF procedures do alter spinal kinematics and multilevel procedures compromise global spinal motion. Along with critical clinical and scientific overview, arthroplasty technology was developed to maintain movement and reduce adjacent segment stress and degeneration. Here we show our 7 years experience with PCM total disc replacement.

**Materials and methods:** We studied radiographs of 270 levels in 158 patients treated with cervical TDR using the PCM device between C3-4 and C7-T1. The mean age was 45.4 years old. 74 patients were operated at one disc level, 62 at two, 16 at three, and 6 at four levels. Radiological (AP, lateral and dynamic) and clinical outcomes were collected preoperatively, 1 week and 1, 3 and 6 months and annually. The NDI, VAS and TIGT questionnaires were used to assess pain and functional outcomes. The McAfee scale for heterotopic bone formation evaluation was applied. For facet degeneration analysis, was used a four grade scale based on CT Scans.

**Results:** The clinical outcomes were statistically significant in all postoperative periods when compared to preop. The degenerative facet join disease in the cervical spine after cervical arthroplasty exists. Using the four grade classification, the majority of patients belong to grade I and II. We didn’t find relationship between the CT scan facet degeneration and clinical results in these stages, except in grade III and IV that outcomes scales had a worsening. From all levels studied, 21(7.7%) revealed some level of HO. Of these, 10 levels were rated to be grade I (47.6%), 7 to be grade II (33.3%), 3 to be grade III (14.28%) and 1 to be grade IV (4.76%). The affected disc level was part of a multi-level procedure in 41.6%, and 58.4% in a single level construction. In 92% of patients that
Complications Following Anterior Cervical Fusion Using Hydroxyapatite from Long-term Follow-up

Aims: Using strut iliac bone to perform anterior cervical fusion (ACF) is a standard method. We started ACF using hydroxyapatite ceramics (HA) to prevent donor site complications in 1992. There have been several reports concerning the complications on the use of HA in ACF. The purpose is to evaluate the clinical and radiographic complications of ACF with HA from long-term follow-up and to confirm the efficacy of HA for ACF.

Methods: Group 1 included 89 patients that underwent ACF using HA without anterior plate. Group 2 included 34 patients that underwent ACF using HA with anterior plate. The average age and follow-up period of group 1 were 54 years and 9 years (> 7 years). Those of group 2 were 61.4 years and 8 years (> 7 years). Radiographic complications involved pseudoarthrosis, subsidence of grafted HA, clear zone around HA, changes of lordotic angle of the fused segment, displacement and crack of HA. Clinical complications involved infections, neurological deteriorations and re-operations. Pseudoarthrosis was determined when there was anterior or posterior displacement more than 1.0 mm and/or change of lordotic angle of the fused segment more than 3 degrees by flexion and extension views. Subsidence of grafted HA was measured as the loss of height of fused segment. All cases without anterior plate used Philadelphia collar for two - three months.

Results: In group 1, 5.6% cases showed clear zone around HA without instability. 94.3% cases showed solid fusion without clear zone around HA and instability. 56% cases had subsidence of HA with an average of 1.6 mm (range, 1-3 mm). 13.4% cases revealed decrease of lordotic angle of the fused segment with an average of 2.8 degrees (range, 1-4 degrees). Cracks of HA were recognized in 15.7%. No collapse and no displacement of HA were observed. Two cases with postoperative hematoma and infection needed re-operation. In group 2, 100% cases showed solid fusion without instability and clear zone around HA. There was no case with crack of HA and screw breakage. 23.5% cases had subsidence of HA with an average of 1.7 mm (range, 1-4 mm). No case showed loss of lordotic angle of the fused segment. There was no case with infections and neurological deterioration. One case with 3-level ACF that had screw back out immediately after surgery needed re-operation by bending the plate. Recovery rates of group 1 and group 2 were 63.6% and 61.9% respectively.

Conclusions: We showed the long-term outcomes of ACF with HA. Both groups had no serious clinical complications and revealed satisfactory neurological recovery rate. Using anterior plating for ACF with HA predominantly decreased subsidence rate of HA and loss of lordotic angle of the fused segment. In addition, the use of anterior plate prevented cracks of HA. Crack of HA is a new complication not seen in standard ACF using iliac bone. But, those cracks of HA have never produced pseudoarthrosis and re-operation. Long-term results of ACF using HA with or without the use of anterior plate were excellent. We conclude that our method is both a safe and a less invasive method of ACF that brings no complications of donor site.
However, the complication rate had a higher rate in the Dynesys arm than in the Fusion arm and this difference was statistically significant, (p = .03). It should be noted that the patient population is small thus the power of testing is low and a larger population should be tested to assure that no other differences surface.

**Conclusion:** Fusion procedures performed better than Dynesys stabilization in all three categories, but the differences were only statistically significant in the complications rate (see results chart). Within the Fusion arm there was one non-union requiring revision due to Anterior Lumbar Interbody Fusion (ALIF) autograft failure requiring ALIF BMP (Infuse™) revision with maintenance of the Dynesys device. Outside the hybridized subset, one case exhibited symptomatic screw failures (2) at four years in a pure Dynesys construct. Halos were a radiographic phenomenon and not a clear indication for device related complications and of no real value in clinical decision making. Our complications included hardware related pain requiring removal (1) and adjacent level degeneration despite stabilization requiring fusion (4). Finally, we feel that our complications in the Dynesys arm underline our current limited understanding for dynamic stabilization system application and validate the need for further post-market surveillance.

**Results:** A statistically significant reduction in IPT at L4-L5 during flexion extension and lateral bending of each of the instrumented conditions with respect to both the intact and destabilized conditions was found (p < 0.01). At L5-S1 significant reductions, with respect to intact, in flexion extension IPT were found in both the two-Level and hybrid conditions (p < 0.006). Furthermore, a significant reduction, with respect to two-level, in flexion extension IPT was found in the hybrid condition (p = 0.011). The hybrid condition showed a decrease in IPT during lateral bending when compared to both the intact and two-level conditions (p = 0.006 and 0.025 respectively).

The flexion extension spherical joint rotation at L5 was significantly less for the two-level condition than for both other instrumented conditions, one-level (p = 0.042) and hybrid (p = 0.022). In addition, the lateral bending spherical joint rotation at L5 was significantly less for the two-level condition compared to the hybrid condition.

**Conclusions:** The results indicate that implantation of each construct results in a significant reduction in IPT but that IPT is greater for the two-level Stabilimax than for rigid fixation at the index level. This is particularly interesting given that range-of-motion did not indicate a difference between these two treatments in this study. The spherical joint rotation results indicate that the two-level device is more constrained at the middle screw (LS) than the one-level device. This result makes intuitive sense given that this is where the top and bottom halves of the device are coupled.

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**In vitro Comparison of One and Two Level Posterior Dynamic Stabilization Device: Inferences from Kinematic Tracking of Device Components Based on Interpedicular Travel and Spherical Joint Rotation**

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**Background:** Posterior dynamic stabilization devices have become of interest due to the potential for these implants to provide controlled interpedicular travel coupled with intervertebral rotation, a necessary requirement for optimal, stable intervertebral motion. Ideally, dynamic lumbar implants should mitigate extraneous motion for the instrumented functional spinal unit (FSU) to prevent further degeneration of the pathologic FSU. The ability for the Stabilimax device to control the kinematic response and appropriate posterior load through the FSU should be fully characterized for both one and two-level constructs in order to understand the potential clinical implications of the device.

**Methods:** Six fresh frozen-human lumbar cadaveric specimens were stripped of all soft tissue excluding the osteoligamentous structures. Each specimen was subjected to pure moment flexion extension, lateral bending and axial torsion loading protocols with load limits equal to +/- 7.5Nm in the intact condition, after destabilization, implantation with a one-level Stabilimax at L4-L5, a two-level Stabilimax extended to L5-S1 and a hybrid construct consisting of a one-level Stabilimax at L4-L5 and rigid rod fixation at L5-S1. The motion of each vertebra was recorded during each test using an optoelectric motion tracking system (Optotrak, Waterloo Canada). Furthermore, the relative motion of pertinent components of the device was tracked during testing using the same technique. Interpedicular Travel (IPT) was defined as the magnitude of the vector describing the translation of adjacent pedicles between peak loading conditions. The rotation of each pedicle screw on the left side of each spine within its spherical joint was also calculated.

**Conclusions:** The results indicate that implantation of each construct results in a significant reduction in IPT but that IPT is greater for the two-level Stabilimax than for rigid fixation at the index level. This is particularly interesting given that range-of-motion did not indicate a difference between these two treatments in this study. The spherical joint rotation results indicate that the two-level device is more constrained at the middle screw (LS) than the one-level device. This result makes intuitive sense given that this is where the top and bottom halves of the device are coupled.
load through the FSU should be fully characterized for both one and two-level constructs in order to understand the potential clinical implications of the device. This is particularly important because this class of devices has demonstrated disparate results between one and two-level constructs.

**Methods:** Six fresh frozen-human lumbar cadaveric specimens were stripped of all soft tissue excluding the osteoligamentous structures. Each specimen was subjected to pure moment flexion extension, lateral bending and axial torsion loading protocols with load limits equal to +/-7.5Nm in the intact condition, after destabilization, implantation with a one-level Stabilimax at L4-L5, a two-level Stabilimax extended to L5-S1 and a hybrid construct with rigid rod fixation at L5-S1. The motion of each vertebra was recorded during each test using an optoelectric motion tracking system (Optotrak, Waterloo Canada).

**Results:** Statistically significant differences were found in the flexion extension ROM between the Intact condition and all other treatments as well as between the Destabilized condition and all other treatments (p<0.04). The lateral bending ROM was significantly less for the two-level Stabilimax compared to both the intact and one-level treatments (p=0.043 and 0.014 respectively). The destabilized, one-level and hybrid treatments resulted in significantly greater axial torsion ROM when compared to intact (p=0.016, 0.017, 0.049 respectively). At L4-L5 a superior shift in the Finite Helical Axis (FHA) was observed during flexion extension for the two-level condition compared to the intact (p=0.016), destabilized (p=0.013) and one-level (p=0.001) conditions. At L4-L5 during lateral bending, a statistically significant superior shift in the FHA was observed for the two-level condition with respect to destabilized (p=0.039). The same trend was observed compared to the intact condition, but the difference was not statistically significant based on the analysis conducted (p=0.055).

Implantation of the two-level device resulted in a statistically significant reduction in flexion extension and lateral bending ROM (p=0.04 and 0.025 respectively) compared to intact at the L5-S1 FSU. Implantation of the hybrid construct resulted in a significant decrease in lateral bending ROM as well (p=0.019). While the reduction in flexion extension ROM for the hybrid construct was not significant, it did show a trend toward significance (p=0.055).

**Conclusions:** The data presented indicate that the mechanics of the one and two-level Stabilimax may differ significantly, particularly in lateral bending. Furthermore, the FHA results indicate that implantation of the two-level system results in shifting the flexion extension center of rotation in the superior direction. A similar trend may exist in lateral bending. These findings may be attributed to the coupled design of the two-level device. Surprisingly, no argument can be made based on this ROM data that the two-level Stabilimax provides more motion than a rigid rod at L5-S1.

**32 Posterior Dynamic Stabilization versus Anterior Dynamic Stabilization in Lumbar Degenerative Disc Disease: A Comparison of Results**

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**Study design:** This study was a prospective clinical study.

**Objective:** The objective of this study was to compare the clinical results of both anterior/lumbar total disc replacement and posterior dynamic transpedicular stabilization. Summary and Background Data: Over the last two decades, both anterior total displacement and posterior dynamic transpedicular stabilization have emerged as alternative treatment options to fusion surgery in degenerative diseases of spine that cause chronic lumbar instability. Clinical studies related to both dynamic systems have yielded satisfactory results; however, the lack of studies comparing the clinical results of these biomechanically different systems is apparent in the literature.

**Methods:** This study was conducted between 2004 and 2008 and included a total of 40 patients (20 in each group). Total disc replacement with anterior dynamic stabilization was performed on 20 patients (11 females and 9 males). The mean age of the patients was 39.5 (ranged from 33 to 50 years), and the mean follow-up period was 28.7 months (ranged from 24 to 32 years). Posterior dynamic transpedicular stabilization was also performed on 20 patients (12 females and 8 males). The mean age of the patients was 43.6 (ranged from 25 to 55 years), and the mean follow-up period was 34.1 months. Clinical and radiologicalevaluations of the patients were carried out preoperatively and in the 3rd, 12th, and 24th postoperative months. We evaluated and compared the average duration of surgery, blood loss during the surgery, and the length of the hospital stay of both groups.

**Results:** There were not any surgical morbidity and/or observed complications in the posterior dynamic stabilization group. In two patients of the anterior stabilization group, however, iliac vein injury occurred during the placement of the lumbar disc prosthesis, but it was sutured during the operation.

**Conclusion:** Positive results in the treatment of symptomatic lumbar degenerative disc disease with both posterior dynamic transpedicular stabilization and lumbar anterior disc prosthesis suggested that both dynamic systems could be important alternative treatment options to fusion surgery. Although both dynamic systems seemed to be similar in terms of providing spine stability, having a short operation time, allowing early mobilization, and an early return to work, the posterior dynamic system was slightly more advantageous than the anterior disc prosthesis because of conveniences in its application and a reduced rate of possible complications.

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Introduction: Using an in-vitro human cadaveric model, the current study served to quantify the multidirectional flexibility properties and changes in intradiscal pressure at the superior operative level and proximal adjacent intervertebral levels following reconstruction using solid and dynamic rod techniques.

Methods: Nine cadaveric lumbar spines were biomechanically evaluated under the following L1-L5 reconstruction conditions:
1. Intact,
2. Solid Rod,
3. Hybrid (flexible L1-L2 and solid rod L2-L5),
4. Dynamic Rod (flexible L1-L5),
5. Laminectomy,
6. Lami+Solid Rod,
7. Lami+Hybrid,
8. Lami+Dynamic Rod (Transition™ and Revere™ Systems).

Multi-directional flexibility testing utilized utilized intact moments of ±10Nm for axial rotation, flexion-extension and lateral bending. Intradiscal pressure at T12-L1, L1-L2 and L5-S1 levels were quantified along with operative and adjacent level range of motion (ROM) and neutral zone (NZ) normalized to the intact spine (100%).

Results:
Lateral Bending: Solid Rod (10.24±3.99) and Hybrid (10.36±3.95), proximal adjacent level ROM (T12-L1) increased compared to the intact spine (p<0.05). These trends were similar to post laminectomy. Distal adjacent level (L5-S1) increased in ROM for Solid Rod and Hybrid versus intact and laminectomy (p<0.05). Proximal operative level ROM (L1-L2) for Hybrid (6.85±2.24), Lami+Hybrid (6.33±1.43), Dynamic Rod (6.03±2.22) and Lami+Dynamic Rod (5.56±1.52) were markedly higher than Solid Rod (4.48±0.78) and Lami+Solid Rod (4.46±1.15) (p<0.05). Operative level ROM (L2-L4) for Dynamic Rod (6.55±2.40) and Lami+Dynamic Rod (5.49±1.77) were significantly higher than Solid Rod (1.24±1.29) and Lami+Solid Rod (1.56±1.38) (p<0.05) (Figure 1).

Flexion-Extension: No significant differences were observed for the proximal (T12-L1) and adjacent levels when comparing the devices (p>0.05). Distal adjacent level (L5-S1) demonstrated an increased ROM for all groups versus intact and laminectomy (p<0.05). Operative level ROM (L2-L4) for Dynamic Rod (4.31±5.00) and Lami+Dynamic Rod (2.19±0.87) were markedly higher than Solid Rod (1.43±0.67) and Lami+Solid Rod (1.55±0.82) (p>0.05).

Axial Rotation: No significant differences were observed at any levels when comparing the devices (p>0.05). Intadiscal pressure at the proximal adjacent level (T12-L1) indicated marked decreases in flexion-extension following Hybrid (148±23 psi) and Dynamic Rod (134±34.2 psi) compared to Solid Rod (176±49 psi) (p>0.05).

Conclusions: Posterior dynamic stabilization demonstrated significantly higher ROM than solid rod in lateral bending across the L2-L4 operative levels. Trends of increased ROM in flexion-extension at the superior operative level (L1-L2) with corresponding decreases in intradiscal pressures at the proximal adjacent level (T12-L1) were also observed. The current study provides a biomechanical basis for dynamic stabilization in long lumbar spinal constructs and may serve to augment ongoing clinical investigations.

[Figure 1]
Results: 16 spinal levels were treated. The operative segment was determined to be solidly fused if there was continuous new bone formation between the spinous processes or between two adjacent laminae. Bony fusion was unequivocal in 4/4 of the operative levels in both Groups I and II. However, upon visual inspection, there was notably greater volume of bone formation with a more radiodense appearance in those specimens where fusion was supplemented with an interspinous plate (Group I). Bony fusion was seen radiographically in 2/4 of the operative levels in the Groups III and IV (those levels without a biologic).

Conclusions: LLIF is a less disruptive approach to traditional instrumented posterior lumbar decompression and fusion. In a sheep model, radiographic and histopathologic fusion was well demonstrated. This procedure results in a fused segment in the lumbar spine when treated in conjunction with an allograft spacer, a spinous process plate, and a biologic.

234 Lumbar Spinal Stenosis Treatment with APERIUS® Percutaneous Interspinous Device (INCA Trial)
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Introduction: Degenerative lumbar spinal stenosis (DLSS) is a debilitating disease with cardinal symptom being Neurogenic Intermittent Claudication (NIC), a position-dependant syndrome. Patients presenting with leg pain and possibly back and or buttock groin pain, have exacerbated complaints in extension (walking, standing) and symptom-relief during flexion. Interspinous devices (IPD) will induce slight flexion and limit extension at the symptomatic level with increase in the dimensions of the spinal canal and neural foramina size and thus induce symptom relief. The APERIUS® Percutaneous Interspinous Spacer is the first percutaneous IPD.

Material and methods: The INCA trial was designed as a multicenter single arm post-marketing study to evaluate the safety and effectiveness of the APERIUS® in patients with degenerative lumbar stenosis with symptomatic NIC. 156 patients with a history of DLSS (L1-L5) at one or maximum 2 levels with symptoms of NIC with or without back pain were included. All patients were followed for 12 months with visits at 48 hours, 7 days, 6 weeks, 6 and 12 months. General anesthesia was chosen in 97% of procedures. Primary effectiveness endpoint was assessed as the mean % change from baseline in ZCQ Symptom Severity at 6 weeks. Other effectiveness outcomes were % change in ZCQ, EQ-5D, VAS pain score (back, leg and buttock groin pain), pain medication and changes in walking distance from baseline to follow-up. Procedure and device related SAE were assessed throughout the complete 12 month follow-up period.

Results: A total of 128 patients completed the study up to 12 months follow-up. Mean age of patients was 65 years (range 19 to 84) with mean complaint duration 41.3 months. Stenosis surgery was done at 1 level in 72 patients, 2 levels in 74 patients and 10 patients received 3 levels which gives a total of 250 devices implanted. Mean total procedure time was 15.5 minutes for 1 level, 24.6 minutes for 2 levels and 39.1 minutes for 3 levels. Primary endpoint, % change from baseline in ZCQ symptom severity score at 6 weeks, was statistically significant (mean change 29%, p < 0.001). Results were evident at 7 days and maintained for up to 12 months. At 6 weeks post procedure, 77% of patients had reached the clinically important improvement with a decrease of at least 0.5 points Improvement in ZCQ Physical function was highly significant from 6 weeks onward (p < 0.001). VAS scores for leg pain decreased significantly from baseline at all time points (p < 0.001) as did back pain and buttock/groin pain scores. A total of 12 SADE were reported during the course of the study. Three were considered procedure related and 9 were considered device related. Return of back pain (4 patients) and spinal claudication symptoms (3 patients) being the most common complaints. At 12 months, 14 (9.3%) devices had been removed.

Conclusion: The results of this pilot study indicate the use of the percutaneous APERIUS® spacer is safe and effective for the relief of NIC complaints in patients with symptomatic DLSS over a period of 12 months. Patients experience immediate pain relief and physical functional improvement is evident shortly after surgery.

340 Functional Dynamic Stabilization in Lumbar Spinal Stenosis with COFLEX® Interspinous Implant - 4 Year Results
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Introduction: A decompression procedure to treat a spinal stenosis may cause instability of the segment. To avoid adjacent level posterior stabilization it is preferred as a non fusion concept. With an interspinous device flexible stabilization is achieved while preserving the intervertebral disc and vertebral structures. It prevents a compression of neuronal space on extension and reduces load on the facet joints. If the ligament band is degenerated the affected segment is also stabilized for rotational movements. Indication is a spinal canal stenosis with or without hypertrophic facet joints.

Material and methods: The purpose of this study is to collect long term clinically relevant parameters for patients treated with the Coflex® implant. Pre- and post-operative data has been obtained using Visual Analog Pain Scores (VAS), Oswestry disability index (ODI) and the SF36. 153 Patients were assessed pre-operatively and post-operatively at 3 month, 6 month, 12, 24, 36 and 48 month.

Results: The mean age of the 77 males was 65 yrs (35-84) and of the 76 females 67 yrs (44-86). 112 single levels of surgery included L2/L3 (4,4%), L3/L4 (23,2%), L4/L5 (70,6%) and L5/S1 (1,8%). 41 multilevel implantations are L2/L3 - L3/L4 (21,9%),
L3/L4 - L4/L5 (70,9%); L4/L5-L5/S1 (2,4%); L4/L5-L5/L6 (2,4%) and one 3-level from L2 - L5 (2,4%).VAS, NDI and SF 36 values decreased significantly postoperatively and were maintained throughout the follow up. VAS scores decreased from a mean score of 7.2 ± 2.1 baseline to 4.4 ± 2.3 at 3 months; 4.3 ± 2.8 at 6 months; 4.3 ± 2.7 at 12 months; 4.5 ± 2.7 at 24 month; 3.6 ± 2.5 at 36 month and 4.0 ± 3.4 at . ODI scores (in %) reduced from 51.2 ± 16.6 baseline to 36.2 ± 18.1 at 3 months, 34.5 ± 20 at 6 months; 34.6 ± 19.9 at 12 months; 36.5 ± 19 at 24 months; 34.1 ± 21 at 36 months and 28.4 ± 22.7 at 48 month post-operative. The SF 36 physical / mental component and total was baseline P 46.8 ± 22.0 M 27.5 ± 9.4 T 64.8 ± 16.5 and improved at 3 month P 36.2 ± 11.0 M 31.9 ± 11.7 T 79.7 ± 17.2; 6 month P 36.7 ± 9.4 M 30.6 ± 12.8 T 79.6 ± 18.5; 12 month P 34.9 ± 10.4 M 22.9 ± 9.4 T 79.4 ± 17.7; 24month P 35.6 ± 10.0 M 30.5 ± 9.4 T 79.5 ± 18.6; 36 month P 35.6 ± 9.1 M 31.3 ± 7.7 T 79.5 ± 19.7 and 48 month P 32.7 ± 12.2 M 29.1 ± 8.7 T 86.6 ± 18.4. 88%, respectively 82% of the patients were completely satisfied or at least satisfied with the result of the surgery 12, 24 months post-operative an no one reported to be unsatisfied at 36 and 48 month. Three cases required a revision. 

Conclusions: The Coflex® implant offers a simple surgical treatment strategy with a low risk potential. First results show good improvement of clinical relevant parameters and a high degree of patient satisfaction. The investigation in this group of patients is continued to collect more long term data.

74 Not Interspinous, but Interlaminar, Not Decompression Device, but Overload Assistance Device: INTRASpine, a Posterior Motion Preservation Device in Lumbar DDD: Biomechanics, Indications and Clinical Results (up to 2 Years Follow up)

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Purpose of the study: All interspinous systems presently available create, albeit in different degrees, a significant reduction of the flexion-extension and, in minor measures, of the bending and axial rotation.

Materials and methods: We present the results of the biomechanical tests in regards to the use of a new device for interlaminar assistance in the degenerative pathologies of mobile lumbar segments. The device, made of medical silicone (65 shore) with a polyethylene terephthalate coating, has an advantage with respect to other similar interspinous devices, which is that it may be implanted more anteriorly (interlaminar) and therefore as close as possible to the center of instantaneous rotation of the segment. Furthermore, with this device, it is possible to restore the physiological lumbar lordosis, also thanks to the augmentation of the supraspinous fibrous complex by means of a robust artificial ligament that is passed around the two adjacent spinous processes.

The indications are:
- Chronic low back pain in black disk with facet-syndrome (pre-operative evaluation with dynamic X-rays and block tests of the facet joints)
- Soft and/or dynamic and foraminal stenosis
- After operations for big expelled disc hernias in young patients so as to prevent the collapse of the disc and the subsequent CLBP
- Insufficiency of the supra-spinal fibrous complex
- Topping of
- After operation for synovial cyst.

Results: The biomechanical tests about the ROM and the clinical results of the Italian prospective multicenter clinical study (up to 2 year follow-up) seem promising. The results was collected by two independent neurologists by telephone interview. Group A (Chronic low back pain in black disk with facet-syndrome): 26 patients, mean age 44,2 years,13 females and 13 males, 23 implanted at one level and 3 at two levels. Mean VAS pre-op: 8,1, at 3 months 2,1, at 2 years 1,3. Mean ODI pre-op: 33,8 at 3 months 15,0, at 2 years 12,8. 2 patients need a second surgery after 6 and 10 months and a 3rd patient with poor results refused further surgical treatment. Group B (After operations for big expelled disc hernias in young patients): 37 patients, mean age 39 years, 21 males and 16 females. Mean VAS pre-op: 8,4, at 3 months 2,1, at 2 years 0,5. Mean ODI pre-op: 40,1, at 3 months 15,2, at 2 years 11,6.No further surgical procedure at moment in this group. Group C (Soft Stenosis without decompression): 14 patients, mean age 56 years, 9 females and 5 males, 11 at 1 level and 3 at 2 levels. Mean VAS pre-op: 8,0, at 3 months 2,6, at 2 years 1,1. Mean ODI pre-op: 36,5, at 3 months 16,2, at 2 years 11,5,1 patient needed a second surgery after 9 months.

Conclusions: The results of the study (not randomized) definitely appear to be satisfying, even if the numbers are not high. We nevertheless feel we should recommend the use of this device after failure of conservative treatment, as a first choice over more invasive surgical operations and especially in the first phase of degenerative cascade in order to slow down its natural evolution.

Breakout 3: Navigation/Biomechanics

380 Investigating TDR Wear-rate Sensitivity to Phasing, Loading and Forward Bending

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Aim: To assess the sensitivity of TDR wear-rate to phasing, load and forward bending angle within the standard ISO inputs.

Introduction: The biomechanics of the functional spinal unit in vivo are not well understood, especially for typical motions during daily living. Hence TDR kinetics are difficult to prescribe for tests in vitro with the consequence that wear-rate and potential for osteolytic reactions are hard to assess. In this study ISO 18192-1 was used as a baseline test for a metal-on-UHMWPE lumbar TDR and then modified for phasing, load and forward bending so as to investigate their effect on wear.

Methods: ProDisc-L lumbar TDRs (Synthes, Inc., PA, USA) were tested in a spine simulator. Four assessments were studied: 1) Standard ISO - to produce a baseline wear-rate
2) **Phasing** - as in (1) but with FE and LB motions in-phase to produce a low-cross-shear environment
3) **Loading** - as in (1) but with the load set to ½ the prescribed value
4) **Forward bending** - as in (1) but with the FE set to ½ the value indicated within the standard.

All tests conducted with 15 g/l protein lubricant. Gravimetric wear measurements were taken every million cycles (MC). Six discs were tested with a seventh acting as a soak control specimen.

**Results:** Compared to the baseline standard ISO results, the in-phase (low-cross-shear) inputs reduced the wear-rate by 62%, halving the axial load reduced wear by 27% and reducing the FE motion by half reduced wear-rate by 49%.

**Discussion:** The baseline standard ISO study produced a wear-rate similar to a previously published study by Nechtow et al. [1].

Placing the FE-LB motions in phase while keeping axial rotation produced a low-cross-shear motion track at the bearing surfaces and decreased the wear-rate. Low-cross-shear wear is a result of strain hardening of the UHMWPE surface due to unidirectional articulation of the joint bearing components which tends to align the polymer chains. The ½ axial load did not produce a halving of the wear-rate as predicted by the Archard wear equation [2]. This result can be explained by the non-linear contact mechanics of UHMWPE under tribological conditions [3]. This means that computational prediction of wear by finite element analysis is limited by the reliance of many models on an Archard based formula.

The ½ FE results are close to that predicted by the Archard wear law, whereby wear is linearly proportional to sliding distance. It can therefore be concluded that both input kinematics and loading parameters have an important affect on wear in metal-on-UHMWPE TDRs which, under certain conditions, cannot simply be predicted from Archard type formulations.

**References:**

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**Do Stand-alone Interbody Spacers with Integrated Screws Provide Adequate Segmental Stability for Multi-level Cervical Arthrodesis?**
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**Introduction:** Postoperative complications after anterior cervical fusions have been attributed to anterior cervical plate profile and the necessary wide operative exposure for their insertion. Consequently, low-profile stand-alone interbody spacers with integrated screws have been developed. While they have demonstrated similar biomechanical stability to the anterior plate in single-level fusions, their role as a stand-alone device in multi-level reconstructions has not yet been established.

**Methods:** Thirteen human cadaveric cervical spines (C2-T1) were non-destructively tested with a custom six-degree-of-freedom spine simulator under axial rotation (AR), flexion-extension (FE) and lateral bending (LB) loading. After intact analysis, eight single-levels (C4-5 & C6-7) from four specimens were instrumented and tested with:
1) anterior cervical plate (ACP) and 2) stand-alone spacer (SAS).

Nine specimens were tested with:
1) C5-7 SAS, 2) C5-7 ACP, 3) C4-7 ACP, 4) C4-7 ACP & posterior fixation, 5) C4-7 SAS, and 6) C4-7 SAS & posterior fixation.

Testing order was randomized with each additional level instrumented. Full range of motion (ROM) data was obtained and analyzed by each loading modality utilizing mean comparisons with repeated measures analysis of variance. Paired t-tests were used for post-hoc analysis with Sidak’s correction for multiple comparisons.

**Results:** No significant difference in ROM was noted between the ACP and SAS for single-level fixation (p > 0.05). However, only ACP significantly reduced operative level ROM compared to intact (p < 0.05). For multisegment reconstructions (two and three levels) the ACP proved superior to SAS. In all planes of bending residual ROM was significantly lower in the ACP group compared to SAS and intact (p < 0.05). In contrast, the SAS failed to provide improved segmental stability over the intact condition (p > 0.05). In spite of this, when either the three-level SAS or ACP constructs were supplemented with posterior lateral mass fixation, there was a greater than 80% reduction in ROM under all testing modalities (p < 0.05) with no significant difference between the ACP and SAS constructs (p > 0.05).

**Discussion/conclusion:** Stand-alone interbody spacers with integrated screws may be a reasonable option for single-level fixation. However, stand-alone interbody spacers should be used with careful consideration in the setting of multi-level cervical fusion. In the setting of supplemented posterior fixation, stand-alone interbody spacers are a sound biomechanical alternative to the anterior cervical plate.
No Profile Cervical Interbody Cage with Lag Screw Fixation Increases Graft Loading and Reduces Bone Resorption Signal when Compared with Static and Dynamic Cervical Plating

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Intro: Cervical intervertebral cages are often supplemented with anterior plates for additional stability. Despite increased fusion and reduce failure rates, cervical plating is associated with increased likelihood of adjacent level degeneration, chronic dysphagia, and the potential for screw migration-induced soft tissue injury. No-profile systems, which increase stability of the cage through vertebral screws, have the potential to provide the stabilizing benefits of plating, improve graft loading characteristics with lag screws design, and reduce complications related to plate prominence. The current study evaluated graft loading and vertebral body remodeling stimulus after fusion using a cage supplemented with a static plate, a dynamic plate, and no-profile lag screws. We hypothesized that a cage supplemented with lag screws would increase graft loading and reduce bone resorption signal when compared to either a locked or dynamic plate.

Methods: An intact finite element model of C4-C7 was utilized. C5-C6 was altered to include an intervertebral cage, which was supplemented with either a locking anterior plate, dynamic anterior plate, or lag screws. All models utilized the STALIF C™ (Centinel Spine, Inc, New York, NY) intervertebral cage with an ideally conforming bone graft. The dynamic plate allowed 0.1 mm of translation at the fixation points. All models were exposed to 100 N of compression and either 2.5 Nm of flexion or extension. Remodeling stimulus and resultant force through the graft was compared between models.

Results: In general, the dynamic plate or lag screws resulted in increased loading through the graft when compared to the locking plate. The lag screws provided the greatest increase in loading through the graft (Figure 1). The bony resorption signal was minimized, and formation was maximized for the lag screw system when compared with both the dynamic and locking plates (Figure 2).

Discussion: The results supported the hypothesis that a lag screw fixation system increases the amount of loading experienced by the graft and reduces bone resorption in the vertebral bodies when compared with plating, which may optimize the mechanical environment to achieve a solid bony fusion. Whether or not the improved interbody cage compression profile with the STALIF™ lag screw design leads to shorter fusion times or increased fusion rates will need to be assessed in a clinical population.

Biomechanical Investigation of the Stabilizing Effect of a Novel Device for Intra-articular Atlanto-axial Stabilization (DIAS)

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Introduction: The unique function and anatomy of the atlanto-axial joint (AAJ), combined with the vascular and neural anatomy, has made stabilization at this level highly challenging. Early fixation to the posterior laminae and spinous process of C2 was associated with poor rotational and translational stability. Newer techniques with oblique trans-articular screw fixation (TASF) across the lateral mass (LM) joints, or inserting segmental screw fixation at the LM complexes (SLMF), (Harms technique) give dramatically improved stability. Unfortunately, both techniques may be technically difficult or contraindicated by local vascular and vertebral artery (VA) anatomy. A novel device was designed and developed to obtain intra-articular stabilization via primary interference fixation within the C1/C2 lateral mass articulation (DIAS). This study characterized the extent of immediate stabilization of C1/C2 using the DIAS device in the setting of C1/C2 instability consistent with Type II odontoid fracture, with comparison to the Harms technique.

Methods: Biomechanical testing was performed using 6 human cadaveric cervical spines (C0-C5, age: 54.7±6.6 years) with load control in Flexion/Extension (FE), Lateral Bending (LB), and Axial Rotation (AR) under a moment of 1.5Nm. Comparison of C1-C2 Range of Motion (ROM) was performed using optoelectronic tracking. ROM was measured in intact state, following destabilization after creation of a Type II Odontoid Peg Fracture, after sequential stabilization using the Harms technique and the DIAS device.

Results: FE ROM of the intact specimens was a mean of 14.1±2.9 degrees. Destabilization increased the ROM to
31.6±4.6 degrees. Instrumentation with the Harms technique reduced the motion to a mean of 4.0±1.4 degrees (p=0.00). The DIAS reduced FE motion to 3.6±1.8 degrees (p=0.00). For evaluation of lateral bending the respective mean rotations were 1.8±1.1, 1.4±5.8, 1.4±0.7 and 0.3±0.5 degrees for the intact, destabilized, Harms technique and DIAS device. For axial rotation the respective mean values were 67.3±13.8, 74.2±16.1, 1.3±0.8 and 0.9±0.7 degrees. All comparisons between the destabilized state and both the Harms and DIAS were statistically significant (p<0.05). Direct comparison of the Harms technique and the DIAS device revealed no significant difference (p>0.05).

Conclusions: The DIAS resulted in interference fixation at the AAJ LMJ with comparable stability to the Harms technique. Perceived advantages with the DIAS include avoidance of fixation below the C2 LM where the VA is susceptible to injury, access to the C1 screw entry point through the blade of the DIAS avoiding extended dissection superior to the C2 nerve root and its surrounding venous plexus, the possibility of intra-articular fusion through and around the DIAS, and the absence of imaging difficulties when looking at posterior interlaminar fusion. Biomechanical testing demonstrated improved construct stiffness with removal of articular cartilage from the LM, and bi-cortical fixation of the C1 LM screw in the DIAS.

Comparison of Patients Undergoing 1- and 2-level Lumbar Fusions Using Demineralized Bone Matrix (Optecure, Exactech Inc.) as a Bone Graft Extender when Compared with Autograft

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Purpose: This study was designed to evaluate the effectiveness of DBM graft (Optecure, Exactech Inc.) as a bone graft extender when compared to autograft in patients undergoing one or two level fusions.

Study design/setting: Single Blind, Multi-Center, Randomized, Prospective Clinical Study implemented at six US sites.

Methods: Patients suffering from lumbar stenosis and instability, who had failed conservative treatments, were enrolled into the study. All participating centers obtained IRB approval prior to initiation of study procedures. Oswestry Disability Index (ODI), SF-12 patient health surveys, and perceived pain noted on visual analog scales (VAS) were collected preoperatively and at 6-week, 3, 6, 12 and 24-month postoperative time points. Surgical approaches included: posterolateral fusion (PLF), combined posterolateral and interbody fusion (PLF/ILF), and interbody fusion (ILF). Operated levels ranged from L2-S1 and in each case instrumentation was utilized. Anteroposterior, lateral, flexion, and extension radiographs were obtained at each time point. The amount of motion and the quality of the boney fusion was evaluated by an independent radiologist. CT also aided in evaluation of fusion mass at 12-months. Fusion was based on presence of continuous bridging trabecular bone in the interbody or posterolateral fusion, < 5 degree angular motion, and ≤ 3mm translational motion on the flexion/extension radiographs.

Results: Ninety-four patients were enrolled and 82 were randomized. Seventy-six of the patients completed at least 6 months of follow up and were evaluated. Thirty PLF, 18 ALIF, 24 PLF/ILF, and four ILF cases were enrolled into the study. There were 49 1-level (27 DBM, 22 ABG) and 27 two level (17 DBM, 10 autograft) procedures. Intraoperative complications were noted in 7 patients; dural tear (4), pedicle fracture (1), coagulopathy (1), and unspecified (1). Fifty-one percent (20/39) of post-operative complications related to back pain /radiculopathy. Clinically significant improvements in VAS, ODI, and SF-12 measures were noted in both groups when compared to the pre-operative time point; however, there were no statistically significant differences. Distribution of harvested autograft was statistically significant (p=0.003) between the 2 groups; A larger volume of local bone was utilized in the DBM group; 30cc versus11cc in the autograft only group. There were no statistically significant differences in fusion between the DBM and autograft only group at 24 months (p=0.311, respectively). At 24 months the 1- and 2-level rates of fusion were 91% in the Optecure group, versus 87.5% and 81.8%, respectively in the autograft only group.

Conclusions: Near equivalent fusion rates were seen in the autograft and the DBM group and 24 month time points. Near equivalent clinical outcome scores were also recorded between the two groups across all time points. The results support the use of Optecure as a DBM extender in 1- and 2-level lumbar fusions. The use of Optecure as a local autograft extender can potentially decrease the morbidity associated with iliac crest bone graft harvest site.

New Method for Performance Analysis of Pedicle Screw Designs

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Introduction: Traditionally, pedicle screw designs have been compared using static pullout. While pullout techniques are standard, they are not clinically relevant as this loading condition is not manifested in-vivo. Further, pullout tests tend to be insensitive to unique design features as the bone within the vertebral body fails in shear. To better differentiate the characteristics associated with pedicle screw designs, this work focused on toggle testing to evaluate mechanical functionality of pedicle screws.

Materials and methods: Bovine vertebrae from T11 to L4 were subjected to bilateral randomized insertions of 45mm long pedicle screws (N=6 for all); (Trio 6.5mm, Expeditum 6.0mm, Pangea 6.0mm, Xia 6.5mm and Osteogrip 6.5mm)
and subjected to sinusoidal toggle testing from ± 340N to 2600 cycles at 0.5 Hz. Load and displacement data were collected at 100-cycle intervals with total deflection at each 100-cycle interval computed. Individual screw deflections were normalized to zero to illustrate increase in toggle versus cycle number. The average deflection per interval was subjected to non-linear regression. The area under the load versus deflection curve at each interval was used to determine the work done for a complete loading cycle with the resulting work summed for subsequent cycles. Statistical comparisons for both the resulting fitted parameters and work done and between screw designs were performed using a one-way ANOVA and a Tukey post-hoc analysis.

**Results:**

**Toggle Fatigue Testing:** The non-linear analyses of each screw type resulted in an exponential fits with R² > 0.94. From the resulting rate (k values) of the exponential regressions, half-life (= ln2/k) computations were performed and revealed that only the Pangea screw displayed significantly reduced half-time to achieve half-life (P < 0.05) as compared to the Osteogrip screw design. The remaining designs displayed comparable and increased settling time.

**Work:** The analysis of cumulative work versus cycle number resulted in a linear function for all screws. (R² > 0.99 for all screws) At 100 cycles, the Pangea screw displayed reduced work transfer with respect to the Osteogrip screw, while other comparisons were not significant. At 500, 1000, 1500, 2000 and 2500 cycles both the Expedition and Pangea screws displayed significantly reduced work transfer with respect to both the TRIO and Osteogrip screws (P < 0.05 for all).

**Discussion:** Half-life may be characterized as a mathematical characterization for settling. As a consequence, screw design performance can be evaluated. It should be realized that the methods displayed in this study could be correlated to patient outcomes with respect to screw design used during surgery. This would permit optimization of thread characteristics. The parameters that can be determined using the toggle test method combined with non-linear analysis may be employed to avoid stress shielding resulting from clinically over rigid configurations. The DL screw displayed work values within the midrange of all screws tested. The combination of a cortical and cancellous thread associated with this may represent an appropriate balance between under- and over-stabilized pedicle fixation. The work data presented in this study can also be correlated to clinical outcomes and may represent a viable indicator of load sharing at a specific vertebral level.

**Results:**

**In vitro** ribosylation significantly altered the mean peak T₁ relaxation times in the nucleus pulposus (p = 0.011; GLM), but not in the annulus fibrosis samples. Furthermore, the mean T₂ values of the NP samples significantly decreased (p < 0.001) with increasing periods of incubation time. The apparent diffusion coefficient revealed that consistent with tissue composition, NP tissues were more hydrated than AF tissue. The in vitro ribosylation altered the ADC in both the NP and AF (p = 0.046; GLM).

**Discussion:** Although NEG does not structurally alter the IVD tissue, the accumulation of AGEs have been shown to modulate water content and alter tissue stiffness. Since MRI relaxation times can provide surrogate measures of tissue hydration, the observed changes in the T₁ relaxation times in NP and AF suggest that the AGEs-mediated changes in water content of the tissue may be detectable by non-invasive biomedical imaging. Thus MR imaging may be a useful adjunct to quantify levels of AGEs in vivo. The decreases of the T₁ relaxation time with reducing water content as mediated by the accumulation of AGEs are consistent with the trends observed in the pathological degeneration of the IVD. The loss of water content within the NP has been shown to initiate a cascade of events that can result in disc degeneration. Although the mechanism is unknown, the accumulation of AGEs may adversely accelerate this process by competitively inhibiting water content. Since AGEs may play a significant role in the pathogenesis of DDD, the ability to detect the molecular level changes due to NEG may provide therapeutic insights and disease mechanisms of disc degeneration.

**Alterations in Magnetic Resonance Imaging T2 Relaxation Times of the Intervertebral Disc Due to Non-enzymatic Glycation**

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**Introduction:** Degeneration of the intervertebral disc (IVD) is characterized by a loss of cellularity, degradation of the extracellular matrix, and the subsequent morphological changes and alterations in biomechanical properties. One of the changes that can occur in the IVD matrix is the accumulation of molecular crosslinks known as advanced glycation end-products (AGEs). AGEs form through non-enzymatic glycation (NEG) that post-translationally modifies the amino residues of the structural components of the IVD matrix including collagen and aggrecan. The increased accumulation AGEs has been implicated in reduced height, the loss of tissue water content, and a stiffening of the matrix and reduced strain energy of the intervertebral disc. Because of the multi-faceted role of AGEs in degenerative disc disease (DDD), a non-invasive method to detect levels of AGEs within the IVD may improve the ability to diagnose the early onset of disc degeneration, and identify the “disc at risk”. Magnetic resonance imaging (MRI) is a useful clinical tool for noninvasively determining the morphology of the IVD. MRI techniques such as measurement of T₂ relaxation time have been shown to correlate with water content. Since we have previously demonstrated that AGEs can modulate water content in the IVD, we sought to determine whether the molecular-level changes mediated by AGEs in the intervertebral disc are detectable by MRI-based T₂ relaxation mapping.

**Methods:** Two sheep spines were obtained from Colorado State, and 18 lumbar and thoracic intervertebral discs were removed. Imaging was performed on a clinical 3.0 T GE Excite MRI scanner.

**Results:** In vitro ribosylation significantly altered the mean peak T₁ relaxation times in the nucleus pulposus (p = 0.011; GLM), but not in the annulus fibrosis samples. Furthermore, the mean T₂ values of the NP samples significantly decreased (p < 0.001) with increasing periods of incubation time. The apparent diffusion coefficient revealed that consistent with tissue composition, NP tissues were more hydrated than AF tissue. The in vitro ribosylation altered the ADC in both the NP and AF (p = 0.046; GLM).

**Discussion:** Although NEG does not structurally alter the IVD tissue, the accumulation of AGEs have been shown to modulate water content and alter tissue stiffness. Since MRI relaxation times can provide surrogate measures of tissue hydration, the observed changes in the T₁ relaxation times in NP and AF suggest that the AGEs-mediated changes in water content of the tissue may be detectable by non-invasive biomedical imaging. Thus MR imaging may be a useful adjunct to quantify levels of AGEs in vivo. The decreases of the T₁ relaxation time with reducing water content as mediated by the accumulation of AGEs are consistent with the trends observed in the pathological degeneration of the IVD. The loss of water content within the NP has been shown to initiate a cascade of events that can result in disc degeneration. Although the mechanism is unknown, the accumulation of AGEs may adversely accelerate this process by competitively inhibiting water content. Since AGEs may play a significant role in the pathogenesis of DDD, the ability to detect the molecular level changes due to NEG may provide therapeutic insights and disease mechanisms of disc degeneration.
Persistent Lumbar Foraminal Stenosis in Spite of Direct Decompression

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Introduction: Foraminal stenosis is a common condition in degenerative spines. While traditional posterior decompression strategies have been shown to be effective in neutral positioning [1,2], they have not been tested in flexion and extension of the spine, which can cause a change in foraminal space [3,4]. Consequently, a true assessment of these techniques' effectiveness has not been quantified. The purpose of this study is to use 3D X-ray reconstructions to compare the effects of a posterior foraminal decompression on intervertebral foraminal area with respect to flexion and extension of the spine.

Methods: Eight cadaveric specimens (L5-S1) were used for this study. The edge of the superior vertebrae and approximately half of the sacrum were cast in quick-set resin (Smooth Cast 300).

Intact Testing: Each specimen was placed into a X-ray compatible pure moment jig modeled after a previously validated pure moment apparatus (Figure 1A) [5]. To ensure minimal image distortion, all parts of the jig directly in the line of sight of the C-arm were made out of plastic. 3D-scans (Philips BV Pulsera) of each specimen were taken under no load, 3.5Nm of flexion, and 3.5 Nm of extension.

Foraminal Area Measurements: The 3D scans were used to create 3D models of the left and right foraminal spaces through segmentation software (Mimics Innovation Suite 13.1). The models of the foraminal space were cut into lateral cross sections 1mm thick (Figure 2), and the lowest cross-sectional area of the foramen was recorded.

Foraminotomy: After intact testing, the left side of each specimen was subject to a direct, posterior approach decompression. After the foraminotomy, the specimen were once again tested and scanned under no load, 3.5Nm of flexion, and 3.5 Nm of extension.

Results: Across all treatment groups, specimens showed a statistically significant (p< 0.05) increase in foraminal area under flexion and a decrease under extension. Additionally, there was a significant difference in relative change of foraminal area after decompression. Specifically, there was a significant difference between the two groups (decompression versus no decompression) in the neutral (178 versus 167mm²) and flexed (200 versus 189mm²) positions, but not in extension (158 versus 155mm²).

Discussion: The lack of an increase in foraminal area under extension (where foraminal area is already the smallest) following posterior decompression suggests that this approach may not be completely successful in treating foraminal stenosis. Further research will entail a comparative study of the anterior and posterior approaches to foraminal decompression with respect to flexion and extension.


Wear Characterization of a Total Spinal Arthroplasty Device Under Different Shear Loads

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Introduction: Wear testing of lumbar spine arthroplasty devices is often performed to evaluate the potential for particle-induced osteolysis. Testing is typically performed using international standards developed for total disc replacements (TDR). Total Spine Arthroplasty (TSA) devices, however, are unique since both the disc and facets are removed to treat the degenerative segment, which may require them to carry different shear loads than other devices. The Flexuspine FSU is a TSA device consisting of a metal-on-metal disc component and a metal-silicone posterior component. The disc has a bearing surface for flexion-extension (F/E) and a coupled lateral bending and
axial rotation (LB-AR) bearing surface. The LB-AR surface, which will be evaluated in this study, has a shear face that couples the two motions while also providing shear resistance. The objective of this study was to evaluate the durability and wear generation potential of the Flexispine FSU under a range of shear loads.

**Methods:** Wear testing of six FSU disc components was performed for 10 million cycles (Mc) using an MTS Bionix Spine Wear Simulator. The implants were declined by 45°, which applies equal shear and axial loads to the implant and increases shear loading relative to testing with the implants declined by 10°. LB-AR motion (±2°) was applied under two shear load levels: Case 1) 424-1414N from 0-5Mc and Case 2) 200-600N from 5-10Mc. These loads were based on the axial loads in ISO/DIS 18192-1 and facet shear loads in ASTM F2694. Testing was carried out in 30g/L bovine calf serum.

**Wear results from a previous study (Case 3) with the disc declined by 10° and tested with ±2° LB-AR under 600-2000N loading (104-347N implant shear; 591-1970N implant axial loading) are also included for comparison (Gimbel, 2010).**

**Results:** Linear wear marks were observed on the shear face and axial loading surface. For Cases 1 and 2, the specimens completed each segment without failure and the wear rates were 3.4 ± 0.2 mm/3Mc and 1.2 ± 0.0 mm/3Mc, respectively. The wear rate from the previous study (Case 3) was 2.6 ± 0.1 mm/3Mc. The LB-AR wear rates for the 3 cases were linearly correlated to the sum of the shear and axial load ($r^2=0.997$).

**Conclusions:** This study demonstrated that the Flexispine FSU disc component is durable under a range of shear loads while maintaining comparable wear rates to the previous study. In vivo spinal shear loading is not well characterized but based on various estimates (Lu, 2005; Potvin, 1991; Frei, 2001), the load scenarios evaluated were comparable to both physiological (Cases 2 and 3) and supra-physiological shear loads (Case 1). The implants’ wear rates were affected by both the axial and shear loads in an additive manner, indicating that both loading modes contribute to the overall wear and should be considered in wear testing of TSA devices.

### Breakout 4: MIS I

#### 76 Least Invasive Lumbar Decompression, Interbody Fusion, and Pedicle Screw Implantation - A Case Study Report

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**Background context:** The open spinal surgery while addressing the pathology often disrupt normal anatomy, entail large quantities of blood loss requiring transfusion; prolonged hospital stay; long duration of narcotic pain medication; protracted rehabilitation programs; incomplete recovery; failure to return to prior occupation and increased cost to the individual and the society. Given the impact of surgical trauma on outcome; the increasing demand by patients for shortest post-operative downtime; the desire of the elderly patients (whose number is increasing) to continue vigorous physical activities, it is reasonable to explore the feasibility of the least invasive methods to remove the disease while preserving the normal anatomy.

**Purpose of study:** To investigate the feasibility of the least invasive lumbar decompression, interbody fusion and percutaneous pedicle screw implantation, for disorders which are usually treated by open decompression, fusion and pedicle screw implantation.

**Study design:** Prospective Study of case series treated by one surgeon in two centers.

**Patient sample:** Case series by one surgeon at two centers.

**Outcome measures:** Operating time; intra-operative blood loss; hospital stay; VAS scores for back and leg pain; Roland-Morris Disability Questionnaire; and post-operative imaging studies.

**Methods:** Patients completed VAS forms and Roland-Morris questionnaires pre- and post-operatively. Surgical procedures included arthroscopic decompression of the foramina and the discs; end-plate preparation and implantation of allograft bone chips and BMP-2 on collagen carrier; and percutaneous implantation of pedicle screws. The patients’ charts were reviewed for operative notes, hospital stay, medications, and imaging studies. The latest x-ray and CT scan films were reviewed and analyzed. Patients were followed up for the minimum of six months.

**Results:** 60 patients met the inclusion criteria. The average age is 52.8 years. The duration of illness ranged 2 months to 32 years. All patients had back and leg pain. Follow-up averaged 12 months. OR time was 2:90 hours. Estimated blood loss averaged 57.6 cc. Hospital stay averaged 2.6 days. Pre- and post-operative back pain averaged 7.5 and 2, respectively (p < 0.005). Pre- and post-operative leg pain averaged 7.0 and 1.7, respectively (p < 0.005). 47 imaging studies available at the last visits including x-ray and CT scan, showed solid fusion in 28 (59.6%) patients, stable fixation in 17 (36.2%), and osteolysis around the pedicle screws in 2 patients (4.2%). All patients had improved motor function and two patients complained of residual numbness. 8 (13%) patients complained of residual discomfort on the extension of the lumbar spine. 1 patient (1.6%) had medial penetration of one S1 screw with S1 nerve root irritation which required revision. One patient with painful loose pedicle screws required hardware removal. Both patients had satisfactory outcome after their second operations.

**Conclusion:** The LINDIF produced satisfactory results in all demographics. Anesthesia time was consistently short, blood loss was negligible. Hospital stay was brief for most healthy patients irrespective of age. The results of this study demonstrate how drastically the surgery related morbidity, and the economics thereof, can be reduced. The outcomes relating to patients in the age group of 71-90 years are particularly encouraging, given their increasing proportion in the population.
Two-year Clinical Outcomes in 119 Patients Treated with a Mini-open, 90° Lateral, Retroperitoneal, Trans-psoas Approach for Lumbar Spine Discectomy and Fusion

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Background: Interbody fusion is an effective treatment for degenerative conditions in the lumbar spine, though traditional anterior and posterior approaches are associated with significant soft tissue disruption and morbidity that decreases the value of the intervention. Advancements in neuromonitoring techniques over the past decade have allowed for the lumbar spine to be accessed through a lateral, mini-open, retroperitoneal, transpsoas approach without neural injury. Long term outcomes of the approach, however, are few.

Objective: To report on a long-term outcomes in using extreme lateral interbody fusion (XLIF®, NuVasive, Inc. San Diego, CA).

Methods: This work reports outcome measures (disability, pain, satisfaction) and fusion status at 24-months for 119 patients treated with XLIF between 2006 and 2008 by a single neurosurgeon. Data was collected through a prospective registry.

Results: Significant decreases in mean disability and overall, lower back, and radicular symptoms were seen at all time points postoperatively (all, p< 0.001). Narcotic medication use decreased significantly from 67.2% preoperative to 34.8% postoperative (p< 0.01). Patient-reported satisfaction was 83.2% overall, 87.0% on relief of pain, and 95% of patients would undergo the surgery again if their outcome was known preoperatively. 87% of patients showed solid fusion at 24-months. XLIF-specific complications included one intra-operative anterior longitudinal ligament rupture, once case of ileus, and two dysethesias which resolved by 12-months postoperative.

Conclusion: The XLIF procedure for interbody fusion, in this series, performed comparably at 24-months postoperative on reported complications, outcomes, satisfaction, and fusion as conventional approaches, with shorter mean operative time and less blood loss.

A Comparison of Perioperative Charges and Outcome between Open Anterior and Mini-open Lateral Approaches for Lumbar Discectomy and Fusion

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Summary of background data: Several recent analyses have shown broad cost-effectiveness for spine surgery. These reports, however, primarily examined conventional open procedures. Minimally invasive techniques may theoretically decrease overall costs with less blood loss (EBL), fewer complications, and shorter hospital stays (LOS), although such reports do not yet exist.

Objective: The objectives of this study were to examine charge data, to assess relative cost, and long-term outcomes of two approaches for lumbar interbody fusion: a mini-open lateral approach and an open anterior approach.

Methods: Retrospective chart review was performed on 202 patients treated at one institution from 2004 to 2008 by two neurosurgeons. 87 patients underwent one- or two-level anterior lumbar interbody fusion (Open group) and 115 underwent one- or two-level mini-open, lateral lumbar interbody fusion (Mini-open group). Both received bilateral pedicle screw fixation.

Results: Demographics were matched between the Open and Mini-open patients with the exception of age, which was greater in the Mini-open group (p< 0.001) and incidence of prior lumbar surgery, also greater in the Mini-open group (p=0.002). The most common diagnoses were degenerative disc disease and stenosis with instability. Mean operative time (ORT), EBL, and LOS for one- and two-level cases were significantly less in the Mini-open compared to Open group. Complications occurred in 16.7% of Open cases and 8.2% of Mini-open cases (p=0.041). Charges for Mini-open were significantly less than for Open for both one- and two-level cases. Mean one-level Mini-
open and Open charges were $91,995 and $102,146, and two-level charges were $124,540 and $144,183, respectively. This represents a 10% cost-savings, based on charges, for one-level and 13.6% for two-level Mini-open over Open procedures. Functional outcomes improved significantly at two years for both cohorts, though the difference between Mini-open and Open patients was not significant.

Conclusions: By using a mini-open lateral, as compared to a conventional open anterior approach, significant clinical as well as cost benefits are seen with similar long-term outcomes.

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Do Lordotic Cages Provide Greater Segmental Sagittal Contour Change in Lateral Lumbar Interbody Fusion (LLIF)
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Summary: LLIF was performed at 64 levels in 43 patients. Lordotic cages were used in 33 and non-lordotic cages in 31. Radiographic segmental sagittal contour was measured pre- and post-op. Lordotic cages produced significant increase in segmental lordosis, while non-lordotic cages did not.

Introduction: Lumbar interbody fusion has traditionally been performed via anterior (ALIF), posterior (PLIF or TLIF) or combined approaches. Lateral Lumbar Interbody Fusion (LLIF) is a new minimally-invasive approach. Lordotic and non-lordotic cages are available. It is not known whether lordotic cages provide measurable sagittal contour change.

Methods: This is a comparative radiographic analysis of consecutive LLIF procedures performed with use of lordotic vs. non-lordotic interbody cages. 43 patients underwent LLIF at 64 levels. Average age was 58 yrs (r=30-83). Ten degree lordotic PEEK cages were used at 33 lumbar interbody levels, and non-lordotic cages were used at 31 levels. The following were measured on x-rays: segmental lordosis at operative level; segmental lordosis at level above and below; anterior and posterior disc heights; and overall lumbar (L1-S1) lordosis. Measurement changes for both groups were compared using paired t-test analysis.

Results: Lordotic cages resulted in a significant increase in lordosis at operative levels (p=0.03), whereas non-lordotic cages did not (p=0.24). Neither cage group resulted in significant change in supra- and subjacent level lordosis (p>0.05 for both groups). Anterior and posterior disc heights were significantly increased in both groups (p<0.01 for both groups). Neither cage group showed significant change in overall lumbar lordosis (lordotic p=0.60 vs. non-lordotic p=0.19).

Conclusion: Lordotic cages provided significant increase in segmental lordosis at operative levels compared to non-lordotic cages, although overall lordosis remained unchanged. Anterior and posterior disk heights were significantly increased by both cages, providing basis for indirect spinal decompression.

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FEA Investigation of Different Surgical Strategies for Protection of the S1 Pedicle Screw in Long Fusion Constructs
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Objective: Long posterior fixations have been shown to have a significant rate of screw loosening or fracture at the lumbosacral junction. Current practice in deformity surgery is to protect the S1 screw with supplemental distal (S2 or iliac screws) or anterior fixation (ALIF). These strategies are not without clinical challenges. AxialLIF has the potential to address the shortcomings of current approaches for stabilizing long posterior fixation due AxialLIF’s unique, presacral access. The objective of this study was to compare the effect of various surgical strategies on L5-S1 segmental range of motion (ROM) and S1 pedicle screw bending moment utilizing a finite element model.

Methods: A 3D sagittally symmetric nonlinear finite element model from L2-Sacrum was developed (Fig.1). Four constructs were considered:

1) L2-S1 posterior fixation (pedicle screws),
2) pedicle screws with distal fixation,
3) pedicle screws with ALIF and
4) pedicle screws with AxialLIF.

Both ALIF and AxialLIF were modeled without distraction of the L5-S1 disc. The anterior annulus of the ALIF construct was compromised to simulate implant insertion. To measure bending moments acting on the screws, strain gages were modeled as shell elements on the cranial, caudal, medial and lateral faces of the screw immediately below the screw head. The resultant screw bending moment was calculated using the Pythagorean Theorem based on the strain read-outs. All constructs were subjected to an unconstrained moment of 7.5Nm in flexion/extension, left bending and right torsion without preload. The overall and segmental ROM as well as the screw bending moment in the construct with pedicle screws alone was found to be in good correlation with in vitro data from six cadaveric lumbosacral spines.

Results: In flexion, all constructs that supplemented the posterior fixation showed a reduction in ROM relative to the pedicle screws alone by 45% with distal fixation, 79% with ALIF and 89% with AxialLIF. Distal fixation and AxialLIF showed the same ROM reduction in extension as in flexion and reductions of 57% and 38% respectively in torsion. Compared to the pedicle screws alone, the ALIF construct showed double ROM during extension (0.37” vs. 0.77”) and had no effect on ROM during the torsion. AxialLIF and distal fixation constructs showed similar reductions of bending moment relative to pedicle screws alone: 87% and 86% respectively in flexion/extension; 29% and 31% respectively in torsion. Compared to pedicle screws alone, the ALIF construct reduced the bending strain by 24% in flexion, increased it by 47% in extension, and had no effect in torsion. The ROM and the S1 screw bending strain were lowest in lateral bending for all constructs and no significant differences were observed.
spondylolisthesis in L5-S1 grade I and II were enrolled. All patients recovered uneventfully and improved of preoperative symptoms. Patients experienced minimal post-operative pain and were discharged before 23 hours in 14 cases. VAS, ODI scores improved post-operatively. 100% Excellent-Good results using Odom scale. There were no cases of postoperative neurologic deficits, pseudoarthrosis, malpositioned or broken screws or rods. No revision procedure was performed.

Conclusions: Current study demonstrates that minimally invasive ALIF with percutaneous pedicle screws is an efficacious option for isthmic spondylolisthesis grade I and II. Posterior laminectomy decompression is not necessary to relieve radicular pain. This technique could be a therapeutic alternative for spinal surgeons.

312 Multiplanar Radiological Assessment and Outcomes of Minimally Invasive Surgical Treatment (XLIF) in Adult Deformity. Follow up out to 36 Months
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Background context: The current study was undertaken to evaluate one site’s early experience with XLIF in lumbar degenerative scoliosis and kyphosis and analyze the role of indirect decompression of the neural elements through restoration of foraminal dimensions and its effect on clinical outcomes. The direct lateral approach (extreme lateral interbody fusion, or XLIF) offers a less invasive and therefore more tolerable surgical option for these patients. XLIF allows for minimally invasive placement of a large anterior graft, facilitating disk height and alignment restoration.

Purpose: To assess the clinical and radiographic outcomes of degenerative lumbar scoliosis patients having undergone XLIF.

Study design/setting: Prospective clinical study.

Patient sample: 62 patients with degenerative scoliosis and 2 patients with degenerative kyphosis with neurogenic claudication and back pain were treated with the XLIF procedure.

Outcome measures: Visual analog pain score (VAS) and Oswestry disability index (ODI) were measured preoperatively and at various time-points postoperatively. Pre- and postoperative measures of scoliosis and lordosis were recorded. DEXA Scan was obtained preoperative.

Methods: 62 patients underwent XLIF for the treatment of symptomatic degenerative scoliosis. In all cases the far-side annulus was disrupted to ensure symmetric disc space distraction and a 50-55mm PEEK interbody implant filled with DBM in a lipid carrier mixed with hydroxyapatite and tri-calcium phosphate granules was placed from side to side across the disc space at the scoliotic levels such that it rested on the strong ring apophysis. 10% of cases included additional internal fixation. Patients were followed clinically and radiographically for up to 36 months postoperatively.

Results: 62 patients with symptomatic degenerative scoliosis and spinal stenosis were included. Mean patient age was 58 yrs (range: 41-76 yrs). XLIF was performed at 1...
to 4 lumbar levels (mean 2 levels) between L2 and L5. Mean operative time was 130 minutes and in all cases measured blood loss was less than 50cc. Patients were typically out of bed, ambulating and advanced to regular diet on the day of surgery, and discharged home the following day. There were no procedural complications. Mean pain VAS decreased from 8.1 preoperatively to 2.8 at 3 months postoperatively, 3.4 at 1 year, 4.8 at 2 years, and 4.6 at 30 months. Mean ODI improved from 53 preoperatively to 19 at 3 months postoperatively, 22 at 1 year, 21 at 2 years, and 28 at 30 months. Scoliotic deformity was corrected from a mean Cobb angle of 22° to 12°, and lumbar lordosis was improved from a mean of 34° to 41°.

**Conclusions:** The rapid postoperative recovery suggests XLIF to be a less morbid procedure than traditional large reconstructive surgeries for the treatment of symptomatic degenerative lumbar deformity. Clinical and radiographic outcomes up to 36-months follow-up show that the XLIF procedure for this condition provides continued pain relief, improved physical function, and maintenance of sagittal and coronal plane deformity correction.

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*An in-situ Cured Silicone Rubber Nucleus Replacement Implanted through a Transsacral Approach.*

**Biomechanical Analyses of the Implant Behavior and the Extrusion Risk**

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**Introduction:** Replacement of the nucleus with an implant often requires a large defect in the annulus, which can increase both the flexibility of a spinal segment and the extrusion risk for the implant. Implantation through a transsacral approach may preserve biomechanically important anatomical structures and prevent extrusion of the implant. The purpose of this study was to investigate the biomechanical behavior of the transsacraly implanted, in-situ cured, silicone rubber nucleus replacement (PNR™), which can be implanted after conventional microdiscectomy.

**Methods:** Six fresh frozen human lumbar spine specimens (L2-S1) were split in two groups: monosegmental L2-3 segments and bisegmental L4-S1 specimens. In the monosegmental group, microdiscectomy was carried out through interlaminar approach. Transsacral nucleus replacement with an in-situ cured silicone rubber implant was performed in the bisegmental group into the segment L5-S1. Both groups were exposed to cyclic loading (100-600 N) for 100,000 cycles. Segment flexibility was tested in the intact state, after microdiscectomy, transsacral nucleoectomy, implantation and 100,000 cycles of loading under pure bending moments (7.5 Nm) in the three main motion planes. After testing, all specimens were dissected and underwent macroscopic investigation.

**Results:** The immediate effect of implantation was a significant segmental stabilization in all planes. In the microdiscectomy group ROM in flexion/extension and lateral bending decreased significantly relative to the intact state, but not in axial rotation. In both groups, the cyclic loading caused a destabilizing effect, but was similar to non-treated segments. No expulsion of the silicon core through the posterior defect could be observed in the microdiscectomy group. Macroscopic observation revealed no visible changes of silicon core position.

**Discussion:** Transsacral nucleus replacement with PNR™ silicone implant provided a restoration of the biomechanical behavior of the intact segment. No implant expulsion was observed even with posterior defect in annulus fibrosus and interlaminar approach in microdiscectomy group. This transsacral approach may also serve as a possibility for the use of other nucleus implant technologies.
Long Term 2 to 4 year Clinical and Functional Outcomes of Minimally Invasive Surgery (MIS) for Adult Spinal Deformity

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Introduction: Traditional surgical approaches for Adult Spinal Deformity are associated with significant blood loss and morbidity; in a population, that is often elderly with multiple medical comorbidities.

Methods: Consecutive series of patients with greater than 2 year follow-up who have undergone MIS Correction of Adult Spinal Deformity were selected for this study. 37 patients fit the inclusion criteria. Deformities included degenerative scoliosis (25), idiopathic scoliosis (6), and post laminectomy scoliosis (6). All underwent deformity correction and fusion using all or a combination of 3 MIS techniques: Lateral Transposas discectomy and interbody fusion(37), AxialLIF L5-S1 interbody fusion(18) and segmental multilevel percutaneous pedicle screw fixation(35). 35 of the patients were staged with the lateral fusion done first followed by the posterior instrumentation and fusion including the AxialLIF done three days later. 2 patients had stand-alone lateral fusion. Fusion was augmented with local bone, Bone Morphogenetic Protein (rh-BMP2) and Grafton Putty DBM at each interbody space and in the Facets. Radiographs, visual analog scores (VAS), treatment intensity scores (TIS), Oswestry Disability Index (ODI) and SF-36 were assessed preoperatively and at each postoperative visit.

Results: Mean age was 67 years (range 22 to 84). Mean Follow-up was 34 mths (range: 24 to 47) with greater than 3 years follow-up in 18 patients. Mean Blood loss and mean surgical time was 247 cc and 239 mins respectively for the posterior instrumentation and fusion including the AxialLIF. Figure 1 charts the clinical and functional outcomes upto 3 yrs.

21 patients had transient thigh dysaesthesia for 2 to 6 weeks, 2 patients had quadriiceps palsy that resolved within 6 months. One patient required removal of a proximal screw at 12 months after fusion was confirmed on CT scan and one patient had an asymptomatic proximal screw fracture with solid fusion. 3 patients needed secondary decompression, one for heterotopic ossification and 2 for persistent stenosis. 1 patient is since deceased of Renal failure and 1 patient developed an unrelated cerebellar haemorrhage that was satisfactorily evacuated with no residual effect. The two patients with stand-alone lateral fusions both developed non-unions and were posteriorly instrumented at 9 months and 1 year post-operatively. Pre-op Cobb angle was 22° (range: 7° to 62°), which corrected to 7° (range: 0° to 22°). Global coronal and Sagittal balance was also maintained at final follow-up. All patients were noted to have solid arthrodesis on plain films. This was further confirmed on CT Scan in 26 patients. No patient had iliac fixation and no failures of sacral screws or sacral fractures were noted.

Conclusions: A combination of 3 Novel MIS techniques allows comparable correction of Adult Scoliosis, with low pseudarthrosis rates and significantly improved functional outcomes at 3 years post-op. MIS techniques may afford surgical options and improved quality of life for the treatment of adult scoliosis.
minus 4.3° to 12.1° (incidence angle was constant). The lumbar lordosis was positive (average 28.8°) demonstrating the importance of the correction. The osteotomy angle planning was increased to pay attention to the femur angulation (reflecting the knee flexion) (18.2° on average). The osteotomy correction was determined on the sagittal plan of the spine in standing position. The pre-operative planning osteotomy to perform was: 28.8° + 18.2° = 47°. On the final result the corrected angle was at an average of 37.4 degrees which is lower than expected to obtain an ideal balance but sufficient to rebalance the spine as demonstrated by the position of post C7 plumb line at the level of the S1 plateau behind the femoral head. In the light of this experience we propose a new calculation method named FBI for « full balance integrated » to determine the best correction needed : the position of the C7 plumb line related to the osteotomy level and the importance of the femur angulation with the vertical reflecting the knee flexion are directly included in the calculation.

**Conclusions:** To obtain a good sagittal alignment in patient with lumbar kyphosis needing a posterior wedge osteotomy, the knee flexion parameter to consider to avoid undercorrection and obtain a good sagittal spine balance.

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**2 SPO on Multi-segment for Correction of Kyphosis in Ankylosing Spondylitis**

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**Objective:** To evaluate the indication, correction and complication of posterior smith peterson osteotomy on multi-segment for correction of kyphosis in ankylosing spondylitis.

**Methods:** Form October 2006 to July 2009, 18 patients with kyphosis in ankylosing spondylitis were treated with surgery. There were 16 male and 2 female with an average age of 27.3 years (22-36 years old). The average case history was 8.6 years (5-14 years). Stable without pain: 7 cases. Active with pain: 11 cases. The kyphosis involved the thoracic and lumbar vertebral body. The average Cobb angle is 73.1° (62°-102°), 3 patients are combined with scoliosis. The average scoliosis Cobb angle was 33.6° 18°-42°. All the patient didn’t have the severe hip joint disease. All patients underwent posterior smith peterson osteotomy on the multi-segment apex vertebra and trans-pedieular fixation, Autogenous and Allogenic bone grafting under general anesthesia. The operating time, blood loss, correction rate, bony grafting, complication, VAS scale, motion range and Patient’s satisfaction were taken for evaluation.

**Result:** There was no major complication of neurological injury and hardware failure. The average surgery time was 192 mins (140-260 mins) and average blood loss volume of 633 ml (450-920ml). The multi-segment osteotomy was continuous osteotomy. The highest level is T67, the lowest level is L34. The average performed levels were 3.2 (2-4 levels). All patients were mobilized with BOSTON brace 7 days post-operatively and discharged 14 days post-operatively. All patients were followed at 3, 6, 9 months post-operatively for bone grafting, correction, fixation evaluation via phone, mail, post the recent X-image. The average follow up time was 3.2 years (1-3.5 years). The pre-operative average kyphosis curve was 73.1°, one week after operation average kyphosis curve was 12.8° (-10°-24°), correction rate was 82.5%. The average kyphosis curve at the latest follow-up was 16.6°, the loss of correction was 3.8°. The pre-operative average scoliosis curve of the patient with scoliosis was 33.6°, one week after operation average scoliosis curve was 5.9°(0°-9°), correction rate was 82.4%. There was no loss at the latest follow-up. All the patient had achieved bony fusion 3 or 6 months after operation. There were 4 cases with the complications (22%). Included: intercostal neuralgia: 1 case; screw lossening: 1 case, superficial skin necrosis: 2 cases, cured within one week of treatment. The average VAS scale was from 5.2 pre-operatively to 2.1 after operation. and less 1 at the latest follow-up. At the latest follow up, the patient’s satisfaction was 100% (18/18).

**Conclusion:** Kyphosis in ankylosing spondylitis always appeared to be curved deformity. The posterior smith peterson osteotomy on multi-segment for correction of this disease is a effective methods with shorter operation time, less blood loss and lower complication rate.

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**449 Changes in Thoracic Kyphosis Negatively Impact Sagittal Alignment Following Lumbar Pedicle Subtraction Osteotomy**


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**Introduction:** Large vertebral resections are frequently utilized in the setting of sagittal malalignment. While the effect of such resection can be anticipated in long fusions, their impact on unfused segments (reciprocal changes; RC) is poorly understood. The objective of this study was to evaluate if RC have a positive or negative impact of spine-pelvic alignment following lumbar PSO in the setting of shorter fusions.

**Methods:** This was a consecutive, multicenter retrospective review of 34 adult patients (mean age=54yo; sd=12) who underwent lumbar PSO with upper instrumented vertebra (UIV) below T10. Radiographic analysis included pre and post assessment of Thoracic Kyphosis (TK), Lumbar Lordosis (LL), Sagittal Vertical Axis (SVA), T1 Spino Pelvic Inclination (T1SPI), Pelvic Tilt (PT), and Pelvic Incidence (PI). Final SVA and PT were analyzed to determine successful realignment (SVA < 4 cm, PT < 20 deg). RC in the thoracic spine was designated...
favorable or unfavorable based upon impact on final SVA and PT.

**Results:** Mean PSO resection was 26° (SD=9°). LL increased from 20° to 49° (p<0.001). SVA improved from 14 to 4cm (p<0.001) and PT improved from 33° to 25° (p<0.001). Mean increase in TK was 13° (p=0.002). TK was unchanged (<5°) in 11 patients. Five patients had a favorable RC and 18 patients had an unfavorable RC. Unfavorable RC was attributed to junctional failure in 6/18 patients. Significant differences in the unfavorable RC group compared to the other patients included; age and greater pre-operative PT, PI, SVA and T1SPI (Table). There was no difference in preoperative LL or PSO degree of resection between RC groups.

**Conclusion:** Significant postoperative alignment changes can occur through unfused thoracic spinal segments following lumbar PSO. Unfavorable RC may limit optimal correction (SVA, PT) and can lead to clinical failures. Risk factors for unfavorable thoracic RC include: older patients, larger pre-op PI and PT and worse pre-op T1 spine-pelvic inclination and are not simply due to junctional failure. Care should be taken with selective lumbar fusion and PSO in older patients and those with unfavorable pre-op spine-pelvic parameters.

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**The Incidence of Acute Neurological Complications Following Decancellation Osteotomy for Fixed Sagittal Deformity**

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**Purpose:** Transpedicular decancellation osteotomy provides correction for fixed sagittal plane deformity and biomechanical stability. There is a paucity of literature regarding the acute neurological complications related to these complex reconstructive procedures.

**Methods:** A prospective consecutive case series of patients with kyphotic deformity and associated sagittal imbalance from a single surgeon were identified. Inclusion criteria were patients undergoing corrective decancellation osteotomy with segmental spinal instrumentation. Medical records, clinic notes, standard upright radiographs pre- and post-operatively were reviewed.

**Results:** 31 patients (F: 16, M: 15) at a mean age of 62.5 ± 5.6 years were followed for a mean follow-up of 26.4 ± 3.7 months. 30/31 patients had previous spinal surgery, and the remaining 1 patient had a kyphotic deformity related to TB. Operative level was C7 (n=1), L1 (n=2), L2 (n=5), L3 (n=16), L4 (n=1), and multiple spinal segments at the T-L junction (n=3). Supplemental interbody fusion was performed by anterior or transposa approach in 55% (n=17). The sagittal vertical axis was 15.4cm preoperatively, 5.3cm postoperatively, and 6.1cm at most recent follow-up. All patients were neurologically intact immediately postoperatively. 1 patient (3%) had a delayed lower extremity neurological deficit after mobilizing in the postoperative period without hardware complication. Nonunion was seen at most recent follow-up in 9.7% (n=3), proximal breakdown in 14% (n=5), and failure of fixation in 14% (n=5).

**Conclusion:** Decancellation osteotomy for the treatment of fixed sagittal deformity is a risky but relatively safe procedure with careful surgical technique. Acute neurological sequelae remains a risk of these complex procedures in patients with fixed kyphotic deformities. The relatively high early complication rate requires careful patient selection and informed decision making prior to undertaking major corrective spinal surgery.

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**Radiographic Comparison of Lateral Fusion (LLIF) vs. ALIF vs. TLIF vs. Posterior Fusion: Analysis of Segmental Sagittal Contour Change**

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**Summary:** 167 patients underwent fusion of 245 lumbar levels via LLIF, ALIF, TLIF or PSF. Segmental lordosis change was measured. All interbody fusion procedures provided significantly greater lordosis at the operative levels compared to posterior fusion.

**Introduction:** Potential advantages of minimally-invasive lateral lumbar interbody fusion (LLIF) include reduced morbidity and blood loss, decreased post-op pain, and faster recovery. Improvement in sagittal parameters is considered an important goal in lumbar fusion. There are no studies comparing restoration of sagittal parameters utilizing the LLIF approach versus standard approaches.

**Methods:** This is a comparative x-ray analysis of 4 lumbar fusion approaches. In a 2-year period, 245 levels in 167 patients were fused: LLIF (43 patients; 63 levels); ALIF (41 patients; 67 levels); TLIF (56 patients; 74 levels); and PSF (30 patients; 41 levels). The following parameters were measured on pre- and post-op standing radiographs: segmental lordosis; overall lumbar lordosis (L1-S1); anterior and posterior disk heights. Comparison of measurement changes between groups were performed using student’s t-test.

**Results:** All interbody procedures produced significantly greater lordosis change compared to posterior fusion alone (ALIF p=0.007; TLIF p=0.019; LLIF p=0.03). The 3 interbody approaches were not significantly different (ALIF vs. TLIF p=0.15; ALIF vs. LLIF p=0.29; TLIF vs. LLIF p=0.80). Only ALIF showed significant improvement in overall lumbar lordosis (p=0.0017). Significant differences were noted in terms of anterior disk height restoration, in the following order: ALIF > LLIF > TLIF > PSF.

**Conclusion:** LLIF provides similar segmental sagittal contour change compared to ALIF and TLIF, and significantly greater compared to posterior fusion alone. Overall lumbar lordosis remains unchanged after LLIF.

**Significance:** This is the first study that directly compares the sagittal radiographic parameter changes provided by the LLIF approach compared to traditional approaches.
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Introduction: Complications following adult spinal deformity (ASD) surgery have a reported incidence of 27%-80%. Understanding risk factors for complications may reduce their occurrence and permit improved operative risk-benefit ratios. The purpose was to identify patient and surgical parameters that correlate with development of major peri-operative complications following ASD surgery.

Methods: This was a multi-center (n=8), retrospective, consecutive, case-control series. A total of 953 patients (2y FU minimum) with ASD were reviewed to identify patients with major peri-operative complications (Case). A randomization table was used to select a control group of patients that did not suffer major complications (Control). Data collected included demographics, past medical history, ASA grade, co-morbidities, preoperative lab values, intra/post-operative parameters, occurrence of peri-operative complication. The two groups were analyzed for differences using ANOVA and Chi Square analysis.

Results: We observed 99 major complications (average 1.4 per patient) in 72 patients (7.6%). The matched cohort consisted of 78. No differences were noted between groups for the following: demographics, pre-op vitals, lab-results, ASA grade, respiratory signs, alcohol or smoking habits, mean operative time, and ICU stay. Chi-square analysis demonstrated that the complication group exhibited a higher percentage of staging procedures (46% versus 37%, p=0.011), a higher percentage of anterior/posterior approach (56% versus 32%, p=0.011; Figure) and a greater prevalence of postoperative anemia (16.7% versus 6.4%, p=0.04).

Conclusion: We report an incidence of 7.6% major complications among 953 consecutive patients. Improved understanding of risk profiles and procedure-related parameters may assist in pre-operative risk-benefit surgical discussions and pre-emptive approaches to reduce major complications. Patients should be counseled that a major complication is more likely to occur in the setting of revision, staged, and anterior/posterior surgery.

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Cadaveric Radiographic Analysis of Indirect Spine Decompression
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Study design: Cadaveric Radiographic CT analysis of canal dimensions and foraminal area.

Background data: Lumbar spinal stenosis is a worldwide prevalent and debilitating condition. The current standard of surgical care is to perform a laminectomy with posterior spinal fusion One alternative technique is an indirect spine decompression through an extreme lateral approach with inter-body fusion. There is paucity of reports in the literature examining the anatomical, biomechanical, radiographical and clinical changes in patients undergoing the procedure.

Objective: The purpose of this study is to report on a cadaveric model of lateral interbody fusion and standardize several pre- and post-operative radiographic variables to quantify the anatomic changes resulting from the procedure.

Methods: Eight L1 to S1 continuous vertebral fresh frozen cadaveric specimens were included in this study. All of the specimens were fixed to individual custom rigid frames. Prior to any intervention, computerized tomography (CT) scans and 3D reconstructions were obtained of each intact specimen. Analyzed variables included disc height (three measurements per level: at the level of the anterior longitudinal ligament, middle of the vertebral body, and posterior longitudinal ligament), foraminal area, foraminal height and foraminal anterior-posterior dimensions, canal area, and anterior-posterior dimensions. The L3-L4 and L4-L5 levels were then instrumented by the senior author following the same surgical technique that involved lateral dissection, placement of two interbody cages and augmentation of the construct with two lateral plates. All of the specimens underwent a post-instrumentation CT scan. A fellowship trained musculoskeletal radiologist, a senior orthopaedic resident and a fellowship trained spine surgeon performed the radiographic measurements in a standardized radiology station using the
same imaging software for each specimen. Inter-observer reliability was excellent and continuously documented during the study. Means from the three measurements were used for all statistical analyses.

**Results:** The evaluation of pre- and post-implantation changes in the cadaveric model at the level of L3-L4 showed a 45% increase in the mean area of the right foramen (137mm² vs 200mm²), 50% increase in the mean area of the left foramen (144mm² vs 216mm²), 43% increase in the mean disc height (mid vertebral level, 5.8mm vs 8.5mm), and 53% increase in the canal area (106.5mm² vs. 163.7mm², p=0.044). At the level of L4-L5, there was a 38% increase in the mean area of the right foramen (135mm² vs. 187.5mm²), 50% increase in the mean area of the left foramen (130mm² vs. 195.2mm²), 57% increase in the mean disc height (mid vertebral level, 5.6mm vs. 8.87mm), and 31% increase in the canal area (115mm² vs. 151.2mm²). There was an 85% increase in the posterior disc height at the level of L4-L5 (5mm vs. 9.25mm, p=0.02).

**Conclusion:** This is the first study to systematically evaluate radiographic changes after indirect spinal decompression using the lateral interbody fusion technique. The authors believe that the results of this cadaveric study support the clinical reports and the rationale previously described for the technique. Clinical correlation of these cadaveric radiographic results is ongoing.

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**Clinical and Radiographic Outcomes Following MIS TLIF Supplemented with Percutaneous Pedicular Screws (PPS): 24 Months Follow up**

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**Background context:** Standard techniques for lumbar pedicle screw fixation involve open exposures and extensive muscle dissection. The purpose of this study was to report the initial clinical experience with a device for percutaneous posterior fixation of the lumbar spine.

**Purpose:** To assess the long-term maintenance of clinical and radiographic outcomes using a combination of minimally invasive transforaminal interbody fusion (TLIF) supplemented with pedicular lumber screw by a percutaneous approach.

**Study design/setting:** Prospective clinical study.

**Patient sample:** 78 patients

**Outcome measures:** Pain visual analog score (VAS for both back and leg pain), Oswestry disability index (ODI) and radiographs were evaluated preoperatively and at various time-points postoperatively.

**Methods:** 78 patients underwent MIS TLIF and PPS for the treatment of symptomatic low back and/or leg pain or dysfunction. A contoured (banana shaped) PEEK interbody implant filled with DBM in a lipid carrier mixed with autograft bone was placed in the disc space at the operative level followed by PPS. Patients were followed clinically and radiographically for up to 24 months postoperatively.

**Results:** The 78 patients ranged in age from 19-72 years. 13 had Grade I or II spondylolisthesis and 9 had a failed prior discectomy. All patients underwent successful percutaneous fixation. 75 patients underwent single-level fusions (73 at L5-S1, 16 at L4-5, 2 at L3-4, 1 at L2-3 and 1 at L1-2), and three underwent two-level fusions (from L4 to S1). The follow-up period ranged from 3 to 24 months (mean 13.5 months). Mean combined operative time was 150 minutes and in all cases measured blood loss was less than 60 cc. Patients were typically out of bed, ambulating and advanced to regular diet on the day of surgery, and discharged home the following 48 to 72 hours. Mean back pain VAS decreased from 7.3 at pre-op to 2 at 3 months, 2 at 6 months, and maintained at 2.8 at 24 months. Mean leg pain VAS decreased from 8.2 at pre-op to 1.2 at 3 months, 1 at 6 months, and maintained at 1.5 at 2 years. Mean ODI improved from 61.2 at pre-op to 11 at 3 months, 8 at 6 months, and maintained at 9.5 at 2 years. Fusion rate was 38% at 6 months, 52% at 12 months, and 78% at 24 months.

**Conclusions:** The current results support prior reports of interbody fusion (TLIF) with percutaneous lumbar pedicle screw placement, with optimal fusion rate and clinical improvement. Paraspinous tissue trauma is minimized without compromising the quality of spinal fixation.

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**Radiographic Assessment of Fusion in Lateral Lumbar Inter-body Fusion Performed as a Stand-alone Procedure**

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**Introduction:** Preliminary reports of lateral lumbar interbody fusion (LLIF) through a minimally invasive transpsoatic approach suggests favorable fusion rates. Inter-body fusion is traditionally augmented with posterior instrumentation for secure circumferential fusion under the same anesthesia. We hypothesize that if there is careful selection of the surgical candidate, appropriate cage dimension with a wide surface resting on the apophyseal ring, LLIF may be successfully performed as a stand-alone procedure. We retrospectively reviewed the radiographic fusion outcomes of LLIF cases from our institution, which underwent this procedure as a stand-alone technique.

**Material and methods:** A retrospective review of 78 consecutive cases was performed who underwent minimally invasive LLIF performed as a stand-alone procedure at 166 levels by 3 surgeons. LLIF was performed as the first step of a staged anterior and posterior fixation, however the second stage was not required in all but 8 patients. The indications were spinal stenosis, degenerative scoliosis, spondylolisthesis and junctional disc degeneration. Each patient included in this study underwent a mini-open, trans-psoatic lateral lumbar inter-body fusion without same stage posterior fixation at first surgery. All patients received dynamic flexion-extension radiographs at 10.4 months. CT scan was performed on 53 patients (67%) at 7.1 months and 26 had dynamic flexion-extension radiograph at 9.1 months. A detailed measurement of plain radiographic parameters was also performed for pre-operative, post-operative and...
final follow-up to assess correction of coronal and sagittal deformity, restoration of disc height and complications like subsidence and end plate fracture. Pre-operative coronal deformity was measured with Cobb’s angle and sagittal deformity by sagittal balance. Clinical outcomes were recorded using VAS, ODI and SF-12 scoring methods.

**Results:** Solid fusion was confirmed by CT scan and dynamic flexion-extension radiographs at 154 levels in 70 patients. There was correction of 2.9 degrees of coronal angulation, and 6.2 degrees of lordosis at each level. 50 patients with 61.7 mm positive sagittal balance was restored by 38.4 mm. Non-union was noted at 12 levels in 8 patients who required a second-stage augmentation of fixation through a posterior approach for non-union, cage subsidence and axial pain. 16 patients had end plate fracture leading to subsidence at 21 levels. There were no incidence of neurovascular injury and cage dislocation.

**Conclusion:** LLIF is an excellent technique in achieving degenerative lumbar deformity correction, treating spinal stenosis and intractable discogenic backache through a less morbid, minimally invasive technique. Historically requiring same stage posterior fixation, the fusion rates of LLIF performed as a stand alone procedure has not been studied. Our results show that LLIF can be a reasonable modality in a select population of patients who have single or multiple level degenerative disc disease. Judicious use of this technique greatly reduces peri-operative morbidity and can be a valuable tool in the armamentarium of the lumbar surgeon.

### Breakout 1: Lumbar TDR

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An Association between the Center of Rotation and Clinical Outcome in Patients Implanted with a Viscoelastic Lumbar Total Disc Replacement


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**Purpose:** To determine if correlations exist between center of rotation and clinical outcomes in patients implanted with a viscoelastic total disc replacement (VTDR).

**Introduction:** Fifty patients with single-level, symptomatic lumbar DDD at L4–S1 were enrolled in a clinical trial of the Freedom® Lumbar Disc at three European sites. Patients were assessed clinically and radiographically at baseline and at 6 weeks, 12 weeks, 6 months, 1 year and 2 years. Oswestry Disability Index (ODI) and Visual Analogue Scale (VAS) pain questionnaires were used to assess clinical outcomes. The VTDR studied is an elastomeric one-piece design with a core that closely replicates the normal biomechanical characteristics of a human lumbar disc. The polymer’s biomechanical properties allow motion in all directions while providing load transfer and shock absorption. The one-piece design allows restoration of disc height and sagittal angle.

**Methods:** A comprehensive, independent review of the radiographic and clinical outcomes of the VTDR study was conducted and analyzed for correlations. Data from preoperative through 2 years were available. ODI scores were classified as evidence of achieving a minimal clinically significant difference (MCID) if the ODI score was at least 15 points lower than at preoperative. The center of rotation (COR) was calculated for the index levels. The coordinate system for COR has an x-axis that is colinear with the superior endplate of the inferior vertebra. The origin is at the center of the endplate, and the y-axis is oriented so that a positive y-coordinate is inferior to the endplate. The COR for the index level was also compared to COR data for an asymptomatic population. Each COR coordinate was classified as abnormal if outside of the 95% confidence interval for an asymptomatic population.

**Results:** Based on the latest available follow-up for each patient, 69% of the patients had achieved at least a 15 point ODI improvement, and 76% of the patients achieved at least a 10 point ODI improvement. At the latest available follow-up, 78% of cases had a normal COR-X and 92% had a normal COR-Y. Based on latest available timepoint for each patient, the improvement in ODI score was significantly better for patients with a normal anterior-posterior (AP) coordinate of the COR (P=0.03). Anterior COR corresponded with anterior placement of the device in the disc space, and patients were almost 7 times less likely to get at least a 15 point improvement in the ODI score if the COR was positioned too anteriorly. This effect can also be seen in the average AP coordinate of the COR for patients who achieved the MCID in ODI. No correlation existed for the cranial-caudal coordinate of the COR.

**Conclusions:** A viscoelastic TDR can restore a normal COR. This is the first study to show that a normal COR correlates to a clinically relevant decrease in patient disability. CAUTION - Investigational device. Limited by Federal (or USA) law to investigational use.

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Three Level Lumbar Disc Replacement - A 2 Year Follow up

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**Purpose:** Multi-level disc pathology in the young active patient is becoming more prevalent with advancing diagnostic modalities. Such cases have often been considered difficult to manage, being “too young” for multi-level fusion and yet suffering considerable pain and disability. This paper highlights the triage, surgical technique issues and rehabilitation designed specifically to optimise results.

**Methods:** Fifteen patients, with discogenic pain, underwent total disc replacement at three affected contiguous levels. Exhaustive non-operative treatment with physical therapy and interventional pain procedures was carried out preoperatively for a minimum of one year. Facet injections at all three levels provided no significant pain relief. All patients underwent pressure controlled, provocative discography at a minimum of four levels, demonstrating severe concordant pain reproduction at three contiguous levels, with healthy adjacent discs. A period of prehabilitation was carried out for
all patients to optimize muscular control. All patients had a minimum follow-up of two years.

**Results:** Oswestry scores improved from 49.5 pre-operatively to 7.6 at 2 years, t< 0.001. Thirteen of the 15 patients considered themselves pain free at final follow up, with VAS falling from 7.80 (back pain) pre-operatively to 0.93 at 2 years, t< 0.001.

**Conclusions:** Multilevel disc replacement surgery is an alternative to traditional arthrodesis, and may provide increased mobility and similar relief of pain without increased risk to adjacent discs.

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**The Effect of Discography on the Surgical Decision in Patients with Chronic Low Back Pain**

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**Purpose of the study:** A reduced frequency of discographies might be the result of increasing worries on long-term effect on disc degeneration. An extended knowledge is needed on in what patients and how discography is most likely to influence the surgical decision. This study is aimed to highlight how discography affects surgical decisions when performed on four different indications in a difficult subgroup of patients with Chronic Low Back Pain (CLBP) supposed to be the result of Degenerative Disc Disease (DDD).

**Methods:** 138 patients treated under the diagnosis DDD at a spine clinic during three years (8% of all) were referred to discography since it was felt that medical history, clinical findings and MRI was insufficient to make a final assessment on whether to propose surgery/not surgery or on what segments to operate. Before these patients with uncertainty were referred to provocative discography the surgeon had to define one out of four alternative indications for the examination and what decision would have been taken if discography was not available. The alternative indications were:

1. Surgery decided, discography to establish whether to treat also adjacent segment. (n:17)
2. Several segments degenerated in MRI, pain likely to be discogenic, discography to evaluate which segments to treat. (n:56)
3. Uncertainty if pain is discogenic but a suspected segment on MRI. (n:38)
4. Uncertainty if pain is discogenic and several segments degenerated in MRI. (n:27)

The decision after discography was then compared with pre-discographic decision and the differences and alterations were analyzed.

**Results:** When the surgeon was certain that pain was discogenic, one segment was added or subtracted in 58% of the patients compared to original pre-discographic decision. When the surgeon was uncertain if pain was discogenic, the final decision went from surgery to not surgery in 42% and in cases pre-discographically planned for surgery, one segment was added or subtracted in 17% of the patients.

In patients with indication “1” all patients were planned for surgery, one (6%) changed to not surgery while 10 (59%) had a change in segments to treat.

In patients with indication “2” 48 patients were planned for surgery (86%), 12 (21%) had a change in surgery/not surgery, while 32 (57%) had a change in segments.

In patients with indication “3” 19 patients were planned for surgery (50%), 15 (39%) had a change in surgery/not surgery, while 11 (29%) had a change in segments.

In patients with indication “4” 7 patients were planned for surgery (26%), 17 (63%) had a change in surgery/not surgery, while no patient had a change in segments.

In all the 27 patients with a preliminary decision only to treat the L5-S1 segment changes on segments were made. The corresponding figure for L4-L5 was 70% and for L4-L5-S1 53%. In total changes were made from the pre-discographic decision in 71% (63-79%) of the patients.

**Conclusion:** When using discography as an added examination in patients where uncertainty remains after normal clinical examination, questioning and MRI, a high frequency of decisions are altered, why, despite the risks with discography, this uncertain patient-group seems to benefit from this added examination.

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**Health-related Quality of Life: How Does Symptomatic Disc Degeneration and its Treatment with Total Disc Replacement Compare to Other Medical Conditions?**

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**Introduction:** Health-related quality of life instruments, such as the Short Form-36 (SF-36), are used to assess patients’ physical and mental health in a variety of illnesses. The purpose of this study was to evaluate the SF-36 scores of patients with symptomatic functionally disabling lumbar degenerative disc disease (DDD) treated with total disc replacement (TDR) in the context of multiple other disease conditions and also to investigate the change in scores after treatment.

**Methods:** The SF-36 scores for the DDD group came from the single-level randomized ProDisc-L Food and Drug Administration (FDA) regulated trial. All patients were diagnosed with DDD based on clinical symptoms, MRI, and in many patients confirmatory discography, and all had failed at least 6 months of non-operative treatment. Data in the current study includes the 158 patients randomized to total disc replacement (TDR) and for whom 12-month follow-up was available. Based on a literature search, articles for other commonly accepted conditions were identified which reported SF-36 scores at baseline and at follow-up. The 12-month follow-up was selected due to the availability of data for this follow-up in multiple studies. Pre- and 12-month post-operative data were collected from the literature for hip replacement, knee replacement, chronic obstructive pulmonary disease (COPD), cancer, and heart disease. To determine the impact of DDD on patients compared to other conditions and also to investigate the change in scores after treatment.
illnesses the baseline Physical Component Summary (PCS) was used. Higher PCS scores indicate better health. Outcome at 12-month follow-up was also compared across the multiple diagnostic groups.

**Results:** At baseline, the DDD patients’ physical health mean score was similar to those in the following groups: hip replacement, COPD, heart disease, and knee replacement (Figure 1). Scores for DDD patients were slightly worse than heart disease patients and worse than for cancer patients. After TDR, the PCS scores improved significantly (p< 0.05). The post-TDR score improved to a level similar or better than post-treatment scores for COPD, knee replacement, and heart disease. Hip replacement had somewhat greater post-treatment scores.

![Figure 1. Comparison of DDD to other diagnoses.]

**Conclusions:** In this TDR patient population, lumbar DDD was associated with levels of pre-operative physical debilitation similar to other medical conditions generally considered to be significant health problems. Treatment with TDR yielded after-treatment results that were comparable to most of these other conditions. The results of this study support that functionally-disabling lumbar DDD is a significant health problem and is as debilitating as several other commonly-accepted disease states. Through careful patient evaluation and treatment, their physical condition can be improved in a manner similar to other significant health problems.

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**Prospective Randomized Multi-center Trial Comparing 3 Lumbar Disc Prosthesis**

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**Introduction:** All lumbar total disc replacements have the potential to maintain motion. However, they may differ in design and function, and these differences may affect their clinical performance. Although there have been several large multi-center studies comparing clinical outcomes of lumbar TDR to lumbar fusion, there are few reports of prospective randomized studies comparing different lumbar disc implant types.

**Purpose:** The purpose of this study was to determine the clinical outcome of patients undergoing lumbar disc replacement, and to compare the clinical outcomes between 3 different implant types.

**Methods:** All patients enrolled at 3 sites in a FDA IDE trial were included in this study. All patients had single level symptomatic pain at either L4/5 or L5/S1. All patients had a retroperitoneal approach. The first 3 patients at each site were non-randomized training cases (Activ L), while all other patients were randomized 2:1 to either the investigational group (Activ L), or the control group (Charite or Prodisc).

**Results:** 162 patients are included in this study (23 Charite, 27 Prodisc, and 112 Activ L). 94 patients were males, and 68 were females. L4/5 was involved in 53 patients, and L5/S1 in 109 patients. The mean operative time for Charite was 109 minutes, for Prodisc 101 minutes, and for Activ L 95 minutes. The mean blood loss for Charite was 257cc, for Prodisc 83cc, and for Activ L 107cc. The length of hospital stay was 2.6 days for Charite, 1.8 days for Prodisc, and 2.0 days for Activ L.

Individuals, the mean ODI for the Activ-L patients decreased from an average of 57.4 at baseline to 18.1 at 24 months follow up, Prodisc fell from 58.4 to 22.0 and Charite from 54.4 to 34.0. For the Activ-L patients the mean baseline VAS for back pain was 80.8 and fell to 18.5 at 24 months. Prodisc fell from 80.7 to 22.7 and the Charite patients fell from 75.1 to 35.1.

**Conclusions:** The results of this prospective randomized study support previous prospective studies which report favorable clinical results for lumbar TDR. In addition, the results of this study demonstrate significant improvement in ODI and VAS in patients undergoing lumbar TDR, regardless of implant type.

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**Outcome Associated with Closure of Anular Defects Following Lumbar Discectomy**

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**Introduction:** Lumbar discectomy is considered the gold standard for surgical treatment of sciatica. While efforts have been made to evaluate the use of minimally invasive discectomy techniques and less aggressive disc removal, relatively few have studied the effect of closing anular defects left subsequent to lumbar discectomy. Patients indicated for a lumbar discectomy at two separate surgical locations were considered for participation in the study. Data from these enrolled patients has been analyzed for outcomes such as re-operation, pain, disability, quality of life and work status.

**Methods:** The post-market, randomized, single-blind (to patient) study with concurrent control design allowed for appropriate group comparison. Intra-operative randomization post-discectomy was done 2:1 (Treatment:Control) using a suture-based implant to close the remaining anular defect in appropriately randomized patients (Treatment) while anular defects in the Control patients remained patent.

**Results:** A total of 119 patients were enrolled in the study,
with an average post-op time of 26.7 months (range 13.1-39.2 months).

Validated patient reported assessments (VAS, SF-12, and ODI) were completed pre-operatively and at each follow-up along with a neurological and adverse event assessment by the physician.

Pre-operative Comparison:

- Control Group; n=39
  - Average Age: 41.6 years
  - Average BMI: 29.4
  - Males: 59.0%
  - Smokers: 48.7%
- Treatment Group; n=76
  - Average Age: 39.1 years
  - Average BMI: 28.3
  - Males: 56.6%
  - Smokers: 42.1%

Additionally, there were 4 patients; in whom defect closure was attempted however a device could not be implanted for the following reasons:

- 2 - Anulus was too calcified
- 1 - Poor anular tissue quality
- 1 - Defect too close to bone spur

Adjunctively closing the anulus resulted in:

- Minimal additional OR time; less than 5 minutes reported in the majority of cases
- No requirement to change surgical access or discectomy technique

Mean follow-up scores as compared to pre-operative values showed:

- Significant (p<0.05) improvement within study groups, maintained throughout follow-up
- No difference between study groups

Return to Work status at the time of analysis:

- Control Group:
  - Mean time of 80.1 days with 74.4% returning to work
  - 75.9% reported a return to same or heavier work activity levels
- Treatment Group:
  - Mean time of 60.2 days with 77.6% returning to work
  - 88.1% reported a return to same or heavier work activity levels

Re-operations:

- Reoperations were categorized as:
  1. Any subsequent surgery including repair of dural tear, I/D for wound infection, fusion and re-do discectomy;
  2. Those specifically due to re-herniation
- Control group:
  - 12.8% overall re-operation rate
  - 5.1% rate of re-operation due to re-herniation
- Treatment group:
  - 7.3% overall re-operation rate
  - 1.3% rate of re-operation due to re-herniation

Conclusions: Adjunctively closing the anular defect post-discectomy is associated with an appreciably lower (though in this analysis not statistically significant) re-operation rate following lumbar discectomy while preserving the positive outcomes of pain and disability improvement. Appropriately powered larger studies may more conclusively demonstrate the effect of closing anular defects on re-operation rates.

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Radiographic Evaluation of a Novel Interspinous/Interlaminar Fusion Implant (Coflex-F™) System to Augment Lumbar Interbody Fusion

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Intro: Lumbar interbody fusion, either via a transfominal, lateral, or anterior lumbar approach, remains the treatment of choice for many degenerative conditions of the lumbar spine. While certain interbody grafts are designed as a stand-alone construct, the majority of interbody fusions are augmented with posterior stabilization. Most commonly, lumbar pedicle screw instrumentation is used, but this technique is associated with a potentially morbid posterior lumbar spine approach, pedicle screw instrumentation which has the potential for neurovascular injury, and higher implant costs. The optimal posterior stabilization device following lumbar interbody fusion would be inserted in a minimally-invasive fashion, avoid excessive radiation, produce minimal soft-tissue damage, and avoid proximity to the neural structures. In contrast to other interspinous fusion plates, the Coflex-F™ (Paradim Spine) interspinous/interlaminar fusion device is a novel, minimally-invasive fusion implant that is placed in between adjacent spinous processes following lumbar interbody fusion, with the stabilizing U-portion of the device providing significant stability to the construct by fixating onto the strong laminar bone, not the more cancellous spinous processes. The purpose of the current study is to report the radiographic data from a multicenter European trial in which the Coflex-F™ device was used to stabilize a lumbar interbody fusion.

Methods: A multicenter European clinical trial was performed to treat patients with degenerative disc disease with lumbar interbody fusion supplemented by Coflex-F™ interspinous fusion implant. A total of 6 surgeons participated in the trial. The diagnoses included degenerative disc disease, up to Grade 1 degenerative spondylolisthesis, disc herniation, and recurrent disc herniation. A total of 90 subjects were enrolled and have been followed up radiographically ranging from 6-24 months post-operatively. Radiographic assessments included:

1) evidence of bridging bone,
2) < 3mm translational motion
3) < 5 degrees of angular motion,
4) fusion success.

A board-certified, independent radiologist performed radiographic assessments.

Results: Of the 90 patients enrolled in the study, 81 patients (90%) had complete radiographic data that permitted assessment of fusion status. Sixty-five patients had flexion-extension films, and 62 patients had all...
radiographic measures available for review. The fusion rate, using established radiographic criteria, was 95.2% (59/62). Specifically, bridging bone was present in 96.3% (78/81), 100% of patients (65/65) had < 3mm translational motion, and 100% (65/65) had < 5 degree of angular motion. Of note, however, 2 of the 3 patients that did not exhibit bridging bone were only 6 weeks post-operatively, and would not be expected to show bridging bone at this early timepoint. Excluding these 3 patients, the fusion rate is 100%.

Discussion: Posterior stabilization to augment lumbar interbody fusion was successfully achieved using the Coflex-F™ device, a minimally-invasive interspinous/interlaminar fusion implant system, which produced a fusion rate of 100% for patients who had at least 3 months follow-up. This posterior stabilization device allows for soft-tissue sparing, reduced blood loss, reduced surgical time, an improved safety profile by avoiding pedicle screw placement and possibly proximity to neural structures, and reduced implant costs. The Coflex-F™ device is an attractive alternative to pedicle screw-based systems to augment lumbar interbody fusion device stabilization.

401 Lumbar Interbody Fusion with Osteosponge® Demineralized Allograft in a Peek Cage as Compared to Fusion with RhBMP-2: Long-term Post Operative Assessment

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Background context: Several grafting materials can be used in lumbar spinal fusion (i.e. allograft, autograft and BMP-2). To date no studies have compared the use of Osteosponge® with BMP as an effective and comparable long-term option.

Purpose: Osteosponge® as a graft material in a lumbar fusion model in conjunction with posterolateral fusion in single and two-level procedures will be compared to Infuse in a blinded manner to demonstrate equivalency.

Study design: Prospective, blinded two to three year cohort.

Outcome measures: A two sample t-test was utilized to measure long-term Oswestry Disability Index (ODI), SF-36, Visual Analog Scale (VAS), and radiologic findings such as: Disc fusion, screw loosening, breakage or motion; as defined by AP, Lateral, Flexion, and Extension X-Ray films. CT scan imaging of spine including Hounsfield scale units.

Methods: 28 patient sample: 16 patients were randomized to Osteosponge® and 12 patients to the Infuse group. During the PLIF procedure, Osteosponge® or Infuse were placed in PEEK cages for anterior fusion. Anterior fusions were accomplished via PLIF procedure and Posterolateral fusions were completed with Actifuse. Clinical and radiologic data were analyzed.

Results: Long-term data shows radiographic and CT scanning of Osteosponge® to be equivalent to BMP-2 in achieving an anterior fusion when used with BMA (bone marrow aspirate) and placed in a PEEK cage. The average X-Ray fusion rating for the Osteosponge® (OS) group was 3.85 and 3.72 (p=0.17) for the BMP-2 group. Leg pain in the OS group was reported as 2.46 compared to 2.83 for BMP-2 (p=0.21). SF-36 score for OS group was 65.4 and for BMP-2 62.8. ODI scores were 15.9 for OS and in the BMP-2 group 22.1, however the difference was not significant (p=0.45).

Housefield unit measurements for fusion density were 194 for OS and 241 for BMP-2 (p=0.12); adjacent level density for OS was 178 and 163 for BMP-2. Back pain for the two groups was not statistically different.

Conclusion: These results suggest that a comparable fusion can be generated with Osteosponge® with an improved quality of life and without the risk of complications as reported to be associated with the use of BMP-2.

64 Physical Capability Outcomes after Total Disc Replacement with ProDisc-L®: A Pilot Study

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Purpose: To date, lumbar disc arthroplasty (total disc replacement, TDR) outcomes have been evaluated using subjective, patient-report measures of pain, health, and functional impairment—measures that do not allow one to quantify improvement in physical performance. The goals of this pilot study were to:
1) determine the feasibility of using seven adapted Work Well™ Functional Capacity tasks as outcome metrics for TDR with ProDisc-L™ (PD-L);
2) evaluate the statistical significance of the magnitude of improvement noted in these tasks one year after surgery as compared to pre-operative testing; and
3) compare the improvements noted in physical capacity to improvements in standard patient-report Oswestry Disability Index (ODI), Visual Analog Scale (VAS) for pain, and change in patient’s usage of narcotics as measured by morphine equivalency.

Methods: The seven Work Well tasks were performed by 22 patients pre-operatively and one year post-operatively. These tasks were selected because they represent typical demands of jobs and of activities of daily life which are known to be difficult for patients with low back pain. Patients’ medical records and previously collected data were retrospectively reviewed for demographic and medical data. Data were analyzed using descriptive statistics and paired t tests. A p-value < 0.05 was considered significant.

Results: There was no difficulty in implementing physical capability outcome testing in the clinical setting, with tasks being completed in approximately 30 minutes. Average percentage improvements in physical capability tasks were as follows: squat, 74% (p=0.001); forward bend, 103% (p=0.001); kneel, 89% (p=0.001); floor-to-waist lift, 100% (p=0.001); horizontal carry, 87% (p=0.001); push 34% (p=0.001); and pull 32% (p=0.001). Improvements were also noted in standard patient-report ODI (-72%, p=0.001), VAS for pain (-75%,
re-intubation, one pulmonary embolism, one posterior intubation for 5 days, one other respiratory distress requiring transfusions and one infection. Complications included 2 MI’s 2 surgeries included supplemental fixation. There was three levels, 12 3-levels and 1 4-level; the majority at L4-5. All but 2 levels were treated in these 479 patients: 386 1-levels, 80 2-levels, 12 3-levels and 1 4-level; the majority at L4-5. All but 2 surgeries included supplemental fixation. There was three transfusions and one infection. Complications included 2 MI’s at 4 and 6 wks, one atrial fibrillation, pneumonia requiring intubation for 5 days, one other respiratory distress requiring re-intubation, one pulmonary embolism, one posterior hardware failure/rod fracture at 6 mos, and one fracture of vertebral osteophytes requiring reoperation. Hospital stay averaged 1.29 days. From pre-op to 24 month follow-up: disk height increased an average 2.6mm; slip decreased an average 3.2mm in spondylolisthesis patients; and VAS pain scores decreased from 8.7 preop to 2.7 at 24 mos. Lenke scores were 2.1 at 3 mos, 1.2 at 12 mos, and 1.1 at 24 mos. Conclusion: Our results demonstrate the usefulness and safety of the XLIF technique in treating morbidly obese patients minimally invasively. Complications are minimal, procedures timely, and outcomes similar to non-obese patients.

Background: Failed back surgery syndrome due to recurrent herniation and foraminal stenosis post-laminectomy/ decompression is commonly seen in spine care. Although conventional surgery for recurrent HNP is nearly as successful as the index procedure, it is a challenge to both surgeon and patient to consider repeat surgery from the same surgical approach. When there is lateral stenosis and extraforaminal HNP, especially at L5-S1, many patients require decompression and fusion as a “salvage procedure”. Study design: A Prospective collection of outcome data in patients with FBSS due to recurrent lumbar disc herniation and/or foraminal stenosis were reviewed and analyzed by an independent reviewer. All surgeries were by a transforaminal endoscopic approach for discectomy and foraminal decompression by 4 surgeons in a single spine group and in an outpatient setting.

Method: Prospective outcome data included Visual Analogue Scale (VAS), Oswestry Disability Index (ODI), and SF 12. The data was collected and recorded at the initial office visit, preoperative and postoperative visits, follow-up visits, and final follow up before discharge. A final clinical rating using modified MacNab criteria by the reviewer summarized the outcome. The surgical method chosen was a shared patient/surgeon decision. All procedures were performed at an ambulatory surgical center. All patients were discharged to home the same day. The average follow up period was, minimum 12 months, average 30 months. Levels involved were L2-3=6, L3-4=6, L4-5=14, L5-S1=11. 1 level=24 patients, 2 levels=5, and 3 levels=1. The endoscopic decompression technique combined foraminal “selective” discectomy with foraminoplasty, decompressing the lateral recess by ventral facet soft tissue and bone resection. Intraoperative chromo-discography outlined the foraminal disc protrusion/ extrusion.

Results: In the 30 Cases of recurrent disc herniation and foraminal stenosis, the average pre-op VAS was 6.2, and ODI 43%. Endoscopic decompression provided Improvement of 4.4 and 33% respectively. “Complications” of the foraminal

Introduction: Minimally invasive procedures are challenging in obese patients whose body habitus may decrease the accessibility of the spine to the instruments necessary to perform these procedures. The XLIF procedure, however, is performed in the lateral decubitus position, minimizing the difficulty of the pannus as it falls away from the exposure.

Methods: In our single-site prospective series of 941 XLIF patients, 479 were identified as obese (BMI>30) and 160 of those were morbidly obese (BMI > 38). Comorbidities, surgical details, hospital stay, complications, pain scores, changes in disk height and alignment, and fusion were assessed.

Results: In all our XLIF patients, no surgery could not be successfully completed due to body habitus. The heaviest patient to date weighed 427 lbs (193.7 kgs); the largest BMI was 61.8 (avg 43.6, range 38.0-61.8). Age ranged from 22-78yrs. Comorbidities included smoking (30%), prior spine surgery (43%), diabetes (30%), CAD (42%), COPD (4%). 586 levels were treated in these 479 patients: 386 1-levels, 80 2-levels, 12 3-levels and 1 4-level; the majority at L4-5. All but 2 surgeries included supplemental fixation. There was three transfusions and one infection. Complications included 2 MI’s at 4 and 6 wks, one atrial fibrillation, pneumonia requiring intubation for 5 days, one other respiratory distress requiring re-intubation, one pulmonary embolism, one posterior hardware failure/rod fracture at 6 mos, and one fracture of

Breakout 2: MIS II

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Extreme Lateral Interbody Fusion (XLIF) in the Morbidly Obese

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[Pre-Post Surgical Data]

The Transforaminal Endoscopic Approach Is Effective for the Treatment of the Most Common Causes of Failed Back Surgery Syndrome (FBSS)

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Complications included 11 (2.2%) pseudoarthroses, nine observed in 48 (8.6%) patients with 29 (5.2%) reoperations. 96 minute operative time with < 50cc blood loss and a 2.1 24-month follow-up. Average treatment variables included least two years through a prospective registry.

Methods:
Study design:
Spine. This study aims to detail long-term complications widely performed as a less invasive approach to the anterior spine. Results of advanced neuromonitoring modalities. The overall complication and reoperation rate in this study is in-line with the least complicated approaches in the literature.

Discussion:
The transfarominal endoscopic approach is ideal for FBSS due to recurrent HNP and lateral stenosis. The approach should be considered as one alternative to fusion in FBSS due to recurrent HNP and lateral stenosis. Residual axial back pain from non-discogenic axial may need further work-up to consider dorsal endoscopic rhizotomy versus the standard decompression and fusion.

Conclusion: Endoscopic Transforaminal Decompression is a less invasive MIS technique that produces good results and does not “burn bridges” for a more conventional decompression / fusion approach. Endoscopic foraminal decompression will add to the surgical armamentarium of MIS surgery and the treatment of FBSS.

Summary of background data: Complications of spine surgery are an unfortunate reality, though the benefits of intervention have been shown to outweigh risks. Outside of the general risks of surgery, spinal fusion procedures carry different risks based on the type of procedure being performed and the extent of exposure used. Among other things, anterior lumbar interbody fusion (ALIF) is regularly associated with increased risk of vascular injury, while posterior approaches generally carry a greater risk of neural injury. Open procedures are also associated with greater intraoperative blood loss and higher associated complication rates than minimally invasive procedures.

Objective: Lateral approach surgery is less studied, but widely performed as a less invasive approach to the anterior spine. This study aims to detail long-term complications using a lateral approach for lumbar interbody fusion.

Study design: Prospective registry.

Methods: 801 patients were treated from 2004 to 2008 with extreme lateral interbody fusion (XLIF) and followed for at least two years through a prospective registry.

Results: 559 of the 801 patients (69.8%) completed at least 24-month follow-up. Average treatment variables included 96 minute operative time with < 50cc blood loss and a 2.1 day hospital stay. A total of 57 complications (10.2%) were observed in 48 (8.6%) patients with 29 (5.2%) reoperations. Complications included 11 (2.2%) pseudoarthroses, nine (1.6%) instances of clinical subsidence, four (0.7%) adjacent segment disease revisions, four (0.7%) lower extremity dysesthesias, and one (0.2%) femoral nerve palsy.

[Complications Table]

Conclusions: Low blood loss, operative time, and length of stay suggest mini-open XLIF minimizes collateral tissue damage. Vascular and visceral complications common to anterior procedures were not encountered, and neural injuries were fewer than commonly reported rates in posteriorly approached procedures. The single instance of nerve injury in this series supports the required use of advanced neuromonitoring modalities. The overall complication and reoperation rate in this study is in-line with the least complicated approaches in the literature.

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Complications in a Mini-open, 90° Lateral, Retroperitoneal, Transpsoas Approach for Discectomy and Fusion in the Lumbar Spine: Two-year Results
W.D. Smith1, G. Christiani2, S. Serrano2, K.T. Malone2
1University Medical Center, Neurosurgery, Las Vegas, NV, USA, 2NNI Research Foundation, Research, Las Vegas, NV, USA

Summary: 16 adult patients with an average Cobb angle of 47° were treated with an anterior release and spinal fusion via a less invasive lateral interbody fusion. While there are predictable perioperative sequelae, there was significant improvement of curve magnitude and various clinical outcome measures at two year post-op.

Introduction: Anterior reconstruction of the adult spine is a widely accepted approach to improve fusion rate and achieve coronal and sagittal correction. We present our experience using the less invasive far lateral interbody fusion (LIF) to achieve these goals.

Methods: This was a retrospective review of adult deformity patients undergoing LIF. Of 58 patients, 16 met the inclusion criteria: Cobb ≥30°, initial surgery for scoliosis, and minimum 2-year follow-up. Exclusion criteria included add-on disease and primary diagnosis other than scoliosis. Clinical, radiographic and outcomes data were analyzed.

Results: There were 15 females and 1 male. Mean age was 56 (23-84) yrs, 7 were idiopathic and 9 were degenerative scoliosis. Mean co-morbidities were 2.6 per patient. Main curve improved from 47° to 17°, the L4 tilt significantly corrected from 23° to 10°. Change in spinal balance, lordosis (L1-S1) or amount of lordosis across the LIF was corrected from 23° to 10°, the L4 tilt significantly corrected from 23° to 10°.

Discussion: The transforaminal endoscopic approach is ideal for FBSS due to recurrent HNP and lateral stenosis. The approach should be considered as one alternative to fusion in FBSS due to recurrent HNP and lateral stenosis. Residual axial back pain from non-discogenic axial may need further work-up to consider dorsal endoscopic rhizotomy versus the standard decompression and fusion.

Conclusion: Endoscopic Transforaminal Decompression is a less invasive MIS technique that produces good results and does not “burn bridges” for a more conventional decompression / fusion approach. Endoscopic foraminal decompression will add to the surgical armamentarium of MIS surgery and the treatment of FBSS.

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a cage requiring revision, and one pleural effusion resolved with chest tube. All patients regained quadriceps function within 6 months of surgery. 9/16 (56%) experienced anterior thigh numbness (2 permanent) and 8/16 (50%) anterior thigh pain for at least 4 weeks post-op. Post-operative improvement at two year follow up for VAS (6.5 to 2.5), ODI (60 to 24) and SRS-22 (2.6 to 3.8) were all statistically significant.

Conclusion: LIF approach is a safe and effective alternative to open surgery for adult scoliosis. Patients with advanced spinal deformities should be made aware of possible post-op thigh numbness, pain and/or transient weakness as sequelae of the less invasive LIF technique.

194 Controlled Motion with the XL-TDR Lateral-approach Lumbar Total Disc Replacement: In vitro Kinematic Investigation L.M. Pimenta1,2, A.W. Tumer1, G.B. Cornwall1, L. Eismann1, A. Cappuccino3
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Purpose: While anterior-approach lumbar disc replacement devices are thought to retain close to “normal” range-of-motion (ROM), they are also inherently unstable due to resection of the anterior longitudinal ligament and annulus. This instability/laxity is manifested as increased neutral zone motion. The XL-TDR device (Nuvasive, Inc., San Diego, CA) is implanted through a lateral approach that preserves the anterior ligamentous and annular structures. This potentially makes the XL-TDR device significantly more stable than those delivered anteriorly. This study investigates the kinematics of XL-TDR in a cadaveric model, and also investigates the contribution of the anterior ligament/annulus to stability.

Methods: Six fresh-frozen cadaveric specimens (L2-S1) were subjected to non-destructive multi-directional testing using the hybrid protocol described by Panjabi, where the total L2-S1 intact ROM at ±8 N·m is applied to the reconstructed conditions. Motion segment kinematics were obtained using an optoelectronic system. Test conditions were: (1) intact spine, (2) XL-TDR at L4-S, and (3) XL-TDR at L4-S with anterior annulus/ligament resected. Total ROM (ROM = NZ + EZ; NZ = neutral zone, EZ = elastic zone) and NZ were calculated for each condition in each loading direction (flexion-extension total, flexion alone, extension alone, lateral bending and axial rotation).

Results: Insertion of the XL-TDR device led to decreased ROM with respect to intact in all directions. This achieved statistical significance for flexion-extension, extension, and axial rotation (p < 0.006). NZ in all directions was not statistically different from intact (p < 0.05; Figure 1), although there was a trend towards decreased NZ in flexion (p = 0.078). Removing the anterior ligament/annulus increased ROM significantly with respect to the XL-TDR condition in all directions (p < 0.003). NZ also increased, with the most significant changes in extension, lateral bending and axial rotation (p < 0.002).

Conclusion: This is the first study to investigate the kinematics of XL-TDR. Retention of the anterior ligament/annulus had a significant stabilizing effect. Device insertion leads to tensioning of the anterior and posterior longitudinal ligaments and remaining annulus. While less ROM than intact was observed, the motion was found to be more controlled (more natural NZ). The XL-TDR NZ motion compares favorably with commercial anterior TDR devices which typically exhibit higher NZ motion, particularly in axial rotation (approx 3× intact; Cunningham, Cappuccino et al., SAS9, 2009). Removing the anterior ligament/annulus illustrated its stabilizing role, with ROM and NZ increasing. Future studies will investigate the potential benefit of controlled XL-TDR motion on facet kinematics, which may have clinical implications related to limiting facet degeneration.

4 Effect Modifiers of Outcome of Surgery in Patients with Herniated Disc Related Sciatica? A Subgroup Analysis of a Randomised Clinical Trial M.P. Arts1, R. Brand2, B.W. Koes1, W.C. Peul3, 1Spine Intervention Prognostic Study (SIPS) Group - Leiden The Hague 2Medical Center Haaglanden, Neurosurgery, The Hague, Netherlands, 3Erasmus Medical Center, General Practice, Rotterdam, Netherlands

Background: Tubular discectomy compared with conventional microdiscectomy has been introduced to speed up the rate of recovery in patients with lumbar disc related sciatica, although similar results have been shown. We performed a subgroup analysis to investigate whether certain patients might benefit more from either two surgical treatments.

Methods: A double-blinded randomised trial was performed to compare the rate of recovery and outcome at 1 year between tubular discectomy and conventional microdiscectomy. Complete and nearly complete recovery, documented on the patient’s global perceived recovery, were defined as good outcome. Effect modification of the allocated treatment strategy by predefined variables on the rate of recovery and outcome at 1 year, were analysed by Cox
proportional hazard analyses and logistic regression analyses, respectively.

**Results:** With respect to the outcome rate of recovery, interaction with treatment effect was present for the variable gender and type of disc herniation. Patients with contained disc herniation (hazard ratio 0.73; 95% CI 0.49 to 1.09) and women (hazard ratio 0.75; 95% CI 0.54 to 1.06) had slower rates of recovery when treated with tubular discectomy. Variables correlated with good outcome at 1 year were level of education and Slump test. Higher educated patients (odds ratio 0.18; 95% CI: 0.06 to 0.59) and patients with negative Slump (odds ratio 0.24; 95% CI 0.06 to 0.92) fared worse at 1 year when they underwent tubular discectomy.

**Conclusions:** Superiority of tubular discectomy compared with conventional microdiscectomy was not demonstrated. Subgroup analyses identified only few variables that were associated with more or less benefit from one of the allocated treatments.

**Abstract: 315**

*Retrospective Evaluation of Minimally Invasive Surgical (MIS) Method for Sacroiliac Joint Arthrodesis*


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**Introduction:** Historically treatment focus in spine has centered on lumbar pathology. In published literature, 15-30% of individuals who presented with lower back complaints had SI joint (SIJ) problems. The incidence of SIJ degeneration is 75% in patients with previous lumbar fusions. A minimally invasive surgical (MIS) procedure may help to address this significant unmet clinical need.

**Relevance:** A triangular, titanium, MIS implant was developed that requires a minimal incision and fluoroscopic guidance. The implants are coated with a porous plasma spray creating interference fit to decrease implant motion. The implant size, geometry, and metallurgy, provide immediate post-op fixation, accomplishing the goal of traditional open SIJ fusion.

**Diagnostic methods:** SI joint diagnoses require appropriate interpretation of a patient’s history, clinical exam, and imaging studies (often hip and lumbar pathology coexists with SI joint). Physical examination includes pain, palpable tenderness, provocative tests, and absence of neurologic deficits. CT or fluoroscopic guided injection provides confirmation of sacroiliac pathology. Some physicians repeat injection to reduce the chance of a false positive. When physical findings point to the SI joint, chronic, degenerative changes in the lumbar spine or bulging discs should not override a diagnosis of SIJ Joint pathology.

**Methods:** The MIS procedure is performed under general in prone position. 4.0mm or 7.0 mm implants are inserted through a 2-3cm incision. The drills, broaches, and implants are cannulated to allow precise placement over a guide pin. This implant is marketed for fracture fixation of large bones, large bone fragments of the pelvis, including SI joint disruptions, and degenerative sacroiliitis. As a rule, patients are implanted with three MIS implants across the SI joint. However, MIS implant numbers may vary based on the size of the patient.

Post-operatively patients are kept non-weight bearing for 6 weeks, depending on the patient’s pain level, and followed by four weeks of partial weight bearing. Routine activities are allowed 12 weeks after surgery. Radiologic studies include X-rays and CTs at 3, 12, and 24-months to document implant position and to observe bone growth across the joint.

**Results:** This retrospective, post-market analysis covers 123 treated patients. To evaluate the procedure radiologic studies were used to document implant position, fixation of implants and observe osseous integration. In addition, patient satisfaction tests were utilized. Some patients exhibited evidence of bone at bone-implant interface at 3 months post-op, as seen on sagittal CT. Clinical significance was consistently good for those patients participating in assessments at 6 months post-op vs. pre-op (follow-up range 3-24 months). 41/123 patients answered satisfaction surveys and 90% indicated they would have the procedure again. Neural foramen encroachment was noted in two cases with no clinical sequelae. Non-optimal implant position was addressed with simple implant revision.

**Conclusions:** This retrospective study reinforces the need for awareness that SIJ problems are common symptom generators. Traditional treatments (e.g., open fusion) have shown limited efficacy. In some patients with residual symptoms after hip arthroplasty or lumbar spine procedures, it may be the SI that is symptom generator. With the advent of this MIS procedure, surgeons may avoid further, unnecessary surgery for failed lumbar fusion patients by looking at SIJ. Multicenter prospective studies are ongoing.

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**Indirect Decompression of Lumbar Spinal Stenosis with Transposas Anterior Lateral Interbody PEEK Cages and Percutaneous Posterior Spine Instrumentation**

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**Study design:** Retrospective review of prospectively collected outcomes data and CT neural canal measurements.

**Objective:** The purpose of this study is to examine the relationship between radiographic changes (via CT Scan) and the canal dimension and foraminal area at the index vertebral segments prior to and after indirect decompression of the neural foramen and correlate with clinical outcome measures.

**Summary of background data:** The use of lateral approach, transposas cages for direct distraction of the intervertebral space for purposes of indirectly decompressing the neural structures has the potential of decreasing the morbidity associated with open laminectomies. This technique can also reduce and correct both the sagittal and coronal
deformities. The addition of MIS (minimally invasive surgery) percutaneous posterior screws will avoid recurrence of the deformity and maintain the canal volumes. **Methods:** Single surgeon, consecutive series (N=20) evaluated for 12-24 months. All patients completed all data points. All patients had a lateral approach trans psoas cage with a lateral anterior interbody fusion and a MIS percutaneous screws and instrumentation. Clinical outcomes were obtained prospectively pre and post operatively using SF-36 Health Survey, Visual Analogue Scale (VAS); Oswestry Disability Index (ODI). CT Scans done preoperatively and postoperatively were evaluated by an independent neuro-radiologist who obtained measurements of foraminal height, foraminal volume and posterior disc heights. **Results:** The average age of patients was 63 y/o (range 49-72). There were 12 female and 8 males with a mean follow-up of 18 mo. (12-24 months). 18/20 patients had severe stenosis and 2/20 had moderate spinal stenosis as read by an independent radiologist. Mean improvement of the foraminal volume was 20% at L4-5, 24% at L3-4, and 30% at L2-3. The functional outcomes presented a 45% improvement of the VAS, 36% improvement of the ODI and a 15 point improvement in the SF 36. There were no crossovers to a laminectomy. **Conclusion:** Small cohort of patients with degenerative adult scoliosis and severe spinal stenosis that have improved clinical outcomes with a MIS lateral approach interbody cage with MIS percutaneous screws, without the need of a laminectomy.

**Methods:** 39 patients underwent MIS treatment (14 MIS TLIF, 25 XLIF) of symptomatic L4-L5 disc. Outcomes and complications are reported. Patients were followed clinically and radiographically for up to 24 months postoperatively. **Results:** A consecutive 14 patients, ranging in age from 19-72 years, 12 M, 2 F, underwent MIS TLIF; and a following 25 patients, ranging in age from 28 - 74 years, 7 M, 8 F, underwent XLIF. All patients underwent single-level fusions at L4-L5. The follow-up period ranged from 2 weeks to 24 months (mean 13.5 months). In the MIS TLIF group mean operative time was 150 minutes and in all cases measured blood loss was less than 60 cc. Average length of stay was 2.2 days. Mean back pain VAS decreased from 7.3 at pre-op to 2 at 3 months, 2 at 6 months, and maintained at 2.8 at 24 months. Mean leg pain VAS decreased from 8.2 at pre-op to 1 at 3 months, 1 at 6 months, and 1.5 at 2 years. Mean ODI improved from 61.2 at pre-op to 11 at 3 months, 8 at 6 months, and 9.5 at 2 years. Fusion rate was 38% at 6 months, 52% at 12 months, and 78% at 24 months. In the XLIF group mean operative time was 68 minutes and in all cases measured blood loss was less than 50 cc. Average length of stay was 1.32 days. Mean back pain VAS decreased from 8.1 at pre-op to 2.8 at 3 months, 3.4 at 1 year, 4.8 at 2 years, and 4.6 at 30 months. Mean ODI improved from 53 at pre-op to 19 at 3 months, 22 at 1 year, 21 at 2 years, and 28 at 30 months. Fusion rate was 28% at 6 months, 48% at 12 months, and 74% at 24 months. **Conclusions:** We found similar clinical and radiographic outcomes between the two procedures, but lower OR times, blood loss, and length of hospital stay in the XLIF group. Back pain in the early postoperative time due to approach manipulation in the MIS TLIF group is notably higher than in the XLIF group.

### Breakout 3: Lumbar Complications

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**Sexual Function and Dysfunction in Patients Undergoing Lumbar Disc Replacement**

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**Introduction:** Impotence and retrograde ejaculation are feared complications following anterior lumbar surgery, and are sometimes cited as notable reasons for deciding against lumbar TDR. Low back pain, however, can have a devastating effect on sexual function. By alleviating or eliminating pain lumbar TDR may have a beneficial effect in sexual function. By alleviating or eliminating pain lumbar TDR may have a beneficial effect in sexual function. **Purpose:** The purpose of this study was to document the prevalence of patients reporting low back pain interfering with sexual function prior to lumbar TDR, and to document the effect of lumbar TDR on sexual function. In addition, the study determines the incidence of sexual dysfunction following lumbar TDR. **Methods:** All patients enrolled in a single site of an FDA IDE study on lumbar TDR were included in this study. All data was collected prospectively. All patients had a retroperitoneal approach by the same vascular surgeon,
and a lumbar TDR by the same spine surgeon. Responses to question 8 in the Oswestry Disability Index were recorded pre-operatively, and at 3, 6, and 12 month follow-up.

**Results:** 57 patients were included in this study. There were 36 males, and 21 females. All 57 patients (100%) reported some degree of impaired sexual function pre-operatively secondary to pain. 42 of the patients (73.7%) reported improvement in sexual function at 12 month follow-up, 9 patients (15.8%) reported no change in sexual function, and 6 patients (10.5%) reported worsening in sexual function after lumbar TDR.

The percentage of males reporting improvement in sexual function was higher than that for women - 78% versus 67%. 4 of the 36 males (11%) reported new onset sexual dysfunction post-operatively. 3 patients (8.3%) reported retrograde ejaculation, and 1 patient (2.7%) reported erectile dysfunction. 2 of the 3 males reporting retrograde ejaculation had complete resolution of symptoms at latest follow-up. Therefore, the final incidence of sexual dysfunction among males was 5.6%.

**Conclusions:** The results of this study demonstrate that lumbar TDR can have a beneficial effect in sexual function in both men and women by alleviating back pain. This beneficial effect is more pronounced in men than in women. The study also documents a very high prevalence of patients reporting some degree of impairment in sexual function prior to lumbar TDR. The study also reports a relatively low rate of permanent sexual dysfunction following lumbar TDR.

The authors believe that when deciding for or against lumbar TDR, the potential for sexual dysfunction must be weighed against the potential benefit in function.

**Purpose:** To document the occurrence of vertebral body splitting fractures (VB-SF) after ProDisc-L™ implantation, to compare the standard U.S. surgical technique to newly developed transitional and modified surgical techniques designed to prevent VB-SFs, to evaluate potential risk factors for VB-SF, and to determine the evolution of VB-SFs over time.

**Methods:** Computed tomography (CT) scans were examined for VB-SFs in Group I (14 standard-technique single-level cases, 4 standard-technique hybrid cases, 5 standard-technique multilevel cases and 1 transitional-technique multi-level case), as well as in Group II (15 modified-technique multi-level cases). Patients with fractures were followed with CT for 5 to 13 months. Demographic and clinical data were collected to identify risk factors for VB-SF.

**Results:** No VB-SFs were observed in the 14 standard-technique single-levels, 4 standard-technique hybrids, or the only transitional-technique multi-level. There were VB-SFs in 4 of 5 interposed vertebral bodies (IVBs) in standard-technique multi-levels. The remaining patient had an anterior keel cut to anterior keel cut fracture which did not transect the vertebral body. In the lone transitional-technique multi-level, 1 of the 2 IVBs had a VB-SF. No VB-SFs were noted in the 15 (17 IVBs) modified-technique multi-levels. The reduction in VB-SFs associated with the modified surgical technique was highly statistically significant (p < .001). The vertebral body height (VBH) of the standard-technique multi-levels was on average 2.9 mm smaller that the VBH of the modified-technique multi-levels (p < .001). However, there was a small VBH subset within the modified-technique multi-levels which did not differ in VBH from the VBH of the standard-technique multi-levels. These small vertebral body modified-technique multi-levels did not have VB-SFs. No other clinical or demographic feature could account for the absence of VB-SF association with the modified surgical technique. A 2-level patient may have suffered an adverse outcome as a result of VB-SF separation and implant dislocation due to trauma 10 days post-operatively. Follow-up CT scans indicated that VB-SFs did not bridge with bone, instead formed sclerotic margins around the fracture. Sclerosis was noted in relationship to the keel in non-fractured vertebral bodies.

**Conclusions:** VB-SFs are rare in single-level PDL™ cases and may be under reported in multi-level applications. VB-SFs tend not to bridge with bone, with sclerotic margins forming around the VB-SF. In the immediate post-operative period, VB-SF in combination with trauma may increase the risk of additional bony injury and implant dislocation. VB-SFs may be prevented by the modified surgical technique reported here.
Introduction: Infectious spondylitis is rare, but a more frequently occurring disease. Unspecific symptoms lead to a delay in diagnosis. Complexity of the illness demands an interdisciplinary approach in diagnostics and treatment which varies from hospital to hospital. General applicable recommendations are not available.

Method: Data were investigated from 90 patients (37 female, 53 male, mean age: 63.5 years) at the orthopaedic and trauma department of our hospital from 2004-2009: patient-related data, risk factors, clinical, radiological and laboratory data and information of diagnostic and therapeutic measures. Mean follow-up was 11.7 months. Retrospective results were investigated for failure in diagnostic and clinical treatment. Documented risk factors included diabetes, immunosuppression, end stage renal failure, alcohol, drug abuse, prior spine surgery and BMI.

Results: 82 patients suffered from back pain, 22 patients presented with fever. Neurological deficits were present in 29 patients. Lumbar spine infection had highest prevalence. Bone and disc affection was double to muscular and epidural. CRP was elevated in 80 patients, WBC in 25 patients. MRI detected spondylitis in 80 cases. Blood cultures were taken in 23 cases, pathogen were detected in 44%. CT-guided biopsies were taken in 23 patients, bacterial infection was proven in 30%. Open biopsies were conducted in 63 patients, bacterial infection occurred in 67%. A causative organism could be identified in 39. Pathogen distribution was according to literature. Gram-positive cocci were responsible for majority of infections. Cardiac-ultrasound was performed in 29 patients. Endocarditis was detected in 3. Mean hospital time was 30 days. 21 patients underwent conservative treatment, 69 patients surgical. Instrumentation was done in 52 cases. Surgical revision was necessary in 25 patients. 30 patients were lost to follow-up. Successful treatment resulted in 54 of 60 patients.

Conclusion: The results show severe flaws in treatment of infectious spondylitis and demonstrate a fundamental need for an interdisciplinary approach to serve our patients best. A standard clinical algorithm based on retrospective results was developed for optimal treatment according to current literature. A guideline for the decision between conservative or open treatment is included as well as for diagnostics and treatment. The simple-to-use algorithm is further used to gain prospective data on treatment and clinical outcome. It may be used as general recommendation for treatment of infectious spondylitis. First results of the established procedure seem to be very promising. Prospective investigation is under way.

Purpose: In Medline there is just one report on rectal injury by using the pararectal AxiaLIF approach. We report a case series of patients who have been fused using the rather new AxiaLIF technique. FDA files also give a steadily changing number on these injuries. This case series reports patients operated on out of the roughly 200 cases done in Austria (figures given by TranS1 in September 2010).

Methods: All 5 patients we report have undergone AxiaLIF fusion at various other facilities. All those patients suffered from obvious rectal injury. None of the patients had previous rectal surgery. All patients suffered of local discitis. Besides that they suffered of pneumonia, sepsis and loosening. Age was mean 63, 3 male, 2 female patients had to be included.

Summary: All patients had to undergo long term antibiotic treatment including local reoperations in 3 cases, while treatment by casting and/or bed rest was successful in 2 cases; in terms of the rectal injuries 3 were successfully treated conservatively, 2 received a colostomy. One patient suffered from septic aortic aneurysm. A full recovery could not be achieved in any of those patients. Besides these outline facts further data will be presented.

Conclusion: Out of our case series and the FDA database we conclude that with the current technique the pararectal approach is a questionable safe one to the rectum. Other troubles in this approach were not addressed by this study but are evident. In respect to all what is known we therefore call for a proper and honest work-up of all those cases worldwide to understand the pros and cons of this approach.

Analysis of Complications with XSTOP

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Introduction: The Xstop is a minimally invasive interspinous distraction device for the treatment of lumbar spinal stenosis. Previous studies have demonstrated the clinical effectiveness of the Xstop. No large series of Xstop complications with over 3 year follow up have been reported to date.

Objective: The objective of this study was to perform an analysis of complications on a consecutive series of patients treated with the Xstop.

Methods: Outcomes data was prospectively collected on a consecutive series of 300 patients with degenerative lumbar stenosis treated with the Xstop from January 2006 through August 2007. This group included patients with or without low grade degenerative spondylolisthesis. Patients were evaluated for complications at regular intervals following implantation of the Xstop. Standard outcomes data including ODI was also collected.

Results: Follow up ranged from 3 - 4.5 years. There were no deaths, major medical complications or new neurologic deficits related to the Xstop. Twenty patients (6.7%) had postoperative complications and ten patients (3.3%) underwent reoperation. There were 5 cases of spinous process fracture and or device migration, 3 new
postoperative radiculopathies, 1 infection, 1 superficial hematoma. Six patients underwent revision Xstop placement, three patients had their Xstops were removed and one was revised to a posterior fusion and laminectomy. Average ODI improved by 34.4 on a 100 point scale.

Conclusions: In our series of 300 patients the Xstop was associated with low complication and reoperation rates. There were no deaths, major medical complications or neurologic deficits associated with the Xstop in our study group. Furthermore the study patients had substantial clinical improvement in ODI score at final follow up of 3 - 4.5 years.

493 Correlation of Thrombophilia and Hypofibrinolysis with Pulmonary Embolism Following Spinal Surgery
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Background context: Numerous articles have reported pulmonary embolism (PE) as a complication of spine surgery, but to our knowledge no publication has investigated the genetic factors associated with PE after spine surgery.

Purpose: To assess the prevalence of genetic abnormalities for thrombophilia and hypofibrinolysis in patients in whom pulmonary embolism developed after spinal surgery, in comparison to a matched control group of patients who did not develop PE.

Study design/setting: Spinal surgery patients with post-operative pulmonary embolism and matched control patients who had spinal surgery without any clinical indication of thromboembolism were evaluated for risks of thrombophilia and hypofibrinolysis.

Patient sample: There are total twenty five spinal surgery patients in which thirteen patients had pulmonary embolism and twelve patients had no indication for pulmonary embolism.

Outcome measures: The patients pulmonary embolism were evaluated or ruled out by spiral computed tomography. Both groups patients were evaluated for thrombophilic and hypofibrinolytic risk factors.

Methods: All of patients were evaluated for risks of thrombophilia and hypofibrinolysis. All of the subjects had been evaluated for risks of thrombophilia and hypofibrinolysis tests included: homocysteine, Antithrombin III, Protein C, ACT protein, Plasminogen activator inhibitor-1 4G/4G, and Prothrombin 3’ UT gene mutation.

Results: The total number of genetic thrombophilic abnormalities identified was higher in the pulmonary embolism group (thirteen abnormalities) than in the control group (seven abnormalities). Only patient with pulmonary embolism were found to have heterozygosity for the plasminogen activator inhibitor-1 (two of thirteen patients; p=0.05 compared with the control group). Patients with pulmonary embolism were much more likely than control group patients to have at least one thrombophilic abnormality (nine of thirteen) compared with control group (six of twelve).

Conclusions: Genetic thrombophilia and hypofibrinolysis were more frequent in patients who had PE after spinal surgery than in those who had not. The presence of prothrombin 3’ UT gene mutation appears to be risk factor for PE in patients undergoing spinal surgery. Currently these tests are rarely available and costly. In the near future they will become available and affordable. Their routine use will help in the preoperative identification of patients with predisposition for PE after spinal surgery, who may require prophylactic anticoagulation and intermittent pneumatic compression of the lower extremities.

FDA device/drug status: This abstract does not discuss or include any applicable devices or drugs.

580 The Presence of Furcal Nerves in the Foramen Affects the Incidence of Post-operative Dysesthesia, an Unavoidable Risk of All Transforaminal Surgical Approaches
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Introduction: Post-operative dysesthesia is a known surgical risk of the transforaminal approach. With endoscopic foraminal surgery, however, visualization of furcal nerves in the foramen has identified a patho-anatomical cause of dysesthesia. An anatomic study in fresh cadavers was initiated to learn more about the incidence of furcal nerves, correlating them with post-operative dysesthesia.

Method: Micro-dissection of the foramen from L1-S1 in 10 fresh cadaver trunks, evaluating variations of exiting nerve position with the presence of anomalous and furcal nerves. Cadaver findings were then correlated with the incidence of these nerves identified in-vivo endoscopically. The incidence and severity of post-operative dysesthesia was then determined when these furcal nerves are visualized, surgically irritated, ablated, or transsected. Meticulous dissections revealed the presence of a fine nerve network that was usually destroyed during the surgical exposure in traditional surgery, or the existence of these tiny 1mm nerve branches were not appreciated.

Results:
1. Ganglia trunk and ganglia: The lumbar portion of each trunk lies on the anterolateral portion of the vertebra bodies along the anterior border of the psoas muscles. Surrounding the disc, there are anterior and posterior complicated plexuses of nerves. On rare occasion autonomic nerves were seen in the foramen.
2. Lumbar ramus: After leaving spinal canal just outside the foramen, the spinal nerve divides into a larger ventral ramus innervating the lower extremity and a smaller dorsal ramus innervating the zygapophysial joint, back muscles and ligaments.
3. Furcal nerves come off the L2, L3, and L4 ventral rami in a regular pattern and descend to join the lumbar plexus. It was discovered that these nerve branches, described “furcal” or “forked” nerves with appear commonly in the foramen, but may be mistaken for the foraminal ligament in endoscopic surgery or inconsequential nerves that can be ignored.
4. In a study of 136 consecutive patients undergoing foraminal endoscopic surgery, 35 furcal nerves were documented from 208 levels (35/208=16.8 %). The highest
incidence was at L2-3, L3-4 (11/33 = 33%) with L4-5 (16/94 = 17%) and L5-S1 (8/80 = 10%). In the 35 patients with foraminal nerves 17/35 = 48.6% developed dysesthesia. The highest level at risk for dysesthesia was L3-4 (3/10 = 30%). Among the 208 levels the risk of dysesthesia is 17/208 = 8%. Treatment with foraminal epidural and sympathetic blocks mitigated the patient’s dysesthesia. 11/17 65% received sympathetic blocks. 8 patients became asymptomatic within 1-3 months, and 1 patient took 6 months to resolve. At the conclusion of this one year study, 2 patients had continued residuals manifested by mild numbness and weakness, but they were never-the-less satisfied that they were relieved of their pre-operative pain. 10 patients with dysesthesia did not have a foraminal nerve. Only one had severe enough dysesthesia to need a sympathetic block.

Conclusion: It is not possible to eliminate post-op dysesthesia when performing surgery through the foramen, whether open or endoscopically. Recognizing the variability of spinal nerve anatomy and the existence of furcal, autonomic and sympathetic nerves in the foraminal “hidden zone” will allow the surgeon to properly advise his patients of the risk/benefit of foraminal surgery. Still, foraminal MIS surgery has less surgical risk and morbidity than traditional open surgery in skilled hands.

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The Efficacy of DuraSeal Xact Sealant System for the Treatment of Intraoperative Dural Tears

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Objective: To evaluate the efficacy of DuraSeal Xact Adhesion Barrier and Sealant System, a polyethylene glycol-based synthetic fibrosis inhibitor, for repair of dural tears occurred during spinal surgeries at the lumbar region.

Background: Dural tear is a possible complications of the lumbar surgery. Main stay in the treatment is the primary closure of the tear by suturing the dura. The most feared complication is cerebrospinal fluid fistula and possible infection. Different glue systems were used in the past as a helping tool in sealing the tears.

Materials and methods: During 2008 and 2009, 159 open lumbar surgical procedures consisting in discectomy and/or decompression were performed. In 15 (9.4%) cases a dural tear was done. In 13 patients the tear was less than 1 cm long while in two cases the tear was longer than that (3 and 5 cm, respectively). When a tear was less than 1 cm long, no suturing of the dura was used and just the DuraSeal was applied. In the remaining two cases with more extensive tearings, suturing of the dura was performed prior to applying the fibrin glue. No wound drainages were ever used. Upon surgery the patients were kept at bed rest for a mean period of 4 days (±1.5). All of the patients were treated with antibiotic and low molecular weight heparin medicators for 7 days.

Results: The wound healed by first intention in all of the patients and in no case cerebrospinal fluid leak was observed. All of the patients left the hospital between 4 and 6 days post-op. The mean follow-up of all the ptients was 4 months and during that period of observation no complications such as fluid leakage, infection symptoms, arachnoiditis symptoms (tethering cord) or others possibly related to dural tear, were observed. All of the patients had improved clinical conditions as compared to pre-operative status. The two patients with major tears had done an MRI 6 months upon surgery and no signs of meningoceole was found.

Conclusion: DuraSeal Xact Adhesion Barrier and Sealant System showed to be an excellent helping tool in sealing tears due to surgical laceration of the dura.

Keywords: Lumbar disc herniation, discectomy, dural tear, liquor leak, fibrin glue

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Prospective, Randomized Study of Surgical Site Infections with the Use of Peri-operative Antibiotics for 24 Hours versus the Duration of a Drain after Spinal Surgery

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Summary: In a prospective randomized study, continuing antibiotics for the duration that a drain is in place after spinal surgery did not decrease the rate of acute surgical site infection.

Methods: 199 patients who underwent multilevel thoracolumbar spine surgery requiring a post-operative drain were enrolled and randomized into two groups: one group receiving 24 hours of perioperative antibiotics and one group receiving antibiotics for the duration that the drain was in place. Data collected included demographics, medical comorbidities, type of spine surgery and surgical site infection.

Results: 6/110 (5.4%) in the 24 hours of antibiotic group developed a surgical site infection while 13/89 (14.6%) in the antibiotic for the duration of the drain were found to have a surgical site infection. The differences between each group were significant (p=0.029). There were no significant differences between the groups with respect to demographics, surgical time, type of surgery, drain output or length of stay.

Conclusion: Continuing perioperative antibiotics for the entire duration a drain is in place after spine surgery does not decrease the rate of surgical site infections.

Breakout 1: Multi-Level Cervical

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Multi-center, Prospective, Randomized, Controlled Investigational Device Exemption Study Comparing 2-Level Mobi-C® Cervical Artificial Disc to Anterior Discectomy and Fusion in the Treatment of Symptomatic Degenerative Disc Disease in the Cervical Spine

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Background context: The Mobi-C® Cervical Artificial Disc (Mobi-C) is designed to preserve motion and disc height at the affected cervical vertebral level. Comparing Mobi-C to the current standard of care, fusion with bone interbody...
Purpose: To evaluate the overall effectiveness of the Mobi-C through 24 months as compared to anterior cervical discectomy and fusion (ACDF) for the treatment of degenerative disc disease (DDD) with radiculopathy or myeloradiculopathy at two levels between C3 and C7.

Study design: The study was conducted at 24 study sites in the USA; 330 two-level subjects were analyzed for effectiveness. A non-inferiority design with a 2:1 randomization (Mobi-C: control) was used.

Outcome measures: The primary endpoint was defined as a composite of individual successes of Neck Disability Index (NDI), no device related subsequent surgical intervention, and the absence of major complications. Secondary endpoints evaluated included: radiographic outcomes - including adjacent segment degeneration and Range of Motion (ROM), neck and arm pain, subject satisfaction, significant neurological deterioration, quality of life, dysphagia, gait, blood loss, operative time, duration of hospitalization, and time to return to work.

Methods: The Investigation Device Exemption (IDE) study was a prospective, randomized, multi-center, controlled investigation. Patient evaluations were performed pre-operatively and at 6 weeks, 3, 6, 12, 18, and 24 months post-operatively.

Results: The individual subject composite success rate for Mobi-C was 70.6% at 24 months. This is 34.2% higher than the 36.4% success rate observed in the ACDF subjects. This establishes statistically superior study results for Mobi-C. Notably, Mobi-C achieved a higher subject success rate by 6 months than ACDF achieved at any timepoint, including 24 months. Mobi-C demonstrated higher rates of success for each component of the primary endpoint (NDI, absence of major complications and absence of device related subsequent surgery). Of the three subcomponents of the primary endpoint, lack of NDI improvement was the primary contributor to patients study failure for both groups. 78.2% of Mobi-C patients demonstrating study defined NDI improvement versus 61.8% for patients receiving ACDF. 3.1% of patients treated with Mobi-C had device related subsequent surgery; and patients receiving ACDF treatment were four times more likely to receive subsequent surgery related to the device (12.4%).

Mobi-C Cervical Disc Replacement for the Treatment of One and Two Level Cervical Degenerative Disc Disease: One Site Analysis Participating in the US FDA Trial

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Background context: Favorable results of improved self-reported outcomes have been previously reported after cervical artificial disc replacement from several Investigational Device Exemption (IDE) clinical trials completed in the USA. This analysis reports safety and efficacy of the Mobi-C disc prosthesis versus fusion for the treatment of symptomatic cervical degenerative disc disease (C3-C7) at 1 or 2 levels at one study site in the FDA approved clinical trial.

Purpose: To analyze clinical outcomes after single or multi-level cervical disc replacement (ADR) using the Mobi-C disc prosthesis, and to compare them with anterior cervical discectomy and fusion (ACDF).

Study design/setting: This is a prospective randomized clinical trial (RCT) comparing the cervical disc replacement (ADR) with the Mobi-C disc prosthesis to fusion (ACDF).

Patient sample: A total of 54 patients were enrolled in the RCT, 38 of which were treated with Mobi-C ADR (71% 2-level, 11% 1-level), and 16 with ACDF (37.5% 2-level, 62.5% 1-level).

Outcome measures: Self-reported measures of neck and arm pain on the Visual Analog Scale (VAS), and Oswestry Disability Index (ODI) were used to assess function and pain.

Methods: This is a report from one site of the US FDA IDE RCT clinical trial for Mobi-C cervical disc prosthesis (LDR Spine, Austin, TX). Self-reported outcomes were measured via Visual Analog Scale (VAS, 10 cm line) for neck pain, and right and left arm pain, and Oswestry Disability Index (ODI) pre-operatively and at 6 weeks, 3, 6, 12, 24 months post-operatively. Multivariate analysis was applied to these data to control for gender, age, BMI, and worker compensation status.

Results: There were significant improvements in self-reported outcomes at each follow-up interval for ADR treated patients: 82% improvement in VAS neck pain (6.7 pre-op vs. 1.2 24 mo), 80% in VAS arm pain (4.9 pre-op vs. 0.99 24 mo), and 76% in ODI (29.5 pre-op vs. 6.9 24 mo). In the fusion treated patients, there was 82% improvement in VAS neck pain (6.7 pre-op vs. 1.2 24 mo), 68% in VAS arm pain (5.6 pre-op vs. 1.8 24 mo), and 46% in ODI (29.0 pre-op vs. 15.7 24 mo).

Post-op vs. pre-op comparisons were significant (p < 0.001). In the multivariate analysis, a significant treatment effect was observed for increased improvement in both VAS scores as well as ODI in the disc replacement treated patients compared to fusion patients (p < 0.01). There was no difference between 1 level and 2 level treated patients. Workers compensation was related to less improvement. Motion was preserved at all disc replacement levels, including multilevel procedures. There were no removals or complications of the Mobi-C device.

Conclusions: Cervical total disc replacement preserves range of motion without compromising the clinical results when compared to fusion. There was slightly greater improvement in self-reported outcome measures of VAS neck and arm pain for patients who received ADR compared to ACDF. Workers Compensation patients self-reported less improvement.

Keywords: Cervical total disc replacement, surgical outcomes, motion preservation

157 Combined Use of Cervical Arthroplasty and Arthrodesis: Our Results in 30 Cases

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Traditional anterior discectomy and fusion has been successfully used in the treatment of cervical degenerative disease. However, incidence of degenerative changes at adjacent levels has been raising concerns. Technical development of cervical disc arthroplasty and their rapid diffusion in surgical practice has been sustained by different studies in literature. Cervical disc arthroplasty satisfy the concept of motion preservation, allowing prevention of the adjacent level disease. We present our series of 30 patients treated with cervical arthroplasty (Prestige- Medtronic) and arthrodesis at the adjacent level (cage in PEEK- Medtronic). The outcome was assessed using the Visual Analog Scale (VAS), the Neck Disability Index (NDI) for estimation of clinical results and imaging in maximal extension and maximal flexion for evaluation of post-operative range of motion. For all the patients considered in the present study follow-up data were available at 2 months and one year from surgery. We performed arthrodesis and arthroplasty as a
single surgical procedure in 22 patients with a symptomatic two-level degenerative disease. In 8 patients fusion was achieved as a result of a previous surgical procedure, and the patients were symptomatic for a subsequent development of an adjacent level disease. In 28 patients we reported improvement of VAS and NDI at follow-up. Two patients were unchanged after surgery. At 12 months a good range of motion was documented in flexion and extension at the level of arthroplasty in all cases. In our experience the use of cervical disc arthroplasty combined with artrodesis allowed good clinical results in term of VAS and NDI. Radiological studies at one year demonstrated that cervical prosthesis maintain motion preservation at the treated level.

To our knowledge, there is no study in literature reporting results in patients treated with cervical artrodesis and cervical arthroplasty to date. Cervical arthroplasty performed in the same setting of arthrodesis or applied as a following surgical option, represent a effective instrument in the treatment of cervical degenerative disease.

421 Clinical and Radiographic Outcomes on a Series of 249 Patients Treated with Single and Multilevel Baguera C Cervical Disc Replacement at 2-year Follow up G. Maestretti1, P. Tropiano2, P. Fransen4, D. Noreiga3, R. Saur1, P. Otten5, P. Vally6, J.-P. Lejeune7, A. Chatzisotiriou8, P. Alcaraz9
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**Background context:** Single level cervical disc replacement is an alternative to traditional anterior cervical fusion in treating some cases of cervical Degenerative Disc Disease. Fusion techniques for multis level pathology are currently documented and remain to be compared to clinical outcomes of multilevel cervical disc replacement.

**Design:** This is an observational European prospective and multi-centric study - data reported at ten European sites including single, multilevel cases and adjacent to interbody cages.

**Objective of the study:** To compare safety and efficacy of cervical disc replacement with the Baguera C prosthesis in [FP1] single and multilevel DDD. Patients were followed up postoperatively at different intervals at 1, 3, 6, 12 and 24 months.

**Patient Sample:** 249 patients were enrolled in this study. 171 patients were treated at 1-level, 41 treated at 2 levels and 2 patients were treated at 3 levels. Additionally the Baguera C was[FP2] used adjacent to a fusion with a cage in 30 patients. The diagnosis was cervical degenerative disc disease between C3 and C7 with symptomatic DH. Population was 106 male 143 female, average age 46 (25-71).

**Methods:** Clinical assessment included VAS scores for arm and neck pain and Neck Disability Index (NDI). Range of motion (ROM) from flexion/extension lateral view were measured.

**Results:** Of all NDI scores recorded, 86.50% demonstrated at least 15 points improvement at two years follow up from pre-op scores. 85.1% of VAS arm Pain scores demonstrated an improvement by ≥ 2 points from pre-op scores and 50.8% for VAS neck Pain scores. The breakdown by levels and adjacent to an interbody cage shown that 80% of reported NDI scores demonstrated at least a 15 point improvement post operatively for two level disc replacement. 82.4% demonstrated a greater than 2 points improvement in VAS arm pain and 53.3% for VAS neck pain. For patients that received both Baguera C and an interbody cage, 72.7% demonstrated a greater than 2 point improvement in VAS arm pain and 41.7% for VAS neck pain. Three (1.8%) cases of subsidence and 4 cases of implant loosening/displacement due to inappropriate sizing were reported.

Available radiographic findings show on average a ROM of 8,2° at 2 years and an overall change in cervical lordosis of 5° from pre-op.

**Conclusion:** With regards to effectiveness, clinical outcomes demonstrated a significant improvement for both the total population (n=249) and for the single level total disc replacement population (n=171). Given these outstanding results single and multilevel TDR with Baguera C can be considered to be safe. Additionally, no significant difference was observed between single and multilevel TDR groups regarding clinical, functional and radiological results. Follow up for this series need however to be extended for up to 5 years at least. The role of the Baguera C prosthesis in multilevel cases as well as in cases to a fused level still need further evaluation although these preliminary results are encouraging.

**9 Modification of the Prestige ST Cervical Artificial Disc to Allow Multi-level Implantation K.A. Pettine1

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**Introduction:** The purpose of this abstract is to describe a modification of the Prestige ST implant to allow multi-level implantation in any patient. The second purpose is to report the safety and efficacy of this modification. The Prestige ST implant has anterior phalanges with screw fixation into the superior and inferior vertebral body that requires a minimum 15mm of vertebral body height to allow multi-level implantation. Modification dovetails the phalanges requiring only 8mm of vertebral body for multi-level implantation. Utilizing the Prestige ST implant in a multi-level fashion is an FDA off-label use of the device. There are currently two cervical FDA approved artificial discs. Each artificial disc has unique characteristics. The ProDisc-C implant allows multi-level implantation without modification. The Prestige does not allow multilevel implantation in most patients.

**Methods:** Every patient from 2007 to April 2010 who underwent a multi-level Prestige ST implant was evaluated and subdivided into groups with (two levels = 10 patients; three levels = 2 patients) and without (two-level = 28 patients, three-level = 2 patients) modification. There was no significant difference in the demographics between the groups. The following illustration demonstrates the modification. Modification of the Prestige ST implant is achieved with a high-speed Dremel saw in approximately three minutes followed by smoothing of the edges. The implant is modified such that the locking screw can still be utilized. Our experience is that approximately 40% of male patients and zero percent of female patients can undergo a multi-level procedure without modifying the Prestige implant.
with standard techniques. The discoplasty was performed in the cervical spine. The ADRs and fusions were done with either one or two level discoplasty at adjacent levels. 10 patients had 2 level ADRs and or fusion in combination. Another aim was to reduce the number of levels requiring surgery. The purpose was to determine the role of discoplasty in degenerative disc disease (DDD) with cord/root compromise. The adjacent level had a contained disc protrusion without significant cord compression that would require a ADR or cervical fusion. The levels that had fusion or an ADR had significant intraoperative discoplasty at levels adjacent to either a cervical fusion or cervical artificial disc replacement (ADR). We present a preliminary/pilot study of combining intraoperative discoplasty at levels adjacent to either a cervical fusion or cervical artificial disc replacement (ADR). The adjacent level had a contained disc protrusion without significant cord compression that would require a ADR or fusion. The levels that had fusion or an ADR had significant degenerative disc disease (DDD) with cord/root compromise. The purpose was to determine the role of discoplasty in preventing adjacent level accelerated degeneration and to reduce axial/radicular pain in combination therapy for less severe contained discs in multi-level DDD requiring surgery. Another aim was to reduce the number of levels requiring ADRs or fusions. 10 patients had 2 level ADRs and or fusion in combination with either one or two level discoplasty at adjacent levels in the cervical spine. The ADRs and fusions were done with standard techniques. The discoplasty was performed intraoperatively through the open surgical corridor using flouroscopy and a plasma energy wand. There was significant reduction in VAS pain scores in follow up (mean VAS pre-op 7.8; post-op 3.0). There were no patients who required re-operation at adjacent levels in follow up (range 6mo-12mo). Further follow up will be required to determine the long term results of this type of combination therapy in the treatment of multi-level cervical DDD in preserving motion and reducing disease progression.

227 Factors Affecting the Choice of Anterior Procedure (TDR versus ACDF) for Cervical Radiculopathy: Analysis of 3-7 Years Follow-up from 4 Randomized Controlled Trials
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Purpose: Total disc arthroplasty has been shown as equally safe and effective as ACDF for intractable radiculopathy due to cervical disc disease. The purpose of present study was to analyze the long-term outcomes from 3 to 7 years follow-up of patients participating in 4 different prospective randomized controlled trials for cervical total disc arthroplasty devices at one or two consecutive levels of the cervical spine.

Methods: Six surgeons from three different institutions within the USA enrolled 275 patients in 4 different FDA investigational device exemption clinical trials for cervical total disc arthroplasty. Although, the primary requirement for all protocols was to have 2-year follow-up, the patients were followed subsequently with annual clinical visits and radiographic studies. Thus, 255 patients have completed 3-7 years follow-up (median 45 months). The results from these long term annual visits were analyzed in an attempt to determine the factors that statistically affected the clinical outcomes in these patients. Multivariate regression analysis was performed to study the influence of various factors on the primary outcomes and possibly identify demographic characteristics that may help surgeons chose a specific procedure i.e. total disc arthroplasty versus anterior cervical fusion for individual patient.

Results: 255 patients with mean age of 50 years (range 22-68 years) completed 36-84 months follow-up (mean 45 months). There was a marginal female predominance (56.5%). 40% were habitual tobacco users, 18% had osteopenic bone mineral density scores and 30% had documented, actively treated lumbar spine disease at the time of cervical procedure. The randomization was 2:1 in favor of total disc arthroplasty (167 TDA versus 88 ACDF). 179 patients (70%) had single level disease and 30% were treated for two levels. The primary outcomes were visual analogue scores (VAS) for neck pain, neck disability index and detailed neurological examination. The data was collected at 6 weeks, 3, 6, 12, 24 months after the surgery and then annually. Both procedures (TDA and ACDF) provided significant reduction in the pain scores and the NDI, however, in the longer term follow-up, NDI proved to be a better outcome indicator (p = 0.01). Although long term outcomes overall were better in younger patients regardless of the index procedure (p = 0.007), nevertheless, TDA provided significantly higher incidence of better long term outcomes in patients older than 50 years (p = 0.03). Habitual tobacco use and osteopenic bone density significantly worsened the outcomes in patients with ACDF (p = 0.02 and 0.04 respectively) but did not affect...
the outcomes after TDA. However, presence of concurrent documented lumbar disc disease at the time of cervical procedure negatively affects the outcome in patients after TDA (p = 0.03) but does not affect the outcomes of ACDF.

**Conclusions:** Statistical analysis reveals that ACDF provides longer term symptom relief than TDA in patients with cervical radiculopathy who have concurrent lumbar degenerative disease. However, TDA is superior to ACDF for patients older than 50 years, habitual tobacco users and those with osteopenic bone density. Considering these demographic factors may help clinicians to choose a surgical option that may afford the best chance of longer term symptom relief.

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**3D Assessment of the Intervertebral Kinematics after Total Disc Replacement at the Cervical Spine in vivo Using the EOS Stereoradiography System**

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**Study design:** A biomechanical study of the 3D kinematics of the cervical spine at the segmental level in vivo after total disc replacement with using the EOS stereoradiography system.

**Objective:** To investigate the intervertebral angular motion in 3D in vivo using the EOS stereoradiography system after total disc replacement, including the assessment of the uncertainty in the measurements.

**Summary of background data:** Intervertebral mobility after cervical disc replacement has been evaluated in flexion extension. The novel EOS imaging system allows the assessment of the 3D mobility of the spine in upright position. The 3D mobility of the cervical artificial disc in vivo has not been evaluated in vivo before.

**Methods:** Nine patients with 16 Mobi-C prostheses (LDR Medical, France) had EOS stereoradiography of the lower cervical spine (C3 to C7) in neutral upright position of the neck, flexion, extension, left and right lateral bending, left and right axial rotation. The angular displacements were measured from the neutral position to every other posture. The metallic endplates of the prosthesis were used as markers. A reproducibility study was done.

**Results:** The range of motion extension, flexion, right axial torsion, and right lateral bending were 3.1° (4.7), 3.1° (7.2), 3.2° (4.1) and 1.5° (3.2) respectively. Axial torsion and lateral torsion, and right lateral bending were 3.1° (4.7), 3.1° (7.2), 3.2° (4.1) and 1.5° (3.2) respectively. Axial torsion and lateral bending were coupled similarly to the normal disc.

**Conclusions:** This study show the feasibility of using the dynamic EOS stereoradiography for measuring disc prosthesis kinematics in 3D in vivo. The uncertainty of the measurement has to be improved for taking full advantage of the EOS system.

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**A Comparative Outcome Evaluation of Lumbar Transforaminal Endoscopic Discectomy versus Micro-lumbar Discectomy for Lumbar Disc Herniation**


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**Purpose:** The objective of this study was to compare the clinical outcome of patients with lumbar disc herniation treated by transfornimal endoscopic discectomy versus micro-lumbar discectomy.

**Study design/setting:** A prospective review of outcome data in patients with lumbar disc herniation treated by transfornimal endoscopic discectomy or micro-lumbar discectomy by 4 surgeons, all with foraminal endoscopic experience in an outpatient setting were analyzed by an independent reviewer.

**Method:** The clinical outcome of 137 consecutive patients who underwent “inside-out” transfornimal “selective endoscopic discectomy” (SED) and 50 consecutive patients who underwent micro-lumbar discectomy (MLD) were compared using Visual Analog Scale (VAS) and Oswestry Disability Index (ODI). A final clinical rating by modified MacNab criteria summarized the outcome. The procedure of decompression and discectomy chosen was a shared patient/surgeon decision. Data was collected and recorded at the initial office visit, preoperative and postoperative visits, as well as final follow up. All procedures were performed in an ambulatory surgical center. All patients were discharged to home the same day. The average follow up time was, minimum 12, average 26 months.
Results: 50 Cases of MLD: L4-5=15, L5-S1=35. Average VAS=6.5, Average ODI 44%. Improvement was 3.8 and 30% respectively. Complications=1 seroma, 1 durotomy. Patients receiving MLD was due to surgeon advice and preference. Patient satisfaction was 92%. Patients in this spine practice, however, were mostly referred for and mostly sought and chose SED when given a choice by the surgeon. The SED group numbered 137, with 290 total levels. L1-2=1, L2-3=3 L3-4=31, L4-5=94, L5-S1=80. Average VAS was 6.6 and ODI was 46%. Improvement in the SED group was 4.1 and 32%. Endoscopic decompression included foraminoplasty for lateral stenosis. In the endoscopic group, 20 patients (14.7%) developed dysesthesia in the 2 week post-operative period. Dysesthesia resolved spontaneously in 10 mild cases within 2 months without treatment but 10 moderate to severe cases of dysesthesia took 6 months to significantly improve or resolve. In spite of the inclusion of more complex degenerative spine problems in patients who were also candidates for decompression and fusion. Improvement in VAS and ODI was comparable to MLD at 4.1 and 32% respectively. Patient satisfaction was high, since many avoided fusion and none were worse. Conclusion: There may be a favorable patient/surgeon bias involved since many patients self selected and sought the endoscopic technique even when decompression and fusion was suggested and offered. In spite of dysesthesia not experienced by MLD patients, patient satisfaction remained high, because patients were advised that dysesthesia as an unavoidable consequence of the foraminal surgical approach during their pre-operative counseling. The more difficult extruded herniations where access was limited was due to anatomic considerations such as extruded, sequestered herniations at L5-S1 made up the majority of the patients selecting the micro-lumbar discectomy. This study confirms the general consensus that MIS surgery provided comparable results with less surgical morbidity. The surgeon factor is one consideration that must be considered by each surgeon as the new paradigm of a share surgical decision becomes the desired concept, and surgeons sought after by patients opting for MIS techniques “force” surgeons into new endoscopic techniques in the current spinal care environment.

304 Retrospective Clinical Evaluation of Interlaminar Lumbar Instrumented Fusion
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Purpose of the study: Lumbar stenosis is a debilitating condition that can be treated by direct decompressive maneuvers. Fusion may also be necessary in cases of stenosis with instability. Despite evidence of long-term success in instrumented fusion procedures, there is also associated morbidity with traditional techniques- specifically the more lateral exposures inherent in pedicle screw placement. Interlaminar lumbar instrumented fusion (ILIF) is a compound surgical solution for the treatment of spinal stenosis. Because this solution requires only a midline incision rather than the far lateral exposure necessary in posterolateral fusion with pedicle screws, it is less invasive to the patient, and therefore should result in less postoperative pain and disability, broadening the applicability of the procedure to even those advanced in age or with pre-existing comorbidities. The purpose of this study is to report early clinical outcomes following instrumented interlaminar fusion.

Methods: This is a retrospective series of patients undergoing posterior decompression and interlaminar fusion for stenosis. Inclusion criteria included grade I spondylolisthesis, availability of pre-op data, and 1 year follow-up. Surgical technique consisted of midline exposure up to the facet joints, removal of the interspinous ligament, decompression, an allograft spacer placed on the interlaminar space overlying the decompression site, instrumentation with an interspinous process plate (Affix, Nuvasive, San Diego, CA), and the use of a biologic in the interspinous/interlaminar space. Outcomes were assessed by Oswestry Disability Index and overall VAS.

Summarize the findings (results): 13 patients met inclusion criteria. Mean age at surgery was 66.1 years (range, 39-80). Mean blood loss was 77.3 cc (range 25 - 200 cc). Levels operated were L4-L5 (13). Mean pre-op ODI was 41.1, and overall VAS 6.2. Mean 12-month post-op ODI was 25.3, and overall VAS 2.7. Improvements of ODI (p=0.05), overall VAS (p=0.0005) were statistically significant. Mean improvement in ODI was 15.8 points, and 46% of patients demonstrated greater than 15 point improvement in ODI.

Conclusions: The ILIF procedure is a less invasive approach to traditional instrumented posterior lumbar decompression and fusion in cases of stenosis. These early results indicate that patients undergoing instrumented interlaminar fusion demonstrated clinically important improvements, including back pain, as measured by validated outcomes measures. This may hold potentially important significance for the treatment of degenerative stenosis since interlaminar fusion entails considerably less surgical exposure, operative time, and morbidity than commonly used techniques of posterolateral fusion in a patient population at risk for post-operative medical complications.

314 Clinical and Functional Results of the Treatment of Degenerative and Extruded Lumbar Disc through a Minimally Invasive Lateral Approach. Is Minimally Invasive Posterior Tubular Discectomy Necessary for Radiculopathy Relief?
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Background context: Degenerative disc disease is often accompanied by a symptomatic herniated disc at the same level making decisions about which surgical option is best for the patients to achieve clinical outcomes more challenging. The purpose of this study was to assess the benefits of combining two different minimally invasive techniques in the treatment of lumbar disc disease associated with an extruded disc: micro-endoscopic discectomy (MED) and XLIF.

Purpose: The purpose of this abstract is to present an alternative to improve clinical and radiological results for lumbar fusion using XLIF standalone in combination with endoscopic decompression.

Study design/setting: Prospective clinical study.

Patient sample: 16 patients

Outcome measures: Visual analog pain score (VAS) and Oswestry disability index (ODI) were evaluated preoperatively and at various time-points postoperatively. VAS assessments was made on back pain and leg pain. Radiological outcomes were measured with plain radiographs. Follow up extended to 3, 6, 12 and 18 months.

Methods: 16 patients underwent micro-endoscopic discectomy (MED) and XLIF for the treatment of symptomatic
low back and/or leg pain or dysfunction. Endoscopic decompression was achieved using the Metrix® Endoscopic System and the interbody graft used in the XLIF procedure was a PEEK interbody implant filled with DBM in a lipid carrier mixed with hydroxyapatite and tri-calcium phosphate granules. 

**Results:** 16 patients with symptomatic two-level lumbar disc disease were included. Mean patient age was 47 yrs (range: 24-68 yrs). All patients had a two-level disease: L4-L5 and L5-S1. Mean combined operative time was 145 minutes and in all cases measured blood loss was less than 40 cc. Patients were typically out of bed, ambulating and advanced to regular diet on the day of surgery, and discharged home the following 24 to 48 hours. Mean back pain VAS decreased from 7 at pre-op to 2.3 at 3 months, 2.8 at 6 months, and 2.3 at 187 months. Mean leg pain VAS was 8.3 at pre-op, 1.3 at 3 months, 1 at 6 months, and 0 at 18 months. Mean ODI improved from 69.1 at pre-op to 11.3 at 3 months, 10 at 6 months, and 9.8 at 18 months. 

**Conclusions:** This study showed that the combination of XLIF and MED is an effective surgical treatment for lumbar disc disease associated with extrusion, demonstrated by clinical improvements. Postoperative recovery is notably faster than following traditional open procedures.

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**Multicenter Minimally Invasive AxiaLIF L5-S1 Interbody Fusion for Anterior Column Support at the End of a Long Segment Construct: Feasibility, Safety, Complications, Early and Late 3 Year Outcomes**

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**Introduction:** Long segment fusion to the sacrum has been reported to have a high pseudoarthrosis rate. Anterior column support to lower the pseudoarthrosis rate has traditionally been performed through open ALIF, TLIF or PLIF. 

**Methods:** We report on 97 consecutive patients status post Minimally Invasive AxiaLIF L5-S1 fusion at the end of a long segment construct performed over the last 4 years at 2 major spine centers. 21 patients underwent 2-level AxiaLIF fixation at L5-S1 and L4-S. All patients had three or more levels fused above the instrumented AxiaLIF levels. 63 patients had fusions extending above the thoracolumbar junction with 20 of these patients having fusions into the proximal thoracic spine. Fusion was augmented with local bone, RhBMP2 (Infuse) and Grafton putty both in the interbody space and the facets posteriorly. Visual Analog Scores (VAS), Treatment Intensity Scores (TIS), SF-36, Oswestry Disability Index (ODI) and Radiographs were recorded. 

**Results:** Mean follow up was 24 months (range: 1 to 44 months). 71 patients have greater than 1 year follow-up with 37 greater than 2 years and 21 patients greater than 3 years follow-up. Mean patient age was 62 years old (range: 22 to 81). Preoperative diagnoses included scoliosis (68 patients) and multilevel degenerative disc disease (29 patients). Clinical and Functional outcomes are charted below (figure 1).

**Figure 1**

At 1 yr solid arthrodesis at L5-S1, was noted in 67/71 patients, further confirmed on CT in 56 of these patients. There were no intraoperative complications with the AxiaLIF fusion. 14 patients had iliac bolt fixation at one center, with 0 patients at the other. One iliac bolt had to be revised secondary to a broken screw. There have been no bowel injuries, sacral fractures or sacral pedicle screw failures. There were two pseudarthroses at L5-S1 with facet screws and both were revised with pedicle screws successfully. There was one late infection with non-union revised with removal of the implant, ALIF and iliac bolt fixation and the fourth patient had sacral pedicle screw loosening revised with additional iliac bolt fixation. There were two patients with superficial wound dehiscence. One patient had a malpositioned AxialIF screw causing radiculopathy, which was satisfactorily and safely repositioned.

**Conclusions:** AxialIF L5-S1 minimally invasive interbody fusion may be a viable alternative for providing anterior column support for long segment fusions to the sacrum. Majority of these patients were not instrumented to the ilium and have shown solid fusion with maintenance of correction up to three years. The absence of distal implant failure may attest to the biomechanical strength of the L5-S1 construct. This procedure may provide similar fusion rates at the L5-S1 disc space and improved functional outcomes when compared with more traditional procedures. More importantly the clinical outcomes suggest that with the AxiaLIF bolt iliac screw fixation may not be necessary in long constructs.

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**Minimally Invasive Posterior Cervical Discectomy, Preliminary Results and Complications**

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**Study design:** Retrospective analysis of data of all patients treated by minimally invasive posterior discectomy for cervical radiculopathy between January 2004 and February 2008. 

**Objective:** To describe our technique and report the outcome of minimally invasive posterior cervical discectomy (MI-PCD) using the MetRx tubular retractor system and surgical microscope. 

**Summary of background data:** Although several studies have been published on posterior minimally invasive approaches to cervical radiculopathy, most have focused on decompression of the nerve root by laminoforaminotomy only without removal of the offending disc. 

**Methods:** The hospital charts, MRI studies and follow up records of all the patients were reviewed. Outcome was assessed by neurological status, visual analog scale (VAS) for neck and arm pain and via the Short Form-36 Health Survey Questionnaire (SF-36). 

**Results:** Thirty two patients were included in this study. The follow up time was 20 to 67 months (mean 39 months). Muscle weakness improved in all patients; sensory deficits resolved...
in 21 patients and improved in 7 patients. Analysis of the mean VAS for radicular pain, VAS for neck pain and all eight domains of the SF 36 showed significant improvement. Complications included one case of incidental dural tear without postoperative CSF leakage and one case of longstanding neck pain.

**Conclusion:** Minimally invasive posterior cervical discectomy is safe and effective in the management of lateral cervical disc herniation manifested by radiculopathy. In addition to eliminating some of the disadvantages of open surgical approaches, it may also have swifter symptoms resolution compared to laminoforaminotomy without discectomy.

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**396 Evaluation of Endoscopic Laminoforaminoplasty for Treatment of Painful Foraminal and Centeral Cervical Stenosis**

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**Method:** 107 consecutive patients with foraminal or centeval stenosis were evaluated with preoperative MRI, history and physical, and Visual Analog Scale (VAS). Surgery was performed in the prone position under conscious sedation (opiate and benzodiazepine mixture). Surgery was performed using a fluoroscopically guided pin tapped into the lamina for proper placement. The operating tube was 14mm in diameter. The soft tissue debridement was performed with Holmium laser and electrocautery. A 6mm round burr was used to remove a portion of the lamina from the midline to the lateral recess. All surgery was performed as an outpatient and given perioperative antibiotics. Only patients with at least 24 months of follow up were included in the study. Outcome was measured in change of VAS scores. A 75-100% reduction of pain was considered excellent, and a reduction of 50-75% was considered good.

**Summary of finding:** A total 107 patients were enrolled with 20 lost to follow up leaving 87 patients (48 male, 39 female). Mean age was 55 (range 38-85). Mean follow up was 30 months (range 24-46). Based on the VAS scores 56 of 87 patients (64%) had 75-100% reduction of pain, 11 patients (13%) had 50-74% reduction of pain, 4 (5%) had 25-49% reduction and 6% (7%) had 1-24% reduction, 8 (9%) had no change of scores, and 2 (2%) had worsening of symptoms by 25-49%. Thus 67/87 (77%) showed to good to excellent results (i.e. at least 50% improvement of pain). Overall mean pre and post operative VAS scores were 7.1 and 2 respectively, which is statistically significant at a 99% confidence interval. Complications occurred in 2 patients. Both patients had intraoperative dural leaks treated with free graft, laser welding, and Duragen brand mesh. There were not cases of infection or neurologic injury.

**Statement of conclusions:** The findings of good to excellent results in 77% of patients with a low rate of complications are supportive of a role for endoscopic surgery emphasizing decompression in the management of painful cervical spinal stenosis. A recent systematic review highlighted the lack of a clear consenus concering the best surgical technique, as anterior discectomy, anterior corpectomy, laminoplasty, and laminotomy were reported to mutually equivalent in terms of outcome (Mummaneni, 2009). In conclusion, symptomatic improvement is comparable to that seen with open surgery with sigifigantly less blood loss, shorter recovery time, less soft destruction with preservation of muscular and ligamentous attachments, no adjacent disc disease and performed with low risk of neurologic injury or infection. In addition, this can performed as an outpatient.

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**572 Evaluation of Fusion Techniques for the L5-S1 Interbody Space, Clinical Strengths and Disadvantages of Different Minimally Invasive Approaches**

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**Introduction:** The development of new minimally invasive spine (MIS) techniques for lumbosacral fusion has provided the spine surgeon multiple methods for fusion at the L5-S1 interbody space. The authors compare clinical and radiographic outcomes from a cohort of prospectively followed patients treated with three modern techniques, MIS-TLIF, ALIF, and AxiaLIF.

**Methods:** Between June 2003 and January 2009, 58 patients were treated for isolated degenerative disk disease of the L5-S1 segment. All patients presented with back pain with or without radiculopathy and had failed conservative management. The average patient age was 43.34 years. Twenty patients were treated with TLIF, 19 with ALIF, and 19 with AxiaLIF. All patients were prospectively followed with pre- and post-operative visual analog score (VAS) and Oswestry-Disability Index (ODI) scores as well as routine radiographic follow-up.

**Results:** Clinical outcome with ODI demonstrated a decrease in ODI of -25 with TLIF, -22 with ALIF, and -24 with AxiaLIF. VAS leg scores decrease 92% in patients treated with TLIF, 76% with ALIF and 71% with AxiaLIF. The time of access to the interbody space was most rapid with AxiaLIF (65m) and slightly longer with ALIF (85m) and TLIF (105m). Radiographic outcomes showed that ALIF produced the distraction of the interbody space (8.6mm); TLIF (6.3mm), AxiaLIF (5.9mm). Fusion with TLIF and ALIF was 95% and AxiaLIF 90%. Subsidence was greatest with AxiaLIF 16% followed by TLIF (12%) and ALIF (9%). Complications included 2 patients with radiculitis following TLIF. There was a single CSF leak (TLIF) and a single lumbar plexus injury (ALIF). There was a single vascular injury (ALIF) and a single visceral injury (AxiaLIF).

**Conclusion:** MIS-TLIF, ALIF, and AxiaLIF are all modern, MIS-type approaches to the L5-S1 interbody space. Patient outcomes suggest each has unique clinical strengths and specific disadvantages. Complications with each approach is unique and primarily related to anatomy of the access route.

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**188 Minimally Invasive Treatment of Adjacent Segment Degeneration via XLIF**

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**Introduction:** The XLIF approach provides a minimally disruptive alternative to anterior column access that allows for large graft placement, disk height restoration, and indirect decompression, while avoiding posterior scar tissue from the previous procedure. Results of ASD treated with XLIF are presented.

**Methods:** Of our single-site consecutive series of 950 XLIF patients, 276 were treated for ASD. Clinical and radiographic measures were prospectively collected and evaluated.

**Results:** Age ranged from 29-91 years (average 61.6 years).
90.6% had one or more comorbidity. 144 patients (52%) were obese or morbidly obese. All but one case included supplemental fixation: 47% unilateral pedicle screws, 4% bilateral pedicle screws, 12% lateral embroidered plate, and 43% laterally tabbed interbody implant. In 15 cases with prior posterior instrumentation, the pre-existing rods were removed unilaterally and revised on that side; in all other cases with prior instrumentation, adjunctive lateral fixation was used. Hospital stay averaged 1.3 days, with 2 blood transfusions and one wound infection. Complications included intraoperative hardware failure (4, revised during same procedure with no incident), ileus (5), gallstone pancreatitis (1), urinary retention (3), kidney stone (1), peritoneal catheter occlusion (1), pulmonary embolism (1), subcutaneous hematoma (1), delirium (1), atrial fibrillation (3), MI at 6 weeks post-op (1), compression fracture at an adjacent level (5), sacral fracture (1), and postoperative quadriceps weakness (1, resolved within 4 weeks of surgery). Average VAS scores improved by 4.6 points from pre-op to 12 months. Average disk height improved from 6.4 to 10.6 at post-op, settling to 8.7mm at 24 mos; slip from 3.5 to 0.6mm. Definitive signs of fusion (Lenke 1-2) were present in 74% at 3 months, 91% at 6 months, 96% at 12 months and 95% at 24 months.

Conclusions: Our experience using XLIF in the ASD population has shown that clinical and radiographic indicators improve commensurately and the overall outcome is encouraging.

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Outpatient Endoscopic Minimally Invasive Spine Surgery: Two-year Follow-up
J. Polikandriotis

Introduction: The safety and efficacy of outpatient minimally invasive procedures are becoming well documented. However, few large studies evaluating these types of outpatient procedures have been presented. The purpose of this study is to assess the complications and 2 year functional outcomes of these procedures.

Materials and methods: A total of 3,958 consecutive outpatient endoscopic decompression procedures were performed from January 2008 through December 2008 at one facility. The average age was 59.1, 31% had previous surgery and the average duration of pain before surgery was 9.5 years. Over 80% of the procedures performed were endoscopic laminotomies/foraminotomies. The remaining procedures included plasma disc decompressions, percutaneous laser decompression, thermal facet ablation and hardware removal. A retrospective chart review including a 12 week, 12 month and 24 month patient follow-up was performed and perioperative complications, VAS, ODI, SF36 and return to work status are reported. Of the 3,958 patients, a total of 1,483 patients completed the 3 month survey, 675 completed the 12 month survey and 369 completed the 24 month survey.

Results: Of the 3,958 procedures performed, there were 0 (0.00%) mortalities, 1 (0.00%) code blues, 5 (0.13%) perioperative infections, 2 medication error (0.00%), 12 hospital admissions (0.30%) and 67 dura leaks (1.69%). As seen below, there were significant VAS and ODI improvements seen at 12 weeks and maintained throughout 2 years. In addition, outside of “General Health”, significant improvements were seen in all SF36 categories. “Physical Limitations” and “Pain” are presented below. * = p< 0.05 vs. Preoperative.

<table>
<thead>
<tr>
<th></th>
<th>Preop</th>
<th>12 weeks</th>
<th>12 months</th>
<th>24 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS</td>
<td>6.16</td>
<td>3.76*</td>
<td>3.58*</td>
<td>3.59*</td>
</tr>
<tr>
<td>ODI</td>
<td>40.5</td>
<td>28.4*</td>
<td>27.9*</td>
<td>26.5*</td>
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<tr>
<td>Phy. Lim.</td>
<td>14.9</td>
<td>33.9*</td>
<td>44.0*</td>
<td>43.9*</td>
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<tr>
<td>Pain</td>
<td>29.7</td>
<td>51.5*</td>
<td>52.7*</td>
<td>53.2*</td>
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</table>

Finally, 59%, 73%, 80%, 80% and 82% of patients reported return to work 2 weeks, 6 weeks, 12 weeks, 12 months and 24 months post surgery, respectively.

Conclusion: An improved understanding of procedure-related risks and outcome expectations is essential in preoperative risk-benefit discussions and decisions. While this study examines the feasibility and success of minimally invasive endoscopic outpatient spine surgery as a whole, this facility is currently dissecting the data into procedure and patient demographic specific outcomes as well.
Intermediate Clinical Outcome of Bryan Artificial Cervical Disc Replacement in the Treatment of Cervical Spondylosis and its Effect on Adjacent Segment Discs

Objective: To observe the clinical outcome and effect of Bryan artificial cervical disc replacement on adjacent levels in intermediate and long term.

Method: From Nov 2004 to Dec 2007, 34 patients (38 discs) underwent Bryan cervical disc replacement in our hospital, single level 30 cases, bi-level 4 cases. The follow-up period was from 29 months to 66 months, average 46.4 months. The data was collected before surgery and 1 week, 3, 6, 12, 24, 36, 48 months after surgery. Clinical outcome was evaluated by SF-36 score, NDI score, neck/arm pain VAS score, Odom’s scale. Neutral lateral and dynamic cervical radiographs were made to measure the flexion-extension range of motion (ROM) and the intervertebral height of adjacent segments. Adjacent segment degeneration was assessed with a new quantitative scoring system. Intraoperative and postoperative complications, reoperations were also recorded.

Results: The Neurological function of each patient was significantly improved after the operation. SF-36 physical component score and SF-36 mental component score were 37.7±11.8, 35.4±15.4 respectively before the operation and significantly increased to 67.9±13.0, 68.0±15.6 respectively at 1-week follow-up, 75.2±14.7, 75.8±19.8 respectively at 48-month follow-up (p<0.05); NDI score, neck/arm pain VAS score also decreased significantly (p<0.05); According to Odom’s scale, the rate of excellent and good outcome was 84.6% at 48-month follow-up. Flexion-extension ROMs of upper and lower segments were 11.28±0.97°, 9.11±1.24° respectively before the operation and significantly decreased to 9.27±0.89°, 7.47±1.17° respectively at 24-month follow-up, 9.03±0.96°, 6.96±1.33° respectively at 48-month follow-up (p<0.05). The postoperative intervertebral height of adjacent segments showed no statistical difference with the preoperative data (p>0.05). The new degeneration scoring system showed that 22% adjacent levels occurred mild degeneration at the last follow-up. 5 artificial discs in 5 patients migrated forward, but the range of motion of 5 discs preserved. There was no prosthesis subsidence or excursion, no heterotopic ossification or spontaneous fusion and no reoperation.

Conclusion: Bryan artificial disc replacement has a good clinical outcome in intermediate term and seems to protect against acceleration of adjacent segment degeneration.

Keywords: Cervical spondylosis, artificial cervical disc replacement, Bryan artificial cervical disc, clinical outcome, adjacent segment degeneration
± 6.0°). Though local lordosis was postoperatively stable, values of C1-C7 lordosis marked a progressive but significant postoperative increase (57±8°at 24 months versus 48±11° before surgery) significant of sagittal re-alignment.

Conclusions: Two years after TDR with Discocerv® prosthesis, clinical and radiological findings show good symptoms relief and satisfaction levels, associated with a low rate of complications, preserved mobility in 94% of cases and normal sagittal alignment.

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Long-term Clinical Experience with SECURE®-C Cervical Disc Arthroplasty
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Purpose: Long-term follow-up is essential to understanding the effects of cervical arthroplasty. This study compares clinical results of semi-constrained cervical arthroplasty using the SECURE®-C Cervical Artificial Disc (Globus Medical, Audubon, PA) with that of traditional anterior cervical discectomy and fusion in a prospective, randomized, Investigational Device Exemption (IDE) clinical trial, at the top enrolling site. Data from post-operative visits up to three years are presented.

Methods: An IDE clinical trial was conducted, with 57 patients enrolled at this site. The first five patients were treated with the artificial disc, and all patients thereafter were randomized 1:1 to either SECURE®-C or control ACDF with the ASSURE cervical plate and an allograft spacer. Patients with single-level symptomatic cervical disc disease (SCDD) between C3 and C7 defined by neck and/or arm pain, herniated nucleus pulposus, radiculopathy or myelopathy were enrolled. All patients were between 18 and 60 years of age, had 6 weeks of conservative therapy, and had a Neck Disability Index (NDI) of at least 30/100. Neck Disability Index (NDI), Visual Analog Scale (VAS) neck and arm pain, SF-36 Health Status Survey, and patient satisfaction are collected pre-operatively and at 6 weeks, 3 months, 6 months, 1 year and 2 years post-operatively and annually thereafter. Data from one center is presented; of the 57 patients treated at this site, 31 were treated with SECURE®-C (first 5 non-randomized plus 26 randomized) and 26 received ACDF. Outcome data from these patients are analyzed.

Results Summary: Both treatment groups demonstrated significant improvement in NDI. Average NDI for all SECURE®-C patients was 46.0 (±12.3) preoperatively, reduced to 7.4 (±11.5) at 6 months, 4.3 (±10.2) at 1 year, 3.6 (±8.4) at 2 years and 5.5 (±10.8) at 3 years. Average NDI for ACDF patients was 56.2 (±13.1) preoperatively, reduced to 7.6 (±8.9) at 6 months, 3.8 (±6.7) at 1 year, 5.7 (±10.4) at 2 years and 2.6 (±3.0) at 3 years. The first five non-randomized patients improved from 44.4 (±15.5) preoperatively to 2.4 (±2.6) at 6 months, zero at 1, 2 and 3 years. Average VAS neck pain scores decreased significantly from 50 (±31.7) preop to 13.1 (±24.4) at 1 year and 7 (±15.7) at 2 years and 11 (±18.6) at 3 years for the SEC group, and from 67 (±26.4) preop to 10.5 (±18.2) at 1 year and 14 (±23.1) at 2 years and 8 (±14.6) at 3 years for the ACDF group. Similarly, SF-36 PCS improved for both groups at all time points as compared to pre-op. No implants required removal, and no complications or device-related events occurred in either treatment group at this top enrolling site.

Conclusion: SECURE®-C cervical arthroplasty and ACDF patients experienced significant postoperative improvement in pain and function. There was no apparent learning curve for these procedures; the first five arthroplasty patients experienced 100% improvement in pain and function (NDI) by one year that has been maintained through three years thus far. Continued follow-up data is needed to determine long-term safety and efficacy beyond three years.
values between the two testing methods. During the shear expulsion tests, 5 implants failed by collapse and expulsion of the superior component and one by subluxation of device. For the pull-out tests all disc components failed by distraction along the screw axis.

**Conclusion:** The shear-expulsion model applied a force through the center of the ball that induced an internal rotational moment on the implant which transferred to the vertebral body through the retaining screws, no longer placing them under tension. This complex loading scenario resulted in a bearing stress that crushed the screw into the bone (often leading to a windshield wiper effect). This methodology provides a more physiologic evaluation of the failure mechanism that occurs during extension and allows for better comparison of retaining features used in spinal implants (screws, keels, teeth).

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**Preoperative Paravertebral Ossification - Critics on the Evaluation of Heterotopic Ossification after Cervical Artificial Disc Replacement**

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**Objective:** To evaluate the incidence and features of preoperative paravertebral ossification (PO) in patients who got artificial disc replacement (ADR), in order to explore the most effective and objective evaluation criteria of heterotopic ossification (HO).

**Methods:** We reviewed the images of 103 patients (62 men and 41 women) who underwent Bryan ADR in our institute during the last 27 month. The average age of the patients was 46.3 years (range from 22.0 to 71.0). The diagnosis were 57 cases of degenerative cervical canal stenosis (DCCS), and 23 cases of cervical disc herniation (CDH). Coronal reconstruction CT scan was applied to evaluate the preoperative incidence of PO.

**Results and discussion:** The presence of preoperative PO was found in 50 cases (48.5%); Logistic regression revealed that preoperative diagnosis contributed the greatest amount of variance. The chance of PO in DCCS patients was 3.95 times of the CDH patients ($P < 0.01$). The occurrence of PO has nothing to do with sex or age ($P > 0.05$). Occurrence rate of HO were reported with varied range as the Bryan disc from 0 to 76.2%. Imprecise of assessment methods may play a role in such a huge variance. Most authors found out that HO was typically observed lateral to the vertebral bodies, thus coronal CT scan is the better way to evaluate the PO. As shown in figure 1, sagittal reconstruction CT and demonstrate no HO at the 37.5 months follow up, but grade 3 HO was shown at coronal CT scan.

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Even if the application of coronal CT to assess of HO can improve the accuracy, there are still other two issues should be mentioned. First, HO and osteophytes have the same predilection sites and can not be distinguished with each other radiographically, but both of them can affect range of motion after ADR, as a result, in this article HO and osteophytes were generally designated as PO rather than being given a specific distinction. The second problem is that, it can not identify the occurrence time of PO. Whether it exist preoperatively or develops after operation. As shown in figure 2, the cephalad adjacent segment haven't got operation, but it has the same grade of PO.
Our study indicates that PO have existed before surgery, so the preoperative data should be compared to make an objective assessment.

**Conclusion:** The existence of preoperative PO need to be heeded. A large component of HO maybe were natural development of preoperative osteophytes. HO should be evaluated by combining flexion-extension radiographs with coronal CT scan, and compared with the preoperative data, to achieve an objective assessment.

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**Predisposing Factors of Heterotopic Ossification after Cervical Artificial Disc Replacement - Over Three Years Follow-up Cohort Study**

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**Objective:** The purpose of this study is to evaluate the incidence and predisposing factors of heterotopic ossification (HO) in patients who got artificial disc replacement (ADR) and followed up for more than 3 years.

**Methods:** In this prospective cohort study, 41 patients who underwent cervical ADR from December 2003 to January 2006 were enrolled. All the patients were followed up for more than three years, with an average of 41.7 months (range from 36.0 to 55.6). The average age at the most recent follow-up was 48.1 years (range from 25 to 73). The preoperative diagnosis were 27 cases of degenerative cervical canal stenosis (DCCS), and 14 cases of cervical disc herniation (CDH). Coronal reconstruction CT scan was applied to evaluate the incidence of HO. The patients were divided into two groups according to HO grades. Scores of 0, 1, and 2 were grouped as “Radiographically Insignificant” and scores of 3 and 4 were grouped as “Radiographically Significant.” ROM at operation level in sagittal plane were compared between the two groups at pre-operation, three-month follow-up and the most recent follow-up. Chi-square test, independent samples t test were carried out with significance level of 0.05 using SPSS version 15.0.

**Results:** Of the 41 patients in the follow-up group, 21 patients (51.2%) show some degree of HO at the most recent follow-up, 6 patients were identified (28.6%) as having Grade 1 ossification, 9 (42.9%) as Grade 2 ossification, 3 (14.3%) as Grade 3 ossification, and 3 (14.3%) as Grade 4 ossification. There was no statistical difference between the two groups at preoperation or three-month follow-up (P > 0.05), but the ROM of “Radiographically Insignificant” group was better at the most recent follow-up (P < 0.01), which means development of HO more than Grade 3 will affect the midterm range of motion (ROM) of ADR. According to the chi-square test the patient who have less preoperative ROM at the operated level or the patient who’s preoperative diagnosis was DCCS would have more chance to have HO at the most recent follow-up. The occurrence of HO was not related to age, sex and preoperative disc height (P > 0.05).

**Conclusion:** Coronal CT scan is a very good method in displaying the occurrence of HO and classification. The development of HO more than Grade 3 can significantly affect the ROM at midterm follow up. Choose the patient who have preoperative ROM more than 10 degree or the patient who got CDH would have more chance to avoid HO at the midterm follow up.

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**Clinical Significance of Hypermobility in Cervical Artificial Disc Replacements**

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**Introduction:** Normal range of motion in terms of total flexion/extension at C4-5 averages 18.8º, C5-6 averages 18.4º and C6-7 averages 15.4º. Cervical artificial discs have been designed to emulate normal spine kinematics. The Prestige ST and the ProDisc-C are designed to allow 10º of flexion from a neutral position and 10º of extension for a total 20º of range of motion. The Bryan allows 22º total range of motion.

**Methods:** Published FDA IDE data was evaluated from the Prestige ST, ProDisc-C and Bryan disc in terms of range of motion at the operated level. Patients with more than 14 degrees of ROM were considered hypermobile. Histograms of each CADR will be presented.

**Results:** Histograms of the Prestige ST, ProDisc-C and Bryan disc indicate 15% of Prestige ST patients, 24% of ProDisc-C patients and 6% of the Bryan disc patients had greater than 14º of total motion in flexion/extension. These results are based on a single flexion/extension x-ray at two-year followup. In terms of the total group, these patients are considered to have hypermobile cervical artificial discs. Internal analysis of these hypermobile patients by each company revealed no difference in their FDA clinical success compared to the average patient with 8 degrees of ROM. Pre-operative flexion/extension views do not correlate with patients who post op develop hypermobility. Overall range of motion of the entire cervical spine remains within normal limits in these patients. Thus, more motion is occurring at the cervical artificial disc replacement than adjacent levels which may decrease the incidence of adjacent level degeneration. This is opposite compared to fusion.

**Conclusion:** The average range of motion reported after CADR is 8º of total flexion/extension, substantially less than the 15-18º considered normal range of motion. If the goal of artificial discs is to emulate normal spine kinematics, hypermobility may be a desirable result. At two-year followup no conclusions can be made whether these hypermobile patients demonstrate long-term clinical advantages.

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**Reversal of Anterior Cervical Discectomy and Fusion with a Cervical Artificial Disc Replacement - Regain Motion after Nine Years Fusion**

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**Objective:** This case report describes a patient who initially underwent anterior cervical discectomy and fusion (ACDF)
for 9 years and revised with artificial disc replacement (ADR). **Case report:** This previously healthy 39-year-old woman presented initially with spontaneous onset of a bilateral hand numbness and leg weakness early in 2001. She was treated at another hospital, and got ACDF operation. Most of her neurological deficits was relieved after operation, but which was repeated 2 months before the second operation and failed of conservative treatment. Her preoperative JOA score was 13, and NDI score was 30. CT myelography shows recurrent of cervical disc herniation at the cephalad adjacent segment which compressed the spinal cord. There was still some osteophyte at the C56 level which also cause the compression to the spinal cord, and solid fusion was present at this level, the facet joints at C56 level was slight degenerated, but remain unfused.

Motion in the cervical spine occurs at both the intervertebral disc and the facet joints. Loss of motion either anteriorly or posteriorly can lead to subsequent ankylosis at the other motion center. If motion can be reestablished at one motion center and the other center has not ankylosed, functional cervical motion may occur. The results of thoracolumbar fractures prove that non-fused spinal segments included in pedicular instrumentation maintained mobility in a high percentage once the hardware is removed, which provides a theoretical basis for this kind of revision.

**Conclusions:** In our case, the range of motion at the revision level at the 2 months follow-up was well preserved, in select cases ADR represents a reasonable alternative to a repeated attempt at fusion.

*Fig1*

If revision with ACDF was conducted the patient would lose one more motion segment and got more chance to have adjacent segment disease again. After rigorous preoperative design, we decided to reversal of ACDF with ADR. With a high speed drill, decompression through the grafted region was effected. The segment was mobilized and there was no intraoperative evidence of a solid posterior element fusion. Then the two prosthesis were placed with a standard method in C45 and C56 levels. The range of motion at the revision level at the 2 months follow-up was 15.1°, her neck symptom and neurologic function were significantly recovered (JOA 16.5, NDI 12).

*Fig2*

**Discussion:** The advantages of ADR include preservation of normal motion in the cervical spine, and reduction of adjacent segment degeneration. There was one case report described reversal of ACDF with ADR, 6 months after first operation. But our report was the first long term case.
of reoperations was higher in the ACDF control group, 10% versus 6.8% in the PCM arthroplasty group. The composite per-protocol primary endpoint outcome was highly significant (p < 0.0001) showing superiority for PCM arthroplasty with 102/130 (78%) (90% confidence interval 72.5% to 84.4%) success versus ACDF controls 55/87, (63%) (90% confidence interval 54.7% to 71.7%) success. There was an observed trend towards improved outcome for patients treated with the PCM-V Teeth device 32/39, 82.1% (90% confidence interval from 71.9% to 91.2%) relative to those treated with the standard press-fit PCM 68/89, 76.4% (90% confidence interval from 69.0% to 83.8%). Though the trend was not statistically significant between PCM types, both groups demonstrated statistically superior outcome to the ACDF control group, as demonstrated by the confidence interval plots of figure 1. The Bazaz results demonstrate that while both the PCM and ACDF groups exhibited an initial postoperative problem with swallowing, the PCM group continued to improve with increasing time following implantation, while the ACDF only improved minimally. The PCM treatments indicated significantly lower incidence of dysphagia at three, twelve and 24 months post-operatively compared to ACDF controls (p < 0.05).

Conclusions: In a prospective randomized clinical study, the neurologic composite outcomes and the clinical outcomes proved superior for PCM cervical arthroplasty compared to ACDF controls at 24 months post-operatively.

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373 Screw Implantation Technique Alters the Stability of Cervical Spine Following Anterior Plate Fixation: A Comparative Finite Element Study

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Introduction: Anterior cervical plate (ACP) has been used for fixation of an unstable spine since 1970. Surgeons secure plates to the vertebral bodies using uni-cortical and bi-cortical screws. However, there are reports documenting screw back-out leading to unsatisfactory bony union [1, 2]. A new tri-cortical method of screw implantation for anterior cervical interbody fixation may hold the plate firmly with a tricortical purchase and thus, providing a better stability. The purpose of this study was to evaluate the biomechanical performance of this alternative approach, compared to other standard methods.

Methods: The validated intact (Fig.1(a)) model was modified to simulate iliac crest cancellous bone graft and ACP system, designed in Solidworks™, at C5-C6 level and the graft was secured using the tri-cortical approach (Fig.1b). The superior screw was placed tricortically at an angle of 35º with respect to the plate and the inferior screw was placed bicortically at 20º angle with respect to the plate (Fig.1e&f). The intact model was also modified to create another model (Fig.1c). This model simulated a single level Atlantis ACP system (Medtronic, Inc.) with four uni-cortical screws (Fig.1d). Appropriate material properties, contacts and boundary conditions were defined for all the models. A compressive follower load of 73.5N and a moment of 1.5 Nm were applied to simulate physiologically relevant motions.

Results: Fig.2(i) illustrates the implanted level motion in both tricortical (TCS) and Medtronic ACP systems, compared to the intact. In extension, TCS provided 20% more reduction in motion, compared to Medtronic system. In all other modes, TCS performed equivalent to the Medtronic. At C4-C5 and C6-C7 levels, all the rotations were similar to intact in both the cases. Maximum endplate stresses at the implanted level were greater in TCS (~100MPa).

Fig.2(ii) depicts the stress distribution on unicortical, bicortical and tricortical screws. Maximum screw stresses were found in the uni-cortical (~430MPa) compared to bicortical (~275MPa) & tricortical (~100MPa). Also, uni-cortical screw had the maximum pull out force in axial rotation (140.9 N in LR & 130 N in RR) than other two types of screws.

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Discussion and conclusions: The tri-cortical system induced higher endplate stresses at the implanted level which may enhance the fusion process. Tri-cortical screw had the lowest stresses and least pull out force. Thus screw backouts/loosening/breakage is less likely to occur for the tri-cortical system, compared to the uni-cortical and bi-cortical system.

References:

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Anterior Cervical Fusion after Closed Reduction for Treatment of One-level Subaxial Cervical Spine Injuries: Comparison of Autologous Bone Graft versus Synthetic Cages Filled with Demineralized Bone Matrix
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Objectives: The purpose of this study is to compare clinical and radiologic outcome of one-level anterior cervical discectomy and fusion for traumatic subaxial cervical injury between autologous bone graft group (Group I) and synthetic cage group (Group II).

Materials and methods: The patients were randomly divided in two groups. Sixty consecutive patients of traumatic cervical injury underwent anterior cervical discectomy and fusion (ACDF) using autologous bone graft (Group I, 25 patients) or synthetic interbody cage (Group II, 35 patients) with plate fixation system in our hospital. The mean age were 46.2 years (Group I) and 48.2 year (Group II). The affected level was C4-5 in 5 patients; C5-6 in 9, C6-7 in 11 (Group I) and C3-4 in 1 patient; C4-5 in 11, C5-6 in 11, C6-7 in 11 (Group II). Clinical outcome were assessed using a ASIA scoring system at follow-up visits. Radiological outcome, anteroposterior as well as lateral and flexion-extension radiographs. Mean follow-up duration were 15.5 months (Group I) and 13.5 months (Group II).

Results: Fusion at the last follow-up examination was demonstrated in all of the patients. In group I patients, the mean interbody angle (kyphotic angle) of 2.8° before surgery was reduced to -4.4° immediately after surgery, and at the last follow-up to be -1.9°. The mean interbody height of 35.8 mm before surgery was increased to 40.9 mm immediately after surgery, and at the last follow-up to be 38.9 mm. In group II patients, the mean interbody angle of 2.1° before surgery was reduced to -1.2° immediately after surgery, and at the last follow-up to be -0.4°. The mean interbody height of 34.5 mm before surgery was increased to 41.9 mm immediately after surgery, and at the last follow-up to be 39.4 mm. There was a no significant difference between the two groups. There was one patient not achieving arthrodesis at last follow up. There were no patients with implant-related complications.

Conclusions: Based on our experience, anterior cervical discectomy and fusion using a synthetic interbody cage with plate system showed at least as safe and effective as traditional interbody fusion with autologous bone graft in patients with one-level subaxial spine injuries. There are some advantages of the lack of donor site morbidity, the cage’s radiolucency for assessment of bridging bone, abscense of graft resorption.

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Comparative Electrogoniometric Study of the Global Cervical Range of Motion and Velocity, after Cervical Disc Herniation, Anterior Cervical Discectomy and Fusion or Disc Arthroplasty
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Introduction: Three-dimensional electrogoniometry (CA6000, OSI) is shown to be a reliable, accurate, reproducible and unconstraint tool for continuous tracking of cervical spine range of motion (ROM) and velocity of motion (VM). Already used in healthy subjects and in patients with cervicalgia or after whiplash, it has never been used to compare the cervical pattern and ROM of patients with cervical disk herniation (HD) before and after anterior discectomy and fusion (ACDF) or cervical total disc replacement (TDR).

The aim of the study was to compare the range, velocity and patterns of global motions of the cervical spine in four different clinical conditions:
1) healthy subject (control group),
2) after HD,
3) after ACDF,
4) after TDR, using the CA 6000 Spine Motion Analyzer.

Material and methods: Since 2005, sixty-three patients (mean age: 48 y (range 26-73 yo)), admitted for cervical HD, were included in our biomechanical study. The ROM and VM...
were measure using the 3D-electrogoniometer (CA6000-OSI) before and/or after treatment. The ROM, VM and patterns of motion were analysed between the first thoracic vertebra and the head for flexion-extension, lateral bending and rotation in neutral sagittal plane position and in full flexion. Thirty-seven patients were measured in preoperative (HD group). In the 63 patients included, 39 were treated by TDR (TDR group) and 23 by ACDF (Fusion group). ROM and VM were compared to the results obtained from 42 healthy subjects (control group).

**Results**: All movements (ROM and VM) tested were significantly (p<0.001) affected in the 3 clinical conditions (HD, ACDF or TDR group) if compared to control group. After TDR, a significant better recovering was observed for the ROM and VM if compare to ACDF group (p< 0.05), without complete return to normal. If compared to preoperative (HD group), only VM were significantly improved after TDR (p< 0.05). After ACDF, all modality of movement (ROM and VM) were significantly reduced if compare to the other group.

**Conclusion**: Using TDR as treatment of HD allows to significantly better restoring the global ROM and VM of the cervical spine if compared to the ACDF. CA6000 electrogoniometer is an interesting tool to measure, in vivo, the impact on the cervical ROM and VM of cervical disc herniation. It allows a quantitative and comparative evaluation of the spine kinematic after the different modalities of treatment available.

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**341 The Influence of Open-door Laminoplasty with Preservation of the Unilateral Musculo-ligament Complex to the Volume of Cervical Paraspinal Muscles on the Early Post-operative Stage**

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**Object**: There is no report about the paraspinal cervical muscle changes after the expansive open door laminoplasty in the literature. This paper is to evaluate the influence effect of open door laminoplasty with preservation of the unilateral musculo-ligament complex on the early stage of post-operative paraspinal muscle volume of cervical spine.

**Method**: 60 patients who experienced open-door laminoplasty with preservation of the unilateral (right side) paraspinal musculo-ligament complex due to cervical spondyloitic myelopathy were reviewed retrospectively. There were 41 males and 19 females with mean age of 58.0 (range, 34-78) years old. The average followed up was 4.3 months. An MRI scan was performed before the operation and at final follow-up. The bilateral posterior muscle area at cross-section plane at each intervertebral level of C2/3, C3/4, C4/5, C5/6 and C6/7 were measured, respectively, on MRI scan using Photoshop software and summed the five ipsilateral area values as the muscle volume. The data were analyzed using SPSS 16.0.

**Result**: (1) There was no significant side-related difference of muscle area at each level (p>0.05) before operation. The muscle areas on the right side are significantly larger than the left side at the levels of C3/4, C4/5, C5/6 (p< 0.05) but not at C2-3 and C6-7 (p>0.05) at final follow-up. 
(2) There was some muscle areas decrease on the left side and increase on the right side at levels of C2/3, C3/4, C4/5, C5/6 after the operation. 
(3) There was no significant difference for the sum of five muscle area (levels of C2/3, C3/4, C4/5, C5/6,C6/7) between the left and right side before operation. But the sums at the right side was significant larger than those at left side (p< 0.05) at final follow-up.

**Conclusion**: Open-door laminoplasty with preservation of the unilateral paraspiianl musculo-ligament complex is less invasive to the posterior cervical muscles and maintain the muscle volume to some degree on the early stage after the operative.

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**577 The Importance to Preserve a Posterior Tension Band in Cervical Stenosis Decompression. A Study with 24 Months Follow up**

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**Introduction**: Traditional methods of cervical decompressive laminectomy require stripping of the posterior cervical muscular, as well as ligamentous, attachments to the spine, some patients will go on to develop iatrogenic swan neck deformity. Minimally invasive techniques allow to preserve the posterior muscle and ligament posterior tension band traduced in short surgical time, less bleeding and quickly reinsertion in daily activities with cervical stability.

**Materials and methods**: Nine patients with cervical myelopathy, due cervical posterior compression in one level and no significant anterior disc disease without radiographic signs of segmental instability, who’s underwent a minimally invasive biportal cervical decompression with a Maxcess retractor (Nuvasive, Inc. San Diego, CA), a number of variables have been reported: patient mean age, vas, owestry and neck disability index on Preop, Pop 6 weeks, 3,6,12 and 24 months, surgical time, amount of bleeding, time to discharge and return to normal activities.

**Results**: Mean patient age: 56 years old, Preop Vas 8.3 , 6 weeks 3.5, 3 months 3.0 , 6 months 2.7 , 12 months 2.4 and 24 months 2.0. Oswestry preop 52 , on 24 months 11. The mean surgical time was 81 minutes, bleeding 30cc, time to discharge 10 hours and return to normal activities was mean 9.8 days.

**Conclusions**: Minimally invasive posterior biportal cervical decompression is an effective ambulatory option to achieve clinical improvement in patients with cervical stenosis with less bleeding, The advantage to preserve the posterior muscle and ligament tension band allow the patients in short time to return to normal activities.
Oral Posters: Lumbar Spine

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The Accuracy of Midline Placement of Total Disc Arthroplasty of the Lumbar Spine Using Different Anatomic Landmarks Under Fluoroscopy
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Background: Total disc arthroplasty promises to be a viable alternative to fusion for degenerative disc disease of the lumbar spine. Correct placement of the prosthesis is critical for optimal function. Malposition of > 3mm predisposes to asymmetric loading, implant wear, implant loosening, and non-physiological stresses on adjacent vertebral segments. Our objective is to measure the visual accuracy of midline placement of artificial disc using four different anatomic landmarks (pedicle, vertebral body waist, vertebral body endplate, spinous process) under fluoroscopy.

Methods: Artificial discs were implanted into three cadaver specimens at L23, L34 and L45. The implant used is the DePuy Charite III artificial disc. An AP image was obtained by fluoroscopy. The fluoroscopy machine was then rotated in the sagittal plane to 2.5, 5, 7.5, 10, and 15 degrees. We then obtained CT scans of the cadavers. We measured the distances from each of the anatomic landmarks studied to the midline of the implant on both fluoroscopy and CT. The means were then compared to evaluate which landmark had the least variability on fluoroscopy when compared to CT. This process was repeated as the fluoroscopy machine was rotated in the sagittal plane to determine what the maximum allowable error in rotation can be to obtain a discrepancy of <5mm.

Results: The mean difference in distance on fluoroscopy at 0 degrees when compared to CT from the pedicle, vertebral body waist, vertebral body endplate and spinous process to the center of the implant was 1.31mm (p = 0.0001), 1.72mm (p = 0.0001), 1.99mm (p = 0.0001) and 3.14mm (p = 0.0002) respectively. The difference in the measurements from the medial border of the pedicle to the midline of the implant when comparing fluoroscopy to CT was the smallest (1.31mm) and was statistically significant (p = 0.0001). When the angle of the fluoroscopy machine was greater than 5 degrees, a mean difference of >3mm when compared to CT was obtained for all anatomic landmarks.

Conclusion: The pedicle is the most consistently identifiable and accurate of the anatomic landmarks studied for placement of total artificial discs in the lumbar spine. Error in rotation of the fluoroscopy machine of > 5 degrees in the sagittal plane can lead to implant malposition.

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Investigating the Potential Effect of “Euphoric Bias” for the New Technology on Results of Randomized Lumbar Total Disc Replacement Trials
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Introduction: The results to date of the lumbar total disc replacement (TDR) vs. fusion trials have shown TDR to produce results similar or superior to fusion. The question has arisen if the results may have been influenced by patients’ enthusiasm for getting the new technology, creating what we have termed “euphoric bias”. The purpose of this study was to compare the results of the same TDR device when randomized as the investigational group vs. its results when serving as a control group.

Methods: Charite TDR device was implanted in three different subgroups of patients at a single center: prospective FDA randomized trial (patients randomized to Charite or fusion) as the investigational device (n=48; investigational group), the same protocol under continued access (not randomized; n=12) and as the control device in the Kineflex-L FDA trial (n=28; Control group; patients randomized to one of the TDRs). Only patients with 24-month follow-up were included in the analysis. In all groups, the same version of the Oswestry Disability Index was used. All patients were treated for single-level disc degeneration at L4-5 or L5-1 unresponsive to a minimum of 6 months non-operative care. There were no significant differences between the three groups based on age, gender, body mass index, or level operated. Data were collected pre-operatively, and 6 weeks, 3, 6, 12, and 24 month post-operatively.

Results: There were no significant differences in Oswestry scores with respect to the TDR groups (Figure 1; ANOVA, p>0.05). All groups improved significantly by 6 weeks follow-up and remained improved throughout 24-month follow-up (p< 0.01). There was also no significant difference in the 24-month re-operation rate between the groups: 6.1% in the investigational subgroup, 0.0% in the continued access, and 3.6% in the control subgroup (p>0.05).
Conclusion: There was no difference in results when comparing TDR as the “new” investigational device to which patients were randomized (has been suggested that results were biased due to patients being pleased to get the TDR), patients knowing they would receive the same device as part of a continued access study, or when the same device served as the control, rather than the new investigational device. This study found that the good results reported for TDR are not likely to be related to a euphoric bias created by being randomized to receive the “newest” technology.

Biomechanical Effects of Sequential Facet Resection on Lumbar Spine Mechanics
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Introduction: Lumbar facetectomy is one of the most commonly performed spinal surgeries. Whether it’s performed for foraminal stenosis or other pathologies, there is always the concern of iatrogenic spine destabilization. Minimally invasive techniques (MIS) have been developed to preserve the joint and ligamentous structures in the area of interest. Despite these advancements, controversy of whether or not one has destabilized the spine after performing a lumbar facetectomy remains. The objective was to investigate the effects of sequential facet resection by comparing the biomechanical stability of four different spine conditions: harvested, after an MIS partial unilateral facetectomy (UF), after an MIS bilateral facetectomy via unilateral approach (BF) and after a traditional laminectomy (TL).

Materials and methods: Eight fresh human cadaveric lumbar spinal segments (four L1-L2, two L2-3 and two L4-5) were tested with three different protocols using a multi-axis robotic testing platform. They included the pure moment method (PM) and two novel testing techniques: a combined load and moment protocol (CLM) and a coupled eccentric loading protocol (CEL). The CLM protocol introduces to the PM an anterior-posterior (A-P) displacement to the flexion-extension (F-E) modes of testing through application of shear and compressive loads, and the CEL protocol introduces the coupling of F-E or lateral bending (LB) with active left and right axial rotation (AR). The purpose of these protocols was to simulate a more physiological mode of testing in vitro. All rotational data were analyzed at an 8Nm end limit for F-E and 6Nm for LB and AR. A non-parametric one-way repeated-measure ANOVA on ranks (Friedman’s test) was employed to analyze the rotational data (p< 0.05). If there a statistical difference was detected, a Student-Neuman Keuls comparison test was then applied.

Results: For both PM and CLM, the UF caused a reduction in motion during flexion and extension (Figure 1). Further facet resection, namely BF and TL, resulted in a significant increase in rotation during flexion and extension compared to the UF condition. During LB tests (using the PM protocol), the UF caused a reduction in rotation for movement towards the surgical side (left) and an increase in rotation during LB away from the surgical side (right). Further facet resection through BF or TL resulted in significant increases in lateral rotation. The inclusion of active axial rotation coupled with F-E or LB in the CEL protocol did not produce any new findings compared to the other two modes of testing.

Conclusions: Unilateral facetectomy was associated with an increase in stability highlighting the efficacy of this surgical procedure. However, the overall biomechanical stability of the spine significantly decreased following subsequent BF and TL surgical resections, indicating the possible need for surgical stabilization.

Effect of Sequential Facetectomies on Lumbar Spinal Stability under Sagittal Plane Loading Mechanics in a Cadaveric Model
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Introduction: Lumbar facets function to limit forward translation during sagittal movement. Any pathology or
surgical intervention that alters the relationship between them may result in spondylolisthesis. Previous in vivo studies have used pure moment (PM) techniques to study facet mechanics. However, this method does not account for the shear force present in vivo, and thus cannot be extrapolated to a clinical situation. A new testing protocol was developed that included a shear force combined with a compressive load and bending moment (CLM). The objective was to analyze the effects of sequential facet resections on facet angle and facet contact surface area, as it relates to their biomechanical stability using two testing protocols. Three surgical conditions were tested and compared to the harvested (H) condition: MIS partial unilateral facetectomy (UF), MIS bilateral facetectomy via unilateral approach (BF) and traditional laminectomy (TL).

**Materials and methods:** Eight human cadaveric lumbar segments (four L1-L2, two L2-3 and two L4-S) were tested in flexion and extension using a multi-axis robotic testing platform. The testing protocols used were the PM and CLM. The CLM protocol is similar to the PM method with the addition of a shear force and a compressive force. The purpose of this protocol was to simulate a more physiological mode of testing in vitro. For the PM tests, the spines were flexed or extended up to an end limit load of 8Nm. For the CLM tests, a combined (compressive and shear) force vector of 264N was applied along with the 8Nm moment. Measures of segmental rotation and AP translation along the disc plane were analyzed using a non-parametric one-way repeated-measure ANOVA on ranks (Friedman’s test) for $p<0.05$. Changes to the facet orientation and surface area were measured from CT images of the H and BF spine conditions using the open source imaging software Osirix. The facet angle and fact contact area measurements were analyzed using a Wilcoxon Signed Rank test (non-parametric paired t-test, $p<0.05$) comparing the intact and bi-lateral facetectomy conditions.

**Results:** CLM testing resulted in the greatest AP translation with the TL condition (Figure 1). Conversely, PM showed no significant changes in AP translation between all spine conditions. The facet angle (in degrees) significantly decreased from the harvested condition (right facet: 36.0±16.5; left facet: 37.3±18.4) when compared to the post facetectomy specimens (right facet: 30.0±17.6; left facet: 33±17.0). A significant reduction also occurred in the facet surface area between the harvested condition (right facet: 0.51±0.09; left facet: 0.52±0.12) and the post-facetectomy condition (right facet: 0.34±0.13; left facet: 0.29±0.07).

**Conclusions:** Spinal instability was only observed with the traditional laminectomy condition using the CLM mode of testing. PM testing methods were unable to induce any significant changes in AP translation. This draws attention to a limitation of using the PM testing method to study the biomechanical effects of spondylolisthesis in vitro.

**466 Intra and Intra-intersegmental Repair for Spondylolysis and Spondylolisthesis**

P.S. Lin, K.J. Zook

**Design:** This is a retrospective cohort study.

**Objective:** The authors describe a novel technique for direct repair of a pars defect utilizing Dynesys™ instrumentation. Moreover, the indications for repair are expanded to include those with disc disease and associated spondylolisthesis.

**Summary:** The challenge in treating pars defects has been that there are few techniques available to stabilize them adequately. The focus has been on fusion across the inter-space versus grafting and instrumentation of the defect itself. We hypothesize that direct repairs of the defect favor maintenance of normal motion characteristics by preserving the functional unit of the disc. This paper describes a motion-preserving procedure, early clinical outcomes and important nuances of the technique shared by the author.

**Methods:** Our series includes 20 patients with symptomatic bi-lateral pars defects. 15 patients met the criteria for single level fixation. 5 patients required the additional fixation of flexible posterior-lateral fusion involving the inferior segment. Rh-BMP and autologous bone graft are utilized and placed within the defect. Follow-up visits and imaging with CT were carried out to two years. Plain film x-rays were used to determine stability while thin-section CT was used to assess healing of the defect.

**Results:** Clinical outcomes for the entire series were: excellent n=14, good n=3, no significant help n=3. The procedure arrested any further slippage in 100% of cases. For those with follow-up >/= 2 years, bone formed in 95% of cases with CT scan demonstrating full healing in over half of these patients. For all cases there is a 5% rate of non-union.

**Conclusion:** Further study and development of the technique via biomechanical testing is on-going; however, the initial results are encouraging. Bone formation appears to be linked to decreasing symptoms in patients with bilateral pars fractures who have failed conservative treatment.

**Figure 1. AP translation of spinal segments along**
Extraforaminal Lumbar Interbody Fusion-ELIF: Anatomic Basis and Technique
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Background and context: A variety of surgical exposures have been utilized for treatment of lumbar disc problems. However there is frequently a compromise between exposure of the disc space, root retraction, and ease of instrumentation. The usual posterior exposure techniques are known to cause substantial muscle damage.

Purpose: This study reports on the anatomic investigations, European surgical application and early North American experience with this muscle separating less invasive surgical exposure method-ELIF.

Study design/setting: Anatomic Dissection and Clinical Utilization, introduction of technique to other surgeons.

Patient sample: 512 clinical patients undergoing spinal fusion.

Outcome measures: Completion of the procedure through the anatomic exposure planned.

Methods: Beginning in 1985 RA described exposure for HNP separating the muscle bundles, this was followed by cadaver dissections in France and refinement of the exposure technique expanding on that described by Wiltse to allow separation rather than splitting of the Multifidus Longissimus interval of the Erector Spinae Complex. Adjustments of the Skin, Fascia, and Muscle incisions allowed direct access to the Transverse Process, Facet, Pedicle and Intervertebral disc space via a single posterior lateral incision without specialized retractor systems. Refinements since 2005 have permitted intervertebral fusion through this exposure.

Results: The anatomic interval and exposure has been reliably defined in cadaver dissection. Dr. RA has accomplished 500+ procedures utilizing this anatomic exposure method 170 were bilateral and 330 unilateral. In North America it has been used in 12 cases since adoption in 2007. The surgical time was 105 minutes for single level fusion, blood loss (less than 50cc reported by RA), and ease of instrumentation is comparable or better than for standard posterior exposures. The separation between muscle sections within the Erector Spinae can with study be reliably identified. No procedure required conversion to alternativetechnique.

Conclusions: Used either unilaterally or bilaterally this technique offers many of the advantages of that described by Wiltse, but expands the range of possible interventions considerably. Even when the intramuscular plain of dissection is difficult to define the procedure can be accomplished reliably. The advantage of less soft tissue injury with standard retractor systems and conventional lighting and magnification methods seems worthy of further study.

Complications of Stand-alone Lateral Lumbar Interbody Fusion and Predictors of Outcome
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Purpose: Minimally invasive transpsoatic lateral lumbar interbody fusion (LLIF) is traditionally performed as a part of circumferential fusion and has gained growing interest in recent years. However, skepticism related to this technique as a stand-alone procedure is regards to non-union, loss of correction of deformity, subsidence of cage and axial pain. The objective of this study was to retrospectively review patients who underwent LLIF as a stand alone procedure at our institute. Patients were followed up with CT scan and dynamic flexion-extension radiographs. 8 patients required posterior instrumented fusion due to complications including non-union, subsidence, loss of correction of deformity and pain.

Methods: Under institutional IRB approval we retrospectively reviewed preoperative parameters including diagnoses, medical co-morbidities, body mass index, Dual emission X-ray absorptiometry (DEXA) scan for osteoporosis, standing scoliosis radiographs for calculation of Cobb’s angle and sagittal balance as well as other radiographic parameters including individual disc height, anterior and lateral spondylolisthesis in order to ascertain the modality and causation of failure. We reviewed peri-operative parameters inclusive of level of fusion, cage sizes and bone graft materials. Patients were followed up with radiographs post operatively and then at 3 months, 12 months and final follow-up. 53 patients received CT scan and 26 dynamic flexion-extension radiographs to assess fusion at 7.1 and 9.1 months respectively.

Results: 8 patients required posterior fusion at a second stage for non-union, loss of correction and progression of deformity, axial back pain, end plate fracture and subsidence of cage. 37.5% of the above had score below -2.5 on DEXA scan, mean positive sagittal balance of 81.7mm, one patient had previous laminectomy at level of interbody fusion. Mean body mass index (BMI) for the above was 28.1. End plate fracture was observed at 21 levels in 78 patients, 11 levels of which were in the 8 failures of stand-alone procedure. Grade III subsidence was noted in 4 levels, grade II in 6 and grade I in one level in the failure group.

Conclusion: LLIF is a valuable tool for achieving fusion through a minimally invasive approach with little risk to neurovascular structures and low peri-operative morbidity. However, the indications and outcome of this technique as a stand-alone procedure has not been reported. Our results indicate astute selection of the surgical candidate is of primary importance. Findings of positive sagittal balance and lumbar kyphosis are probable predictors of poor outcome. Additional factors like high BMI, osteoporosis, previous laminctomy and undersized cage selection may be contributory to non-union rates and requirement of a second stage posterior fixation surgery. We believe in appropriately selected patients that multi-level LLIF procedures can be successful.
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Evaluation of the L5-S1 Interbody Space with Trans-sacral L5-S1 Fusion (AxiaLif)
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Introduction: Pre-sacral minimally invasive spinal (MIS) L5-S1 fusion continues to emerge as an important treatment for disease of the lumbosacral spine. Disk height (DH) loss and distraction are important radiographic outcomes, and the authors present initial radiographic findings and discuss their implications in 26 patients.

Methods: Between June 2005 and January 2009, 26 patients were treated with MIS L5-S1 pre-sacral interbody fusion. There were 12 females and 14 males, with an average age of 48.7 yrs. The authors considered these radiographic parameters: anterior and posterior disc height (ADH, PDH) relative to endplate (% Farfan method), percentage increase or decrease of ADH or PDH following operation; DH relative to implant (% modified Farfan) at follow-up. Predictors of DH loss are reported and analyzed.

Results: Using a fixed end-plate length (Farfan method), average ADH distraction was 46.7% (range 26.9-144.0) and PDH distraction 4.1% (~30.0-69.4) in eleven patients. The increase in ADH was significant (p = 0.05, student’s t test). Inter-rater reliability was .95. DH loss of 15.9% (2.4-31.9) was observed in 22 patients at 7.44 months (range 2-11 months). In 16 patients with pedicle fixation, DH was 9.9% (range 2.6-17.9). In 8 with transfacet fixation, DH loss was 20.9% (12.6-31.9%), (p < 0.001). Smoking history, age, time, and degree of distraction did not predict disk height loss. Weight > 250 lbs was predictive with multiplicative analysis (p = 0.04). Inter-rater reliability was .87.

Conclusion: MIS pre-sacral fusion provides significant distraction of the anterior disk space. DH loss with time is similar to established approaches for interbody fusion. Preservation of post-operative DH may best preserved with pedicle screw fixation.

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A Study of the Effects of Screw Position on Load Transfer in and around a Lumbar Pedicle Screw Using Non-idealized FEA
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Introduction: Excessive stress concentrations in bone after screw fixation in the spine can lead to localized bone failure and screw loosening, which can lead to implant failures. Similarly, increased stresses on the screw can lead to screw breakage. Angulated screw insertion during fixation has been advocated as enhancing screw fixation strength because of increased axial pullout strength, especially in bone with poor bone quality. The objective with the current study was to investigate the optimal trajectory of pedicle screw placement in the lumbar spine using non-idealized series FE-modeling. The hypothesis was that there is an ideal pedicle screw orientation for a given patient.

Methods: Surface data of seven L4 lumbar vertebrae from human spines (mean age 54.6±15.9 yrs, 3 M, 4 F, mean L4 body volume: 65.1±10.9 cm3) were extracted from CT images (ScanIP, SimpleWare, Exeter, UK) and finite element models of L4 were constructed after a meshing process (ICEM, ANSYS, Canonsburg, PA). Loads of 500 N were applied to the proximal tip of a pedicle screw inserted into the left pedicle, simulating flexion, extension, right and left axial rotation. 9 different screw trajectories were compared: a combination of 3 angles in the axial plane (lateral, straight, medial) and 3 in the sagittal plane (superior, center, inferior, Fig. 1). The maximum equivalent stresses on the cortical bone, screw and cancellous bone during the four directions of loading were studied using the seven FE-models having the same material properties but different geometries. In addition, the effects of 6 vertebral geometries (vertebral body height, width, pedicle angle, pedicle width, total length of the screw path, and vertebral volume) on maximum stresses were studied. Statistical analysis was performed using one-way RM-ANOVA and Pearson product moment correlations.

Results: The greatest relative stresses occurred in cortical bone, followed by in the screw and cancellous bone. The maximum stresses varied the most with screw angle in cortical bone, followed by in the screw and cancellous bone. The greatest stresses occurred during flexion. Ignoring sagittal plane angulation, medial screw trajectories resulted in significantly greater stresses in cancellous bone than lateral screw trajectories. Ignoring axial plane angulation, superior trajectories resulted in similar stresses in cancellous bone as inferior screw trajectories. A given size screw will produce smaller cancellous bone stresses in a larger vertebra. Superior and lateral screw placement in a vertebra with a narrow pedicle will produce greater stresses on the screw.

Conclusions: The geometry of a vertebral body, including the pedicle, has an effect on the force distribution patterns during simulated loading of a pedicle screw in the lumbar spine. The effects of different screw trajectories are influenced by vertebral geometry, with generally larger vertebrae resulting in less cancellous stress for most screw trajectories. Bone quality aside, it is possible to assess which pedicle screw orientations for a given patient should minimize stresses.

[Fig. 1. Lateral view of L4 with angled screw.]
Multi-planar MIS lateral Lumbar Fusion Construct Stability Using a Combination of Lateral and Spinous Process Plating: Equivalence to Bilateral Pedicle Screw Fixation

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Introduction: Previous testing has shown the high biomechanical stability of the XLIF approach interbody cage alone compared with the intact spine. The 2-bolt lateral plate has been shown to add stiffness in lateral bending and axial rotation, but little change in flexion-extension. The stability offered by the spinous process plate should reduce motion in the flexion-extension plane, and therefore a combination of lateral and spinous process plates may increase stability in all directions; potentially to the extent of bilateral pedicle screws.

Methods: Ten spines (L1-L5) were subjected to multidirectional non-destructive flexibility testing. Each spine was tested under the following conditions: (1) intact, (2) L3-4 discectomy with interbody cage, (3) lateral plate, (4) lateral + spinous process plates, (5) spinous process plate, (6) ipsilateral pedicle screws, (7) bilateral pedicle screws. ROM was evaluated and normalized to intact. Differences were examined using repeated-measures ANOVA and Holm-Sidak comparisons.

Results: The interbody cage alone significantly reduced ROM in all directions with respect to intact. Bilateral screws provided the most rigid supplemental fixation. The lateral plate was not significantly different from the cage alone in flexion-extension, but was more rigid in lateral bending and axial rotation. The spinous process plate significantly improved flexion-extension rigidity over standalone, but was not significantly more rigid in lateral bending or axial rotation. The addition of the spinous process plate to the lateral plate combined to reduce motion in all planes, providing rigidity statistically equivalent to bilateral pedicle screws.

Conclusion: The lateral plate was significantly more rigid than the cage alone in lateral bending and axial rotation, while the spinous process plate was significantly more rigid in flexion-extension. The combination of both plates provided improved rigidity in all directions that was statistically equivalent to bilateral pedicle screws.

Significance: The clinical question is how much rigidity is necessary to prepare the best environment for interbody fusion. This study demonstrates the increased rigidity of supplemental fixation including the combination of lateral and spinous process plates.

Study design: Cadaveric biomechanical study. Objective: This study aims to evaluate effectiveness of the lateral cage + lateral plate fusion construct in the following ways:

a) Kinematic assessment of biomechanical stability across instrumented levels
b) Characterize cage migration (or motion) during representative cyclic loading

Materials and methods: Eight fresh frozen human cadaveric lumbar spines (L1-S1) were denuded of any musculature and were rigidly potted at L1 and S1. Specimens were subjected to incremental quasi static pure moment loading in flexion/extension (F/E) (with and without preload), right and left lateral bending (L/B) and axial rotation (A/R) up to 7.5 Nm. Specimens were instrumented with laterally placed cage + lateral plate at L3-L4 and L4-L5 levels. Kinematic signatures were recorded pre- and post-op using the Optotrak motion measurement system. Following post-op kinematic testing, each specimen was cyclically loaded on a biaxial testing machine for 2500 cycles in F/E (4.0 Nm + 400N follower load), L/B (2.0 Nm) and A/R (5.0 Nm) using specially designed fixtures. Custom designed rigid body markers were developed to firmly attach to the cage (laterally, opposite to plate fixation end) to continuously track cage motion along all three planes (anterior-posterior {A/P}, medial-lateral {M/L} and inferior-superior {I/S}) during each cyclic loading mode.

Results: Kinematic results across both instrumented levels (L3-L4 & L4-L5): Average F/E motion showed a significant decrease of 39% (pre-op: 10.9°; post-op: 6.7°; p = 0.0005). A/R showed a significant average decrease in motion of 48% (pre-op: 4.6°; post-op: 2.4°; p = 0.004). L/B motion recorded significant decrease of 57% (pre-op: 11.4°; post-op: 4.9°; p = 0.0001). F/E with 400N preload showed an average decrease in motion of 34% post-op, (pre-op: 6.8°; post-op: 4.5°; p = 0.087), but this was not significant.

Cage motion from cyclic loading data: Axial rotation showed largest cage motion in A/P compared to the I/S and M/L directions (1.51 mm, 0.51 mm and 0.73 mm respectively with p<0.006). Flex/Ext recorded maximum average motion in A/P compared to M/L directions and I/S directions (0.71 mm, 0.41 mm and 0.1 mm respectively with p<0.0033). Lateral bending recorded maximum average motion in M/L direction, however this not significantly higher than A/P or I/S motions (1.47 mm, 1.2 mm, 0.6 mm respectively).

Discussion and conclusion: Fusion constructs are designed to provide maximum stability to allow bone growth and complete fusion at instrumented levels. Up to 60-70% motion was still observed post-op across both instrumented levels (L3-L4 & L4-L5) for various loading modes along with quantifiable cage motion in various planes during cyclic loading. The results indicate that the lateral cage + lateral
plate fusion construct did not provide rigid fixation at the instrumented levels. To the author’s knowledge, this is a unique study that incorporates non-radiographic method to analyze cage motion. Further biomechanical studies should be performed to evaluate and compare different constructs in providing maximal stability and fixation.

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Hydrogel Barrier - An Alternative to PTFE in Preventing Adhesion Formation during Anterior Spine Surgery in a Sheep Lumbar Fusion Model
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Objective: Despite serious vascular complications that may arise, the anterior approach to the vertebral spinal column is often preferred when treating a variety of degenerative, dysmorphic or neoplastic conditions of the spine. In these procedures, access to the anterior lumbar spine is obtained using a trans or retroperitoneal exposure that requires mobilization of the aorta, vena cava and iliac vessels. Vascular complications as high as 5-10% have been reported. Revision spine surgery from the anterior approach is even more difficult due to extensive scar formation that prevents mobilization of the great vessels required to reach the affected levels of the spine. PTFE based adhesions barriers (Preclude®) have been used to prevent scarring of the great vessels during anterior spine surgery. In this study, a hydrogel cloth material EnGuard™ is evaluated as a potentially more effective barrier to prevent scar formation following anterior spine surgery.

Methods: A trans-retroperitoneal approach was made to expose the lumbar levels of the sheep spine. Interbody fusion at L2/L3 and L4/L5 levels of sheep (n=3) was performed using commercially available PEEK spacers (Synthes). At alternating levels within the same sheep, the fusion site was covered with Preclude® (Gore, Phoenix, AZ) or EnGuard® (Replication Medical, Inc., Cranbury, NJ) barrier materials. The sheep were humanely euthanized at 7 and 30 days. A force gage was used to measure the amount of force required to release the barrier sheets from the fusion site. Histology was performed to evaluate tissue response to the barrier materials.

Results: The EnGuard™ exhibited significantly less tissue attachment force than the Preclude®. The implant served as a physical barrier between tissue, preventing tissues from adhering to one another with no obvious degradation of the implants over the course of this study. 30 day implant pullout force of Preclude® was over four times greater than EnGuard™ (significant at p< 0.05).

A thin, but organized layer of cells was seen adjacent to the implant at three weeks and did not appear to change over time. Tissue between bone and the implant surfaces and muscles and the implant surface shows a thin layer of fibrous tissue adjacent to the hydrogel without penetration of cells into the hydrogel layer. Surrounding the hydrogel, a normal tissue response with minimal signs of inflammation was observed.

Conclusion: In this study, hydrogel sheet is an effective barrier to tissue ingrowth. The visible plane of dissection coupled with the presence of a thin layer of fibrous tissue suggest that it may be an effective barrier material for use in anterior spine surgery.

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Predicting anterior Column Load Transfer at Multiple Levels in the Thoracic Spine Using Surface Strains and Neural Networks Analysis
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Introduction: A previous technique of using surface strain data and neural networks analysis to assess load transfer across the posterior spinal column during in vitro loading has been incorporated into recent experiments. A new method was conceived in which strain gauges were used to assess anterior column load transfer in vitro. This new technique was used to assess load transfer simultaneously across two anterior thoracic bodies separated by a burst fracture. Such information is useful in understanding the effect on load transfer of different injuries and implants.

Methods: Seven T9-L1 human spine segments were potted and subjected to impact loading in a weight drop apparatus, creating burst fractures at T11 (verified by x-ray). A total of twenty uni-axial strain gauges were then attached just under the superior endplate of T12 (n=10) and above the inferior endplate on T10 (n=10). Changes in surface strain were recorded during flexibility testing (7.5 Nm flexion [FL],
right lateral bending [RLB] and left lateral bending [LLB]), upright posture with 70 N, 110 N and 150 N preloads, and during flexion with 70 N follower load. After testing, the T10 and T12 vertebral bodies were disarticulated and post-hoc calibration loads (25 to 400 N in axial compression) were applied at defined points on a plate positioned across the inferior end plate of T10 and superior end plate of T12, respectively. Silicone rubber (Dow Corning 3110 RTV) was molded to fit between each endplate and the metal plate used for load application, to ensure even load distributions during calibration. Computational models were created using experimental surface strain data recorded during calibration and neural networks analysis software (Predict by Neuralware), and used to assess load transfer (magnitude and load location points) across the inferior T10 and superior T12 endplates that had occurred during experimental testing. Data were analyzed using one-way RM ANOVA/Holm-Sidak with P< 0.05 considered significant.

Results: Mean compressive loads were greater across the T12 superior endplate vs. the T10 inferior endplate during all loading configurations (Fig. 1). Load location points did not vary between levels during flexion (with or without preload) in anteroposterior or mediolateral directions, or during lateral bending in the anteroposterior direction. However, location shifted mediolaterally during lateral bending, following the direction of bending, with a greater magnitude at T10 (P=0.009) vs. at T12 (P=0.2). Conclusions: The difference in load transfer across T10 and T12 may be related to the induced burst fracture injury at T11 and/or differences in orientation of T10 and T12 relative to the loading vector due to kyphosis. The method of using anterior strain and neural networks analysis to assess load transfer across multiple spinal levels, requiring no cutting into tissue to insert sensors (which could alter important load transfer patterns), shows great promise and has possible applications for a wide range of adjacent level load transfer studies.

![Graph showing mean body loads](image)

**Objective:** The terminal screws in long posterior fixation constructs have an increased risk of failure due to excessive loads but there is a paucity of information describing the load magnitudes. Pedicle screw loads have been quantified previously but these studies have not attempted to determine the orientation of these loads. The objective of this study was to describe the orientation of bending moments acting on the S1 screws during simulated physiologic loading.

**Methods:** Six L2-pelvis lumbar spine specimens were obtained, carefully dissected and potted. Specimens were tested in four instrumentation states: 1) posterior fixation with pedicle screws from L2-S1 (PS), 2) iliac screws + PS, 3) AxiaLIF + PS and 4) ALIF + PS.

Pure moments were applied at ±7.5 Nm in each anatomic plane with no compressive preload. The S1 pedicle screws were instrumented to directly measure biplanar screw bending by positioning strain gages in two independent half bridge configurations. Screws were individually calibrated to measure bending in Nm. The orthogonal strain gaged surfaces of the S1 screws were carefully aligned with the anatomic planes of the spine by rotating the screws until an alignment pin was parallel to the spinous processes. The signs of the two strain channels were compared to determine the quadrant in the coordinate plane that the screw bending moment vector occupied and the angle was calculated using arctangent equations. Calculations were only performed at the peak applied moments.

**Results:** The S1 screw bending moment vectors were oriented in the cranial direction for flexion with small deviations from the vertical axis for pedicle screws and ALIF + PS (< 9°) and larger variations for AxiaLIF + PS and iliac screws + PS (up to 51°). Similar results were observed in extension but the bending direction vectors were oriented caudally. Axial torsion exhibited the most consistent orientation of the bending moment vectors. In right torsion, the left screw bending moment vector was oriented diagonally in the lateral/cephalad direction while the right screw vector was oriented in the caudal/medial direction. The directions of the vectors were consistent with high bending moment magnitudes (>0.4 Nm) but displayed a large degree of variability with small magnitudes.

**Questions?** (866) 423-9440 (U.S.) +1(630) 995-9994 (Int’l)
Conclusion: Long posterior fixation is oriented parallel to the long axis of the spine, which may lead to the incorrect assumption that all forces also occur in this direction. While true for flexion-extension, the spine is typically subjected to loads that are significantly more complex during the activities of daily living. These data therefore suggest that the loosening and potential failure of the caudal-most screws in a long fusion construct are the result of multi-planar loads being transferred to the screw via the fusion rods.

65 Effect of New Dynamic Stabilization System on the Segmental Motion and Intradiscal Pressure

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Introduction: Dynamic posterior stabilization is an alternative to fusion in the treatment of lumbar degenerative diseases. The aims of such techniques are to preserve motion at the joint and restore normal segmental kinetics to the spine. The purpose of this in vitro study was to analyze the influence of new lumbar posterior dynamic stabilisation device (PDSD) on lumbar intersegmental range of motion (ROM) in all the three motion planes, and intradiscal pressure (IDP) in flexion-extension.

Methods: Seven fresh frozen lumbar cadaveric spines (L3-S1) were extracted with intact discoligamentous complexes. The specimens were loaded in a spine tester (pure moments of ± 10Nm - steps of 1Nm) in all the three principal motion planes. Four situations were studied: Intact, Instrumented, Injured plus instrumentation, Injured. Injury performed included a section of supra and interspinous ligaments, ligamentum flavum, resection of the lower portion of the overlying lamina and upper portion of the underlying lamina. The implant has three rigid titanium alloy elements: a movable piston rod and a fixed attached to the spine by a pedicle screw, a hollow cylindrical body containing two viscoelastic silicone implants. L4-L5 functional unit ROM was recorded using a three-dimensional opto-electronic based motion analysis system (Polaris™). EOS® low dose stereoradiography was performed before testing for three-dimensional reconstruction.

Three miniature pressure transducers were placed and secured in the intervertebral disc space of L4-L5 (anterior annulus:AA, nucleus pulposus:NP, posterior annulus:PA). Amplified ODP were recorded synchronously. Wilcoxon matched-pairs signed rank tests were run to assess significant differences between the four tested conditions. Statistical results at p< 0,05 were considered significant.

Results: The mean ROM was 9.9± 2.8 (5.9-14) in flexion-extension (FE), 8.3±1.7° (5.5-10.4) in lateral bending (LB) and 6.3°±1.2 (4.4-7.8°) in axial rotation (AR). Additional implantation of the system led to a significant reduction in ROM compared to the intact spine: 17% in FE (p=0,009), 23.4% in LB (p=0,009) and 13.6% in AR (p=0,02). Injury led to a significant increase in ROM compared to the intact spine:39.4% in FE(p=0,014), 12.6% in LB (p=0,009) and 16.4% in AR (p=0,009). Injury and dynamic stabilization led to a decrease in ROM compared to the intact spine: 9.7% in FE (p=0,054), 17.1% in LB (p=0,009) and 5.2% in AR (p=0,155).

In extension, IDP significantly decreased in the AA (-24.81% p=0,045) and in the NP (-20.91% p=0,022) for instrumented spine. IDP significantly decreased in the AA (-24.81% p=0,045) and in the NP (-20.0% p=0,022) for injured spine plus instrumentation.

Discussion: The PDSD allowed segment stabilization in all three motion planes. The influence of dynamic stabilization system seems to depend on the biomechanical characteristics of the implant itself. Pressure measurements were here performed in three different disc locations, which provided complementary information compared to most in vitro studies where pressure changes are evaluated in the nucleus only. Load sharing with the intervertebral disc after implantation was found primarily in the neutral position and in extension.
Oral Posters: MIS, Navigation, Deformity

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Changes in Neuroforaminal Dimensions with 2 Level Axial Lumbar Interbody Fusion at L4-S1 with Graduated Distraction through the Implant
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Aims: Paracoccygeal approach to L4-S1 levels with transsacral instrumentation is a recent development. The design of the 2 level transsacral implant can theoretically allow distraction of the disc space and the neuroforamen utilizing a differential thread pitch at L4-L5 and manual distraction at L5-S1. The purpose of this study was to examine the changes in neuroforaminal height at L4-L5 and L5-S1 after insertion and graduated foraminal distraction using the 2 level transsacral implant.

Methods: Six fresh human cadaveric lumbar spines were harvested keeping the soft tissues intact. The discectomy and insertion of the transsacral implant was performed through the presacral space via a working channel formed by passing a series of reamers over a guide wire. Radial disc debulkers, tissue extractors and rasps were used for discectomy. The implant was a 2 piece assembly that consisted of the L4-L5 and sacral segment lagged together by a distraction rod. The pitch differential between L4 and L5 components distracted the L4-L5 disc space, while the L5-S1 disc space was manually distracted by the driver, which engages the distraction rod. The distraction rod was designed to rotate in the L4-L5 segment while the sacral segment acted as an anchor. Distraction was carried out by rotating the screw driver through half a rotation at a time. B/L neuroforaminal heights at L4-L5 and L5-S1 were measured preoperatively and then at every half rotation of the driver using a manual caliper. Distraction was continued until either the driver lost resistance or the implant was seen backing out at the sacrum.

Results: Mean L4-5 neuroforaminal height increased from 18.2 ± 3.1mm to 20.3± 2.9mm on the left and from 18.8±2.8mm to 20.6± 2.3mm on the right (P< 0.05). Mean L5-S1 neuroforaminal height increased from 15.7±3.0mm to 18.4 ±2.8mm on the left and from 15.6 ±2.1mm to 18.3 ±1.8mm on the right (P< 0.05). Figure 1 shows the increase in neuroforaminal height at L5-S1 as the disc space is distracted. The slope was significantly greater than zero with approximately 1mm/revolution of the driver. Maximum distraction occurred between 2-3.5 revolutions of the driver.

Conclusion: In this in vitro model, the two level transsacral implant caused a significant increase in the neuroforaminal heights at L4-L5 and L5-S1. Graduated manual distraction was possible at L5-S1 with an average of 1mm neuroforaminal distraction per revolution allowed for the first 2 revolutions. On further distraction, the transsacral screw can start loosing purchase. The ability and the limit of L5-S1 distraction, especially beyond the first 2 revolutions of distraction, can be difficult to predict based on variables like bone quality and disc space pliability. Clinical effect of neuroforaminal distraction with this implant is still to be determined.

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Clinical Evaluation of Open and MAS® TLIF for the Treatment of Symptomatic Lumbar Degenerative Conditions
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Introduction: Minimally invasive spine procedures have been shown to result in a faster patient recovery with lower patient morbidity rates but are often associated with difficult learning curves and initial increases in procedure times before the new technique is mastered. This study prospectively compares one surgeon’s usual open TLIF procedure with an early MAS TLIF experience to identify evidence of learning curve during adoption of a less invasive technique.

Methods: The operative data of 20 consecutive TLIF cases were prospectively documented. Nine open TLIF cases were completed by a surgeon with extensive open TLIF experience, followed by the same surgeon’s first 11 MAS TLIF cases. Surgical statistics and perioperative data was evaluated for evidence of learning hurdles during adoption of the new surgical technique.

Results: 9 patients (78% female) were treated at 13 levels in the open group. 11 patients (64% female) were treated at 11 levels in the MAS group, difference in number of levels treated between groups was not statistically significant (p=0.056). Patient age in the open group ranged from 35 to 85 with a median of 62 years. Age ranged from 30 to 69 in the MAS group with a median of 61 years. Operative time averaged 120.1 minutes for open procedures and 106.5 minutes for MAS cases. Length of hospital stay averaged 3.7 days for open procedures and 2.8 days for MAS procedures. 66.7% of Open patients and 100% of MAS
patients experienced less than 100cc of blood loss. The remaining 33.3% of patients in the open group had blood loss between 100 and 300cc. Differences in blood loss between technique groups was not statistically significant (p=0.054). Complications included two instances of wound dehiscence in the MAS TLIF group and one instance of wound dehiscence and a dural tear in the open TLIF group.

**Conclusion:** Results tended toward decreased blood loss, shorter procedure time, shorter hospital stay, and fewer approach related complications for the minimally invasive procedures in comparison to traditional open procedures, with no evidence of a learning curve during adoption of the MAS technique.

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**Reduction in Radiation (Fluoroscopy) while Maintaining Safe Placement of Pedicle Screws during Lumbar Spine Fusion**

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**Aims:** Reports of pedicle screw placement in the lumbar spine have shown medial pedicle perforations with nerve root impingement in addition to lateral pedicle and vertebral body perforations that can impinge the nerve root within the psoas. Routine use of fluoroscopy is thought to reduce the risk of perforations but is associated with increased radiation to both patient and cumulatively to the surgeon. A new pedicle drilling device (PediGuard®) which uses electrical conductivity differentiation at the tip for assessing bone versus soft tissue has been developed to improve the safe positioning of pedicle screws. This device not only warns of impending medial breach but is the only device available to detect lateral breach. The purpose of this prospective randomized, controlled study is to report the results of using the PediGuard device to reduce radiation exposure while drilling the pilot hole for pedicle screw placement.

**Methods:** 18 patients with a diagnosis of lumbar degenerative spine having a posterior spinal fusion (all by the principal investigator [C.D.C.]) were enrolled in the study. The average age of the patients was 55 ± 12 years. Postoperatively, all patients had a CT scan of all screws placed. These scans were reviewed by an independent reviewer (A.F.S). Screws were considered ‘in’ (< 2 mm of breach [considered clinically insignificant]), or ‘out’ (≥ 2 mm of breach [possibly clinically significant]).

In a randomized fashion, the surgeon inserted the titanium screws in his standard fashion. EMG testing was not done by the surgeon (C.D.C.). A total of 78 screws (39 via standard probe and 39 with PediGuard assist) were analyzed.

<table>
<thead>
<tr>
<th></th>
<th>In (or &lt; 2mm breach)</th>
<th>Out (or ≥ 2mm breach)</th>
<th># Fluoro shots</th>
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<tbody>
<tr>
<td>Standard manual technique (N=39)</td>
<td>38 (97.5%)</td>
<td>1 (2.5%)</td>
<td>7.5 ± 2.0</td>
</tr>
<tr>
<td>PediGuard technique (N=39)</td>
<td>38 (97.5%)</td>
<td>1 (2.5%)</td>
<td>2.3 ± 0.5</td>
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**Results:**

There was no significant difference in breach rate ≥ 2mm by either of the two methods (p = 1.000), with only one screw out in each group. Fluoroscopy shots averaged 5.2 (range, 0 to 15) per screw in the PediGuard group vs. 7.5 (range, 2 to 17) in the standard group (p < .001). This represents an average decrease of 2.3 (30%) fluoroscopy shots per screw with PediGuard. There were 202 total fluoroscopy shots used in the PediGuard group vs. 293 in the standard group.

**Conclusions:** In this prospective, randomized trial of a pedicle drilling device that uses electrical conductivity differentiation at the tip for assessing bone versus soft tissue, the number of fluoroscopy shots was reduced by 30% as compared to a standard drilling probe while maintaining a 97.5% accurate, safe screw placement.

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**Minimally Invasive Treatment of Adult Scoliosis with XLIF: Radiographic Outcomes and Predictors from a Prospective Multicenter Study**

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**Background:** Surgical intervention of adult scoliosis has traditionally been performed using large open anterior and/or posterior procedures to improve spinal alignment and effect neural decompression. This report summarizes the early radiographic outcomes of a minimally invasive approach (XLIF) for the treatment of adult scoliosis as part of an ongoing prospective non-randomized study.

**Methods:** 107 patients were treated for adult scoliosis with XLIF at 14 US IRB-approved centers. Radiographs and clinical outcomes were collected preoperatively and postoperatively at 2 weeks, 3, 6, 12, and 24 months; however, this report details short-term results (up to 3 months) only as the study progresses in follow-up. Radiographic measures included lumbar lordosis (L1 to S1), coronal Cobb angle, device subsidence/migration, anterior and posterior disc height, listhesis, and coronal and sagittal balance. To minimize the effects of radiographic magnification all linear measures were collected as a ratio of a reference endplate or vertebral body height, and reported as a percentage change.

**Results:** Measures were collected from 93 patients (74.2% female, 11.1% smokers) between 48 and 87 years old treated at 280 levels from T11 to L5. Up to 6 levels were treated. Average BMI was 28.4 kg/m². Supplemental fixation included pedicle screws and/or lateral plating; bilateral pedicle screws (59.3%), unilateral pedicle screws (23.3%), and anterolateral plating (4.4%); 16.1% of levels were stand-alone. Radiographic measures are reported in Table 1. At baseline, 42 patients were hypolordotic (> 40°) with an average lumbar lordosis of -24.74° (range: 0 to -40°). Hypolordosis in these patients was significantly corrected to an average of -38.2° at post-op (p < 0.001). Cobb angle was corrected by 40% from baseline to post-op (p < 0.001). Spondylo/retrolisthesis was significantly
reduced from an average baseline magnitude of 7.3% to a post-op magnitude of 6.0% (p=0.002). All corrections were maintained at 3 months (p>0.05).

Coronal Cobb correction was significantly affected by supplemental fixation (p=0.002), with the greatest corrections achieved in patients with bilateral posterior pedicle fixation and the least achieved in patients with no supplemental fixation (11.7° vs. < 1°). Incidence of subsidence was 5.4% at post-op and 26.2% at 3 months. Subsidence at 3 months was significantly affected by supplemental fixation (c², p=0.008), with the highest rate of subsidence in segments with no supplemental fixation (55.6%). No segments required revision for subsidence. There were no reports of implant migration.

**Conclusion:** Using XLIF in the treatment of adult scoliosis, significant reduction in coronal and sagittal plane deformity was achieved and maintained through the three-month evaluation. Supplemental posterior fixation (placed open or percutaneously) optimized deformity correction and reduced subsidence and is recommended in this patient population.

![Table 1](image)

### 112 Percutaneous Pedicle Screw and Rod Fixation with Minimally Invasive Lumbar Interbody Fusion in Recurrent Lumbar Disc Herniation - Long Term Follow up of a Consecutive Series of 14 Patients

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**Introduction:** Same-level recurrent lumbar disc herniation complicates outcome after primary discectomy in a subset of patients, occurs in 10% of patients and is associated with substantial health care costs. Study results reveal operation induced destabilisation due to necessary resection of spinal canal structures without using minimal invasive procedures if possible. We present the clinical characteristics, the long term follow up including new X-ray and CT Scans of the lumbar spine and the neurological status of 14 consecutive patients treated with percutaneous pedicle screw and rod fixation with minimally invasive lumbar interbody fusion in recurrent lumbar disc herniation and Modic type I or II erosive osteochondrosis.

**Patients and methods:** We reviewed the charts, patient records, X-Ray, CT-scan and MRI of the lumbar spine, operative reports and clinical notes of our patients with recurrent lumbar disc herniations and erosive osteochondrosis between 2007 and 2010 and obtained the late follow up with a clinical questionnaire and neurological examination (VAS, Oswestry Disability Index, MacNab criteria) within the spine unit and carried out new X-Ray and or CT Scan of the lumbar spine. Data collection was completed in n=14 of 14 operated patients (median follow up: 3 months; 3-30 months; mean age 54 years; 44-60 y; 6 female and 8 male; at least 2nd recurrent herniation of lumbar disc). Clinical and radiographic assessment using standard scales was acquired prospectively in pre-defined time intervals (VAS, Oswestry-Score, MacNab criteria).

**Results:** 14 patients (6 female, 8 male) with a mean age at presentation of 54 years (range 40-60) have undergone single level percutaneous pedicle screw and rod insertion and minimally invasive lumbar interbody fusion L4/L5 or L5/S1 at our institution between 2007 and 2010. Median operation time: 190 min (150 - 230 min), with an average X-ray exposure time of 3.35 min (1.5 to 5.5 min). Blood loss was in median 150 ml (120 - 370 ml). Median postoperative resting time in hospital was 7 days (5-12). Significant postoperative pain relief and mobility improvement could be documented with the VAS (69 to 30) and the Oswestry Disability Index (68% to 24%). All patients had significant benefit from surgery at follow up. No patient had to undergo reoperation.

**Conclusion:** Dorsal open approaches are most often used for the fixation of the lumbar spine, even in the situation of recurrent disc herniation in combination with erosive osteochondrosis. This technique often causes significant trauma to soft tissue structures as well as to spinal ligaments and the nerves, carries a higher morbidity rate and results in bleeding and later functional disturbances. Percutaneous Pedicle Screw and Rod Fixation with minimally invasive lumbar interbody fusion is a gentle, soft tissue, nerve protecting and safe procedure for lumbar fixation with a good stabilizing effect and fusion rates comparable to conventional more invasive techniques. The invasivity of this procedure is less compared to the classic spondylodesis combined with the opportunity, to protect the scarred nerve root.
Posterior MIS Treatment of Thoraco-lumbar Spinal Neoplasms

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Introduction: The treatment of patients with neoplasms affecting the axial spine, both benign and malignant, can be approached in a variety of ways, each with its own risks and benefits. In an effort to reduce patient morbidity, blood loss and hospital length of stay, we have employed several posterior less-invasive techniques to decompress and stabilize the thoraco-lumbar spine in patients with a variety of spinal neoplasms.

Methods: The author has retrospectively reviewed the charts of 28 patients treated with one of three posterior less invasive methods (MIS) of decompression including: micro-tubular decompressive laminectomy and facetectomy, micro-tubular transpedicular partial or complete corpectomy, or micro-tubular costo-transverse partial or complete corpectomy. In these patients anterior column reconstruction was performed, where necessary, using either Polymethylmethacrylate (PMMA) or VBR cage insertion. Three-column fixation was performed using percutaneous pedicle screw insertion and augmented with PMMA where indicated. Results were compared with a separate cohort of patients treated with “open” posterior decompression and stabilization procedures.

Results: The mean age of the MIS group was 54 years as compared to 47.5 years of the “open” group. A variety of disparate pathologies were treated including benign (schwannoma, neurofibroma, meningioma, giant cell tumor), and malignant (breast, prostate, GI, renal cell, and thyroid metastases, multiple myeloma and sarcoma) tumors. All lesions resulted in preoperative pain and neurological deficits. There were no cases of new postoperative neurological deficits; deficit stabilization or improvement was seen in all patients. There was one case of hardware failure in each group, requiring reoperation within one month postoperatively. The mean postoperative length of stay was significantly less in the MIS group (3 days) as compared to the “open” group (9.4 days). Additionally, mean blood loss was significantly less in the MIS as compared to “open” group, 736 cc’s vs. 2500 cc’s, respectively.

Conclusions: Posterior less invasive techniques of decompression and stabilization of the thoraco-lumbar spine should be considered as a treatment option for patients with both benign and malignant neoplasms involving the spine. Length of hospitalization and blood loss is significantly less in the MIS as compared to open group.
of patients who underwent the XLIF procedure for the treatment of degenerative scoliosis, perioperative measures were compiled to identify the short-term outcomes of the procedure. Intraoperative data collection included surgical details, operative time, estimated blood loss, and complications. Postoperative complications, length of hospital stay, and neurological status were recorded.

**Results:** 107 patients (mean age 68 years; range 45-87) were treated with XLIF. 28% had at least one comorbidity. A mean of 4.4 levels/patient (range 1-9) were treated. Supplemental pedicle screw fixation was used in 75.7% of patients, 5.6% had lateral fixation and 18.7% had standalone XLIF. Mean operative time and blood loss were 178 min and 50–100 cc. Mean hospital stay was 2.9 days (unstaged), 8.1 days (staged; 16.5%), 3.8 days overall. 5 patients (4.7%) received a transfusion, 3 (2.8%) required ICU admission, 1 (0.9%) required rehabilitation services. Major complications occurred in 13 patients (12.1%): 2 (1.9%) medical, 12 (11.2%) surgical. Of procedures that involved only less invasive techniques (XLIF standalone or with percutaneous instrumentation), 9.0% had one or more major complications. In those with supplemental open posterior instrumentation, 20.7% had one or more major complications. Early reoperations (3, for deep wound infections) were associated with open posterior instrumentation.

**Conclusion:** The morbidity in adult scoliosis surgery is minimized with less invasive techniques. The rate of major complications in this study (12.1%) compares favorably to reports from other studies of surgery for degenerative deformity.

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**The Effectiveness of Universal Clamps in Controlling Coronal and Sagittal Profile in Surgical Correction of Neurological Scoliosis**

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Spinal surgery in patients affected by neurological scoliosis is associated with increased bleeding, less satisfactory bone stock, longer fusions, and the necessity for fusion to the pelvis. The goal of treatment is to maintain a spine balanced in the coronal and sagittal planes over a level pelvis. Because hybrid constructs are associated with lower risk of complications and better sagittal correction, in our study we used a construct combining lumbar transpedicular screws and thoracic Universal Clamps (UC). The aim of our study is to assess the validity of the hybrid construct respect to deformity correction and restoring thoracic kyphosis in a prospective series of patients affected by neurological scoliosis. Between 2007 and 2010 we treated 92 patients affected by neurological scoliosis (65 F, 27 M). The aetiology was mostly cerebral palsy. The mean pre-operative Cobb angle was 96°±25°, while the mean pre-operative thoracic kyphosis was 19°±8° (ranging from -15° to 62°). In all cases we performed a posterior approach only. In our construct we use a mean of six lumbar pedicle screws, seven thoracic UC, five hooks at the upper end of the curve, one or two iliac screws in case of pelvic obliquity greater than 20%, one or two rods on the concave side, one rod on the convex side and one iliac dedicated rod. In 3 patients a second posterior surgery was scheduled 15 days apart in order to strengthen the effect obtained by concave ribs section by adding several UC, thus treating a rigid thoracic deformity. Mean operative time was 240 ± 30 minutes in one step surgery (plus 120 ± 30 minutes in staged-surgery) with a mean blood loss of 1200 ± 400 ml. Mean radiation exposure time was 6 seconds (range 4.5-7). The mean post-operative Cobb angle was 22°±17° (average percentage of correction of 77±9% in the coronal plane), whereas the mean post-operative thoracic kyphosis was 26°±6° (average percentage of correction of 40±6% in the sagittal plane). In particular, the percentage of correction in cases with thoracic lordosis was about 120%. In patients with pre-operative kyphosis between 30° and 40°, physiological values were maintained. Furthermore, normal kyphosis was achieved in patients with pre-operative hyperkyphosis (>40°). At 36-months follow-up the average loss of correction was 7°±2° in the coronal plane and 2°±1° in the sagittal plane. Minor complications (pneumothorax, pleural effusion, atelectasia, intestinal disorders) occurred in 22 patients (24%), while major complications (infections, pseudarthrosis, rods breakage, iliac screw stress shielding, UC slippage, lamina breakage, dural leaks) was recorded in 9 patients (10%). The hybrid construct appears safe and effective in the treatment of neurological scoliosis, providing a good correction of the deformity and reducing operative time, radiation exposure and blood loss respect to all-screws constructs. The amount of coronal correction is excellent and the control of sagittal profile, in our experience, is better than with all-screws assembly. Moreover, the deformity reduction technique using the UC, progressively translating the spine toward the rods in the sagittal plane, has proved to be effective in controlling sagittal profile in patients affected by neurological scoliosis.

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**Do Intra-operative Antifibrinolytics Reduce Blood Loss in Adolescent Idiopathic Scoliosis? A Prospective Randomized Comparison**

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**Summary:** The benefit of the routine use of antifibrinolytics during spinal fusion surgery for AIS is unclear. We found a significant reduction in blood loss but not transfusion rate with antifibrinolytics compared with placebo. TXA, but not EACA, is effective in reducing post-operative drain output as well.

**Background:** Antifibrinolytics are known to reduce blood loss. However, the benefit of using these medications for patients with Adolescent Idiopathic Scoliosis (AIS) is unclear. No study has compared tranexamic acid (TXA), epsilon aminocaproic acid (EACA), and placebo to directly assess blood loss, drain output, and transfusion rate in a prospective randomized study.
Methods: This is a prospective, randomized, double blinded comparison of TXA, EACA and placebo used intra-operatively in patients with AIS. 74 patients with AIS were randomly assigned to one of the treatment arms or the placebo group. TXA was administered at 10mg/ kg for a loading dose followed by 1mg/kg-hr, while EACA was given at a 10 fold higher dose. The physicians, patients, and researchers were blinded to the patient’s treatment designation. Estimated blood loss (EBL), pre, intra and post-operative hematocrit, blood product usage, and post-operative drain output were recorded. An ANOVA with Tukey’s post hoc analysis was used to compare groups. No pharmaceutical funding was received for this study.

Results: AIS patients received TXA (n=18), EACA (n=21), or saline (n=35) in the operating room (57F, 17M, mean age 15, range 11-21). Average blood loss with TXA (607 ± 545ml) or EACA (671 ± 517ml) was less than placebo (1038 ± 880ml) (p<0.05). Total drain output was decreased with TXA (684 ± 355ml), but not EACA (1,161 ± 549ml), compared to Saline (1,125 ± 479ml) (p<0.05). Similarly, total blood loss was reduced with TXA (1329 ± 567ml), but not EACA (1863 ± 857ml), compared to Saline (2,126 ± 1,187ml) (p<0.05). There was no difference in the number of units transfused, duration of surgery, and hematocrit during surgery when comparing the three treatment arms. EACA may prevent a post-operative decrease in hematocrit compared to Saline (p = 0.06). There were no thromboembolic, renal, or major wound complications.

Conclusions: We report that antifibrinolytic treatment reduces blood loss but not transfusion rate in AIS. Total drain output and total blood loss were reduced with TXA, but not EACA, compared to Saline. Both treatment options were equivalent in terms of intra-operative blood loss.

Significance: Our study provided level-one data comparing TXA, EACA, and placebo in AIS.

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Impact of Upper Fusion Level on Outcome in the Setting of Adult Spinal Deformity: Effectiveness of the Clinical Impact Classification in Guiding Treatment
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Introduction: Adult spinal deformity (ASD) is complex due to the range of deformity patterns and clinical presentation. The ASD Classification (Schwab & al) permits a relevant description of patients based upon health related quality of life measures but outcomes based upon fusion level (upper instrumented vertebra: UIV) by Classification has not been reported. The purpose was to determine if the ASD Classification is effective in guiding selection of the UIV.

Method: This is a retrospective review of a multicenter ASD prospective database. The study included 1071 patients, 166 male and 903 female, (mean age 59.6yo, SD=12) with minimum 1-y follow-up. Inclusion criteria were long fusion with lower instrumented level of L5 or S1 and UIV of L1 or above. Patients were classified according to: ASD Classification, UIV and outcomes measures. An analysis of variance was applied to detect differences between groups based upon outcomes changes for the following UIV groups: T1-3, T4-6, T9-11, T12-L1.

Results: Distribution by UIV was: T1-3 n=206, T4-6 n=242, T9-11 n=466, T12-L1 n=157. No significant difference was noted in terms of global balance or lumbar lordosis modifiers across UIV groups. By SF-12, SRS pain and SRS activity scores, the T1-3 UIV demonstrated the least improvement. By SRS mental score T12-L1 UIV had greater improvement than T1-3 and T9-11 groups. For patients with marked sagittal malalignment, T4-6 UIV showed greater improvement than other UIV groups. The T9-11 UIV group never outperformed all other UIV groups for any of the Classification categories

Conclusion: In this large multi-center prospective study, the application of the ASD Classification demonstrates significant differences in HRQOL outcomes by proximal fusion level for long fusions. These findings lay an important foundation for the development of treatment algorithms for surgical planning. The T1-3 UIV group fared worst in this study. The T4-6 UIV offers best outcomes when marked sagittal malalignment is present. The T9-11 UIV was never the best in terms of outcome for any of the Classification groups. Ending fusion in the thoracolumbar junction leads to favorable SRS mental component scores for patients without significant malalignment.

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A prospective, Randomized, Controlled Clinical Trial for the Evaluation of a Laser Navigation System (LNS) Used in Computed Tomography Guided Lumbar Spinal Interventions
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Background: For successful spinal intervention procedures detailed anatomical information and precise placement and guidance of the needles are pivotal. A novel Laser Navigation System (LNS) was developed to provide an exact needle route planning tool. In a preliminary interventional spine phantom study and consecutive clinical trial the LNS was now employed during computed tomography-guided perineural steroid injections in patients with chronic lumbar radiculopathies.

Methods: In a prospective, randomized, controlled trial 30 patients with chronic lumbar radiculopathy were treated with CT-guided perineural steroid injections. Each patient received two treatments. At a first appointment the patients were treated with a conventional freehand CT-guided injection (method A), whereas at a second treatment date patients received a LNS-assisted CT-guided injection (method B) or vice versa. Needle position adjustments and number of CT scans were exclusively conducted in accordance to individual medical needs. During method A, the intervention was planned at the CT workstation monitor plotting the path of the probe and marker distance. The needle entry point on the skin of the patient was determined via CT gantry laser
and distance measurement. The exact entrance angle of the probe relies on the physician’s degree of experience and stepwise approach to the target area was assured by consecutive scans. Using method B, the needle path was also planned and plotted on the CT monitor. The LNS transferred the planned entrance route and needle angle via a visible laser beam on the patient’s skin and the physician now aligned and inserted the probe according to the beam. The results of both methods were analyzed using the DICOM-image viewing software JiveX (Visus, Bochum).

Results: Using the new LNS prototype, intervention precision could be improved (each p< 0,0001 comparing planned and actual penetration point as well as planned and actual needle angle in both groups). In 9 out of 10 cases the needle at was positioned using the LNS at first go, therefore reducing risks of unintended punctures, pain and radiation exposure (p < 0,0004 comparing number of control scans necessary until final needle position).

LNS also accelerated the workflow by increased speed and improved predictability of the therapeutic process (p < 0,006 for the comparison of the time difference between planning screen and image with placed needle).

Conclusion: LNS is a promising and intuitive new technology for CTD guided percutaneous interventions. An experienced medical team could work significantly faster, safer, and patient-friendly with LNS. It is likely that particularly less experienced specialists and MTRA will benefit from this innovation. Ongoing evaluations will examine the suitability of any axial interventions.

Introduction: The fractures and DDD of the upper thoracic spine are extremely rare and only publishable as case reports. The classic approaches to the cervico-thoracic junction and upper thoracic spine are anterior midline approaches like Smith-Robinson, Field, Nazarro, Binet and others. They are very invasive with high damage of tissue and classic open ones. The remained and well-known problems beside tissue damage are to reach target to T3 and T4 and below. Therefore the indication for dorsoventral instrumentation even in instable B- and C-type fractures are decreased to pure posterior instrumentation.

Purpose: The purpose of this investigation is to show, that the new approach to T1-T5 is endoscopic possible, as a standardized approach technique with a low complication rate.

Methods: 11 patients of one center are retrospectively enrolled in 10 years with instable fractures between C7 - T5. They have been operated by one specialized endoscopic surgeon. All patients showed B- or C-type fractures (AO-classification of Magerl, Aebi M. et al. 1994). All of them underwent CT - scanning after 6-12 months and clinical follow-up, analyzing general complication rate, approach related morbidity and neurological follow-up. The CT-scan with 2D-reconstruction in sagittal, coronal and transversal plane analyzes the control of fusion to strut graft and rate of correction losses.

Results: 11 patients were collected since 2000 to 2009 with mono-bi-tetra segmental fractures as B-/C-type fractures. No A-type fracture was treated anterior. 10 patients underwent purely the high transaxillary endoscopic approach (HTEA). 1 patient with etage-fractures between C7 - T4 afforded a combined approach of HTEA with Smith-Robinson approach for fusion C6 - T5 in one session. All patients underwent acute posterior instrumentation. One temporary lesion of long thoracic nerve was found with complete remission. No other complication was found esp. no lesion of brachial plexus or frozen shoulder. The fusion rate in CT-scan 2D was 100%. The positioning of patient and OR-performance were standardized. The morbidity of iliac crest belonged to 17,5%. No general complication occurred.

Discussion/conclusion: The new approach affords a special positioning of patient in lateral decubitus positioning with an anteflected-abducted shoulder as a 4 point fixation. The prerequisite is a normal ROM of shoulder. The approach is a lateral intercostal endoscopic approach regarding the thoraco-dorsal vessels and long thoracic nerve. There is no damage of bone or vessel necessary to reach the target area of T1-T5. Other classic approaches afford diverse osteomies of clavicle, sternum or ribs to reach the spine. Nevertheless they are classic open approaches and the oppersite of Minimal-Invasive-surgery. Especially the combination of the new approach with extended Smith-Robinson for fusion of C6 - T5 showed the correct, standardized and suitable solution to a difficult etage-fracture of cervico-thoracic junction and upper thoracic spine.

The new approach is completely a diverse approach to classic ones as anterior midline approaches and performed firstly in 2000 by author. It is a good alternative approach for treatment of fractures and DDD in T1 - T5 spine.
The extract medium was prepared by immersing sterilized basalt fibers in DMEM, with surface-to-liquid ratio of 1 cm²/ml for 72 h at 37°C. The fibroblasts were seeded into 96-well plates at a density of 4x10³ cells/well and incubated in 5% CO₂, 37°C. After 24 hours, in 50% of the cells the medium was replaced with basalt fiber extracts medium, while the remaining cells were cultured in DMEM as a control. After 1, 4, and 7 days of exposure to treatments, cell viability was assessed by MITT assay.

Fibroblasts were seeded on the sterilized basalt fiber fabrics and incubated in 5% CO₂, 37°C for 7 days. After 1, 4, and 7 day treatment, cells were fixed, stained with propidium iodide and observed by a fluorescence inverted microscopy.

**Results:** Cell viability from MITT assay showed 13-fold increase in cell number after culturing in basalt fiber extract medium for 7 days. The relative viabilities of fibroblasts were no less than 93% (95% in day 1, 93% in day 4, and 97% in day 7) with no significant difference from the untreated control (p > 0.05). The morphology and orientation observation of the fluorescent staining demonstrated the contact guidance, that is, the principle direction of fibroblasts aligned with the fabric direction (Figure 1), while the fibroblasts presented a random orientation in the control.

**Conclusion:** To our knowledge, this was the first study of basalt fibers in kyphoplasty biomaterials. Results of the present study indicated that basalt fibers were noncytotoxic to fibroblasts. Basalt fibers further provided contact guidance to fibroblasts, which might be an important feature of this new biomaterial because the guidance could induce bony ingrowth along predefined directions to maximize the overall mechanical strength. Therefore, the basalt fiber enhanced CPC could provide initial biodegradation via incorporated bony ingrowth along the loading direction via contact guidance. However, before its clinical applications, substantial experiments such as mechanical test and in vivo evaluation are necessary to ensure its efficacy and long-term safety.

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**Oral Posters: Biologics, Wear, Non-Surgical**

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**Capacitive Coupling Reduces Instrumentation Infection in a Rabbit Spine Model**

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**Introduction:** Postoperative spine infections are a taxing complication and cause significant morbidity. Patients are subjected to long-term antibiotics and often revision surgery with instrumentation removal. Electrical current through hardware detaches biofilm allowing antibiotic penetration. Capacitive coupling delivers a safe dose of alternating current through non-invasive electrodes. We hypothesized that capacitive coupling in addition to antibiotics would decrease infection rate compared to antibiotics alone.

**Methods:** Thirty rabbits were subjected to a well established spine infection model with systemic ceftriaxone prophylaxis. Two noncontiguous titanium rods were implanted inside dead space defects at L3 and L6. All sites were challenged with 10⁶ colony forming units of Staphylococcus aureus. Rabbits were then randomly treated with either a capacitive coupling or control device. The capacitive coupling field encompassed both of the noncontiguous sites. Both instrumentation and soft tissue bacterial growth was assessed after 7 days using a standardized quantification technique.

**Results:** Capacitive coupling treated sites showed a statistically significant decrease in titanium rod infection. The incidence of capacitive coupling treated hardware infection was 41% compared with 88% in the control group (p< 0.05). However, there was no statistical difference in soft tissue infection rates. In addition, soft tissue bacterial load was not decreased with capacitive coupling use. There was a trend towards decreased infection incidence in sites treated with continuous capacitive coupling therapy when compared to intermittent therapy.

**Conclusion:** Capacitive coupling non-invasively delivers an alternating current that detaches biofilm from instrumentation. Long term, capacitive coupling may aid in treatment of biomaterial-centered spine infections; bacterial eradication may be successful without removal of instrumentation allowing for improved stability.

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**Monitoring Adipose-derived Human Mesenchymal Stem Cells in vivo: Urine Gaussia Luciferase Expression**

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**Introduction:** Luciferase-mediated bioluminescent imaging is a powerful ex vivo technique to assess in vivo biological processes, providing a noninvasive means to account for cell viability. The purpose of this study was to evaluate *Gaussia luciferase* (*Gluc*) in monitoring implanted adipose-derived human mesenchymal stem cells (Ad-HMSCs, xenograft) viability in vivo and after recombinant human bone morphogenetic protein (rhBMP-2) exposure. Ad-HMSCs and their survival are of interest because they have the propensity to differentiate into osteoblasts and generate bone. The following study investigates our hypothesis that higher photon measurement of *Gluc* activity in urine is associated with increased cell viability in vivo.

**Methods:** Ad-HMSCs were isolated using standard cell culture techniques, maintained in preadipocyte media, and introduced to a lentivirus encoding *Gluc*. Posterolateral spinal fusion was performed in rats. Cells were implanted into the paraspinal muscle bed across the L4-L5 transverse processes. Urine was collected by experimenter bladder expression daily over the first two weeks, then every other day until sacrifice. Urine *Gluc* expression was assessed via a luminometer in
relative light units per second (RLU/s).

Results: Results showed that the average RLU/s values from rats with 5x10^6 Ad-HMSCs engineered with 0.003 mg/ml rhBMP-2 on ACS were the highest, followed by the 5x10^6 Ad-HMSCs exposed to rhBMP-2 on ACS, then the 5x10^6 Ad-HMSCs/ACS (no rhBMP-2), and finally the rhBMP-2/ACS only (no cells, control) (p< 0.05). In vitro results were similar to in vivo study findings, wherein Gluc expression was only observed during the first 2-3 weeks after infection. Data suggest that decreased Gluc expression was possibly due to deletion of Gluc (target DNA), cell mutation, limited integration, or unstable infection rather than cell death.

Conclusion: Gluc urine-based assays facilitate frequent interval measurements in longitudinal studies and avoid the invasive procedure of terminal tissue harvest to evaluate the stem cells.

405 Preclinical Study of Human Allograft Amniotic Membrane as a Barrier to Epidural Fibrosis in the Early Wound of a Postlaminectomy Rat Model

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Purpose: Epidural fibrosis and adhesive dural scarring poses potential problems in lumbar spine revision cases and may in part be responsible for recurrent post-operative pain. The purpose of the current study is to evaluate the use of human amniotic membrane for prevention of dural adhesions in a well established post-laminectomy animal model.

Methods: Thirty two mature male Harlan Sprague-Dawley rats had bilateral laminectomies (L5 and L6) and a right unilateral “joystick” disc injury (L5-6). Sixteen rats received no treatment (control group) whereas the other sixteen animals received the human amniotic roofing barrier (Amnioshield™, Alphatec Spine, Carlsbad, CA) over the entirety of the laminectomy site. Animals survived for 8 weeks. For each group, 8 animals were dedicated to histological analysis. The other 8 animals were allocated to biomechanical testing with dissection and exploration of the scar-dura interface post-testing. Histology analysis involved formalin fixation, ethanol dehydration, polymethylmethacrylate embedding, milling to approximately 100-micron axial sections and staining with Masson-Goldner Trichrome (collagen). Intervertebral foramen fibrosis of the right L5 spinal nerve was quantified using a biomechanical methodology measuring the load-to-failure of the nerve as it is pulled free from the intervertebral foramen. The segmental L5 spinal nerve proximal and distal to the intervertebral foramen were freely dissected, isolating the segment of the nerve within the intervertebral foramen. The nerve was displaced distally at a constant velocity of 1cm/min along the axis of the spinal nerve and load-to-failure (grams) was measured for each animal. Behavioral changes to assess pain were monitored daily during the post-operative period for all animals. Tactile allodynia (behavioral changes) was evaluated utilizing von Frey hairs of logarithmically increasing stiffness to assess the withdrawal response at specific forces (grams) (indicative of pain).

Results: Histological analysis demonstrated clearly demarcated borders of the amniotic barrier separating the epidural fibrosis from the dura while the group with no barrier demonstrated epidural scar directly on the dura with visual obstruction of the dural sac (Figure 1). The axial pullout force required to remove the right L5 nerve root for the no barrier group (194.5±154.2g) demonstrated an approximately 50% greater force required than for the group with a barrier (98.1±98.4g). The barrier group also demonstrated significantly greater tolerance to pain (14.4±1.2g) than the no barrier group (11.1±5.4g) during behavioral testing (30% difference). Dissection of each specimen found that the scar could not be separated from the dura in the no barrier group while the barrier group demonstrated a clear tissue plane and the scar was easily removed without disruption to the dura.

Conclusion: The barrier group consistently demonstrated evidence that the dura was not as affected/adhesed to the epidural scar as the no barrier group when evaluated via histology, biomechanical evaluation of foraminal adhesions, tissue dissection/exploration and pain tolerance.

Figure 1: Histology of no barrier (left) and barrier (right) groups demonstrating scar formation and location.

117 Intradiscal Injections of Autologous Conditioned Serum (ACS) for Lumbar Disc Pain

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Background: Biology offers several strategies for restoring the degenerating disc, including the use of natural proteins that increase matrix accumulation and assembly, enhance the number of disc cells, or in other ways lead to restoration of the native healthy disc. This is the basis for administering Autologous Conditioned Serum (ACS). When peripheral blood is withdrawn and incubated with etched glass beads, leukocytes within the aspirate enrich the plasma with anti-inflammatory cytokines,
such as IL-1Ra, as well as growth factors, including FGF-2, TGFβ, and HGF. After centrifuging and filtering, the ACS is returned to the body. It has been used successfully, by way of local injection, for the treatment of human and equine osteoarthritis and radiculopathy.

Methods: A non-blinded, prospective study was conducted to evaluate feasibility and efficacy of ACS injections in patients suffering from lumbar disc pain. 19 patients had a discography and three intradiscal injections of ACS once per week for three consecutive weeks and were followed for six months. Outcome was measured by patient administered outcome instruments (VAS, ODI).

Results: Patients with showed a clinically remarkable and significant reduction in pain and disability after the ACS injection series. Mean improvement was 58% in VAS. 11 out of 19 patients reported at least 50% pain improvement. No serious side effects occurred. There were no infections in this series.

Conclusion: Although, these results must be confirmed in larger clinical trails, the use of ACS in the intervertebral disc could be worthy of consideration given its impressive safety record and rich mixture of growth factors, cytokine antagonists, and, possibly, additional helpful agents.

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Identification of Fibronectin Aggrecan Complex (FAC) Associated with Inflammatory Cytokines in Cervical Radiculopathy Resulting from Herniated Disc

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Introduction: Both inflammatory markers and fragments of structural matrix proteins have been identified in the pathophysiology of lumbar intervertebral disc disease and of painful conditions of synovial joints. In particular, a Fibronectin-Aggrecan Complex (FAC) containing the G3 domain of aggrecan bound to fibronectin has recently been identified in painful meniscal pathology (1), and validated in a larger series (2). The FAC has also been associated with relief of symptoms following successful treatment of radiculopathy due to lumbar herniated disc (3). We sought to investigate the presence of inflammatory cytokines and the FAC in individuals undergoing surgical treatment for cervical radiculopathy secondary to herniated disc.

Materials and methods: This study was a single center prospective, consecutive case series of patients undergoing disc lavage prior to treatment of radiculopathy due to cervical disc herniation. A total of 11 patients with radiculopathic pain and MRI positive for disc herniation elected for single level cervical discectomy and gave informed consent for study participation. Lavage was performed by needle injection and aspiration upon entering the disc space for fluoroscopic localization prior to discectomy. The lavage fluid was assayed for cytokines IL-6, interferon-gamma (IFN-γ), monocyte chemotactic protein 1 (MCP-1), and macrophage inflammatory protein-1 beta (MIP-1b), as well as for the FAC and pH. All patients were treated by a single board-certified, fellowship-trained orthopedic spine surgeon.

Results: There were seven females and four males with mean age 50.6 years (standard error 9.7; range 36 - 70). The mean (standard error; range) in picograms/milliliter for IL-6 was 7.9 (4.4; 0 - 44), for IFN-γ was 25.3 (15.5; 0 - 159), for MCP-1 was 16.1 (11.9; 0 - 121), and for MIP-1b was 6.1 (2.8; 0 - 29). The optical density at 450nm of the FAC was 0.151 (0.036; 0.1 - 0.32), and the pH was 6.68 (0.1; 6.10 - 7.15). There were statistically significant correlations between MCP-1 and FAC (p = 0.036), and between FAC and pH (p = 0.008).

Conclusion: Biochemical analysis of injured cervical intervertebral discs reveals inflammatory markers such as MCP-1, fragments of structural matrix proteins such as FAC, and a relationship with pH. Complex interactions among inflammatory markers and structural matrix proteins have also been observed in the lumbar disc disease and in painful intraarticular pathology of the knee. Further evaluation of the FAC as a possible cartilage breakdown product associated with painful inflammation in the cervical spine appears warranted.


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The Effectiveness of OP-1 (rhBMP-7) in Promoting in situ Fusion in Children Affected by Symptomatic Grade I Isthmic Spondylolisthesis: A 3-years Follow-up Study

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Osteogenic protein-1 (rhBMP-7) is a member of the transforming growth factor-beta superfamily of extracellular proteins involved in bone growth and formation. Long bone repair and spinal fusion studies have demonstrated the efficacy and safety of OP-1 in adults. This is the first report on use of OP-1 in paediatric spinal surgery. The trial was approved by the local Ethical Committee. Between 2004 and 2006 14 patients (mean age 13 years, range 8-16) affected by symptomatic grade I isthmic spondylolisthesis were treated by intertransversary in situ fusion (Wiltse approach). All patients gave written informed consent. A mixture of small bone chips obtained from in situ decortication, OP-1 (eptotermin alfa, 3.5 mg) and autologous stem cells taken from iliac bone was used in all procedures. A TLSO brace was used in the postoperative time for two months. Results were evaluated by X-rays and CT at 1, 3, 6, 12 months and yearly
thereafter. Mean follow-up was 36 months (range 30-60). Mean operative time was 120 minutes (range 90-150) with mean blood loss of 300 ml. Overall complete fusion was observed at one-month X-rays control in all but 2 patients (85%) presenting with unilateral fusion. These results were confirmed at following X-rays and CT controls. At 3-months follow-up 3 seromas were recorded (21%); complete recovery was achieved by steroid therapy in 1 case and reintervention in 2 cases. This is the first experience on OP-1 (rhMBP-7) use in paediatric spinal surgery. Many studies have reported the safety and efficacy of OP-1 as a replacement for iliac crest autograft in posterolateral lumbar fusion in adults. In children OP-1 has recently proven to be effective in healing of persistent nonunion with no major adverse event recorded. In the present study spinal arthrodesis was achieved in 85% of paediatric patients by a short operative time, low bleeding and reduced postoperative pain, with a mild incidence of seroma at 3-month follow-up (21%). Further studies are needed to better understand the efficacy and benefit of this technique in pediatric patients.

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Can the Intra-discal Inflammatory and Degenerative Changes Be Prevented after Annulus Puncture? A Study on the Blocking Effect of a Kind of Polyactic Acid Patch
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Objective: PLA (polyactic acid) patch has proper steric configuration, sufficient mechanic strength and flexibility. This study aims to find out whether the intra-discal inflammation after annulus puncture can be prevented by sealing the pinhole left after annulus puncture with a PLA patch stuck by Shunkang medical glue.

Methods: Twenty healthy New Zealand white rabbits (weighing 2.0-2.5 kg) were randomly assigned to 4 groups (n=5): groups A, B, C and D. Group A was fake surgery group, the intervertebral disc tissue was harvested. The PLA patch sticked with medical gel and benefit of this technique in pediatric patients.

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Wear Rate Comparison between Polycrystalline Diamond, CoCr, and UHMWPE in High Wear Environments
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Purpose: Total disc replacement (TDR) devices have been restricted to designs with large, congruent articulations due to the limited wear properties of available orthopedic materials. TDRs that facilitate more natural motion could be designed if there were materials available which could resist the higher wear conditions. For example, Dimicron’s aggressive TriLobe design is self-centering and energetically stable, and it emulates the natural motion of an intact intervertebral disc, but is not feasible using traditional materials due to it small, incongruent articulating surfaces. The objective of this study was to compare the wear properties of Dimicron’s medical grade polycrystalline diamond with wear properties of cobalt chrome (CoCr) and ultrahigh molecular weight polyethylene (UHMWPE) in aggressive high wear conditions.

Methods: A modified pin-on-disc, crossing-path wear test was used to measure the wear rates of PCD-on-PCD, CoCr-on-CoCr, and CoCr-on-UHMWPE. The discs were placed in the inferior position on an oscillating plate, moving in a figure-eight pattern. The figure-eight motion was 10mm long by 5mm wide. The pins had an initial 11.5mm radius and were loaded at 133N normal to the disc. In a typical pin-on-disc test, a wear flat develops on the pin and the wear rate is reduced as the contact area increases. The TriLobe design uses three lobes sliding in three non-conforming lenses which prevents wear flats from developing. To better approximate this condition, the fixture holding the disc was placed on an air bearing and was allowed to rock in response to the movement of the load. The test took place in 25% bovine serum, and at a speed of less than two Hertz. Two sets of each material were tested, one set to 2.0 million cycles and the other set to 14.0 million cycles. Wear rates on the rocking-discs were measured using a high resolution coordinate measuring machine because the wear in the PCD specimens was not detectable gravimetrically.

Results: The diamond specimen averaged 0.0036mm3/MC of wear over the first 2 million cycles. The CoCr-on-CoCr specimen averaged 1.4mm3/MC and the CoCr-on-UHMWPE averaged 4.7mm3/MC over 2 million cycles. The PCD specimen taken to
14 million cycles had and average wear of 0.0022mm/MC compared to 2.4mm/MC and 9.5mm/MC for CoCr-on-CoCr and CoCr-on-UHMWPE respectively. **Conclusions:** Using the pin-on-rocking-disc test to approximate small, non-congruent articulating surface wear, both CoCr-on-CoCr and CoCr-on-UHMWPE wore at rates that were orders of magnitude greater than medical grade PCD. At two million cycles, CoCr-on-CoCr had worn nearly 400 times more than PCD and CoCr-on-UHMWPE wore more than 1300 times greater. During the last 12 million cycles the wear in non-diamond specimen accelerated, while the diamond wear rate decreased. At the end of 14 million cycles CoCr on itself and on UHMWPE specimens had worn at more than 1100 times and nearly 4300 times greater than PCD, respectively. Coupled with the inherent biocompatibility, high strength and toughness, and ultra low friction of diamond, the wear performance of PCD makes it an attractive material for TDR applications. PCD could be used in current designs to alleviate concern over wear debris and ion release, or it be used to open up the design space for the next generation of TDR devices.

**Introduction:** Total disc arthroplasty (TDA) is designed to preserve motion and to decrease the risk of accelerated degenerative disease at adjacent levels. The clinical significance of wear debris is reported after TDA. One of the goals in designing new implants is to use materials with low wear rate-behaviour, which produces wear debris with low biological activities. Our goal was to compare the biological response of Ultra High Molecular Weight Polyethylene (UHMWPE) and carbon fibre reinforced PEEK(CFR-PEEK) wear debris in epidural space.

**Materials and methods:** Thirty six female rabbits were randomly allocated to 3 groups: CFR-PEEK, UHMWPE-particles and sham. The particles were implanted into the epidural space of the cervical region by percutaneous technique (fluoroscopic guidance). Neurobehavioral observations were conducted at pretreatment, on day 1-14 postinjection, then weekly. The rabbits were sacrificed at 3 and 6 months. Histologic sections from the regional lymph nodes, organs, from remote and implantation sites, were analyzed for any abnormalities and inflammation.

**Results:** Expect of three animals of CFR-PEEK group, none of the animals showed any neurological or musculoskeletal abnormality. The neurological deficits presented immediately after injection and did not progress. Blood results from predeath samples were consistent with preoperative blood work values. There was no evidence of systemic toxicity. Histopathological examination revealed, that crystalline wear debris was seen in the vertebral canal of examined test injection sites surrounded by inflammatory cells. Regardless of the implantation time, both CFR-PEEK and UHMWPE particles remained at the implant site. The inflammation was limited to the epidural space around the particles. The image shows the histopathological response to wear debris in epidural space after 6 months: a. UHMWPE-group and b. CFR-PEEK group.(* cervical spinal cord, X epidural space with different wear debris and + bony lamina). The time(3 or 6 months) after implantation did not effect the extent of histological response.

**Conclusion:** The established percutaneous implantation of wear debris in the cervical epidural space could be used as a standardised in vivo model to simulate the biological consequences of debris after TDA. CFR-PEEK and UHMWPE show similar histopathological changes in the cervical epidural space. The inflammation was limited to the epidural space around the particles. In past studies, CFR-PEEK demonstrated an excellent wear behaviour with a wear rate reduction in comparison to UHMWPE in in vitro studies. Therefore CFR-PEEK based articulations may be a good alternative to UHMWPE on metal and have a high potential for next generation disc replacements.

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**In vitro Fatigue Evaluation of Polymer Dampeners Utilized in a Total Spine Arthroplasty Device**

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**Introduction:** Lumbar disc and facet degeneration is a common cause of pain and disability. Fusion treats both disc and facet pain but restricts motion and alters adjacent segment kinematics. Total disc replacements (TDR) allow motion but only treat disc degeneration. Total Spine Arthroplasty (TSA), however, treats both pain generators and allows motion. The Flexuspine FSU is a TSA device that replaces the three-joint complex with TDR and posterior dampener components. The posterior dampener consists of a metal rod and cylindrical silicone dampeners that act in compression to resist pedicle screw motion. The objective of this study was to characterize the fatigue behavior of the dampeners.

**Methods:** Compression fatigue testing was performed using an MTS test machine. Cylindrical silicone dampeners were placed between washers on dowel pins to simulate the FSU rod component and tested in 37°C deionized water or 30g/L serum. Compression up to 40% strain was cyclically applied for 10Mc and 20Mc (n=6 each) at 4 Hz in a sinusoidal manner with a rigid stop controlling the maximum displacement. Load soak specimens served as controls. Dampener length was measured with a digital caliper and weight was measured over time. Static testing to 40% strain was also performed on a subset of specimens (n=5 control, n=2 at 10Mc, n=3 at 20Mc) upon completion of fatigue testing using an Instron test machine. Stiffness was determined in the initial toe region and final linear region since the load-displacement curves were non-linear.

**Results:** The specimens remained intact through 20Mc. Circular indentations in the top/bottom surfaces and an
indentation ring in the middle of the internal surface was observed over time. The length decreased by an average of 2.7±0.8% after 10Mc and 4.1±0.9% after 20Mc. The average wear rate was 0.08mm/Mc for each damper, which was consistent over time. Compressive stiffness slightly increased after 10Mc (+1% toe region; +25% linear region) and slightly decreased after 20 Mc (-13% toe region; -9% linear region).

Conclusions: Compression fatigue testing was performed on the silicone damper component of the Flexuspine FSU device. This testing demonstrated that the dampeners could withstand 40% compression for up to 20Mc without failure while still maintaining their geometric and mechanical properties. This corresponds to more than 15° of flexion-extension and approximately 160 years of clinical use (assuming 125,000 significant bends/year), which is greater than the expected in vivo ROM and the lifetime of the device (Phillips, 2010).

Fatigue damage and wear of the dampeners was observed over time as expected. Compression into the washers resulted in circular indentations on the top and bottom surfaces. Deformation of the dampeners at higher strains resulted in an indentation ring in the center of the internal surface. Abrasion of the dampeners against the washers and dowel pins resulted in a wear rate of 0.8mm/Mc. The findings of this study support the use of a properly selected polymer for a posterior damper of a TSA device.

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Long-term Wear Characterization of a Total Spinal Arthroplasty Device
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Introduction: Total spinal arthroplasty is a promising alternative to fusion because it treats the main pain generators yet also allows motion. Flexuspine's FSU device is comprised of a metal-on-metal Core component (two paired cobalt chrome halves that allow flexion-extension, lateral bending, and axial rotation) and a posterior Damper component (cobalt chrome rod construct with silicone dampeners, referred to as inner and outer dampeners), which provides physiological resistance to motion. Previous full range of motion (ROM) wear testing has been performed for the FSU device (Gimbel, 2010). The objective of this study was to verify the long-term durability of the device under simulated daily-use conditions and compare the wear to that observed during full ROM testing.

Methods: Wear testing of five FSU devices and a load soak control was performed for 40 million cycles (Mc) using an MTS Bionix Spine Wear Simulator. The motion profile (applied at 4 Hz) consisted of flexion between 0.5 and 2.5° and compression between 700 and 1600N. These values were calculated based on loads and motion determined during walking (Pare, 2008; Cappozzo, 1984). Testing was carried out in 30 g/L bovine calf serum at body temperature and the disc component was declined by 10º to generate shear loading. A similar testing setup was used for full ROM testing, which was performed for 10 Mc with -3/+6º of F/E and 600-2000N axial loading (Gimbel, 2010).

Results: The Core components averaged 0.01±0.01mm/Mc during the long-term F/E testing compared with 0.66±0.10mm/Mc during the full ROM F/E testing. The outer damper weights increased initially for the long-term test due to fluid uptake and then averaged a wear rate of 0.02±0.02mm/Mc per damper compared with 0.20±0.25mm/Mc during the full ROM testing.

Conclusions: Comparisons were made during long-term testing, which represents walking, and full ROM testing, which represents worst case F/E motion based on previous cadaver testing (Phillips, 2010). The wear rates observed in this test were greatly reduced from those observed in the full ROM testing; Core component and outer damper wear rates during the long-term test were approximately 2% and 10%, respectively, of those observed in the full ROM testing. The wear rates during the full ROM testing were consistent with those observed for artificial disc replacements tested under similar conditions (9.78mm/Mc for a metal/polymer disc and 4.91mm/Mc for a metal/metal disc as found by Bushelow, 2007).

All specimens completed the long-term testing without failure demonstrating durability under these conditions. Assuming 1 million gait cycles and 125,000 significant bends occur each year (Hedman, 1990), 40Mc of the long-term testing and 5Mc of the full-ROM testing would represent approximately 40 years of clinical use. So although the wear rates were much less for the long-term testing, they become more significant when compared over a 40 year time frame due to the larger number of cycles per year (12% cobalt chrome and 80% silicone wear relative to the full ROM wear). This suggests that long-term testing and full ROM testing are both important in evaluating the overall wear of a device.

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Efficacy of Epidural Injections with Autologous Conditioned Serum (ACS) for Lumbar Radiculopathy
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Background: A new biologic therapy, based on the local administration of Autologous Conditioned Serum (ACS), is used for back pain treatment. ACS is generated by incubating venous blood with medical grade glass beads. Peripheral leukocytes produce elevated amounts of endogenous anti-inflammatory cytokines such as interleukin-1 receptor antagonist (IL-1Ra) and growth factors including IGF-1, PDGF and TGF-β that are recovered in the serum.

Methods: To evaluate the efficacy of ACS for the treatment of lumbar radicular compression a prospective, double-blind, reference-controlled trial was conducted. 84 patients were treated by epidural perineural injections with either ACS, 5 mg or 10 mg triamcinolone. Treatment was applied once per week for three consecutive weeks and followed for six months. VAS of low back pain and Oswestry Disability Index (ODI) were used as outcome parameters. Data were submitted to a repeated measurements analysis of variance with effects on treatment group and time.

Results: All studied patients with lumbar back pain showed a clinically remarkable and significant reduction in pain and disability. From week 12 to the final evaluation injections with ACS showed a consistent pattern of superiority over both triamcinolone groups with regard to the VAS, but statistical significance was observed only at week 22 in
direct comparison to the 5mg group. However, there was no statistically significant difference between the two triamcinolone dosages during the 6 months of the study. **Conclusion:** ACS is an encouraging treatment option for patients with unilateral lumbar radicular compression. The decrease in pain was pronounced, clinically remarkable and superior to steroid injection.

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**Predicted Wear Pattern of an Artificial Disc Simulated as Stand-alone vs. Simulation in a Motion Segment FE Model**

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**Purpose:** Wear debris evaluations for artificial discs are conducted in simulators using the ASTM/ISO standards. Although the motion patterns are based on biomechanical literature, the clinical relevance of these profiles is debated. These tests primarily evaluate wear related parameters of one disc design against another and thus are unable to simulate clinical scenarios. Our aim is to delineate the differences in simulations of device alone and device in situ for a given loading profile using the finite element technique and to understand the wear trend for upto 8 million cycles.

**Methods:** FE model of an artificial cervical disc was created in Abaqus™ (Fig. 1A). Flex/Ext= ±7.5°, LB = ±6°, Rotation= ±4° via time-dependent amplitudes within a single loading step were applied with a varying preload of 50N-150 N at 1Hz as per ISO18192. A subroutine based on Archard’s law simulated the abrasive wear on the polymeric core up to 8 million cycles; wear coefficient was derived from existing literature. The disc was then placed in a ligamentous C5-C6 FE model subjected to the same boundary conditions as described above (Fig. 1B)

**Results:** The von-Mises stresses in the Disc model were distributed around the edges, maximum being 16MPa. The maximum stresses for the Disc+FSU case exceeded the Disc Model case by 54MPa. A lift-off phenomenon was observed during extension for Disc+FSU model. The linear wear contour for the Disc+FSU case (Fig 2A) was lopsided while the Disc model showed uniform distribution, maximum wear occurring at the outer peripheral edges, in comparison to the center (Fig. 2A). The linear wear in the Disc+FSU model was 5 times lesser than the Disc model after 8 million cycles while the difference in cumulative volumetric wear was 10 times (Fig 2B). After 5 million cycles the wear contour remained the same for upto 8 million cycles. There was also no significant increase in the linear wear rate for both the cases after 5 million cycles. The average volumetric wear rate was 0.93 mm³ /million cycles for Disc only model and 0.094 mm³ /million cycles for the Disc+FSU model.

**Discussion:** Stress patterns and wear rate outcomes were different for the Disc alone as compared to the Disc+FSU case. Micro-separation/Lift-off in THA is detrimental, and it cannot be ruled out at the disc interface in-vivo. This simulation also confirms the biphasic nature of wear. This can be explained by the phenomenon of smoothening of surface roughness and flattening of the contact area with time. This increased contact area leads to reduced stress and eventually lower wear rate.

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**Preoperative Patient Education in Elective Spinal Surgery**

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**Aims:** Patient education (PE) has been employed by many authorities in order to deal with patient anxiety, pain control and overall satisfaction. While the literature suggests its effectiveness in joint reconstruction, data are missing in spine surgery. The purpose of this study is to report on the effectiveness of PE in patients undergoing elective spinal surgery.

**Methods:** We retrospectively analyzed the data on patients that underwent PE (Spine Precare Class) from October 2009 to March 2010. All patients that were discharged home throughout the study period, were called whether they participated in the class or not, with emphasis placed on their satisfaction with the nursing care and overall pain management. 155 patients accepted to participate to the phone survey, 60 males and 86 females (55.5%). Mean age was 55 years (range: 25-84). They all underwent elective spinal surgery, with admitting diagnosis of cervical and lumbar discogenic pain being the most prevalent. Of the 155 patients surveyed, 77 (49.6%) had attended the PreCare educational class that was offered by the hospital while 78 (50.3%) did not attend the class. Groups where compared to determine if class attendance made a difference in terms of overall satisfaction and pain management satisfaction (X2). Univariate analysis (Fisher’s exact test) and multivariate
analysis (logistic regression) was performed to determine whether factors such as age and sex affected the outcome. Differences were considered significant at p=0.05 level.

Results: 97% of the participants in the PreCare class were satisfied with their pain management vs. 83.3% in the control group (p=0.02). There was also a non-significant trend for better overall satisfaction in the precare class group (90.9% vs. 84.6%). In the subgroup analysis (univariate) males had a higher group satisfaction than females (p=0.04). Also those patients in 65-74 years age group were positively affected by education (p=0.02).

Conclusions: The implementation of our Spine PreCare program has had a positive impact on patient satisfaction, especially in terms of pain management. Patient education represents a viable, efficient and inexpensive intervention in patients undergoing spinal surgery.

284 Does Measuring Hematocrit during Surgery Predict Blood Loss?
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Summary: In a prospective study, we find ABG and CBC measurements may or may not correlate with operative blood losses. Change in hematocrit during surgical exposure does predict overall blood loss in AIS.

Background: Estimating blood loss during spinal deformity surgery for scoliosis is challenging. In the operating room clinicians often rely on arterial blood gas (ABG) and complete blood count (CBC) measurements of hematocrit to predict estimated blood loss (EBL) and inform transfusion decisions. The purpose of this study was to evaluate the accuracy of hematocrit measurements in estimations of EBL.

Methods: Data was prospectively collected from 30 patients with Adolescent Idiopathic Scoliosis (AIS). CBCs were collected two weeks prior to surgery, after intubation, and in recovery. ABGs were collected at incision, anchor placement, rod placement, and skin closure. Intra-operative data included fluid administration, volume of transfused blood, and EBL, estimated to be three times the cell saver volume which was given to patients during skin closure.

Results: Of the 30 patients with AIS, eight were omitted for having an autologous or allogeneic blood transfusion, or incomplete laboratory data (13F, 9M, average BMI 23.4, mean age 14.8). Changes in hematocrit obtained before and after surgery as measured by CBC (R=−.034) did not correlate with blood loss. Hematocrit changes from incision to the start of skin closure as measured by ABG (R=0.412) had a weak correlation with EBL. However, the hematocrit change during surgical exposure had a significant positive correlation with overall blood loss (R=0.512, p<.05).

Conclusions: We report that CBC and ABG measurements during spinal fusion for AIS are generally not reliable predictors of EBL. However, the change in hematocrit during surgical exposure did predict EBL. Hematocrit evaluation during surgical exposure in combination with blood pressure, heart rate monitoring, ABG assessment of tissue perfusion (pH, PO2, PCO2), and cell saver volumes are the most valuable indicators of EBL.

441 Spine Surgery at an Ambulatory Surgery Center
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Purpose: The purpose of this paper is to ascertain whether spine surgery can be safely performed at an ambulatory surgery center (ASC). This question has important ramifications for providing quality spine surgery care at lower costs. Seven hundred and ten consecutive spine surgeries performed at an ASC from spring 2005 through 2008 were prospectively evaluated.

Materials and methods: All cases were evaluated with ODI, NDI andVAS values. The patients were evaluated at pre-op, three-month, six-month, one-year and often two-year follow-up. The analysis also included minutes in the operating room, recovery and convalescent center as well as patient satisfaction. This data will be presented. Insurance analysis of costs at an ASC vs. hospital was performed by an outside BCBS analysis. Surgery type and patient numbers are listed below.

Instrumented Spine Surgery
333 Patients
Anterior Cervical Fusion
1 Level : 108 Patients
2 Level : 82 Patients
3 Level : 3 Patients
Cervical Artificial Disc: 57 Patients
Lumbar Artificial Disc: 83 Patients
Non-Instrumented Spine Surgery 377 Patients
Lumbar microdiscectomies and/or nerve decompressions
In 193 anterior cervical fusion patients, there were no perioperative complications and no unplanned transfers with statistically significant improvement at two year follow up in NDI andVAS values (p < 0.01). Cervical artificial disc replacements were performed in 57 patients. There was statistically significant improvement in NDI andVAS at two-year follow-up to a p-value < 0.02. There were no perioperative complications and no unplanned transfers in these patients. Lumbar artificial disc replacements were performed in 83 patients. One patient had an unplanned hospital transfer. There was a statistically significant improvement in ODI andVAS to a p-value < 0.001 at two-year follow-up.
Non-instrumented spine surgery was performed in 377 patients. One patient had a perioperative complication. There were no unplanned transfers to the hospital. All of the patients undergoing an anterior cervical fusion, cervical and lumbar artificial disc replacement and non-instrumented lumbar spine surgery were released home within 24 hours of their surgery.
Outside insurance audits indicate a 60% cost savings when performing these procedures at an ASC versus a standard hospital setting. Patients reported a 97% satisfaction rate.

Conclusions: Prospective analysis of 710 spine cases at an ASC indicate anterior cervical fusion, lumbar nerve decompression, discectomy, lumbar and cervical artificial disc replacements can be safely performed with efficacy at an ASC.
**Plenary: Lumbar Therapies**

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A Full Economic Evaluation of Disc Prosthesis vs. Lumbar Fusion in Patients with Chronic Low Back Pain - A Randomized Controlled Trial with Two-year Follow up

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Background: Patients with chronic low back pain may in selected cases be treated with surgery. The gold standard today is lumbar fusion (FUS), using a variety of procedures. Total disc replacement (TDR) aimed at motion preservation is increasing in popularity.

Purpose: Different treatment techniques should be compared with respect to costs, clinical effects and cost-effectiveness.

Study design: We conducted a full health economic RCT comparing cost effectiveness of the surgical concepts of TDR and instrumented FUS in patients with chronic low back pain. The economic perspectives were those of the Society and the Health care sector.

Patient and methods: After approval from the ethics committee, between 2003 and 2005 in all 152 patients with what was understood as discogenic pain in one or two motion segments between L3 and S1 since at least one year, and where conservative treatment had been tried and failed, were randomized using the closed envelope technique. Diagnosis was mainly based on medical history, clinical examination, radiographs, and MRI. Patients in the TDR group (n=80) received Charité/Prodisc/Maverick. Patients in the FUS group (n=72) were operated according to instrumented PLF or PLIF. Directly after surgery patients were told to active. FU in this single center study was two years.

Outcome measures: All relevant direct costs (investigation, treatment, rehab, medication, relatives) and indirect costs (work absenteeism) were identified, measured and valued. Cost information was collected using a comprehensive patient based cost diary after 1-3-6-12-18-24 months, plus probabilistic analysis.

Results: FU was 99%. Societal cost for TDR was SEK 599,560 (400,272), and for FUS SEK 685,919 (422,903) (ns). TDR was significantly less costly from a healthcare perspective, SEK 22,996 (43,055-1,202). Number of days on sick leave among those who returned to work was 185 (146) in the TDR group, and 252 (189) in the FUS group (ns). The total gain in quality adjusted life years over two years was 0,41 units for TDR and 0,40 units for FUS (ns). The net benefit (with CI) was SEK 91,359 (-73,643 - 249,114) (ns).

Conclusion: It was not possible to state whether TDR or FUS is cost-effective after two years. Since disc replacement and lumbar fusion are based on different conceptual approaches, results should be followed over time.
Introduction: Sexual activity is often altered in patients suffering from chronic low back pain. The aim of this study was to evaluate conditions for sexual activity in a series of patients treated by lumbar total disc replacement, the incidence of retrograde ejaculation in men and the influence of the surgical access in such troubles.

Material and methods: 389 patients were analysed prospectively in this study and 164 men were treated by a L5-S1 disc arthroplasty. Sexual activity was evaluated through the Oswestry questionnaire and graded from 1 (normal sexual life) to 5 (impossible for pain reasons). Each patient was evaluated in the preoperative period, at 3, 6 and 12 months postoperatively.

Results: Based on preoperative questionnaire, 61% of the patients were at least severely restrained in their sexual life due to their lumbar pain. At final follow-up, 93% of the patients were classified as group 1 or 2 and none of them were classified as 4 or 5. In the subgroup of men operated at the lumbarosacral junction, 5 patients out of 164 reported a retrograde ejaculation (3% of the cases) always transient between 6 months and 1 year postop. In such cases, surgical access was trans-peritoneal in one case and left retro-peritoneal in 4 cases.

Discussion: Sexual disorders after anterior surgical approach are well-known and are related to lesions of the hypogastric plexus. According to this study, such lesions are less frequent via a right retro-peritoneal access for the lumbarosacral junction. Its seems therefore an interesting alternative for one level total disc replacement. In case of muti-level procedure, a two-time approach associating a right access L5-S1 and a left retro-peritoneal access above may be a solution to avoid sexual complications. Deterioration of sexual life is a part of the symptoms reported by patients suffering from chronic low back pain. Total disc replacement seems efficient on these symptoms as well as lumbar pain.

A Prospective Clinical Comparison of 3 Biomechanical Types of Lumbar Disc Replacements: A Semi-constrained Device, a Controlled Translation Device, and an Unconstrained Device Minimum 3 Year Follow-up

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Background content: Lumbar total disc replacements have different mechanisms and levels of constraint. These inherent properties of the implant may have biomechanical significance on the motion segment, adjacent segments and surrounding structures and may alter the patient’s clinical course.

Purpose: To determine if there are differences in clinical outcomes based on type of ADR implant by evaluating data from a prospective randomized FDA clinical trial.

Study design/setting: Patients were evaluated from three different sites by three separate surgeons who had one of three different types of ADR.

Patient sample/methods: One of three ADRs were implanted into each patient as part of a FDA clinical trial. Charite (23), Prodisc (27) and Activ-L (112) were randomly selected for implantation into a group of people with similar demographics and inclusion/exclusion criteria.

Outcome measures: Patients were evaluated using ODI, VAS, and SF-36 3, 6, 12, 24, and 36 months post op. These patients also had a clinical evaluation.

Results: Overall mean ODI across all groups decreased from 56.7 to 21.7 at 3 yrs. Individually, the mean ODI for the Actv-L patients decreased from average 57.4 at baseline to 11 at 36 month follow up, Prodisc fell from 58.4 to 14 and Charite from 54.4 to 39.5. The VAS back score across all groups decreased from a mean of 78.9 to 29.4 at 36 months post-operatively. For the Actv-L patients the mean baseline VAS for back pain was 80.8 and fell to 10.7 at 36 months. Prodisc fell from 80.7 to 28.0 and the Charite patients fell from 75.1 to 49.6. Physical health score from SF-36 rose from baseline of 29.7 to 50.4 in the Actv-L pts, 28.3 to 48.6 in Prodisc and 30.7 to 39.9 in Charite pts. ROM for the Actv-L implant increased from 7.4 to 9.9. ROM of the other 2 implants decreased as compared to baseline.

Complications: One patient undergoing the Charite procedure had an incisional hernia and another had an intra-operative left iliac vein tear. Two patients undergoing implantation Actv-L device had onset of new leg pain postoperatively that had resolved at 9 month follow-up. One Actv-L patient required a posterior foraminotomy. Another Actv-L patient had a proximal DVT. Two Prodisc patients required removal of the Prodisc implant and conversion to a fusion as a result of bilateral pedicle fractures with polyethylene subluxation that occurred greater than 6 months after index surgeries.

Conclusions: The controlled translation device (Activ-L) had the greatest improvement in VAS, ODI, and SF-36 as compared to the other 2 devices. The controlled translation device was the only implant to show an increase in ROM as compared to baseline. Statistical analysis was not possible due to FDA ongoing study status. All three implants appear efficacious in reducing ODI and VAS as well as an increase in physical and mental parameters of the SF-36. Overall operative time, blood loss, length of hospital stay and complications were comparable. Two bilateral pedicle fractures with polyethylene subluxation occurred in the Prodisc group at a delayed time requiring implant removal and fusion.

Retrospective Analysis of Metal on Metal Lumbar Arthroplasties to Report on the Incidence of Metal Hyper-sensitivity in 217 Consecutive Patients

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Purpose of the study: Spinal disc arthroplasty implants are chiefly manufactured from metal and / or polymer materials. These materials include titanium, cobalt-chromium-molybdenum, stainless steels, ultra-high-molecular-weight-polyethylene, and PEEK. Biological reaction to wear debris of knee and hip arthroplasties ultimately requires clinical studies for assessment. Research into biological reaction of metal-on-polyethylene and metal-on-metal wear debris of knee and hip arthroplasties is well progressed, spinal arthroplasties are however not as well documented. The need therefore exists to evaluate the clinical outcome of metal-on-metal spinal disc arthroplasties.

Method: The Swedish Spine Register (SweSpine), in full use for 12 years, provides a resource for retrospective evaluation...
of adverse events and of clinical outcome. Adverse medical conditions are recorded within the register, which therefore serves as a closed loop of patient feedback for the period recorded. This database was used to select only lumbar arthroplasties featuring CCM-on-CCM wear couples (Kinflex, Maverick and Flexicore). These devices feature "mobile core" and "ball and socket" type of bearing surfaces.

**Summary of the findings:** In one clinic a total of 217 patients (103 male, 115 female), were treated with 337 "metal on metal" total lumbar disc replacement at one, two or three segments between 2003-10-08 and 2009-05-13. One-hundred and ninety seven cases were eligible for two year follow-up. TDRs were performed utilizing Kinflex in 69 cases and Maverick in 140 cases and FlexiCore in 11 cases. Average age and weight was 41.0 years and 76.6kg respectively. A total of 56 patients had previous spinal operations; 172 were active in sports, 27 were smokers. No reported cases of metal hypersensitivity or metallosis induced pseudo-tumours were recorded on the register or reported elsewhere.

**Conclusion:** Data from SweSpine provided record of the non-occurrence of symptoms from metal hypersensitivity or metallosis induced pseudo-tumours within this consecutively treated patient-group evaluated.

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**Is Lumbar TDR Able to Restore and Maintain Segmental ROM in L5/S1 in a Mid-term Period of 3 Years?**

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**Introduction:** Lumbar DDD is supposed to change characteristiques of segmental alignment and motion pattern. These changes may lead to facet irritations or ALD. Divers IDE trials have revealed general benefit and safety of lumbar arthroplasty. How-ever, especially for L5/S1, there have been multiple discussions on the effect and benefit of TDR in mid- and long-term follow-up regarding alignment and segmental ROM of the index-level and a potential protection of adjacent levels.

**Purpose:** This clinical investigation was performed to proof, if new designs of lumbar disc prosthesis are able to restore Lordosis and ROM in L5/S1 over a mid-term period of 3 years.

**Methods:** Patients from 2 centers, enrolled in a prospective multi-center study have been evaluated over a period of 3 years. All patients have been presented with DDD in lumbar level L5/S1. Enrolled patients did follow the inclusion and exclusion criteria and specific indication patterns. Patients were treated with a new type of lumbar disc prosthesis (activ L) with limited translation which give surgical possibility of a new offset technology in anterior-posterior dimension. Data were collected prospectively. Radiographs were analyzed by an independent cor-lab (frictionless GmbH) using computer-aided measurements. Segmental alignment is measured in the sagittal plane from neutral films between the superior and inferior endplates of superior & inferior vertebrae in units of degrees.

ROM is measured in the sagittal plane from maximum flexion and extension films in units of degrees and Average Disc Height (ADH) as mean value between Anterior Disc Space Height and Posterior Disc Height (distances between anterior (posterior) edge of inferior endplate of the superior vertebra and the corresponding edge of the inferior vertebra). Device Loosening was defined as more then 50% radiolucency of at least one metal component.

**Results:** Segmental Lordosis was restored from 20.2° +/- 10.3° to 29.3° +/- 6.6°(p = 0.001). Publications [Stagnata and Gelb] showed values of 21 +/- 6 and 24 +/- 7 for un-symptomatic volunteers. ROM could be improved from 6.0° +/- 3.3° to 10.5° +/- 7.0° with an increase of 4.5° (75%). For other types of prosthesis lower post-op values for the L5/S1 ROM have been demonstrated. Healthy volunteers show a mean ROM for L5/S1 of approx. 14° [Hayes, Percey]. The average disc height could be restored from 4.5mm +/- 2.3mm to 11.6mm +/- 1.4mm, with an increase of 7.1mm (158%). There was no device loosening and no device breakage.

**Discussion/conclusion:** Function and clinical outcome of TDR are highly related to restoration of lordotic alignment, ROM and disc space height to approx. physiological values. Especially lordotization and ROM seems to have an influence not only for short-term results of the index-level, but also for long-term-results and potential complications as facet joint degeneration and adjacent level disc degeneration in the long-term run. Our data suggests that TDR with activ L is able to restore disc space height, lordotic alignment and ROM to approx. physiological values. Especially the post-OP ROM values of activ L in L5/S1 showed very good results with 11,3°, which is much more then reported from other types of prosthesis.

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**Treatment Options for Two-level Symptomatic Disc Degeneration: Comparison of Total Disc Replacement, Fusion, and Hybrid**


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**Introduction:** Symptomatic two-level disc degeneration has traditionally been treated with fusion after non-operative interventions have failed. The purpose of this study was to compare peri-operative data and outcomes of two-level total disc replacement (TDR), combined anterior/posterior (360) fusion, and the hybrid combination of TDR at one level and fusion at the other.

**Methods:** The primary outcome measure was the Oswestry Disability index (ODI). Data were collected from the two-level ProDisc-L vs. 360 fusion FDA IDE trial, and from a log of all TDR cases performed at our center. For the non-IDE study patients, charts were reviewed and the peri-operative data and ODI scores were recorded. Only patients with a minimum of 12 month follow-up data were included in this analysis.

**Results:** The groups did not differ in age or body mass index values. The operative time and length of hospital stay were significantly greater in the 360 fusion group than in either of the other two groups (p < 0.05; ANOVA). The pre-operative ODI score was greater in the 360 group, but there were no significant differences in the post-operative scores or the percentage improvement from pre- to post-operative ODI values.

**Table 1. Comparison of peri-operative parameters and ODI scores in the three groups.**
Conclusions: The 360 fusion group was associated with significantly longer operative time and length of hospital stay. There were no significant differences in outcome between the three groups based on ODI scores. With a larger sample size, the fusion group may have a greater percentage improvement; however, the greater score in this group preoperatively may skew the comparison.

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Role of Endplate Morphology on Lumbar Disc Arthroplasty Clinical and Radiographic Outcomes
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Introduction: Endplate morphology (EPM) has been hypothesized to affect post-op device orientation, subsidence, and ultimately what mechanical function is provided to the patient. Understanding these hypothesized effects may lead to better patient outcomes, yet little data are available. The goal of this study was to better understand the importance of EPM to a patient who receives a lumbar disc replacement.

Methods: A total of 96 investigational patients at one site from the prospective randomized IDE (n=38), the continued access (n=43), and the continued access metal ion studies (n=15) for Maverick, followed up to 5 years. Clinical outcomes, intervertebral rotation, disc height and lordosis (disc angle) were measured at pre-op, 2 and up to 5 years post-op using validated, computer-assisted methods. EPM, subsidence and implant migration were graded by an independent radiologist using VEYBR classification (Yue and Bertagnoli).

Results: Although there were no statistically significant differences between the different endplate morphologies and the improvement in leg or back pain score was exactly the same as described in the Oetgen et al Alpro Disc study: type IV (convex) > II (concave) > I (flat) > II (hooked) > V (combination). In contrast, the average improvement in ODI score was greatest for the flat and hooked endplate morphologies (approximately 40 pts). Concave, convex, and combinations of convex and concave morphologies had a lower improvement (approx 32 pts), although there were no significant differences between morphologies (P=0.85). There were no significant differences between endplate morphologies with respect to how much disc height was lost between the 6 week and subsequent time points. However, the average loss in disc height was 1.1 ± 1.2 mm, so the variation was only slightly greater than the error in the measurement technology (approx 1 mm). The sample size was therefore too small to determine if a difference truly exists. Interestingly, there was a significantly greater increase in sagittal plane intervertebral rotation from pre-op to 5 years post-op in those patients with flat or hooked endplates (P<0.05). A nearly significant relationship was found between the change in disc angle relative to pre-op and the type of endplate morphology (P=0.07), as well as for the relationship between changes in anterior disc height and morphology (P=0.1).

Conclusion: Consistent with Oetgen et al, a significant association between endplate morphology and clinical outcomes was not found. The exact same trends were found for Maverick patients in the relationship between improvement in back pain and EPM as was previously reported for ProDisc patients, suggesting that an effect may prove to exist when a larger sample size is analyzed. A significant relationship was found between endplate morphology and the improvement that was achieved in intervertebral rotation.

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Does Reconstruction of the Anterior Longitudinal Ligament (ALL) Improve the Results of Lumbar Artificial Disc Replacement (ADR)?
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The ALL is the most important stabilizer of the lumbar motion segment. Several authors have reported the most common reason for ADR failure is facet pain. Biomechanical data repeatedly emphasizes the importance of the ALL in decreasing facet forces. The Embrace™ embroidered graft containment device is flexible and provides rotational and extension stability to ADR. Biomechanical analysis of the Embrace device has been performed by Cappuccino, et al. The Charité and ProDisc-L lumbar ADRs were evaluated before and after reconstruction of the ALL with the Embrace. Axial rotation was reduced by 32% for Charité, 40% for Prodisc (p< 0.05). Extension was reduced by 24% for Charité and 19% for ProDisc (p< 0.05). Facet micro-strain was significantly decreased (p< 0.05). This is the first report on its clinical safety and efficacy.

Methods: Thirty-nine patients underwent ADR followed by ALL reconstruction with the Embrace device. Clinical outcomes (VAS, ODI) were prospectively collected on all patients. Minimum follow-up was one year. 24 patients received a Charite device and 15 received a ProDisc-L device. The average age of all patients was 38.8 years. 19 were males and 20 were females. The average patient BMI was 27.5. 27 patients underwent one-level ADR, and 6 patients received two-level ADR. 4 patients underwent hybrid (one fusion level, one ADR level), and 2 patients received a three-level hybrid.

Results: Pain and function were significantly improved at
6 and 12 months compared with pre-op values (Table 1). Based on Purcell FDA criteria for clinical success, defined as >15 point improvement in ODI and no reoperation, major complications, or decreased nerve function, 78.6% of patients were a clinical success at one year follow up. There were no differences in the outcome data between ProDisc-L, Charité, one-level, two-level or hybrid patients. These results are superior to the one-level IDE data reported in the Charité (63% success) and ProDisc-L (63.5% success).

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<th>Combined ODI and VAS Averages</th>
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(Table 1)

Conclusion: ADR with ALL reconstruction using the Embrace™ embroidered graft containment device resulted in significant clinical improvement. FDA clinical success in these more complicated patients was 78.6% at one year follow up. This is superior to the one level ProDisc (63.5) and Charité (63%) success. Coupled with prior reports of biomechanical advantage, this construct may be a promising addition to ADR.

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Relationship between Pre-operative Expectations and Post-operative Satisfaction and Functional Outcomes in Lumbar & Cervical Spine Patients: A Multi Center Study
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Introduction: Back pain is one of the most common health problems, leading to the utilization of healthcare resources, work loss, and sick benefits. Patient expectations influence post-treatment outcomes, both surgical and non-surgical. There is little research on the importance of pre-operative expectations in spine surgery. Existing studies evaluate the technical aspects of interventions and functional outcomes but fail to take into account patient expectations. This retrospective analysis of prospectively collected multicenter data aims to explore the relationship between pre-operative expectations and post-operative outcomes and satisfaction in lumbar and cervical spine surgery. The authors hypothesized that expectations dramatically affect spine patient satisfaction independent of functional outcomes.

Methods: Prospectively collected patient entered data from lumbar and cervical spine patients from two study centers collected using a web based patient health survey system was analyzed. The study included patients who underwent operative intervention (decompression with or without fusion) with at least a 3-month period of follow-up. Pre-operative expectations were measured using the MODEMS expectation survey. Post-operative satisfaction and fulfillment of expectations were measured using the MODEMS satisfaction survey. Post-operative functional outcomes were measured using the ODI and SF-36. Multivariate ordinal logistic regression modeling was used to examine predictors of post-operative satisfaction. Multivariate linear regression modeling was used to examine predictors of functional outcomes.

Results: 402 patients were included in the study. Significant predictors of increased satisfaction include: higher fulfillment of expectations regarding work (p=0.003) and pain relief (p=0.008), greater post-operative SF-36 (p=0.04), and lower pre-operative expectations regarding ability to exercise (p=0.03). Lumbar spine patients were more satisfied than cervical-spine patients. Significant predictors of better post-operative function include: higher expectations regarding sleep (p< 0.0002), fulfillment of expectations regarding work (p=0.0001), sleep (p=0.03), and daily activities (p=0.02). Cervical spine patients had better functional outcomes (p=0.006).

Conclusions: This study showed that pre-operative expectations and their fulfillment influence post-operative satisfaction in lumbar and cervical spine patients. This underlines the importance of taking pre-operative expectations into account in order to obtain an informed choice based on patient preferences.

Breakout 1: Nucleus

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Long Term Follow up of a Prospective Randomized Study of Chemonucleolysis Compared to Surgery
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Purpose of the study: Assessment of long term results of Chemonucleolysis vs. surgical enucleation in soft disc herniation

Material and methods: From 1982 to 1985, 100 patients with symptomatic disc herniation were randomly allocated to receive either Chemonucleolysis or standard discectomy after a three months trial of conservative treatment. Ten of the chemonucleolysis had no relief of leg pain at three months and had surgery. The results at one year showed no significant difference between the groups. In 1995, a 10 - 13 year follow up was conducted. Sixty one of the original 100 patients responded, 32 were from chemonucleolysis group and 29 from the surgical group. In addition, 32 patients agreed to have a lumbar spine radiograph, 18 from the chemonucleolysis and 14 from the surgery group. In 2009, a 25 - 27 year follow up was conducted. Forty four patients out of original 100 patients responded. 24 were from chemonucleolysis group and 20 from the surgical group.

Results: The clinical outcomes were measured using the MacNab Criteria. The disc height of the affected disc was measured from the lateral lumbar spine radiograph and compared to the adjacent disc above expressed as a percentage. The results of two groups of patients were compared using Chi square and T test for independent samples. At 10 - 13 years, by the Macnab criteria, 20 (63%) had excellent 3 (9%) good, 5 (16%) fair and 4 (13%) poor results in the chemonucleolysis group and 18 (62%) had excellent 3 (10%) good, 4 (14%) fair and 4 (14%) poor results in the surgery group. At 25 - 27 years, 7 (29%) had excellent 8 (33.5%) good, 3 (12.5%) fair and 6 (25%) poor results in the chemonucleolysis group and 7 (33.5%) had excellent, 7 (33.5%) good, 4 (19%) fair and 3 (14%) poor results in the surgery group. Patients with poor result in Chemonucleolysis group consisted of four

 Friday, April 29th
patients who had early surgery post chemonucleolysis, three of whom also had co-existing pathology, a poor result post TKR, post fracture neck of femur, and one had fibromyalgia. Poor results in surgical group were due to persistent back pain.

The radiological outcome revealed that the mean initial disc height in the chymopapain group was 88.4% compared to 83.1% in the surgery patients. At 10 - 13 years it was 76.2% and 74.7% respectively, and at 25 - 27 years it was 62% and 67.2% respectively.

**Conclusion:** The clinical results at all three time points have shown no statistically significant difference between the patients treated initially by either chemonucleolysis or surgery. In addition there is a small loss of disc height following both treatments over time with no statistical difference between the two treatments. The added benefit of using chymopapain injection as the primary treatment is that it is of lower cost and no detrimental effect on the long term outcome. Chemonucleolysis should have a wide role in treatment of sciatica due to intervertebral disc herniation.

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**Role of Nucleoplasty in the Treatment of Discogenic Axial Low Back Pain**

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**Introduction:** Chronic discogenic pain is a condition afflicting a fair majority of adult population. The treatment ranges from non operative treatment (physiotherapy, acupuncture, chiropractic manipulation) to major interventional surgery (disc replacement/spinal fusion). A lot of minimally invasive procedures have been developed over time ranging from primary chemonucleolysis in 1964 to intradiscal electrothermy in 2000. Nucleoplasty is one such procedure.

Nucleoplasty is a minimally invasive procedure that utilizes the principle of radiofrequency ablation to achieve volumetric reduction, reduction of intradiscal pressure and disc decompression. Literature supports the role of nucleoplasty in discogenic leg pain to an extent but the effectiveness in terms of back pain has not been evaluated much so far. The discogenic leg pain has various treatment options of root block, endoscopic discectomy, and open microdiscectomy with successful outcome in treating the leg pain. Back pain still remains a major disabling problem which is yet to be addressed in a minimally invasive way.

**Objective:** To evaluate the effectiveness of nucleoplasty in the treatment of chronic discogenic axial low back pain in patients who failed conservative treatment for a period of 3 months.

**Subjects:** 30 patients undergoing nucleoplasty performed by a single surgeon at one or more levels from Oct 2008 to Dec 2009 were included in the study. Patients with clinically symptomatic back pain with or without leg pain who failed conservative treatment were included.

The patients with working diagnosis of infection or malignancy, clear cut nerve root pain with working diagnosis of disc prolapse, pregnancy and children were excluded. All patients who underwent the procedure had discography carried out for the levels in question.

**Study design:** Patients were assessed clinically with using the Visual analog Scale (VAS) back and leg, Oswestry disability index (ODI), and Short Form-36 (SF-36) preoperatively. MRI was studied for evaluation of degenerate disc with regards to disc height, presence and location of annular tear. In the post operative period they were followed at 6 weeks, 3 month, 6 month and 1 year.

**Outcome measures:** The patient satisfaction was determined by VAS back and leg, ODI and SF-36 at 6 months and 1 year. Clinical and radiological outcomes were compared with preoperative outcome measures to ones at 6 month and 1 year.

**Results:** Significant improvements was noted only in 66% (20/30) of the treated patients. The ones that improved showed significant improvement in outcome indicators of ODI, VAS (back) and SF-36.

We analysed the reason for success in the population that improved after the procedure. Presence of high intensity zone (HIZ) indicating annular tear was associated with poor outcome. Patients with positive discography (11/18) surprisingly did not show an improvement as against the ones with negative discography (9/12).

**Conclusions:** Nucleoplasty has an effective role in the treatment of patients with chronic discogenic back pain in a select group.
results for the control arm were similar to prior PMA data. **Conclusions:** This is the first report from the U.S. on data from two sites participating in an ongoing IDE pivotal study evaluating the safety and efficacy of NUBAC. The preliminary analysis of data from these two sites show significant improvements in pain and disability, and that range of motion and disc height were maintained, similar to the control arm. NUBAC patients had shorter operative times and shorter hospital stays as well as less intraoperative blood loss.

**105** Percutaneous Laser Disc Decompression by 980nm Biolitec Laser for Herniated Lumber Disks

*A.R. Patel*, Image Documented Herniated Intervertebral Disc in 172 Patients

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**Aim & objective:** The objective of this study to illustrate the use of PLDD, a minimally invasive procedure for contained disc herniation, which has been developed to treat symptomatic patient (failed conservative methods).

**Background data:** Percutaneous laerdisc decompression (PLDD) is a procedure in which herniated intervertebral discs are treated by reduction of intradiscal pressure through laser energy. This is introduced by a needle inserted into the nucleus pulposus under local anesthesia and fluoroscopic monitoring. The small volume of nucleus vaporized results in sharp fall of intradiscal pressure, with consequent migration of the nucleus away from the nerve root or thecal sac, temporary denaturation of portion of nucleus protein resulting in reducing capacity to pressurize annulus . First proposed by Dr. Deniel choy, Columbia University, New York, USA. In1986 thereafter, million of patients operated with 89% success rate. US-FDA and AMA had approved the PLDD.

**Materials and methods:** A nonrandomized, nonblinded study is conducted in male and female patients with symptomatic, image documented intervertebral herniated discs in 172 patients-174 discs, using PLDD only modality in 162 cases and PLDD with epidural lavage in 10 patients. They were observed over a period of 11/2 month to 5 year. Treatments were carried out under CT/Fluoroscopy guidance/Cathlab with local anesthesia and day care or single day indoor stay.

**Results:** At follow up, back pain was eliminated or reduced in 80% of the patients. Regarding sensorimotor impairment, PLDD did have a positive effect on 90% of the patients. (Modified Mac nab criteria) All patients noticed relief in pain and function improvement. The results of this study confirm the previous reports on ozone chemonucleolysis in lumbar disc herniations with results no different from surgical discectomy. Its advantages stay in its minimal invasiveness, absence of complications and lowering of hospital and social cost.

**Keywords:** Lumbar disc herniation, chemonucleolysis, ozone, percutaneous surgery, microdiscectomy

**Conclusions:** This is the first report from the U.S. on data from two sites participating in an ongoing IDE pivotal study evaluating the safety and efficacy of NUBAC. The preliminary analysis of data from these two sites show significant improvements in pain and disability, and that range of motion and disc height were maintained, similar to the control arm. NUBAC patients had shorter operative times and shorter hospital stays as well as less intraoperative blood loss.

**136** Intradorsal Ozone Chemonucleolysis vs. Microdiscectomy: 48 Months Follow-up

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**Objective:** Comparison of efficacy between intradiscal ozone chemonucleolysis versus microdiscectomy in patients affected by non-contained lumbar disc herniations.

**Background data:** In the past 10 years, the quantity of literature on use of ozone in the treatment of lumbar disc herniations has been rapidly growing. The results seems promising with complication rates almost nil.

**Materials & methods:** Prospective, non-randomized, self-selected, control study with follow-up at 1, 2 and 4 years. From January till June 2005, 45 patients, mean age 45 yy (20-77), affected by low back and leg pain due to non-contained (extruded) lumbar disc herniation, were included in the study. Patients were informed adequately regarding the two treatment options: ozone chemonucleolysis and microdiscectomy, and they self selected their treatment. The symptoms duration prior to treatment was 5.9 months (±2.5) for ozone group and 3.3 months (±4) for microdiscectomy. In all cases neurological examination was found negative for palsy (≥ 4 on Fisher scale). The ozone chemonucleolysis group included 30 patients, mean age 45.8 yy, and microdiscectomy group included 15 patients, mean age 40.1 yy. Patient outcomes were assessed using the Visual Analogic Scale and Roland-Moriss Disability Questionnaire at different time periods.

**Results:** At 12 months 27 patients (90%) in the ozone group and 14 patients (93.3%) in the microdiscectomy group showed a clinically relevant improvement in pain (P < 0.001, Wilcoxon test) and function (P < 0.001, Wilcoxon test). At 24 months 2 patients from the ozone group went to microdiscectomy while 1 patient repeated the ozone treatment. In the microdiscectomy group 1 patient presented a new disc herniation at the level adjacent to the original one and was operated. At 4 years, 2 patients from ozone and one from microdiscectomy group were lost from the follow-up. Furthermore, one patient from microdiscectomy group underwent fusion surgery for increase in low back pain. Finally, at 4 years follow-up, 73.3% (P < 0.001) of patients from ozone group and 73.3% (P < 0.005) of patients from the discectomy group maintained a statistically significant improvement as compared to the baseline values. There were no significative differences between two groups regarding the pain and function improvement.

**Conclusions:** The results of this study confirm the previous reports on ozone chemonucleolysis in lumbar disc herniations with results no different from surgical discectomy. Its advantages stay in its minimal invasiveness, absence of complications and lowering of hospital and social cost.

**Keywords:** Lumbar disc herniation, chemonucleolysis, ozone, percutaneous surgery, microdiscectomy

**155** Variations in Anular Defect Characteristics in Herniated Lumbar Disks: A Feasibility Study of Anular Repair and an Attempt to Confirm Carragee Population Data on Defect Size

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**Introduction:** Carragee has studied the size of the hole in the anulus and the effect of defect size on the rate of recurrent HNP and revision surgery. However, Carragee’s paper did not report other characteristics such as defect location (mid anulus vs. adjacent to the inferior or superior end plate) nor tissue quality (intact/frayed/calcified). These additional characteristics (along with defect size) determine the feasibility of anular repair. Suturing (technically easiest/cheapest-and presently already on the market) applies only in situations where the anular tear is mid substance with good adjacent tissue. Defects adjacent to bone require a bone anchor for the suture (currently none available for clinical
use). Large anular holes necessitate a technically challenging, expensive barrier reconstruction (technology still limited to clinical trials).

**Purpose:** This study had two primary research questions: 1) what is the incidence of anular defect characteristics that determine the percentage of HNP patients who might be candidates for anular repair/reconstruction? and 2) does our cohort confirm the population distribution seen in the Carragee study regarding anular defect size.

**Methods:** A 100 consecutive patient cohort undergoing surgery for single level, primary HNP by the senior author were prospectively studied between December 2008 and March 2009. Size and location of the anular defect (mid substance/adjacent to superior or inferior end plate), tissue quality and Carragee Type (fragment/fissure, fragment/defect, fragment/contained, no fragment/ contained) were noted.

**Results:** There were 68 males/ 32 females (higher risk for males p=0.0003), average age 47. There were 55 right herniations and 45 left. 64% had mid substance defects/good adjacent tissues (suture applicable). Defect adjacent inferior end plate (21%), adjacent to superior end plate (8%) - bone anchor potentially applicable (29%). Thus, total potential repair patients (93%). Repair was not feasible in 7% due to calcification of the disc. Carragee categories (% ours/Carragee), Fragment Fissure (33/49), Fragment Defect (11/18), Fragment Contained (45/23). No Fragment Contained (11/8). Significant difference between our cohort vs. Carragee all categories (chi-square test p< 0.0001).

Using presently available anular suturing technology, 64% of the patients in this study would be candidates for anular repair. If a bone anchor was developed, 93% of patients would be candidates for reconstruction.

The primary reason for inability to repair was a calcified disc. No patients had thinning or shredding of the annulus to a degree that would prohibit anular reconstruction.

The statistically significant variation in all Carragee defect size categories was a surprise. Carragee population data on defect size was not confirmed. The true population incidence remains uncertain.

**Conclusions:** With the available suturing techniques, more than a third of patients with a disc herniation will not be candidates for anular repair/reconstruction.

A bone anchor needs to be developed to elevate anular repair as an option for almost all lumbar HNP patients.

Additional studies of Carragee defect categories will be necessary to more accurately define the population incidence of various types of anular failure. Determining reliable population incidence is key for accurately calculating the cost effectiveness of anular repair technologies.

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**Can an Annular Repair Device Prevent Recurrent Disc Herniation and Interrupt Degenerative Disc Disease? A New Motion Preserving Annular Repair Device Prevents Recurrent Herniation and Maintains Disc Height**

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Lumbar disc herniation is a common symptom of low back pain and often requires surgical intervention. The outcome of the surgery is a factor of the surgical proficiency, annular wall competency, disc degeneration and patient expectations. There are many publications describing discectomy techniques, outcome measures, reherniation and reoperation rates and disc height changes. These reports suggest reherniation and reoperation rates can occur in about 15% of patients and poor patient outcomes can occur in about 28% of patients with most recurring symptoms manifesting within twelve months of the discectomy procedure.

A novel PEEK annular repair device has been developed with a complex geometry to be inserted into an annular defect following discectomy surgery. The device is self retaining with a feature for retention and occupying a voided space within the disc space; structurally supports disc height between adjacent vertebrae; and, seals the annular defect while promoting a fibrous capsule response on the posterior aspect of the device. Biomechanical testing was completed to demonstrate safety and led to a feasibility study by the authors.

A prospective study for patients with single level lumbar disc herniation was initiated. Patients failed conservative therapy, had MR confirmation of disc herniation before surgery and met inclusion and exclusion criteria before consenting to the study. Baseline ODI and VAS scores were measured prior to surgery. Discectomy surgeries were performed either open or using MIS techniques. Following the discectomy the disc space was measured and prepared for the implant. Follow-up intervals are post-op, 6 weeks, 3, 6 and 12 months from surgery and include clinical assessment, evaluations and imaging.

Twenty patients were enrolled in the study. Mean age was 43±14 years and 50% of the patients were male. All patients were discharged one day after surgery. All patients have completed minimum six month follow-up visits and eight...
patients have one year follow-up. There are no recurrent disc herniations. Disc height and sagittal alignment have been maintained. Flexion and extension radiographs demonstrate segment motion preservation. MR images provide evidence of a thin fibrous cap covering the posterior aspect of the implant and annular defect. CT images confirm dense bone surrounding the implant at the adjacent vertebrae without observation of latent patient pain. Mean baseline ODI was 77%±8%; mean six month ODI was 7%±6% and mean one year ODI was 2%±2%. Mean baseline VAS was 72mm±10mm, mean six month VAS was 9mm±10mm and mean one year VAS was 4mm±5mm. Two patients required revision surgery unrelated to a recurrent herniation. The new annular repair device does not affect the discectomy procedure and is easy to use. The implantation step adds approximately seven minutes to OR time. The device is retained and there have been no observations of recurrent disc herniation. Imaging results and pain scores confirm annular repair implant benefits. Study data for ODI and VAS demonstrate continued improvement in patient outcomes over one year follow-up whereas published discectomy patient benefits typically plateau after three months. Does disc height, motion preservation or a physiologic response to the annular repair device improve patient outcomes? Longer term follow-up data is being collected.

555 Selective Endoscopic Discectomy and Thermal Annuloplasty for Chronic Lumbar Discogenic Pain: An Endoscopically Guided, Visualized Intradiscal Electrothermal Procedure
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Introduction: The pathogenesis of lumbar chronic discogenic pain (CLDP) has been hypothesized, studied, and generally accepted by clinical studies, but few treatment methods have gained universal acceptance. After non-surgical treatments fail, the choices of traditional surgical intervention are limited. The purported mechanism of each surgical procedure’s effectiveness is dependent on one or a combination of the following concepts:1. Eliminate or modify motion at the diseased mobile interspace (fusify); 2. Relieve intradiscal protrusion and pressure(discsectomy); 3. Ablate neural sensors in the perianular regions (IDET).

Endoscopic Selective Discectomy and bipolar radio-frequency thermal annuloplasty was used to test the hypothesis that chronic leakage of the inflammetogenic by-products of a degenerating nucleus pulposus through the defects in the annulus fibrosus sensitizes neural sensors in the perianular regions, resulting in a painful inflammatory response. If the hypothesis is correct, removal of the inflammetogenic material (discectomy) and ablation of the neural sensors in the annular defects and closure of the defects, (thermal annuloplasty), would decrease discogenic pain.

Method: An IRB approved prospective study of 113 consecutive patients undergoing endoscopic thermal annuloplasty for chronic lumbar discogenic pain with a minimum follow-up of two years served as the basis for this report. In Contrast to the strict patient selection necessary for subsequent IDETstudies, we included all patients with degenerated, protruding discs severe concordant discogenic back pain with provocative discography.

Results: Seventeen patients (15%) had excellent results; thirty-two patients (28.3%) had good results; thirty-four patients (30.1%) had a fair result; thirty patients (26.5%) had poor result. Inflammatory granulation tissue and nucleus pulposus embedded in the annular layers were common findings. Two patients experienced severe dysesthesia, one fully recovered and and one patient with unrecognized co-morbidities of epilepsy and peripheral neuropathy had permanent radiculopathy.

Discussion: Stratification of the Good and Excellent results allowed refinement of the patient selection process to the current selective nuclectomy and radio-frequency thermal annuloplasty technique. SED with thermal annuloplasty then produced consistent clinical results when compared to IDET. The addition and combination of selective discectomy with visualized thermal annuloplasty serve as an improved, “visualized IDET” for discogenic back pain. This is the first known clinical experience report in the English literature on a visualized electro-thermal technique. Using the technique described, our satisfactory results are comparable to more conventional, but more invasive surgical therapies such as fusion and Total disc Replacement, but with much less cost and surgical morbidity.

Conclusions: The posterolateral transfominal endoscopic approach to the disc allows for intradiscal visualization and probing of the annulus and nucleus pulposus. This tissue sparing access portal opens the door to new intradiscal treatment as a surgical therapy that does not “burn any bridges” for subsequent non-surgical and surgical treatment. The transfominal access portal utilizing an endoscope will allow further research into the generators and causes of discogenic pain in the early stages of disc herniation. It also allows for earlier and more effective surgical treatment in a population of patients with prodromal symptoms of disc herniation and radiculopathy.

Breakout 2: Innovative

298 Prospective Randomized FDA IDE Pivotal Study of Symptomatic Lumbar Spinal Stenosis Patients Treated with ACADIA™: Interim Perioperative and Clinical Outcomes for the Investigational Device
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Introduction: Patients suffering from neurogenic claudication or lumbar radiculopathy secondary to lumbar spinal stenosis and/or instability are often treated with surgical decompression and segmental stabilization. Spinal arthrodesis is the current standard of care for restoring segmental stability however changes in lumbar biomechanics due to the elimination of motion at the index level have the potential to accelerate degenerative changes at adjacent levels. ACADIA™, an anatomic facet replacement device, may provide the required stability while also preserving the natural balance of forces in the lumbar spine, thus mitigating the risk of accelerated degenerative changes at adjacent
levels. The interim perioperative and clinical outcome data for the ACADIA™ prospective, randomized FDA IDE pivotal trial is reported herein.

**Methods:** Patients diagnosed with symptomatic lumbar spinal stenosis at L3/4, L4/5 and/or L5/S1 received the ACADIA™ device at a single level. Bilateral facetectomies and laminotomies were performed to achieve decompression of the neurovascular structures. Pedicle screws were placed and implant bone beds were prepared on the dorsal aspect of each pedicle with specialized instrumentation. Articulating facet implants were fixed to the pedicle screws and a cross connector was attached. Outcome measures including Oswestry Disability Index (ODI), Visual Analog Scale (VAS) pain scores for the back and legs and the Zurich Claudication Questionnaire (ZCQ) were recorded at baseline, 6 weeks, 3, 6, 12 and 24 months.

**Results:** Ninety-one patients at 16 centers have received the investigational device with 86 and 41 patients completing the 3 and 12 month follow-ups, respectively. Training cases accounted for 20 patients while 71 patients were randomized to ACADIA™. Patients ranged in age from 34 to 81 with a mean age of 60. The mean BMI was 30 kg/m². Mean operative time, blood loss and hospital stay were 172 minutes, 387 mL, and 2.7 days, respectively. The L4/5 level was treated in 84.6% of the patients while the L3/4 and L5/S1 levels comprised 8.8 and 6.6% of the cases, respectively. The mean ODI improvement was 29 points (63%) and 33 points (70%) at 3 and 12 months, respectively. The mean VAS leg pain improvement was 66 points (84%) and 72 points (89%) at 3 and 12 months, respectively. The mean VAS back pain improvement was 52 points (74%) and 55 points (79%) at 3 and 12 months, respectively. The mean VAS leg pain improvement was 66 points (84%) and 72 points (89%) at 3 and 12 months, respectively. The mean ZCQ symptom severity improvement was 1.73 points (66%) and 1.72 points (66%) at 3 and 12 months, respectively. The mean ZCQ physical function improvement was 1.21 points (69%) and 1.22 points (71%) at 3 and 12 months, respectively. The ZCQ patient satisfaction scores were 1.36 and 1.37 at 3 and 12 months, respectively.

**Discussion:** The perioperative results for ACADIA™ are comparable to published data for decompression with instrumented posterolateral fusion. Large early improvements in functional and pain outcome measures were seen even at 3 months and maintained out to 12 months. While this interim data is strong, long-term follow-up is needed to determine whether or not ACADIA™ reduces the incidence of adjacent segment disease when compared with fusion.

**153 Clinical Outcomes from a Prospective Study on Archus Total Facet Arthroplasty System for Treatment of Lumbar Stenosis with Degenerative Spondylolisthesis**


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**Purpose:** To report clinical outcome on a subgroup of patients with lumbar stenosis and degenerative spondylolisthesis who participated in a randomized prospective trial on the Archus Total Facet Arthroplasty System (TFAS).

**Method:** Data was obtained from a subgroup of patients who were a part of a multi-center prospective randomized controlled trial on TFAS. Ten patients with lumbar stenosis and grade 1 degenerative spondylolisthesis underwent total facet arthroplasty at one institution between April 2007 to January 2009. Outcomes were measured based on clinical examination, questionnaires (including the Zurich Claudication Questionnaire, Visual Analog Scale for Pain, Oswestry Disability Index), and radiographs. Data were collected at pre-operative, 1, 3, 6, 12, and 24 month post-operative visits. Adverse events occurred during this period were also reported.

**Results:** Ten patients ranging from 50 to 74 years of age (mean age 62.6 years), who underwent total facet arthroplasty at L4-5 after decompression, were followed for 2 years. The Zurich Claudication Questionnaire (ZCQ) Symptom score showed statistically significant improvement (p<0.05) from baseline at 1, 3, 6, and 12 months. The mean Visual Analog Scale (VAS) for back pain also showed significant improvement (p<0.05) at 1, 3, 6, and 12 months, while the VAS for leg pain had improvement (p<0.05) at all post-operative visits. The mean Oswestry Disability Index (ODI) did not demonstrate any statistically significant improvement (p>0.05). Neurologically, 2 patients developed dysesthesia post-operatively at L2 distribution. The post-operative segmental angular motion (SAM) measured on lateral flexion and extension radiographs taken at each visit demonstrated no significant change (p>0.05) from preoperative measurement.

Four catastrophic adverse events were recorded which
included 2 stem breakages, 1 hardware loosening and migration, and 1 cement extrusion into the canal. Three of the 4 patients had BMI (mean 38.2) at the upper end of the spectrum (group mean 33.0), and all 4 patients required subsequent conversion to fusion. 

**Conclusion:** The Archus TFAS has demonstrated reasonable pain relief and functional improvement during the 2 year followup period. However, given the high incidence of catastrophic adverse events (40%), its safety is a serious concern. The risks of this innovative device outweigh its benefits and short-term success, and is not currently recommended for the treatment of lumbar stenosis with degenerative spondylolisthesis.

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**The Reliability of a New Computed Tomography Imaging Grading System of Lumbar Facet Arthropathy**

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**Purpose of the study:** Our goal is to report a new classification for facet arthropathy and to compare it with the currently established classifications. In our previous study we determined that both Pathrea and Fujiwara classification revealed only a “fair” intra and inter-observer reliability. We intend to analyze all parameters pertinent to facet arthropathy and select the most reliable criteria to create a reproducible, simple and clinically significant classification. We also intend to compare the results between attending spine surgeons, fellows and radiologists.

**Methods:** A total of 7 fellowship-trained orthopedic spine surgeons and 2 orthopedic spine fellows, 3 fellowship trained physiatrist and 2 fellowship trained radiologists evaluated 50 levels from L3-L4 through L5-S1 on parallel axial MRI (T1 and T2) and CT images. The degree of osteoarthritis was graded on a 8-point scale based on the presence of joint narrowing, osteophyte formation, subchondral cysts, sclerosis, effusion, synovial cysts, fragmentation and fusion. The 4 criteria with highest reliability were selected. One point was given for the presence of the radiographic criteria, giving a total of 4 points maximum. Grading was performed during 2 sessions. Weighted kappa statistics were used to describe inter- and intraobserver agreement.

**Summarize the findings:** The radiographic criteria selected with higher intra-rater reliability were; joint narrowing (0.55), osteophyte formation (0.68), subchondral cysts (0.62) and fusion (0.62). CT had a higher intra-rater reliability when compared to MRI (0.51 vs. 0.31). The new classification mean inter-rater reliability among attendings, fellows and radiologists were 0.4, 0.26, 0.35.

**Conclusions:** Previously established grading systems for facet arthropathy have only fair agreement. We report a simpler method of grading facet arthropathy with a significantly higher reproducibility. This is classification can vital in the decision of utilizing a total disc arthroplasty in the lumbar spine.

Orthopaedic spine surgeon attendings have a higher agreement percentage and kappa values compared to fellowship trained radiologists and spine fellows.

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**Vertebral Growth Modulation in the Porcine Scoliosis Model assessed by Computed Tomography: 3-D Effect of a Corrective Tether**


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**Introduction:** In theory, vertebral growth modulation through a convexly placed tethering implant in the setting of scoliosis would lead to progressive vertebral correction in the coronal plane (Hueter-Volkmann Principle). Using an established Porcine Scoliosis Model, this study aims to investigate the impact of a non-fusion corrective anterior convex spinal tether on an induced deformity, examining detailed vertebral morphology and axial rotation.

**Methods:** This IACUC approved Study included 10 immature Yorkshire Pigs divided into 2 groups: tether release group (TR, n=5) and corrective tether group (CR, n=5). All animals underwent induction of scoliosis. Once >50° was noted on radiographic follow up a second surgical intervention was pursued: TR had release of the inducing tether; AC had tether release and placement of a corrective tether over the 5 apical vertebrae. Both groups were observed for 20 weeks, then euthanized. Fine cut CT scans were used to create a volumetric 3D reconstruction of the apex (3vertebrae, 2discs). Student T-test was used to evaluate differences between groups.

**Results:** Regarding absolute vertebral heights, no significant differences were observed between TR and AC in posterior and concave side vertebral body heights. However, significant reduction was found in anterior and convex side vertebral heights in AC; anterior: TR 8.9cm vs. AC 7.9cm (p< 0.01) and convex: TR 9.8cm vs. AC 8.7cm (p< 0.01). No significant difference was found in apical vertebral body volumes between TR 18.3cm³ and AC 17.7cm³, while the AC group presented bigger vertebral endplates: TR 5cm², AC 5.5cm² (p=0.01). A significant reduction in coronal wedging angle of 18° was found between TR 36.1° and AC 18.1° (p< 0.01). A significant increase in sagittal kyphosis was observed over the apex: TR +6° and AC -9.6° (p=0.04). A 25% correction in apical rotation was achieved.

**Conclusion:** This study demonstrated that using an anterior tether, favorable growth modulation was possible without affecting the overall vertebral volume and led to a 3 plane correction of the scoliosis: correction of coronal Cobb, reduction of axial rotation, restoration of sagittal kyphosis.
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An Innovative Solution in the Treatment of Facet Arthropathy: The Facet Resurfacing Concept
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Introduction: Lumbar total disc replacement (TDR) has been successfully used as an alternate to anterior fusion that can also restore the interbody geometry while preserving segmental motion. Patients with significant spinal stenosis and facet arthropathy, however, are often excluded from having TDR as increased segmental motion can exacerbate dorsal spondylotic changes. The exact cause of facet arthropathy is not yet clear but degeneration is usually the main cause of this type of degenerative arthritis where the pain is caused due to the loss of cartilage between the joints. Medication, physiotherapy and injections are three main treatments that can be given to facet arthropathy patients, but the results are not sufficient. Here we present a new facet resurfacing device to treat facet arthropathy due to facet degeneration.

Materials and methods: 13 patients underwent facet resurfacing procedures. The surgery consisted in a posterior minimal invasive approach to the zygapophysial joints. The capsule was opened and the device was inserted using a special instrumentation. Three patients suffered from facet degeneration after lumbar total disc replacement, and 10 patients had facet arthropathy at an adjacent level to posterior fusion. A facet impingement was seen in all fusion cases, due to the posterior rod. All patients that had posterior fusion had the screws and rods removed at the time of surgery.

Results: The mean surgical time was 109.2 minutes, with a mean blood loss of less than 50cc. All surgeries occurred without any intra operative adverse event. Preoperative VAS was 8.25 and decreased to 1.5 only 3 months after surgery. The preoperative ODI was 58.5 and deceased to 18 at 3 months follow up visit. The radiological exams show good positioning of the device in all operated cases, with no statistical difference in range of motion at the operated levels.

Conclusion: This new device represents a dynamic facet resurfacing system that provides a safe surgical option in the treatment of facet arthropathy. Our surgical data demonstrates that it can be safely applied through a posterior approach with low surgical morbidity and good functional and radiographic outcomes in patients with facet pain. Additional long-term, randomized studies will be needed before conclusive statements can be made regarding the efficacy of the Zyga facet resurfacing system.

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Vertebral Body Stapling vs. Bracing for Patients with High-risk Moderate Idiopathic Scoliosis
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Study design: Retrospective review
Objective: To compare results of vertebral body stapling (VBS) versus bracing for patients with moderate idiopathic scoliosis using identical inclusion criteria.

Introduction: VBS has been presented as an alternative treatment strategy for patients with adolescent idiopathic scoliosis. Preliminary results of VBS cohorts have been published. The efficacy of bracing for AIS has been questioned, and the issue of compliance and the psychosocial problems add to the desire for additional alternatives to bracing as a treatment. This study reports a retrospective comparison study of VBS versus bracing only for patients with moderate idiopathic scoliosis using identical inclusion criteria.

Methods: We retrospectively reviewed 43 of 49 patients (88%) with idiopathic scoliosis treated with VBS for a minimum of 2 years. Inclusion Criteria: 1) Diagnosis of idiopathic scoliosis; 2) age at least 8 years at time of first visit; 3) curve size of 25-44° at first visit; and 4) Risser sign of 0 or 1 at first visit.

Thoracic curves were stapled using a thoracoscopic technique utilizing CO₂ insufflation and single lung ventilation. Lumbar curves were stapled using a minimally invasive retroperitoneal exposure. All staples were inserted under fluoroscopic control. Failure was defined as curve progression greater than 10° at follow-up.

The bracing cohort was a consecutive series of patients derived from the Goteborg bracing database that were treated between 1968 and 1994 and queried to meet identical inclusion criteria as the VBS group. From this bracing database, 165 curves in 129 patients (with 36 patients having both thoracic and lumbar curves) were identified.

Results: The two cohorts were thought to be comparable with the exception of age at the start of treatment. The average age of the VBS group vs. the bracing group was 10.5 years vs. 12.7 years, respectively (p<.0001). Average curve size was 31 vs. 32° (p=.4) and average follow-up was 41 vs. 43 months (p=.09). For thoracic curves 25-34°, VBS had a success rate of 80% versus 63% for bracing (p=.09). In thoracic curves 35-44°, VBS had a success rate of 80% versus 63% for bracing (p=.2). In thoracic curves 35-44°, VBS and bracing both had a poor success rate (18% and 51%, respectively) (p=.08). For lumbar curves 25-34°, VBS had a 77% success rate versus only 63% for bracing (p=.5), and for lumbar curves 35-44°, VBS had a 67% success rate versus 60% for bracing (p=1.0). Adjustment for age at match in both cohorts (average age 10.5 years) showed more progression in the brace group results but did not change the conclusions.

Conclusion: In this comparison of two cohorts of patients with high-risk moderate idiopathic scoliosis (25-44°), there were no statistical differences in treatment results. However, the trends may be considered clinically important. For treatment of thoracic and lumbar curves 25-34°, the results of VBS for curve stabilization and improvement showed a trend towards slightly better success than those treated with bracing. With the exception of thoracic curves 35-44°, the data suggest that VBS could be used as an alternative to bracing for patients who are struggling with the ramifications of brace wear. For thoracic curves 35-44°, additional strategies are needed such as a posterior hybrid rod and or anterior tethering technology.
Progressive Spinal Deformity Correction via an Anterior Based Tether in a Porcine Scoliiosis Model: A Detailed Radiographic Analysis


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Introduction: Non-fusion techniques for surgical correction of scoliosis in an immature spine have recently received substantial interest. Using an established Porcine Scoliiosis Model (PSM), this study aims to investigate the impact of an anterior convex spinal tether on radiographic alignment changes with growth (non-fusion)

Methods: This IACUC approved Study included 10 immature Yorkshire Pigs divided equally into 2 groups; tether release group (TR) and anterior corrective tether group (AC). All animals underwent scoliosis induction surgery (max. coronal Cobb: 17°-25°) at 12 weeks of age and progressed a mean 4.0°/week. Once >50° was noted, a second surgical intervention was pursued: TR had release of the inducing tether; AC had tether release and placement of a corrective device over the 5 apical vertebrae. Both groups were observed for an additional 16 weeks with bi-weekly radiographs. Student t-test was used to investigate radiographic differences between groups.

Results: No significant differences existed between TR and AC regarding: induced Cobb angle, days with deforming tether, or coronal and sagittal alignment before the 2nd intervention (all, p>0.05).

Coronal Plane:
Significant differences in Cobb angle between TR and AC animals were noted following the 2nd intervention (TR: 44.4°±2.2° and AC: 35.0°±2.4°; p=0.001) and bi-weekly beyond 4 weeks (p<0.01). Final Cobb measurements were 45.0°±2.9° for TR and 24.4°±9.0° for AC (p=0.001).

Sagittal Plane:
No significant differences existed in sagittal alignment between TR and AC animals immediately following the 2nd intervention (TP: 14.4°±26.2° and AC: 16.2°±10.2°; p=0.88) and at final follow up, TR: 16.2°±20.9° and AC: 21.2°±12.3° (p=0.65).

Conclusions: Using the PSM, this study investigated radiographic differences between control and treatment groups. Application of a non-fusion anterior based convex staple-screw-tether resulted in significant progressive correction of the coronal spinal deformity (~50%) without significant sagittal plane re-alignment. Data from this study support the possibility of clinical techniques for non-fusion scoliosis correction in the immature spine through growth modulation.

Biomechanical Analysis of a Novel Cervical Spine Posterior Fixation Using Bio-derived Tendon in the Goat Cervical Ligament Complex Injury Model

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Introduction: The stability and motion of posterior cervical spine has considerable limitations regarding torn ligament complex. Conventional posterior cervical spine fixations are associated with high rates of loss of motor function in adjacent segment. Non-fusion techniques may offer potential alternatives for recreating a valid dynamic stability. The biomechanical testing was performed with the purpose of investigating a novel cervical spine posterior fixation using the bio-derived freeze-dried tendon could provide enough stability and motion preservation in animal cervical ligament complex injury model.

Materials and methods: Fifteen fresh cadaveric C2-C6 sheep cervical spine specimens were harvested and tested for the data of intact status as normal control group. Then, through resection of the ligament complex in posterior cervical spine (C3-C4), the unstable spines were randomly divided into three groups:
(1) injury control group (n=5)
(2) screw-rods fixation group: stabilization with screw-rods on C3-C4 (n=5);
(3) tendon reconstruction group: stabilization with bio-derived freeze-dried tendon on C3-C4 (n=5), freeze-dried tendon were cross-fixed with “8” shaped in the 3-4 cervical bilatera facet joints.

After implanting insertion, the specimens were loaded nondestructively with pure moments cycled from 0.75 to 3.5 Newton-meter for flexion, extension, right and left lateral bending, and axial rotation on a test apparatus. The range of motion (ROM) data for each fixation scenario was calculated, and a statistical analysis was performed respectively (P<0.05, ANOVA).

Results: In flexion loading, the ROM values of the tendon fixation group and screw-rods fixation group indicated there were significant differences (P<0.05), while the tendon fixation group and normal control group shared no significant differences (P>0.05). In lateral bending and axial rotation mode, the ROM values of tendon fixation group increased largely compared with screw-rods fixation group (P<0.05), however the ROM values of tendon fixation group had no significant statistically difference with normal control group and injury control group (P>0.05).

Discussion: The novel cervical spine posterior fixation using the bio-derived frozen dried tendon can provide enough stability in flexion motion, and do not limit the lateral bending and axial rotation motion which have provided simulated range of motion in animal model. Whether the novel fixation and the bio-derived material could prove a good biocompatibility and Mechanical Properties remains to be established in further studies.

Keywords: Cervical posterior fixation; ligament complex; biomechanics; stability; motion preservation
Breakout 3: Vertebroplasty

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Kiva Kyphoplasty (BENVENUE MEDICAL, INC.) - A New Kyphoplasty System in Comparison to (VP)
Vertebral compression fractures (VCF). The purpose of our study was to investigate the functional outcomes, safety and radiographic outcomes after the treatment of painful osteoporotic vertebral fractures treated with Kiva Kyphoplasty. The VP group served as control group.

Materials and methods: 47 patients (32 females and 15 males, mean age 69) with 72 osteoporotic vertebral compression fractures (VCF) were treated with Kiva. Three months follow up in 40 patients (27 females and 13 males) with 61 treated VCFs are reported. Thirty nine patients (28 females and 11 males, mean age 66 years) underwent 52 VP procedures. Three months follow up in 28 patients (22 females and 6 males) with 38 vertebral treated are reported. Patient-related outcomes of pain (Visual Analogue Scale) and disability (Oswestry Disability Index) were assessed pre- and postoperatively and after 3 months. Correction of vertebral height and kyphotic deformity were assessed by radiographic measurements. Cement leakage was evaluated by CT scan postoperatively.

Results: Mean pain visual analogue scale and Oswestry Disability Index significantly improved in both patients groups from pre- to post-treatment (P< 0.0001), this improvement being sustained up to 3 months follow up. A gain in height restoration and a reduction of the post-operative kyphotic angle were seen post-operatively and at 3-months in the Kiva Kyphoplasty group. Cement leakage was noted in of 5.5% of the Kiva procedures and 59.6% of the VP procedures.

No symptomatic cement leaks or serious adverse events were seen in the Kiva group during 3-months of follow up. Two patients in the VP group had a lung embolism due to a cement leakage, both of which were treated conservatively.

Conclusion: Kiva Kyphoplasty and verteoplasty are two minimally invasive procedures that provide immediate pain relief and improved functional ability in patients with osteoporotic VCFs. Both procedures are able to stabilize the fracture in the three months follow-up. Site specific application of a PEEK device and delivery of the cement through PEEK implant resulted in the added benefits of height restoration and lower cement leakages intraoperatively in the Kiva Kyphoplasty group.

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Endplate Anatomical Restoration May Reduce Adjacent Fracture Occurrence when Using a New Cranio-caudal Expandable Implant for Vertebral Compression Fracture Treatment
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Background: Literature about subsequent adjacent vertebral fractures occurring after VCF treatment has shown that there are fewer subsequent fractures when using balloon kyphoplasty than with non-surgical care. In the same time, a recent biomechanical study has demonstrated the role that can play the endplate deformity on the disc pressure profile load sharing and then on the adjacent fracture occurrence.

Purpose: The purpose of this study is therefore to analyze the occurrence rate of subsequent adjacent vertebral fractures when using a new vertebral cranio-caudal expandable implant (VCCEI) in combination with PMMA cement injection.

Study design: A prospective observational study enrolling 134 patients has been designed to evaluate the ability of the VCCEI to restore the anatomy of the fractured vertebrae and to limit the occurrence of adjacent fractures.

Patient sample: Mean fracture age was 32.4 days at the time of surgery. Assessments of clinical and radiological parameters were performed prior to surgery, after surgery, 6 months postop [30 patients - 34 VCF], 12 month postop [14 patients - 16 VCF] and 18 month postop.

Outcome measures: Using CT scans images, heights restoration, endplates’ angles changes were obtained for each scheduled visit [preop/exit/6m/12m]. Any subsequent fracture was registered within the follow-up period using XRay and CT scans exams.

Methods: CT scan data were analyzed by an independent laboratory (LBM, ENSAM - PARIS) to build a 3D reconstruction of the involved vertebra for each evaluation step. Then, 3D reconstructions were superimposed using a validated matching algorithm based on anatomical points on the posterior arch to evaluate the study parameters.

Results: The VCCEI allows achieving VCF reduction thanks to an anatomical restoration of the injured endplate as well as a kyphotic angle improvement up to 92%, and up to 10.8 mm height increase in the anterior part. More interestingly only 2 subsequent fractures were reported at 6 month (none at 12month) over 34VCF corresponding to a lower rate of adjacent fractures when compared to balloon kyphoplasty and non surgical care.

Conclusion: While providing an anatomical restoration of the vertebral body including the vertebral endplates, this new procedure could be of interest when looking at the adjacent fracture occurrence rate in the mid and long-term results.

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Clinical and Radiological Outcome after Radiofrequency Kyphoplasty - One Year Follow up
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Background: Radiofrequency (RF) Kyphoplasty provides a minimally invasive procedure to treat vertebral compression fractures. The monopedicular approach of the system can shorten operation time. Using radiofrequency-activated cement with high viscosity, leakages should be reduced and a high standard of patient safety assured. The RF-Kyphoplasty may therefore provide a safe and easy alternative to vertebroplasty or other kyphoplasty systems. The purpose of our study was to investigate the functional outcomes, safety and radiographic outcomes one year after the treatment of painful osteoporotic vertebral compression fractures with RF Kyphoplasty.

Purpose: To assess the efficacy and safety of RF-Kyphoplasty in treating thoracic and lumbar spinal osteoporotic fractures that result in pain, functional impairment or instability.

Materials and methods: 114 consecutive patients (mean age 70 years) with 210 fresh osteoporotic vertebral compression fractures (as determined through MRI imaging) were treated with RFK using the StabiIT Vertebral Augmentation System (DFine Inc. San Jose, CA). The StabiIT
System provides a navigational osteotome to create a site and size specific cavity prior to delivering ultrahigh viscosity cement with an extended working time (done by applying radiofrequency energy to the cement immediately prior to entering the patient). 78 Patients were available for a follow-up after 12 month.

Preoperatively, postoperatively and after 12 month, conventional radiographs were taken and assessed for vertebral body height and kyphotic deformity. Postoperatively and at follow up, adjacent level fractures and cement leakage were assessed. Patient-related outcomes of pain (Visual Analogue Scale) and disability (Oswestry Disability Index) were assessed pre- and postoperatively and at the follow up.

Results: Mean pain visual analogue scale (from 0: no pain to 100: maximum pain) improved significantly from pre- to post-treatment (84 to 25, p< 0.001). After 12 month, pain reduction continued down to 12. The Oswestry Disability Index decreased from pre- to postoperatively from 39% to 24%, and to 13% after 12 month (p< 0.001). An increase in vertebral body height as well as a decrease of the kyphotic angle was seen post-operatively and at the follow up. Cement leakage as evaluated on plain radiographs was noted in only 9 patients, none of the symptomatic. 4 patients had suffered an adjacent level fracture which was treated subsequently. No procedure-related serious adverse events were seen in the treated patients. General satisfaction with surgery was over 90%.

Conclusion: RF Kyphoplasty is a safe and easy invasive procedure that provides immediate pain relief and improved functional ability in patients with osteoporotic vertebral compression fractures. Functional outcome measures of pain and disability improved significantly immediately post-operatively and at the 12-month follow up. Cement leakage and complication rate can be reduced significantly compared to the rates reported for vertebroplasty. Specic cavity creation and delivery of ultra-high viscosity cement in RF Kyphoplasty resulted in some height restoration and reduction of kyphotic deformity.

91 Spinal Instability Predicting Score (SIPS) for Subsequent Fractures after Vertebroplasty in Patients with Osteoporotic Vertebral Compression Fractures
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Introduction: Augmentation procedures, such as vertebroplasty (VP) and kyphoplasty (KP), have emerged as the standard treatments for Osteoporotic vertebral compression fractures (VCFs) patients not responding to conservative treatment. However, these procedures have problems with subsequent fractures (SFs). The purpose of this study was to evaluate the spinal instability factors related to SFs after vertebral augmentation procedures.

Methods: We retrospectively reviewed patients who underwent augmentation procedures for osteoporotic VCFs. Between May 2003 and November 2007, 659 patients underwent vertebral augmentation procedures. Among those patients, 285 patients (Vertebroplasty (VP), n=231; Kyphoplasty (KP), n=54) with X-ray follow-up > 6 months were enrolled. SFs were classified into the following 4 groups: 1) no SFs (NSFs; no subsequent fractures), 2) neo-fractures (NFs; new vertebral fractures involving another vertebrae after a new history of trauma), 3) HFs (new vertebral fractures involving another vertebrae without a definitive history of trauma), and 4) kyphotic compression fractures (KCFs; progressive collapse and kyphotic changes of augmented vertebrae in the same vertebrae). We treated the patients with additional augmentation procedures for HFs and NFs, and conservative management for NSFs and KCFs. We analyzed SFs patterns of patients who underwent VPs. Each occurrence rate was studied for factors that may induce SFs due to instability; scoring was performed related to the HFs occurrence rate only. By summation of those scores, we obtained corrected SIPS for SFs. The items of the SIPS included fracture site (score, 2–5), vertebral augmentation level (2–6), vertebral height (1.5–10), vertebral kyphotic angle (1.5–6), spinal column kyphotic angle (1–6). After correcting the SIPS by factors which possible preventing HFs (0 ~ (-b)), based on the corrected SIPS in VPs, the SFs risk group were classified into the following four groups: group A, no risk group (12~13.5); group B, low risk group (12~13.5); group C, moderate risk group (14~18.5); and group D, high risk group (19~).}

Results: The SFs types for VPs were as follows: NSFs, 112 cases (48.28%); HFs, 65 cases (28.02%); NFs, 35 cases (15.09%); and KCFs, 19 cases (8.19%). The pre-operative VAS scores for VP were as follows: NSFs, 8.46; HFs, 8.58; NFs, 8.51; and KCFs, 8.47. The final follow-up scores were as follows: NSFs, 2.37; HFs, 3.72; NFs, 3.03; and KCFs, 3.26. In the SFs risk group, the possible percentage of HFs according to the corrected SIPS were as follows: { NFs } / { total FFs = possible percentage of HFs } [ NFs, SFs, and KCFs ] - group A: (84.06%) / (0%) / 0%, 10.14%, 5.80%
Vertebral Body Compression Fractures in the Early Old Aged Patients

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Purpose: Vertebral augmentation may reduce the patient’s pain significantly after osteoporotic vertebral compression fractures (VCFs). However, in some cases, subsequent fractures after vertebral augmentation procedures often deteriorate the patient’s lifestyle seriously. Therefore, initial treatment of osteoporotic VCFs is very important for remaining lifestyle of old aged patients. The purpose of the current study was to evaluate the significance of stabilization on augmentation procedures and to evaluate the effectiveness of vertebral augmented transpedicular screw stabilization (VATSS) for patients with osteoporotic VCFs.

Materials and methods: This study retrospectively evaluated the patients with VCFs who underwent the augmentation procedures between May 2003 and August 2009. Among those patients, only following patients were included in the current study: 1) less than 75-year old age 2) first event fracture 3) single level fracture and 4) exceeded 6 months of X-ray follow-up after augmentation procedures. The current study included the 172 patients into the following 3 groups. Group A (n=95), patients who underwent a Vertebroplasty (VP) procedure; group B (n=42), patients who underwent a Kyphoplasty (KP) procedure; and group C (n=35), patients with unstable burst fractures who underwent the VATSS procedure (open, 20 cases; percutaneous, 15 cases). In group C, the surgical procedure included polymethylmethacrylate vertebral augmentation of the fracture vertebrae, one level above and below the fracture level with short segment transpedicular screw stabilization.

Treatment outcomes were measured based on the changes in vertebral height, kyphotic angle, VAS (visual analogue scale) and the rate of subsequent fractures. The subsequent fractures classified with 3 groups. 1) Hammer fractures (HFs), 2) new fractures (NFs) and 3) Kyphotic collapsed fractures (KCFs) of augmented vertebrae those were progressive collapse and yphotic changes of augmented vertebrae.

Results: In order of the group A / group B / group C, the mean Age was as follows: 66.7 / 67.9 / 61.2 years. In order of preoperatively / postoperatively / at last follow up, the
vertebral height changes: group A (70.3% / 76.6% / 71.8%); group B (55.7% / 70.8% / 64.6%); group C (42.5% / 81.2% / 76.6%), the kyphotic angle change: group A (15.0° / 11.4° / 13.7°), group B (17.4° / 11.2° / 13.8°); and group C (23.5° / 9.8° / 11.4°). In order of preoperatively / last follow up, the VAS change was as follows: group A (8.53 / 2.69) group B (8.86 / 2.79); group C (8.73 / 1.88). In order of HF / NF / KCFs, the subsequent fracture occurred as follows: group A (24 cases [25.3%] / 11 cases [11.6%] / 8 case [8.4%]); group B (5 cases [10.3%] / 5 cases [10.3%] / 3 cases [7.1%]); and group C (0 cases [0.0%] / 3 cases [8.6%] / 0 cases [0.0%]).

Conclusions: Based on radiologic follow-up, in group C, the vertebral height and kyphotic angle were more improved after the augmentation procedures and the improvement was well-sustained. According to these results, we expect that the stabilization of unstable spinal segments may reduce subsequent fractures. Therefore, in which VCFs are localized at a focal level, VATSS will be a useful method for decreasing the subsequent fractures and increasing the life quality in osteoporotic VCFs.
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The Role of Minimally Invasive Spine Surgery in the Treatment of Degenerative Spine Pathologies - 5 Years Clinical Overview

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**Objective:** Clinical 5 years overview on the role of minimally invasive spine surgery in the treatment of degenerative spine pathologies and its effect on standard spinal surgical procedures.

**Background:** Distinction is to be made between regular spine surgeries with minimally invasive access (MIASS) and the true minimally invasive spine surgeries (MISS). The first ones are regular spine surgeries like fusions, discectomies, laminectomies etc, where the access to the target of the surgery is been done in a minimally invasive way through smaller incisions and with less tissue destruction (example: endoscopic discectomy, percutaneous pedicle screws etc).

The second type or the true minimally invasive procedures are techniques that, independently of the access routes, use technologies, materials and intellectual properties whose aim is the treatment of the pathology in a radically different way (example: laser, RF, vertebroplasty, interspinous devices, etc).

**Materials and methods:** The Authors overviewed five years of surgical activity, i.e. 2400 surgical procedures for degenerative spine pathologies, by clinical file analysis and out-patient or telephone interviews. Of these, 55% were of the true minimally invasive type while the rest were regular spine surgeries of all types with both standard and minimally invasive accesses. The patients’ reported improvement with the true minimally invasive surgeries on year 1 and year 5 was respectively, 82% and 71% while the patients’ reported improvement with standard types of surgeries on year 1 and year 5 was, respectively, 94% and 82%.

**Results:** Even if the rate of success of the MISS procedures is, approximately, 10% lower than the one of the standard surgical procedures, the curious thing is that we never before have had such a high percent of satisfaction with the standard surgical procedures. What was found is that with the introduction of MISS the standard procedures were done exclusively when a strict combination of clinical and radiological indications did indicate the surgery and, in some cases too, only after the minimally invasive surgeries did fail to improve the clinical status. So, while the use of the minimally invasive procedures did reduce the total number of standard procedures by some 20-25%, it, absurdly, improved in a significant way their rate of success.

**Conclusions:** A possible explanation for this might come from the fact that while in the past the standard procedures have been performed frequently on patients with border-line indications, with the introduction of MISS, these patients were no more candidates for standard procedures but instead the MISS procedures coped well with them. And what was found further more is that border-line indication patients are those that benefit most from these techniques.
CLINICAL: INTERSPINOUS AND LIGAMENTOPLASTY

19 Prospective Evaluation of a Dorsal Decompression and Posterior Dynamic Flexion-limiting Stabilization in Patients with Spinal Stenosis and Degenerative Disc Disease: Six Month Follow up

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Background: Patients who present with leg pain caused by stenosis can also present with a complaint of activity related back pain. This can be related to the stenosis itself, and other times caused directly by the degenerative changes of the segment. These patients are typically treated with decompression and spinal fusion. While decompression alone can result in significant instability of the treated segment and subsequent restenosis, early fusion may facilitate early degeneration and stenosis of the adjacent levels. The dynamic posterior spinal stabilization system LimiFlex (Simpirica Spine Inc, CA, USA) has been developed to limit flexion of the segment, thereby reducing forces borne by the disc, addressing the low back pain and stabilizing segments without the need for fusion. Here we are presenting initial six-month results of a prospective patient surveillance study to evaluate the clinical and radiological outcomes in patients treated with the LimiFlex device.

Material and methods: 30 patients (12 males and 18 females) with low back pain and leg pain due to spinal stenosis and degenerative disc disease were treated with interlaminar decompression of one to four levels. Five patients also showed degenerative listhesis Meyerding grade I. Discectomy was performed on three patients with combined discogenic stenosis. The LimiFlex device was placed after decompression was completed on the treated level. For patients with multi-level decompression, the segment of highest instability as assessed by Meyerding grade, angular motion on preoperative radiographs, or intraoperative findings of instability, was stabilized. Three times the implant was placed at L2/3, twelve times at L3/4 and fifteen times at L4/5. Follow-up was completed at three and six month after surgery, and data was available for 26 patients (87%) at six month time point. Preoperatively and during the follow-ups, patients were assessed through self-reported Visual Analog Scale (VAS), and the Oswestry Disability Index (ODI) was documented, along with Odom’s criteria and patient satisfaction. Adverse events (AE) and serious adverse events (SAE) were logged. All clinical data was monitored through an independent clinical trial monitor. Outcome of functional radiographic scans pre- and postoperatively and at follow ups was assessed, and the segmental alignment was evaluated for any signs of instability.

Results: At the six month follow up, the median pain scores (VAS) of both back and leg pain were improved significantly from pre- to post-intervention as were the ODI, and the pain free walking distance (subset 4 of ODI). Odom’s criteria were good to excellent in all but two patients assessed, and patient satisfaction with surgery was above 90% at six month. Four patients had SAEs, none of them related to the implant. Radiographic assessment showed no increase of segmental instability after decompression on levels treated with LimiFlex.

Conclusion: Interlaminar decompression with LimiFlex stabilization in patients presenting with leg pain and activity-related back pain due to spinal stenosis and degenerative disc disease led to a significant clinical improvement in pain and function. Segmental instability after decompression was avoided. Further long-term results are needed to evaluate if adjacent level stenosis and re-stenosis of treated levels can be avoided, and if this procedure is superior to interbody fusion in early stages of degenerative disc disease.

CLINICAL: POSTERIOR DYNAMIC PÆDICIAL STABILIZATION

31 Clinical Outcomes of Degenerative Lumbar Spinal Stenosis Treated with Lumbar Decompression and the Cosmic ‘Semi-Rigid’ Posterior System


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Background: Although some believe that the rate of postoperative instability is low after lumbar spinal stenosis surgery, the majority believe that postoperative instability usually develops. Decompression alone and decompression with fusion have been widely used for years in the surgical treatment of lumbar spinal stenosis. Nevertheless, in recent years several biomechanical studies have shown that posterior dynamic transpedicular stabilization provides stabilization that is like the rigid stabilization systems of the spine. Recently, posterior transpedicular dynamic stabilization has been more commonly used as an alternative treatment option (rather than rigid stabilization with fusion), for the treatment of degenerative spines with chronic instability and for the prevention of possible instability after decompression in lumbar spinal stenosis surgery.

Methods: A total of 30 patients with degenerative lumbar spinal stenosis (19 F, 11 M) were included in the study group. The mean age was 67.3 years (40-85). Along with lumbar decompression, a posterior dynamic transpedicular stabilization (dynamic transpedicular screw-rigid rod system) without fusion was performed in all patients. Clinical and radiological results for patients were evaluated during follow-ups in the 3rd, 12th and 24th months postoperative.

Results: The average follow-up period was 42.93 months (24-66). A clinical evaluation of patients revealed that, compared to preoperative assessments, statistically significant improvements were observed in the Oswestry and VAS scores in the last follow-up control. Compared with preoperative values, there were no statistically significant differences in radiological evaluations, such as segmental lordosis angle (α) scores (p=0.125; p>0.05) and intervertebral distance (IVS) scores (p=0.249; p>0.05). There were statistically significant differences between follow-up lumbar lordosis (LL) scores (p=0.048; p<0.05). We observed minor complications, including a subcutaneous wound infection in two cases, a dural tear in two cases, CSF fistulas in one case, a urinary tract...
Infection in one case and urinary retention in one patient. The L5 screw loosening was observed in one of our three-level decompression cases. We did not observe screw breakage or perform revision surgery in any of these cases.

**Conclusions:** Posterior dynamic stabilization without fusion applied to lumbar decompression leads to better clinical and radiological results in degenerative lumbar spinal stenosis. In order to avoid postoperative instability, especially in elderly patients that experience degenerative lumbar spinal stenosis surgery with chronic instability, the application of decompression with posterior dynamic transpedicular stabilization is likely an important alternative surgical option to fusion as it does not have fusion-related side effects, is easier to perform than fusion, requires a shorter operation time and has low morbidity and complication rates.

**CLINICAL: POSTERIOR DYNAMIC PEDIcular STABILIZATION**

**33**

**Comparison of Posterior Dynamic and Posterior Rigid Transpedicular Stabilization with Fusion to Treat Degenerative SpondyloListhesis**

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	extsuperscript{1}Pendikli State Hospital, Neurosurgery, Istanbul, Turkey, 	extsuperscript{2}Kartal Training-Research Hospital, Neurosurgery, Istanbul, Turkey, 	extsuperscript{3}American Hospital, Istanbul, Turkey, 	extsuperscript{4}Istanbul Physical Therapy and Rehabilitation Training Hospital, Istanbul, Turkey

This article describes the clinical and radiological outcomes of a comparison of posteriordynamic transpedicular stabilization and posterior rigid transpedicular stabilization with fusion after decompression in the treatment of degenerative spondyloListhesis. This prospective clinical and radiologic study was conducted between 2004 and 2007 and included 46 patients, of whom 33 were women (71.7%) and 13 were men (28.3%). Mean patient age was 61.67 years (range, 45-89 years). Twenty-six patients who underwent lumbar decompression and posterior dynamic transpedicular stabilization were followed for a mean of 38 months (range, 24-55 months). In the fusion group, 20 patients who underwent lumbar decompression and rigid stabilization with fusion were followed for a mean of 44 months (range, 26-64 months). The intervertebral space measurements of the dynamic group at the preoperative examination and at 12 and 24 months postoperatively were statistically significantly higher than the intervertebral space measurements of the fusion group (P < 0.05). In the dynamic group, complications occurred in 2 patients; the first was a screw malposition, which was improved with revision surgery within 1 month of the initial surgery, and the second was a fusion performed in the 2nd year in 1 patient because the patient reported continued pain. In the fusion group, adjacent segment disease was observed in 1 patient, with subsequent reoperation. Lumbar decompression and posterior dynamic transpedicular stabilization yield satisfactory results in the treatment of degenerative lumbar spondyloListhesis and can be considered a valid alternative to fusion.

**CLINICAL: NAVIGATION, IMAGE GUIDED SURGERY AND ROBOTIC ASSISTANCE**

**34**

**Comparative Clinical Results between Conventional and Computer-assisted Pedicle Screw Installation in the Degenerative Lumbar Scoliosis**

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**Introduction:** The clinical appearance of degenerative scoliosis is varied from an instability pattern to neurogenic claudication. Maintain and stabilization of lumbar lordosis after well decompression is important. Instrumentation can provide an adequate stabilization. It has 13.4% to 40% pedicle perforation in pedicle screw placement. The aim of this study is to evaluate its clinical results in degenerative lumbar scoliosis patients treated surgically with and without computer assistance.

**Material and method:** Between January 2003 and December 2008, there were eighty-five patients with degenerative lumbar scoliosis. 67 females and 18 males patients were treated by posterior instrumentation and decompression. The average age at surgery was 59 years. The mean follow up was 35 months.

**Results:** The conventional Cohort was composed of 52 patients, with 426 screws from T11 to S1. The computer-assisted Cohort was composed of 33 patients, with 270 screws from L1 to S1. In the finial follow-up, 83% of the patients were satisfied with pain relief and increased walking ability. The average curve correction was 40%, and lumbar lordosis increase from 35° to 47°. There were three patients with radiulopathy and one required revision for screw malposition in the conventional Cohort, whereas no patients in the computer assisted group were surgically retreated for postoperative neurological deficits. The operative time is not significantly different between the groups but the plain radiography is significantly more exposure in the conventional group (p < 0.05).

**Discussion:** Degenerative scoliosis is appearing more frequently because of increased life duration. Lumbar decompression, fusion, and instrumentation are appreciated for most of the patients. By reports, the pedicle screws placement has 13.4% to 40% pedicle perforation and most is insignificant clinically, but the malpositioned screws still had 7.7% caused radicular pain or weakness. The computer assistance can provide well accuracy of screw instrumentation and decrease the incidence of incorrectly positioned pedicle screws by many reports, it is consistent in this clinical findings.

**Conclusions:** No major complications were related with screw placement in the computer assistance Cohort. The technique has been shown to be safe in the surgical treatment of degenerative lumbar scoliosis associated with spinal stenosis and the significant occupational radiation exposure can be reduced.
Reported Re-operations in Lumbar Total Disc Replacement: Analysis of the Literature


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Introduction: One important evaluation of any spine surgery procedure is the re-operation rate. Lumbar total disc replacement (TDR) has been used in Europe since the 1980s and in the USA since 2000. The purpose of this study was to perform a meta-analysis of the peer-reviewed lumbar TDR literature to determine the re-operation rate and reasons for re-operation.

Methods: A literature search using PubMed was performed to identify lumbar TDR studies published through May 2010. Search keywords were lumbar total disc replacement/artificial discs/arthroplasty, human, and English language. Articles that were preliminary results of later publications or from the same patient population were excluded. Case reports, review articles, and articles reporting only on one specific topic, such as heterotopic ossification, were also excluded. During review of the articles, it was noted that several articles reported only on removal of the TDR or re-operation attributed to device failure; these articles were excluded as they were not inclusive of all re-operations in the patient population. Data recorded from each study included patient age, gender, length of follow-up, number of patients and levels operated, number of re-operations, and the reason for re-operation. Two researchers reviewed the articles for inclusion in the review and also to increase consistency in the recording of the data.

Results: Fifteen articles were included in the analysis. Results are reported separately for devices that are no long in use (Charite I and II, Acroflex I and II). Data for the current devices (Charite, ProDisc-L, Maverick, and Flexicore) came from seven countries on three continents. The majority of studies had a minimum of 24-month follow-up. Two studies had a minimum of 10-year follow-up. Among current devices, the pooled re-operation rate in 934 patients implanted with 1,231 TDRs was 8.9% (Table 1). The most common reason for re-operation was ongoing or new pain onset (43 of the 83 re-operations). In 16 operations the rate was 8.9% for current devices. This was improved from the 15.8% for first and second generation implants.

Conclusion: Considering the long-term use of TDR and the number of publications reporting clinical results, the lack of consistency in reporting re-operations was disappointing. Many articles did not report re-operations and others reported only those specifically related to device failure. Several others did not clearly report if the re-operations were at the TDR level or another spinal level. The lack of consistency in reporting re-operations caused difficulty in deriving a composite rate across multiple studies. However, when including studies that reported all spine-related re-operations the rate was 8.9% for current devices.

<table>
<thead>
<tr>
<th>Approach / surgery related</th>
<th>Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incisional hernia</td>
<td>8</td>
</tr>
<tr>
<td>Hernia</td>
<td>1</td>
</tr>
<tr>
<td>Vascular</td>
<td>3</td>
</tr>
<tr>
<td>Infection</td>
<td>1</td>
</tr>
<tr>
<td>Wound revision</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
</tr>
<tr>
<td>Device</td>
<td>5</td>
</tr>
<tr>
<td>Poor device seating/positioning</td>
<td>2</td>
</tr>
<tr>
<td>Device dislocation</td>
<td>2</td>
</tr>
<tr>
<td>Core subluxation</td>
<td>2</td>
</tr>
<tr>
<td>Core coxidation</td>
<td>1</td>
</tr>
<tr>
<td>Core extirpation</td>
<td>2</td>
</tr>
<tr>
<td>Pain (no further description)</td>
<td>18</td>
</tr>
<tr>
<td>Pain (non-TDR level)</td>
<td>3</td>
</tr>
<tr>
<td>Pain (TDR level)</td>
<td>6</td>
</tr>
<tr>
<td>Hemiated disc (non-TDR level)</td>
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</tr>
<tr>
<td>Facet syndromestenosis</td>
<td>11</td>
</tr>
<tr>
<td>Distraction injury - foot drop</td>
<td>1</td>
</tr>
<tr>
<td>Subsidence</td>
<td>2</td>
</tr>
<tr>
<td>Vertebral body fracture</td>
<td>2</td>
</tr>
<tr>
<td>Segmental hyperlordosisis</td>
<td>1</td>
</tr>
<tr>
<td>Reason for re-op not provided</td>
<td>6</td>
</tr>
</tbody>
</table>

Table 1. Overview of re-operation types.
these symptoms into one question. Also problematic is that in those two studies, the time period over which patients were asked to indicate their average pain intensity was different. While all three studies evaluated patient satisfaction, a different method was used in each. The details in how adverse events and re-operations also varied in the studies. The number and details of the components used to define a successful outcome for an individual patient varied across the three trials as well.

**Conclusions:** An attempt was made to use meta-analysis techniques to evaluate data from FDA-regulated trials for three lumbar TDR devices versus fusion. However, this could not be accomplished and represents a great missed opportunity to learn much from these large prospective, randomized trials. Although on the surface it appeared all studies used ODI, VAS, and satisfaction as outcome measures, there were differences in the actual instruments used as well as definitions applied to success and other measures. It is hoped that increasing awareness of the problems of using non-validated or altered versions of questionnaires will result in a greater effort to use standardized instruments to allow data pooling and comparisons across multiple studies in order to facilitate addressing the increasing demand for evidence and comparative effectiveness in spine surgery.

**CLINICAL: PROSTHESIS**

41 Lumbar Total Disc Replacement vs. Fusion: Analysis of Cost Comparison Studies

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**Introduction:** The primary challenges to the adoption of new technology are safety, effectiveness, and cost. For lumbar total disc replacement (TDR) the first two have been addressed in multiple prospective, randomized studies finding the results of TDR to be similar or superior to fusion for the treatment of painful disc degeneration. However, concern remains over the cost, which has been addressed in several studies. The purpose of this study was to analyze the methods and results of existing studies comparing costs of lumbar TDR vs. fusion.

**Methods:** A literature search of cost analysis studies comparing TDR to spinal fusion was conducted using PubMed. Four such publications were found. Additionally, one recently presented study was also included.

**Results:** The five studies use different methodologies. Some used large scale claims databases, others averaged changes attributable, at least in part, to the difficulty of collecting reliable, comprehensive cost data. However the results were consistently the same. That is, the cost of TDR was lower or similar to fusion with the exception of one study reporting that stand-alone ALIF with autogenous iliac crest graft and no cage (not clinically a widely-used model) was less expensive than TDR. The variability in the study methodology may actually be a strength in that regardless of the cost comparison method used, the same results were obtained in the various studies. The results of these studies support the concept that cost containment should not be considered an impediment to the adoption of lumbar TDR in appropriately-selected patients.

**CLINICAL: PROSTHESIS**

42 Bone Mineral Density Scanning in Potential Lumbar Total Disc Replacement Patients

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**Introduction:** Bone quality has always been an important consideration for spinal instrumentation, particularly with respect to pedicle screw pullout. With the increasing use of motion preserving technologies, rather than fusion, bone density is of greater concern as vertebral body fracture is a potentially devastating complication. The purpose of this study was to describe our experience with bone mineral density (BMD) assessment in potential total disc replacement (TDR) patients.

**Methods:** A group of 54 patients who were considered TDR patients (either for TDR only or as part of a hybrid TDR/fusion
procedure) at a single clinic during an 18 month period underwent BMD assessment. The patients included 21 males and 33 females with a mean age of 44.2 years, ranging from 28 to 62 years. Then mean body mass index (BMI) was 26.6 ranging from 18.3 to 35.3. Patients with osteoporosis or osteopenia, defined by the World Health Organization as a dual energy x-ray absorptiometry (DEXA) T-score value of less than -1.0, are not considered candidates for lumbar TDR.

**Results:** Among the 54 patients, three (5.5%) who were considered candidates for TDR had T-scores of less than -1.0. Due to their low BMD values, they instead underwent fusion. All three patients were male with ages of 39, 49, and 56 years. Their BMI values ranged from 24.4 to 30.7.

**Conclusion:** In this group of patients, the surgical plan was changed from TDR to fusion based on DEXA values in 5.5% of patients. Of note, the low DEXA scores were in males with BMI scores in the range of high-end of normal to obese - not the stereotypical osteoporotic/osteopenic patient. The percentage of patients in this study with low BMD values may be biased as not all patients considered for TDR were scanned. However, surgeons in our practice have increased use of DEXA scanning for surgical screening. It is easily performed and is inexpensive. It is hoped that the results of this study will increase awareness of the importance of DEXA scanning in spine surgery candidates.

### BASIC SCIENCE: BIOMECHANICS / BASIC SCIENCE

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**Validation of a New Method to Calculate the Orientation and Magnitude of Loads Applied to Pedicle Screws**

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**Purpose:** Pedicle screws are the most frequently used type of spinal instrumentation and form the foundation for a wide array of both rigid and dynamic spinal stabilization systems. Although the use of pedicle screws is widespread, long fusion constructs in particular have been reported to have an increased incidence of screw loosening and failure at the caudal-most screw. The safety and efficacy of pedicle screws has been well established in the literature but no data exists describing the orientation of the loads acting on the screws. Such data may aid in improving screw design and understanding the complex loading mechanics of the spine. The purpose of this study was to validate a novel method of quantifying pedicle screw load orientation and magnitude.

**Methods:** Four pedicle screws were instrumented to measure biplanar screw bending by positioning strain gages in two independent half bridge configurations. Parallel, flat surfaces (5 x 4.2 mm) were machined on the threaded portion of each screw just below the screw head to create a square cross section for the application of four strain gages. Screws were calibrated to measure bending moments by hanging calibrated weights a known distance from the strain gages. Following calibration, screw load orientation was quantified using a custom fixture that allowed screws to be fixed at rotational increments of 30 degrees about their long axis throughout a 360 degree arc. At each 30 degree increment, moments of 1.32, 2.64 and 4.83 Nm were applied by hanging weights from the tip of each screw and the calibrated output of both strain channels was recorded. The signs of the two strain channels were compared to determine the quadrant in the coordinate plane that the screw bending moment vector occupied and the angle was calculated using arctangent equations. Resultant strain magnitudes were computed using the Pythagorean Theorem.

**Results:** The correlation between the true and the calculated angles differed by an average (± SD) of 0.36 ± 1.49° across the four screws for all rotational increments and loading conditions. The greatest variation between the true and calculated angles occurred at the four orientations where the loads were in-line with the strain gages. On average, the calculated bending strain magnitudes deviated from the true magnitudes by 0.05 ± 0.04 Nm at the 1.32 Nm moment, 0.01 ± 0.02 Nm at 2.64 Nm and 0.05 ± 0.03 at 4.83 Nm.

<table>
<thead>
<tr>
<th>True angle (deg)</th>
<th>Average calculated angle (deg)</th>
<th>Deviation from true angle (deg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0°</td>
<td>1.7 ± 0.6°</td>
<td>1.7 ± 0.6°</td>
</tr>
<tr>
<td>30°</td>
<td>30.3 ± 0.6°</td>
<td>0.3 ± 0.6°</td>
</tr>
<tr>
<td>60°</td>
<td>59.4 ± 0.6°</td>
<td>-0.6 ± 0.6°</td>
</tr>
<tr>
<td>90°</td>
<td>88.6 ± 1.0°</td>
<td>-1.4 ± 1.0°</td>
</tr>
<tr>
<td>120°</td>
<td>121.0 ± 0.9°</td>
<td>1.0 ± 0.9°</td>
</tr>
<tr>
<td>150°</td>
<td>151.1 ± 1.1°</td>
<td>1.1 ± 1.1°</td>
</tr>
<tr>
<td>180°</td>
<td>181.3 ± 1.2°</td>
<td>1.3 ± 1.2°</td>
</tr>
<tr>
<td>210°</td>
<td>209.7 ± 1.3°</td>
<td>-0.3 ± 1.3°</td>
</tr>
<tr>
<td>240°</td>
<td>239.1 ± 1.1°</td>
<td>-0.9 ± 1.1°</td>
</tr>
<tr>
<td>270°</td>
<td>269.1 ± 1.3°</td>
<td>-0.9 ± 1.3°</td>
</tr>
<tr>
<td>300°</td>
<td>300.8 ± 0.7°</td>
<td>0.8 ± 0.7°</td>
</tr>
<tr>
<td>330°</td>
<td>331.5 ± 1.0°</td>
<td>1.5 ± 1.0°</td>
</tr>
</tbody>
</table>

**Conclusions:** The techniques developed in this study for directly measuring orientations and magnitudes of pedicle screw bending moments were accurate and reproducible. These methods can be universally applied to pedicle screw based fixation systems to determine loading characteristics. Biomechanical testing of fusion constructs with high failure rates using strain gage instrumented pedicle screws may aid in identifying alternative strategies to alleviate excessive screw loads.
BASIC SCIENCE: POSTERIOR DYNAMIC PEDICULAR STABILIZATION

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The altered kinematics resulting from posterior dynamic stabilization in the lumbar spine has implications as to the longevity of implants, directly through screw loosening and breakage, and indirectly through altered biomechanics associated with stress shielding. It has been postulated that semi-rigid or dynamic fixation provides a more favorable motion distribution, a potentially advantageous benefit for both fusion and maintenance of physiologically safe adjacent level stresses. In this study, the authors evaluated the kinematics of a novel posterior dynamic stabilization (PDS) system, TRANSITION®, when used adjacent to rigid fixation in a calf model.

Three intact calf spines (T12-L5) were tested by applying a pure moment of ±10 Nm. The displacement control protocol for testing adjacent level effects was applied, as described by Panjabi. Initially, the total T12-L5 range of motion (ROM) was determined in an individual intact specimen. In all subsequent tests for the respective specimen, the displacement of the spine was set as the intact total ROM values in flexion-extension. A series of two load/unload cycles were performed for each motion with data analysis based on the final cycle. All three specimens were tested in the following sequence:
(1) Intact;
(2) Bilateral rigid fixation at L3-L4 [anterior integrated spacer and plate, INDEPENDENCE®, with posterior pedicle screws and titanium rod, REVERE® Stabilization System, Globus Medical];
(3) Bilateral transitional fixation with a semi-rigid L2-L3 and rigid L3-L4 fixation [anterior integrated spacer and plate, INDEPENDENCE®, and TRANSITION® at L2-L4]; and
(4) bilateral rigid fixation at L2-L4 [anterior INDEPENDENCE® at L3-L4 with posterior pedicle screws and titanium rod at L2-L4, REVERE® Stabilization System, Globus Medical].

Unless otherwise stated, when percentage change is discussed, the percentages are calculated through differences in normalized ROM of surgical groups when normalized to the intact spine motion (100%).

Test results showed that single-level rigid fixation led to hypermobility at the super-adjacent level of 117% (Figure 1). Subsequently there was a sharp change in between fixed and non-fixed segmental ROM from 15% (rigid, L3-L4) to 117% (uninstrumented, L2-L3). Incorporation of a flexible TRANSITION® element between rigid and uninstrumented levels created a ROM profile which varied from 20% (rigid, L3-L4), to 47% (flexible, L2-L3) to 102% (uninstrumented, L1-L2), following a trend of “doubling” motion of each sequential segment. Therefore, the TRANSITION® device provides a less abrupt change in stabilization from rigidly fixated to completely uninstrumented. One limitation of this study is the lack of correlation between biomechanics and in vivo behavior following incorporation of the graft material into a fusion. In this respect, the present biomechanical model represents the stress situation immediately post-operatively or following posterolateral fusion.

[Figure 1. ROM by construct type]

BASIC SCIENCE: BIOMECHANICS / BASIC SCIENCE

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Dynamic Spine Stabilizer Reduces Adjacent Intervertebral Disc Pressure during Flexion
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1National Taiwan University, Institute of Biomedical Engineering, Taipei, Taiwan, Republic of China, 2National Taiwan University Hospital, Department of General Surgery, Taipei, Taiwan, Republic of China

Introduction: Recently, the dynamic spine stabilizer has gaining its popularity for the merit of preserving the normal functional movement of spinal column, and possibly, the prevention of early disc degeneration. However, clinical reports of early disc degeneration were still reported. The efficacy of dynamic stabilizer in minimizing the risk of disc degeneration has not reached to consensus conclusion yet. Biomechanical studies have showed that the excessive intradiscal pressure (IDP) may induce the disc degeneration. The purpose of this study is to find the IDP of stabilized level and adjacent level at different level of dynamic constrains.

Methods: Specimens Preparation. Eight 4-level lumbar motion segments were dissected from 6-month old pigs. All soft tissues except the surrounding ligaments and facet capsule were carefully removed. Specimens were wrapped in saline-soaked gauze and stored in the freezer until the experiment.

Pressure Transducer. A miniature 20 G needle type pressure transducer was used to measure the IDP. The pressure transducers were inserted into the center of implant level and adjacent cranial level (Figure 1A).
**Dynamic Stabilizer.** A home-made dynamic spinal stabilizer was designed to control the range of motion (ROM) of implanted motion segment. This stabilizer is able to control the ROM of motion segment by adjusting the block and shaft for linear and rotary constraints (Figure 1B).

**Experimental protocols.** The ROM of total and individual level of intact and injured spinal column under 6 Nm flexion and extension pure moment were first recorded. The injury was created by damaging the mid level bilateral facet joints. After the injury, the injury level was implanted by a tradition rigid fixation device. Then, a displacement controlled rotation was applied. Then, the home-made dynamic stabilizer was implanted to tune the ROM of implant-level into these 9 intervals at the same displacement controlled rotation. The IDP of implant-level and adjacent cranial level of these 9 setting was recorded.

**Results:** For an intact motion segment, the IDP of mid level and adjacent level were 0.086(0.079) MPa and 0.098(0.173) MPa during 6 Nm extension, and were 0.63(0.26) MPa and 0.63(0.11) MPa during 6 Nm flexion. The injury of posterior elements increased the IDP of injury level to 0.61(0.28) MPa during 6 Nm extension, but less affected the IDP of adjacent level. The posterior injury did not affect the IDP of injury level and adjacent level during flexion. The rigid fixation reduced the IDP of implant level and adjacent level of injured spinal column to 0.159(0.094) MPa and 0.178(0.189) MPa at the same extension deformation. However, the rigid fixation increased the IDP of implant level and adjacent level of injured spinal column to 0.822 (0.382) MPa and 1.341 (0.976) MPa at the same flexion deformation. Compared to the rigid fixation system, the dynamic spinal stabilization at all constraint level did not affect the IDP during the extension motion. However, the stabilization system did reduce the IDP of adjacent level when the constraint was set from 20% to 90% looseness during the flexion motion.

**Acknowledgement:** National Science Council, Taiwan (NSC 99-2321-B-002-035)

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**CLINICAL: FUSION**

79

**Larger Footprint TLIF Interbody Device Provides Early Postoperative Pain Control**

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**Purpose:** We have previously reported a 97% fusion rate for our open transforaminal interbody fusion (TLIF) technique demonstrated by postoperative CT studies. We sought to evaluate whether a larger foot print TLIF interbody device would provide for early postoperative pain control. Thus the clinical success of patients undergoing elective single-level open TLIF with AVID, a new PEEK articulating device with a larger footprint, was evaluated at 4 weeks and 3 months postoperatively.

**Methods:** Fifty-one consecutive patients seen between August 6, 2009, and June 1, 2010, undergoing single-level TLIF with the AVID PEEK articulating device were included in this retrospective study. Patients were excluded if they had a prior lumbar fusion (4 patients) or were covered by worker’s compensation (6 patients). The patients’ average preoperative lumbar back pain using the Visual Analogue Scale (VAS) was compared with their average postoperative lumbar pain at 4 weeks and 3 months.

**Findings:** Patients included 28 (68%) women and 13 (32%) men, average age of 52±15 (17 to 80) and average body mass index of 30±6 (22 to 43). Average number of weeks to first follow-up was 4.8±1.5 (median 4 weeks), and average number of weeks to second follow-up was 14.9±2.5 (median 14 weeks). Six patients had only leg pain at baseline. Average low back pain improved from 5.2±1.9 at baseline to 1.7±2.1 at first follow-up (FFU) (p<0.001). Median VAS scores were 5 at baseline and 1 at FFU. This improvement persisted at 3 months (1.7±2.1 VAS at 3.5 months, p<0.001). Of the 35 patients indicating low back pain on their VAS prior to surgery, 20 (59%) indicated a pain level of 0-1 on their VAS at their FFU visit. Only five (15%) patients showed no improvement at FFU. At 3 months, 20 (60%) of patients still reported an average low back pain score of 0 to 1. Patients continued to improve with only two patients reporting their average low back pain to be unchanged from baseline.

**Conclusion:** In patients undergoing an elective open TLIF procedure using the much larger footprint interbody AVID cage, we found that a majority of the patients rated their pain 0-1 by 4-6 weeks postoperatively. The early pain control was maintained at 3 months followup. We feel the larger footprint and peripheral placement of the cage played a role in our ability to achieve excellent pain control by the first postoperative visit.

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**Average Lumbar Pain Measured on the VAS at First Follow-up**

<table>
<thead>
<tr>
<th>VAS</th>
<th>Before Surgery</th>
<th>0-1</th>
<th>2-3</th>
<th>4-5</th>
<th>6-10</th>
<th>Row Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-3</td>
<td>7 (88%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>8 (24%)</td>
<td></td>
</tr>
<tr>
<td>4-5</td>
<td>5 (50%)</td>
<td>2 (20%)</td>
<td>3 (30%)</td>
<td>0 (0%)</td>
<td>10 (29%)</td>
<td></td>
</tr>
<tr>
<td>6-10</td>
<td>8 (50%)</td>
<td>4 (25%)</td>
<td>2 (12%)</td>
<td>2 (12%)</td>
<td>16 (47%)</td>
<td></td>
</tr>
</tbody>
</table>

Column Totals: 20 (59%) | 7 (20%) | 5 (15%) | 2 (6%) | 34* |

*One patient seen at three weeks for incision check and the VAS was not completed.
*One score decreased from 8 to 6 within the same stratification.

**[VAS at First FU]**
**Introduction:** The goal of most motion preserving technologies is to maintain the normal center of rotation (COR). However, measurement of the COR is imprecise in the spine. Panjabi (1979) showed that for motions of less than 5°, there is an error of greater than 10mm in the location of the COR. Clinical studies (Anand, 2010) reported a median flexion/extension range of motion (ROM) of 3.5°. Another quality indicator, Interpedicular Travel (IPT) has the difficulty that IPT is associated with ROM; the greater ROM, the greater IPT. As an alternative, we propose evaluating the ratio of IPT/ROM (the Kinematic Indicator), as a way of describing motion quality. The purpose of this study is to assess the Kinematic Indicator’s ability to describe a set of clinical motion data from patients undergoing surgical treatment for lumbar spinal stenosis.

**Methods:** Maximum voluntary flexion-extension radiographs were obtained preoperatively from 70 single level patients as part of an IDE study of a pedicle screw based dynamic stabilization device. The radiographs included a calibration marker. The radiographs were independently assessed using validated, computer assisted methods accurate to better than 1° and 1mm. Interpedicular distance was measured between the mid-pedicular axes of adjacent vertebrae using points slightly posterior to the superior articular process of each vertebra. IPT was calculated as the difference in interpedicular distance in flexion minus that in extension. ROM was measured using end plate markers. Rotation and IPT were measured at the index level. Data for each patient was plotted on a graph of IPT vs. ROM and a best fit line created through the data. The $R^2$ value for the line fit was evaluated to determine the effectiveness of the approach.

**Results:** The average age of the patients was 58 years of age (range: 35-82). The L4-L5 level represented 78% of the index levels, with remainder at L5-S1, L3-L4 and L2-L3. The median rotation at the index level was 3.5° (range 13.1°). The median IPT at the index level was 2.3mm (range 10.5mm). The graph of IPT vs. ROM is shown in Figure 1, including the best fit line. The best fit line had a slope of 0.71, passed through the origin and $R^2$ equaled 97%.

**Discussion:** The best fit line described 97% of the variation in the data, showing that Kinematic Indicator performs well in describing the kinematics of the population. The slope of the line was 0.71, which we define as the Kinematic Indicator. The value is similar to that derived from Wharton (2009), of 0.68 (9.2mm of IPT and 13.6°ROM) examining asymptomatic individuals. In conclusion, the Kinematic Indicator appears to provide a good representation of motion quality and may be useful in evaluating in vivo kinematics for different motion preserving technologies.

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**BASIC SCIENCE: BIOMECHANICS / BASIC SCIENCE**

**81**

**A Clinical Assessment of a New Technique to Assess Motion Quality**

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**Introduction:** Quality indicators are used to provide a way of describing motion quality. The purpose of this study was to evaluate the line fit to determine the effective of the approach. Results: The average age of the patients was 58 years of age (range: 35-82). The L4-L5 level represented 78% of the index levels, with remainder at L5-S1, L3-L4 and L2-L3. The median rotation at the index level was 3.5° (range 13.1°). The median IPT at the index level was 2.3mm (range 10.5mm). The graph of IPT vs. ROM is shown in Figure 1, including the best fit line. The best fit line had a slope of 0.71, passed through the origin and $R^2$ equaled 97%.

**Discussion:** The best fit line described 97% of the variation in the data, showing that Kinematic Indicator performs well in describing the kinematics of the population. The slope of the line was 0.71, which we define as the Kinematic Indicator. The value is similar to that derived from Wharton (2009), of 0.68 (9.2mm of IPT and 13.6°ROM) examining asymptomatic individuals. In conclusion, the Kinematic Indicator appears to provide a good representation of motion quality and may be useful in evaluating in vivo kinematics for different motion preserving technologies.

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**CLINICAL: LUMBAR FUSION (I.E. MIS, TLIF, XLIF, AXIAL LIF, ALIF)**

**83**

**Alterations in Disc Height, Foraminal Height and Foraminal Width Following One- and Two-Level AxiaLIF: A Radiological Analysis**

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**Background context:** Degenerative changes of the lumbar motion segment often lead to stenosis of the spinal canal or neuroforamen. Axial lumbar interbody fusion (AxiaLIF) is intended to indirectly increase and stabilize foraminal dimensions by restoring disc height in patients with degenerative disc disease, thereby relieving axial and radicular pain.

**Purpose:** To investigate the effects of AxiaLIF on anterior disc height, posterior disc height, foraminal height and foraminal width as well as to determine the effectiveness of this minimally-invasive technique for indirect decompression and restoration of disc height.

**Study design:** Retrospective linear radiological analysis study.

**Patient sample:** 81 patients who met the inclusion criteria and underwent a 360 degree lumbar interbody fusion at L4-S1 or L5-S1 with AxiaLIF between November 2008 and May 2010.

**Outcome measures:** Change in anterior lumbar disc height, posterior lumbar disc height, foraminal height and foraminal width.

**Methods:** All patients who underwent a 360 degree lumbar interbody fusion at L4-5 and L5-S1 with AxiaLIF between November 2008 and May 2010 were included. The preoperative and 3-month postoperative digital radiographs were reviewed and analyzed. Disc heights were measured in the planes of the anterior and posterior surfaces of the adjacent vertebral bodies. Foraminal height was measured as the maximum distance between the inferior margin of the pedicle of the superior vertebra and the superior margin of the pedicle of the inferior vertebra. Foraminal width was...
measured as the shortest distance between the edge of the superior facet of the caudal vertebra and the posterior edge of inferior endplate of the cranial vertebra. Potential magnification error between pre- and post-operative radiographs was corrected using the anterior vertebral height of L5 vertebra.

**Results:** Our study shows that there is a mean increase of 42.0% in posterior disc height (PDH) at L4-5 and 21.5% in anterior disc height (ADH) at L4-5 and PDH mean increase of 33.6% and 16.3% in ADH at L5-S1 in 2-level AxiaLIF cases. Similarly the mean change in foraminal height (FH) was 12.6% at L4-5 and 10.8% at L5-S1 in 2-levels AxiaLIF. The mean change in foraminal width (FW) at L4-L5 was 19.9% and 29.1% at L5-S1 in 2-levels AxiaLIF. In the single level AxiaLIF group, the mean change in PDH was 43.1%, the ADH change was 17.5%, the average change in FH was 14.4%, and mean change in FW was 25.3%. The change is reflected as a percentage of the preoperative value. All changes from preoperative to postoperative values were statistically significant.

**Conclusions:** AxiaLIF appears to be an effective minimally invasive device to increase disc height and neuroforaminal area. Our findings appear equivalent to anterior lumbar interbody fusion and transformaminal lumbar interbody fusion in terms of indirect decompression and increase in disc height. This, in combination with the added benefit of preserving the annulus, anterior longitudinal ligament, and posterior longitudinal ligament, suggests the AxiaLIF is an excellent alternative for this patient population. However, additional follow-up studies are necessary to confirm the long-term ability of the implant to maintain fusion and preserve the improvements in disc and foraminal area.

**CLINICAL: FUSION**

86

**Spinal Fusion in the USA: Analysis of Trends from 1998 to 2008**

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**Introduction:** Since the earliest descriptions of spinal fusion by Hibbs and Albee in 1911, arthrodesis has been one of the most commonly employed procedures for treating conditions of the spine including deformity, trauma, degenerative disc disease and spondylolisthesis. Today, fusion is the standard treatment for various spinal conditions, with degenerative causes being the most common indication.

This current study provided an analysis on the utilization of spinal fusion procedures during the period of 1998 to 2008, while also reporting detailed patient and healthcare system related characteristics associated with spinal fusion. In this report, we compared trends in spinal fusion to other notable inpatient procedures, including laminectomy, hip replacement, knee arthroplasty, percutaneous transluminal coronary angioplasty (PTCA) and coronary artery bypass graft (CABG). The goal was to provide the most recently available epidemiologic data on spinal fusion and other inpatient procedures to clinicians, researchers and administrators. This will allow for assessment of need and allocation of hospital resources. It may also serve to stimulate future research.

**Methods:** Data were obtained from the Healthcare Cost and Utilization Project Nationwide Inpatient Sample for the years 1998-2008. Discharges were identified using International Classification of Diseases, Ninth Revision, Clinical Modification procedure codes for the following procedures: spinal fusion, laminectomy, hip replacement, knee arthroplasty, percutaneous transluminal coronary angioplasty and coronary artery bypass graft. Population-based utilization rates were calculated from USA census data.

**Results:** Between 1998 and 2008, the utilization rate for spinal fusion increased by 2.1-fold (111%) from 64.5 cases per 100,000 adults in 1998 to 135.5 in 2008 (p< 0.001). In contrast, during the same time period, laminectomy decreased by 1.2%, hip replacement increased by 32.4%, knee arthroplasty increased by 101.4%, PTCA increased by 23.2% and CABG decreased by 46.8%. For primary cervical fusion, lumbar fusion and thoracic fusion, the utilization rates increased by 1.9-fold, 2.4-fold, and 1.6-fold, respectively (p< 0.001). Between 1998 and 2008, mean age for spinal fusion increased from 48.8 years-old to 54.2 years old (p< 0.001), in-hospital mortality decreased from .29% to .25% (p< 0.01) and mean total hospital charges associated with spinal fusion increased 3.3-fold (p< 0.001). The national bill for spinal fusion increased 7.9-fold (p< 0.001).

**Discussion:** Frequency, utilization and hospital charges of spinal fusion have increased at a higher rate than other notable inpatient procedures in this study from 1998 to 2008. This increase could be influenced by multiple factors, such as recent advances in spinal fusion technology, improved understanding of the human spine, increased number of fellowship trained spine specialists and a general push towards minimally invasive surgery. In addition, patient demographics and hospital characteristics changed significantly, particularly noting that while the average age for spinal fusion increased, the in-hospital mortality decreased. The changes in utilization and demographics associated with spinal fusion identified in this study can be used to assess the effect of changes in medical care, direct health care resources, and future research.

**CLINICAL: LUMBAR FUSION (I.E. MIS, TLIF, XLIF, AXIAL LIF, ALIF)**

88

**Mi-TLIF with One Cage and Pedicle Screw System for the Treatment of Lumbar Spondylolisthesis**

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**Objective:** To evaluate the clinical outcome and advantages of Mi-TLIF(minimally invasive transformaminal lumbar interbody fusion) with one cage and pedicle screw system in the treatment of spondylolisthesis and lumbar spinal stenosis by comparing with traditional surgical method(PLIF).
Methods: From August 2009 to June 2010, 26 patients with lumbar spondylolisthesis underwent MI-TLIF (minimally invasive TLIF) with one cage and pedicle screw system while 28 cases of spondylolisthesis underwent traditional PLIF (Posterior Lumbar Interbody Fusion). The two groups were compared by surgical technique, operation time, insitition length, outcome, bed time, JOA score and statistical analysis. At the same time, prevention and treatment for surgical complications had been noted, as well as surgical approach selection, was also described.

Results: In TLIF group, mean operation time was 240 ± 36 (210 ~ 340min), bleeding average 360 ± 42ml (300 ~ 600ml), incision length 3 ~ 4cm, bed stay time 5 to 7 days, JOA score before surgery 18, after surgery 24. In traditional PLIF group, mean operative time 220 ± 15 (190 ~ 350min), bleeding average 520 ± 36ml (500 ~ 1000ml), incision length 16 ~ 22cm, bed time 45 ~ 90 days, JOA score score preoperative 17, postoperative 25. In both groups, length of incision, postoperative bed rest time has significant difference (P < 0.05), and postoperative JOA score, operative time has not statistically significant difference (P > 0.05).

Conclusions: MI-TLIF with one cage and pedicle screw system for the treatment of lumbar spondylolisthesis shows great advantage in blood-loss, incision length, bed stay time by comparing with traditional method (PLIF). It is a valuable method of minimally invasive spinal surgery with less paravertebral soft tissue injury, high efficacy and rapid recovery. But it requires a higher surgical techniques and more difficult procedures which was based on traditional surgery experience.

CLINICAL: IDENTIFYING AND TREATING THE PAIN GENERATOR

95 Evaluation of the Functional Anesthetic Discogram as a Screening Tool for Lumbar Fusion to Treat Degenerative Disc Disease

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Background: Degenerative disc disease is the cause of significant pain and disability. Generally, most patients recover with standard non-operative treatments including rest, physical therapy, and anti-inflammatory medications. However, there are many questions regarding the treatment of those patients who have tried the standard non-operative treatments and still remain symptomatic. Lumbar fusion and disc replacement are potential options. However, MRI and provocative discograms have been demonstrated to have poor reliability in screening these patients for surgery. The functional anesthetic discogram (FAD) is a test where a balloon catheter is inserted into a disc that tested positive during discography. The balloon is inflated and this docks the catheter in the disc. Then, the patient is allowed to get off the procedure table and recreate their most painful positions. Then, a local anesthetic is injected through the catheter and the patient repeats the movement again. The pain scores before the injection of the anesthetic and after are recorded.

Study design: Retrospective cohort review.

Objective: To determine the accuracy of the functional anesthetic discogram in screening patients with lumbar disc degeneration for surgery.

Method: A retrospective review was performed of all the patients at our institution who had the functional anesthetic discogram. The test was considered positive if the patient’s pain decreased by at least 50% with the FAD. Follow up was at least 1 year.

Results: Overall, there were 21 patients who had the FAD. Of the 7 patients who had at least a 50% reduction of their pain with the FAD and subsequently underwent surgery, all 7 had at least a 50% reduction in their pain. The mean VAS prior to surgery was 8.2, the mean VAS after surgery was 3.3. Also, all 7 of these patients returned to work and were still working as of their last follow up. There were 3 patients who had surgery despite no improvement with the FAD. All 3 of these patients reported no improvement with surgery. Of the remaining 11 patients, 9 patients did not improve with the FAD and did not have any surgical intervention. 2 patients did improve with the FAD but chose not to have surgery.

Conclusion: Lumbar fusion or disc replacement for disc degeneration remains a topic of much debate. Proper selection of these patients for surgery is critical for a good outcome. The FAD appears to be an effective screening tool on initial inspection.

BASIC SCIENCE: BIOMECHANICS / BASIC SCIENCE

98 The Mechanical Role of Different Macroscopic Changes in Lumbar Intervertebral Disc Degeneration: A Randomized Numerical Study

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Purpose of the study: Intervertebral disc degeneration is related to progressive changes in the disc tissue composition and morphology, such as water loss, disc height loss, endplate calcification, osteophytosis. These changes may be present separately or in various combinations, as more commonly observed in the clinical practice, and may have contrasting effects on the biomechanics of the degenerated segment. However, little is known about these effects. In this work, a wide range of clinical scenarios of disc degeneration, in which the most common degenerative changes are present in various combinations, is investigated by means of randomly generated finite element models.

Methods: A poroelastic nonlinear FE model of the L4-L5 human spine segment was employed and randomly scaled to represent 10 spine segments from different individuals. Six different degenerative characteristics (condition of nucleus pulposus, annulus fibrosus and endplate cartilage; height loss; osteophyte formation; diffuse sclerosis) were modeled in 30 randomly generated models, 10 for each overall degree of degeneration (mild, moderate, severe). For each model, a daily loading cycle including 8 hours of 200 N compression representing the night rest and 16 hours
of 500 N compression modeling the standing position was considered. Two flexion-extension cycles were also simulated, directly after the application of the 500 N load and directly before its removal.

Findings: A tendency to an increase of stiffness with progressing overall degeneration was observed. Therefore, instability for mild degeneration was not predicted. Nucleus degeneration reduced the daily height change of the disc; annulus degeneration had no influence on this result. However, both parameters were significantly correlated to a decrease in the flexion-extension range of motion. Also osteophytosis, diffuse sclerosis and disc height loss induced a reduction of daily disc height change and spine flexibility. Endplate sclerosis significantly limited the disc rehydration during the rest period.

Conclusions: The present investigation of the biomechanical effect of different combinations of degenerative changes may help to better understand disc degeneration from a biomechanical point of view. These findings might provide a basis for discussion about the choice of appropriate treatments for degenerative disc disease, both conservative or surgical, for specific clinical cases. Since all the considered macroscopic changes were found to be mechanically relevant, they should be taken into account by grading systems for disc degeneration whenever possible.

Acknowledgments: This project is funded by the EU FP-7 project GENODISC (HEALTH-F2-2008-201626).

BASIC SCIENCE: POSTERIOR DYNAMIC PEDICULAR STABILIZATION

104 Biomechanical Effect of Posterior Dynamic Stabilization Topping-off Fusion

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Purpose: Degenerative disc disease at the level adjacent to an immobilized (fused) spinal segment is a well-recognized condition, believed to result from the supraphysiological biomechanical stress and increased range of motion (ROM) created by the rigid fixation of the lumbar spine [1]. It is hypothesized that topping a fusion with a posterior dynamic stabilization (PDS) system may diminish these increased stress and ROM and subsequently, reduce the incidence of adjacent level disc disease. The objective of this study was therefore to determine the biomechanical effect of PDS by measuring stresses and ROM of a segment adjacent to fusion prior and after PDS instrumentation.

Methods: A three-dimensional osseo-ligamentous L1-S1 FE-Model with muscles load was validated based on in-vivo data and used in this study. The model was adapted to simulate fusion at L4-L5 topped off with PDS at L3-L4 using the following analogue systems:
- Dynesys’ system
- PEEK rod with fixed screws at the fusion level, topped with screws that retain their polyaxial feature (VIPER™ Semi-Constrained Screw, DePuy Spine, Raynham, MA) (Fig. 1).

Results: All results were expressed relative to a normal spinal segment (referred to as “intact”), without adjacent instrumentation. Analyses included ROM as well as facet loads and intradiscal pressures, as shown in Table 1.

Conclusions: PDS topping off a fusion was shown in these models to control motion, relieve facet loading and reduce intradiscal pressure on adjacent segment to fusion. Assuming that these stresses contribute to adjacent-level disc disease, these data indicate that PDS topping off a fusion may provide some protection against fusion-induced adjacent-level degeneration. In addition, reduced bone screw interface loading further suggests that PDS may be an option to avoid adjacent segment disc disease.

References: 1. Eck, J.C., S.C. Humphreys, and S.D. Hodges,

**CLINICAL: LUMBAR NON-FUSION (I.E. MIS DISCECTOMY, PERCUTANEOUS DISCECTOMY)**

110

Percutaneous Posterolateral Transforaminal Endoscopic Discectomy: Clinical Outcome, Complications and Learning Curve Evaluation

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**Background:** Surgery for herniated lumbar disc is intended to provide relief of pain and disability. The technological development combined with better understanding of endoscopic anatomy has made endoscopic discectomy an appealing surgical option. Our goal was to retrospectively evaluate clinical outcome, complications rate and learning curve with percutaneous posterolateral transforaminal endoscopic discectomy.

**Methods:** Transforminal endoscopic discectomy was performed from 2004 to 2008 in 150 patients. 124 patients were available for follow up. Demographic data, pain evaluation by VAS, Oswestry Disability Index, postoperative complications, neurological status, operation time and subjective patient satisfaction were recorded for each patient.

**Results:** Satisfactory clinical outcome as reflected in the VAS (mean 3.6) and ODI (mean 21%) scores is reported. 26 patients required additional surgery because of continuing symptoms. In the assessment of surgical learning curve, we found a statistically significant difference (p value 0.043) for fewer revision surgeries as the surgeons became more experienced. Thirty patients (24%) had at least one previous back surgery prior to the index endoscopic discectomy. Patients that had endoscopic discectomy as a primary surgery achieved significantly lower VAS (p value 0.04) and ODI (p value 0.004) scores in comparison to patients having endoscopic discectomy as a revision surgery. The combined Complication rate in this patient series was 1.6%.

**Conclusions:** Based on our results and experience, transforminal endoscopic discectomy technique has a satisfactory clinical outcome with a low total complication rate. We acknowledge the steep learning curve of this technique, which can be overcome with training and suitable patient selection.

**Keywords:** Stress fractures, vertebral fractures, kyphoplasty, osteoporosis.

**CLINICAL: NAVIGATION, IMAGE GUIDED SURGERY AND ROBOTIC ASSISTANCE**

113

Prospective Multi-center Evaluation of Percutaneous Lumbar Pedicle Screw Placement using the Oblique or “Owl’s Eye” View

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**Introduction:** Few studies have focused on the oblique technique as a potentially more accurate method of placing percutaneous lumbar pedicle screws without direct visualization. A prospective, randomized, IRB-approved study was undertaken to evaluate the accuracy and safety of the oblique technique using computer assistance (NeuroVision® Guidance, NuVasive, San Diego, CA) to facilitate orienting the C-arm into the oblique view efficiently and accurately.

**Methods:** After providing informed consent, patients were randomized into one of two groups: one underwent placement of lumbar pedicle screws using the oblique technique with the assistance of Guidance; the other group underwent screw placement per the surgeon’s usual technique using fluoroscopy alone (non-Guidance). Fluoro time, screw placement time, and EMG thresholds were recorded intraoperatively for both groups. A neural exam and fractures can result in back pain and the vertebral body may collapse which can lead to retropulsion of bone into the spinal canal causing spinal cord compression. We retrospectively review the patients with occult osteoporotic vertebral fractures treated by kyphoplasty at our institution to reveal whether kyphoplasty can prevent the vertebral body with occult osteoporotic vertebral fracture from collapse and alleviate the pain.

**Methods:** In this retrospective study, we reviewed 18 patients with occult osteoporotic vertebral fractures at our institution from January 2008 to January 2009. The occult osteoporotic vertebral fractures were diagnosed by magnetic resonance imaging (MRI) and/or bone scintigraphy. All the patients were treated by kyphoplasty and the pain and vertebral body height were measured pre-, post-operation and at the follow-up. The visual analogue scale (VAS) was used to determine the relief of back pain. The anterior body height was measured on a lateral radiography.

**Results:** Follow-up ranged from 12 months to 24 months. Mean VAS decreased from 8.2±1.4 preoperatively to 2.7±0.8 postoperatively, and maintained at 2.8±1.2 at final follow-up. The mean anterior body height before kyphoplasty was 98.8%±8.9%. It maintained at 98.9%±9.1% postoperatively, at 98.7%±9.0% at final follow-up.

**Conclusions:** Kyphoplasty was useful for prophylactically stabilize body with occult osteoporotic vertebral fractures and prevent body from collapse. Meanwhile, kyphoplasty can alleviate the pain caused by occult osteoporotic vertebral fractures.

**Keywords:** Stress fractures, vertebral fractures, kyphoplasty, osteoporosis.

**CLINICAL: NAVIGATION, IMAGE GUIDED SURGERY AND ROBOTIC ASSISTANCE**

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Can Kyphoplasty Prevent Vertebral Body with Occult Osteoporotic Fracture from Collapse?

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¹The First Affiliated Hospital of Soochow University, Suzhou, China

**Background and objective:** Occult osteoporotic vertebral fractures can result in back pain and the vertebral body may collapse which can lead to retropulsion of bone into the spinal canal causing spinal cord compression. We retrospectively review the patients with occult osteoporotic vertebral fractures treated by kyphoplasty at our institution to reveal whether kyphoplasty can prevent the vertebral body with occult osteoporotic vertebral fracture from collapse and alleviate the pain.

**Methods:** In this retrospective study, we reviewed 18 patients with occult osteoporotic vertebral fractures at our institution from January 2008 to January 2009. The occult osteoporotic vertebral fractures were diagnosed by magnetic resonance imaging (MRI) and/or bone scintigraphy. All the patients were treated by kyphoplasty and the pain and vertebral body height were measured pre-, post-operation and at the follow-up. The visual analogue scale (VAS) was used to determine the relief of back pain. The anterior body height was measured on a lateral radiography.

**Results:** Follow-up ranged from 12 months to 24 months. Mean VAS decreased from 8.2±1.4 preoperatively to 2.7±0.8 postoperatively, and maintained at 2.8±1.2 at final follow-up. The mean anterior body height before kyphoplasty was 98.8%±8.9%. It maintained at 98.9%±9.1% postoperatively, at 98.7%±9.0% at final follow-up.

**Conclusions:** Kyphoplasty was useful for prophylactically stabilize body with occult osteoporotic vertebral fractures and prevent body from collapse. Meanwhile, kyphoplasty can alleviate the pain caused by occult osteoporotic vertebral fractures.

**Keywords:** Stress fractures, vertebral fractures, kyphoplasty, osteoporosis.
VAS pain assessment were obtained pre- and immediately post-op. A post-op CT scan was also obtained to determine screw placement accuracy.

**Results:** A total of 47 patients (27 females and 20 males) have been enrolled to-date. Primary surgeries included instrumented ALIF (9), XLIF (18), and/or TLIF (22). Of the 214 screws evaluated post-op by CT, 11 (5.1%) breaches occurred: 8 (3.7%) medial, 2 (0.9%) lateral, and 1 (0.5%) inferior; 10 of the 11 pedicle breaches were less than 2mm in magnitude, and 1 breach in the non-Guidance group was 2-4mm in magnitude. None of the breached screws required revision, and there were no significant differences in clinical improvements between patients with breached screws (n=7) and those without (n=40). Use of Guidance resulted in a statistically lower fluoro usage per screw (p< 0.001, figure 1) and quicker placement of guidewires (p< 0.001). Although there was no statistical difference in the average time it took to place each screw, average times trended lower with the use of Guidance (p=0.059).

**Conclusion:** The oblique technique for percutaneous pedicle screw placement using NeuroVision Guidance provides feedback on the appropriate targeting of the pedicle and successfully reduces the amount of fluoroscopy used without significantly adding to the time required for placing pedicle screws.

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**BASIC SCIENCE: BIOMECHANICS / BASIC SCIENCE**

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Relevance of Using a Compressive Preload in the Cervical Spine: An Experimental and Numerical Simulating Investigation

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**Study design:** In Vitro human cadaveric and numerical simulating evaluation of a compressive preload in the cervical spine.

**Objectives:** To analyse the influence of a compressive follower preload on the biomechanical behaviour of the cervical spine.

**Summary of background data:** Simulating compressive action of muscles a follower load attends to reproduce a more physiological biomechanical behaviour of the cervical spine. Only few experimental studies reported its influence on kinematics and intra-discal pressure in the cervical spine.

**Method:** The present study was divided in two parts: part 1: In Vitro investigation; part 2: numerical simulating analysis.

**Part 1:** Twelve human cadaveric spines from C2 to T2 were evaluated intact and after application of a 50N follower load. All tests were performed under load control by applying pure moments loading of 2 N.m in flexion/extension (FE), axial rotation (AR) and lateral bending (LB). Three-dimensional displacements were measured using an optoelectronic system and intra-discal pressures were measured at 2 levels.

**Part 2:** Using a 3D finite element model, we evaluated the influence of a 50 N and 100 N compressive preload on intradiscal loads, facets forces and ranges of motion. Different positions of the follower load along the antero-posterior axis (± 5 mm) were also simulated.

**Results:**

**Part 1:** Mean variation of cervical lordosis was 5 ± 3°. The ROM slightly increased in FE whereas it consistently decreased in AR and LB. Coupled lateral bending during AR was also reduced. Increase of hysteresis was observed on load-displacement curves only for AR and LB. Intradiscal pressures increased but the aspect of load-pressure curves was altered in AR and LB.

**Part 2:** Using the FE model, only minimal changes in ROM were noted following the simulation of a 50 N compressive load for the three loading conditions. Compared to intact condition, less than 10% variation was observed with regard to the different magnitude and positioning simulated. Intra-discal loads and facets forces were systematically increased by applying compressive preload.

**Conclusions:** Although the follower load represents an attractive option to apply compressive preload during experimental tests, we found that this method could affect the native biomechanical behaviour of spine specimen depending on which movement was considered. Only minimal effects were observed in FE whereas significant changes in kinematics and intradiscal pressures were observed for AR and LB.
The Influence of Correction Loss in Thoracolumbar Fractures Treated by Posterior Instrumentation: A Minimum 7-year Follow-up

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We retrospectively studied patients who underwent posterior pedicle screw instrumentation for thoracolumbar fractures to explore the relationship between correction loss after the operation and clinical outcome. The study included 52 patients, with a minimum postoperative follow-up of 7 years (mean of 9.8 years). From the analysis of radiographical and clinical outcomes, we found that the relevant factors of patients’ back function were:

(i) preoperative anterior vertebral height (AVH; regression coefficient [B] = [1]0.075, p = 0.045); and
(ii) the latest follow-up anterior vertebral height (B = [1]0.100, p = 0.043).

This indicates that the patient’s function could be worse if the anterior vertebral column is compressed more severely at the time of injury, and that the function could also be worse if the anterior vertebral height is decreased at the latest follow-up. However, the loss of AVH was not correlated with the Oswestry Disability Index (ODI) value, which means the loss of AVH following surgery has no influence on the patients’ back function. Therefore, we recommend that the AVH should be restored as much as possible by posterior instrumentation during the treatment of thoracolumbar fractures. Reducing the loss of correction to maintain the postoperative AVH is also critical. In addition, although the influence of correction loss on the ODI value was not significant, we conclude that it does influence the functional outcome through changing the latest follow-up AVH.

Selective decompression of lumbar root canal was performed on 216 lumbar radiculopathy patients. The recovery of spinal cord function was evaluated by LBOS assessment. The surgical method is accord to the nerve root canal stenosis site selection of different depressive range and methods. Resection of the joints should narrow entrance area within the joint flank, usable axons bite, bone resection with grinding, drill ground thin from bilateral resection, 30 percent area around the joint, it will not affect the stability. When the middle area in which should be paid attention to narrow the root ganglion back, with superior products and resection of the spondylolysis first part, can obtain pressure existing lumbar olisthe, scrape spoon or a bit of lumbral vertebrae bone clamp removal of soft tissue.

We found that 134 cases (62.04%) were excellent, 48 cases (23.15%) good, 22 cases (10.19%) fair, 10 cases (4.62%) poor, the percentage beyond fair was 85.19%.

Selective decompression of lumbar root canal is really an effective and safe procedure to treat lumbar radiculopathy.
Minimally Invasive Surgery (MIS) for Instrumented Lumbar Fusion is an attractive concept with obvious advantages between the surgeon, patient and even worker’s compensation patients and carriers’. The benefits offer a benefit it must have an effect on the outcomes of the patient in terms of providing for a shorter hospitalization, more rapid entry into physical therapy, rapid advancement into a work conditioning environment, a quicker improvement in overall functionality and the final outcome a faster return to work with limited restrictions. The impetus for the development of this technique centers on a wish to avoid paraspinal muscle damage and the associated sequelae that can occur as seen in the classic open approach. This damage has been shown to increase postoperative pain and diminished functional capabilities and can lead to chronic postoperative pain syndromes and prolonged disabilities. MIS has been shown to lessen paraspinal muscle damage as seen in the works of Sihvonen, Kawaguchi, Styl, Gejo, Kim and Suc, and Stevens and has been confirmed in these studies to lessen postoperative pain and improve rehabilitation.

A study was undertaken to see the effect that MIS has on patient outcomes when compared to the Standard Open approach (OA) for instrumented lumbar fusion surgery. 200 cases were included in the study with 100 cases placed into each group: MIS versus OA and followed for two years. All were single level fusions performed either at L4-5 or L5-S1 by the same surgeon. All patients were evaluated for age, diagnosis, duration of surgery, blood loss, duration of hospitalization, narcotic use and duration, rehabilitation and return to work status and fusion results. Outcomes were measured using the Oswestry Disability Index (ODI), Back Pain Score (BPS), Leg Pain Score (LPS) and SF-36 and rehabilitation were collected using Functional Capacity Evaluations (FCE).

Results revealed in the OA group: OR time (110 min), blood loss (300 ml), duration of hospitalization (3.3 days), duration of narcotic use and quantity (51 hrs/220 mg) and fusion rate (92.8%). In the MIS group: OR time (125 min), blood loss (100 ml), duration of hospitalization (1.5 days), duration of narcotic use and quantity (25 hrs/120 mg), and fusion rate (93.3%). Outcome measurements revealed the following: ODI: OA group 52.5 preop 28.4 postop; MIS group 53.9 preop 19.2 postop. BPS: OA group 16.4 preop 8.1 postop; MIS group 15.9 preop 5.1 postop. LPS: OA group 14.0 preop 6.7 postop; MIS group 15.8 preop 3.7 postop. SF-36: OA group 27.6 preop 39.7 postop; MIS group 21.7 preop 48.6 postop. Rehabilitation was measured using the Oswestry Disability Index (ODI), Back Pain Score (BPS), Leg Pain Score (LPS) and SF-36. Results were collected using Functional Capacity Evaluations (FCE).

Conclusion: MIS offers advantages for the properly selected patient in terms of shorter hospitalization, less blood loss, quicker rehabilitation, shorter use of narcotics, and sooner RTW with proven improvements in all outcome measurements.

**Clinical: Trauma: Fractures and Spinal Cord Repair**

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**Minimally Invasive Treatment of Thoracolumbar Spine Fractures**

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**Introduction:** ThoracoLumbar spinal injuries are common, especially in blunt trauma such as motor vehicle accidents and falls. These injuries often necessitate operative interventions to restore stability to the spinal column. While more traditional methods of spinal fusion are successful for these injuries, newer minimally invasive techniques have been developed and show promise in the setting of traumatic injury.

**Methods:** All surgical cases from the senior author over a period of 30 months were reviewed. Cases of minimally invasive fusions done for thoracolumbar trauma were identified. Laminectomies and kyphoplasty/vertebroplasty were included. These cases were assessed for operative time, length of hospital stay, and estimated blood loss. The exact procedure and number of levels fused were also recorded.

**Results:** Of the 95 minimally-invasive cases done over a 30 month period by the senior author, 30 of these were minimally invasive fusions for thoracolumbar spinal trauma. The average number of levels fused was 5. Average estimated blood loss was 254 ml. Average operative time was 3 hours and 40 minutes. Average hospital stay was 8.9 days.

**Conclusions:** Minimally invasive spinal fusion techniques are promising and growing in popularity. Minimally invasive techniques in general have been shown to reduce length of stay, post-operative pain, and blood loss. There may be a particular utility for minimally invasive techniques in spinal trauma for these same reasons. A direct comparison of minimally invasive techniques with more traditional methods of spinal fusion for trauma is warranted to assess these topics.

**Clinical: Deformity**

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**Surgical Treatment of Adolescent Idiopathic Scoliosis in Patients with Congenital Heart Disease: Comparison of Three Different Types of Constructs**

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The incidence of scoliosis in patients with congenital heart disease has been reported to range between 4% in those patients who have not undergone operative treatment and 11% in children who have undergone cardiac surgery. These curves usually develop quite early and are very severe, requiring surgical treatment. Between 2006 and 2010 we provided corrective surgery for idiopathic scoliosis in four patients (3F, 1M, mean age 15 years, ASA 2) previously undergoing cardiac surgery, respectively for correction of tetralogy of Fallot (TOF, two cases) and heart transplantation for end-stage cardiac failure (two cases). The patients affected by TOF presented an high-grade thoracic curve (Lenke type 1, mean pre-operative Cobb angle: 95°), while the two patients undergoing heart transplantation presented a double-major curves (Lenke type 3, mean pre-operative Cobb angle: 70° for thoracic curves and 40° for lumbar curves). In all cases we provided a posterior instrumentation, but using 3 types of constructs: hybrid construct in three cases (lumbar pedicle screws plus thoracic Universal Clamps in two cases, lumbar pedicle screws plus thoracic hooks in one case) and all-screws construct in one case. In heart transplanted patients a continuous Midazolam and Remifentanil infusion was performed in anesthesia procedure. The average percentage of correction was about 70%, with mean operative time of 240±30 minutes and mean blood loss of 800±200 ml. No neurological complications or wound infection occurred. In high-grade thoracic scoliosis we reported a pleural effusion. No reintervention or anterior surgery was performed. Patients with congenital heart disease undergoing general surgical procedures have a significant rate of perioperative complications. The most important operative aspect is therefore the reduction of blood loss that could become very dangerous. In particular, in heart transplanted patients the denervated heart lacks the ability to respond acutely to hypovolemia or hypotension with reflex tachycardia. Moreover, the immunosuppressed state increases the heart transplanted patients susceptibility to infections, altering the response to surgical stress and delay healing. However, orthopaedic elective procedures are not categorically contraindicated, but require special precautions. In our series we performed three types of posterior spinal instrumentation, with similar results and without major complications. However, among these systems, the hybrid construct using lumbar pedicle screws and thoracic Universal Clamps provided a satisfactory correction of the deformity, with an excellent sagittal control, and reduced operative time, radiation exposure and blood loss respect to all-screws constructs. In this study we have demonstrated the efficacy and safety of various types of spinal fixation in corrective surgery for idiopathic scoliosis in children undergoing cardiac surgery for congenital heart disease.

**Background:** Lateral lumbar trans-psoas interbody fusion has been proposed to be less invasive than anterior lumbar interbody fusion (ALIF) and to offer improved fusion and improved restoration of interbody height and segmental alignment compared to posterior interbody fusion techniques (PLIF, TLIF). Lateral trans-psoas fusion has recently been used to treat deformities including degenerative scoliosis and isthmic spondylolisthesis.

**Study design and methods:** This retrospective review examined preoperative and postoperative characteristics of twenty-seven consecutive adult patients who underwent deformity correction using trans-psoas interbody fusion. All patients were treated by a single surgeon at a single medical center in the US. Multi-modal intra-operative neuromonitoring was performed, with multiple quadriceps leads, and scrotal leads used in males. The retroperitoneal approach was performed under direct visualization, using modified hand held retractors to visualize the psoas muscle. The psoas was traversed under direct vision and with fluoroscopic guidance using sequential dilators. Gentle deformity correction was accommodated by wide bilateral release of the annulus as well as by application of large interbody implants (range 11mm to 18mm height, 40 to 60 mm width), extending over the lateral aspect of the ring apophysis and lateral vertebral body. Staged posterior instrumented fusion was performed with or without decompression. Hospital charts and operative data were retrospectively reviewed to determine the number of levels operated, average blood loss, complications, postoperative time to independent ambulation, and time to discharge from hospital.

**Results:** Fifteen patients had fusion at one level while nine patients had fusion at two levels and three patients had fusion at three levels. Average blood loss for lateral interbody fusion was 20cc and average blood loss for posterior procedure was 310cc. All patients were able to ambulate on the first post-operative day. Average hospital stay was five days. The most frequent complication (5/27 patients, 18%) was transient unilateral iliopectos weakness on the approach side, which improved by the first (2 week) postoperative visit. Transient anterior thigh numbness on the approach side was also frequently observed (6/27 patients, 22%). Transient numbness along L3 distribution was seen in one patient who recovered uneventfully. Ureteral injury was seen in one patient which was treated with percutaneous nephrostomy and healed without further consequences.

**Conclusions:** It has been proposed that lateral trans-psoas interbody fusion may offer improved safety and efficacy for lumbar deformity treatment, as compared to ALIF, PLIF, or TLIF. The lateral interbody fusion can be safely applied to deformities if certain technique modifications are followed. Careful attention to these modifications will be required in order to best compare lateral interbody fusion to the established alternatives in future large clinical trials.

**CLINICAL: LUMBAR FUSION (I.E. MIS, TLIF, XLIF, AXIAL LIF, ALIF)**

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*Sagittal and Coronal Deformity Correction through Minimally Invasive Trans-psoas Lateral Interbody Fusion; Complication Avoidance by Modification of Surgical Technique*

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CLINICAL: LUMBAR NON-FUSION (I.E. MIS DISCECTOMY, PERCUTANEOUS DISCECTOMY)

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Our Experience with Percutaneous Bilateral Facet Motion Augmentation System: A Report of 60 Cases
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Minimally invasive surgical techniques have been rapidly diffusing in recent years. Different devices are now available for the treatment of lumbar spine degenerative disease. They allow a good symptoms relief as well as a short time of surgery and hospitalization. We present our experience with a novel system for percutaneous bilateral facet motion augmentation. This system was designed to limit painful spinal motion, enlarge the foramina and achieve intradiscal decompression. It is composed of a bilateral titanium anchor connected to a silicone stabilizer.

Since February 2009 we used the percutaneous facet motion augmentation system at our institution. Major indications were single level degenerative disc disease and spinal stenosis.

We consider 60 patients for the present study. Mean age was 46.6 years old (range 38-72). Treated levels were L4-L5 (28 cases), L3-L4 (12 cases), L5-S1 (12 cases) and L2-L3 (8 cases).

We performed the surgical approach under spinal anesthesia whenever was applicable (53% of patients). Follow-up data were recorded at 2-months and 6-months. Clinical results were assessed using the Visual Analogic Scale (VAS) and the EQ-5D questionnaire.

Overall results were satisfactory in 56 patients. Mean pain VAS score improved from 7.7 at baseline to a value of 2.2 at 2-months follow-up. The remnant 4 patients had minimal or no changes. Two of these patients were subsequently treated with traditional transpedicular stabilization system.

Mean procedure time was 26 minutes (range 18-40 minutes). Early mobilization was possible 12 hours after surgery in all patients. Hospital discharge was possible at 24-36 hours. No intra- and post-operative complications were observed. Preliminary results are good and promising. Surgical technique is easy and satisfy requisites for a minimally invasive procedure. Percutaneous bilateral facet motion augmentation system represents a modern option to spinal fusion in selected cases.

BASIC SCIENCE: MIS FUSION-STABILIZATION

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Biomechanical Investigation of a New Implant for Facet Fusion
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Introduction: It is assumed that a high stiffness of a spinal motion segment should be obtained with implants as a major prerequisite in order to achieve bony fusion. Therefore fusion with cages is often combined with additional internal fixators. This instrumentation, however, causes soft-tissue trauma, which motivates the development of less invasive surgical techniques. Regarding this effort a new biodegradable facet fusion implant has been developed that can be inserted directly into the facet joint space and then melted and anchored in this position using an ultrasonic welding process (BoneWelding® technology). The implant inhibits segmental movement directly at the joint and should make an additional internal fixator dispensable. The aim of this in vitro study was to determine the biomechanical behavior of the new method during flexibility testing in comparison to the stabilization with an internal fixator.

Methods: For fusing the facet joints a biodegradable polymer (PLDAL 70/30) is inserted percutaneously into the facet joint space. The material melts at the contact area between bone and implant using ultrasonic energy and yields into the trabecular structures of the facet joints. The new method, developed by SpineWelding AG (Schlieren, CH) was compared in this in vitro study to the commonly used stabilization method with an internal fixator. For the tests, three L2-3 and three L4-5 segments with a median age of 75 years were used.

After implanting an anterior cage (Syncage, Synthes CH) the segments were additionally stabilized with an internal fixator (CD Horizon® Legacy, Medtronic), which was later replaced by the new facet fusion implant. Flexibility of both methods was measured in all three motion planes at ±7.5 Nm in a custom built spine tester.

Results: The internal fixator as well as the new facet fusion implant showed a significant reduction of the range of motion (ROM) in all three motion planes. The median values of the ROM after inserting the facet fusion implant were 23% of the intact ROM during flexion/extension, 25% during lateral bending and 60% during axial rotation. The differences between fixator and facet fusion implant, however, were marginal and not significant.

Discussion: The BoneWelding® technology provides an interesting alternative for minimal invasive stabilization of spinal motion segments and seems to achieve similar primary stability compared to an internal fixator. Exemplary histological investigations showed that the melted polymer anchored into the trabecular structures of the bone and achieved the bonding of the facet joints. The behavior of the implant during long term cyclic loading still has to be clarified.

BASIC SCIENCE: INNOVATIONS NON-CONVENTIONAL

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Biomechanical Investigation of a New Annulus Reconstruction Implant after a Provoked Nucleus Extrusion
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Introduction: A common method to treat herniated discs is to remove the sequester followed by a partial or the complete removal of the nucleus to avoid a reherniation. Removing too much nucleus material can lead to a non-physiological biomechanical behavior of the treated segment, whereas removing too little material can increase the risk of a re-
herniation. Therefore it would be desirable to close the annulus defect in order to preserve as much nucleus material as possible. The aim of this in vitro study was to determine the reliability of a new annulus reconstruction implant in a disc herniation model.

Methods: To simulate a worst case scenario, human spinal segments were inspected until three L2-3 and three L4-5 segments could be selected for the tests. All specimens had to prove during intradiscal pressure measurement that the nucleus still features hydrostatic behavior. In all six specimens with a median age of 58 years a rectangular defect was created with 6 x 10 mm (height x width) at the posterior annulus. Subsequently a complex cyclic load was applied until a visible nucleus extrusion occurred. The extruded material was pushed back into the disc and the annulus defect was treated with the Barricaid ARD implant (Annulus Reconstruction Device, Intrinsic Therapeutics Inc.). The ARD consists of a metal anchor that was inserted below the superior endplate of the inferior vertebra and a mesh that was placed inside the disc to seal the annulus internally (figure).

[Figure: X-ray image of the implanted ARD. Visible ]

Disc height and flexibility of the specimens was measured in all three main motion planes with a spine tester (intact, defect and implanted). Afterwards a cyclic loading test was conducted to provoke re-herniation. The specimens were mounted in a servo hydraulic material testing machine and loaded with 4-24 Nm at 5 Hz while they could rotate with 360°/s.

Results: Compared to the intact state, the provoked herniation caused a median reduction of the disc height of 0.6 mm that could be restored up to 0.2 mm with the implant. The increase of the range of motion (ROM), however, could only be improved slightly. In contrast the fundamental result was that in no case a re-herniation was visible in the macroscopic inspection after 100,000 cycles.

Discussion: This in vitro study showed that, in general, it seems that it is possible to reliably seal an annulus defect with an implant. On the basis of previous investigations we tried to simulate a worst case scenario with this herniation model. The nucleus of the specimens showed still hydrostatic behavior in all cases so that nucleus extrusion during cyclic loading was presumable. After the implantation of the ARD this risk was still existent. Concluding the new generation of the Barricaid ARD seems be able to prevent the nucleus from re-herniation.

Discussion:

This in vitro study showed that, in general, it seems that it is possible to reliably seal an annulus defect with an implant. On the basis of previous investigations we tried to simulate a worst case scenario with this herniation model. The nucleus of the specimens showed still hydrostatic behavior in all cases so that nucleus extrusion during cyclic loading was presumable. After the implantation of the ARD this risk was still existent. Concluding the new generation of the Barricaid ARD seems be able to prevent the nucleus from re-herniation.
CLINICAL: PROSTHESIS

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Nubac Disc Lumbar Arthroplasty: Clinical Study and Results
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Introduction: Patients presenting with discogenic low back pain along with radicular or neurological symptoms secondary to nerve root compression due to disc prolapse represent a difficult and challenging patient population for the spinal surgeon to diagnose and treat. For these patients who have failed conservative care, currently there is no other treatment option other than discectomy followed by fusion of the accompanying motion segment. Fusion, however, represents the end stage of the treatment continuum. In this continuum of treatment for DDD that is unresponsive to conservative care, minimal invasive disc arthroplasty is preferred for patients with early to moderate DDD over a more aggressive and comparatively higher risk treatment, such as total disc replacement or fusion. NUBAC is a nucleus replacement device consistent with this premise. Clinical evaluation of the NUBAC is ongoing and results are presented.

Methods: The major indication for NUBAC is discogenic back pain with or without leg pain caused by DDD in patients who have failed conservative care for at least 6 months. Patient pathology and surgeon preference determined which of the three surgical approaches was used to implant the NUBAC device - posterior, lateral or anterolateral.

47 patients with an average age of 37 years were implanted with the device. Twenty-seven completed one year follow-up and eighteen completed two year follow-up. 53% were male, 96% underwent single level surgery. 72% were implanted at the L5S1 level with the remainder at L4L5. 2 patients (4%) were implanted anterolaterally, 10 patients (21%) laterally (ALPA approach) and 33 posteriorly (70%) after a microscopic microdiscectomy. Intra-operative and post-operative vascular and neurological complications as well as ODI and VAS scores at pre-op, 6w, 3m, 6m, 12m and 24m were recorded.

Results: The average operating time was 85 minutes with an average estimated blood loss of 36 mL. There were no major intra-operative complications. ODI scores improved preoperatively from 50.3 and 54.9, to 20.9 and 13.3 at one year, and 21.8 and 12.3 at two years, for the lateral and posterior approaches, respectively. VAS scores improved preoperatively from 50.3 and 54.9, to 20.9 and 13.3 at one year, and 21.8 and 12.3 at two years, for the lateral and posterior approaches, respectively. Average disc height was 8 mm preoperatively and at 12 months was 9 mm.

Conclusions: In this series of patients, Nubac has demonstrated to be an effective surgery for DDD and can be considered a valid tool for slowing down the degenerative cascade of the lumbar disc. Selection of the patients is demanding as well the surgical technique when using the posterior approach. An international multicentric study is now involving more patients.

BASIC SCIENCE: BIOMECHANICS / BASIC SCIENCE

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The psoas major muscle (PM) is the only paraspinal muscle that arises anteriorly to the lumbar spine and crosses the hip joint. Although the PM is considered an important hip flexor, its role as a lumbar spine mover/stabilizer is still not fully understood. Several investigators have detailed the gross muscle anatomy of PM to gain an understanding of its spinal function. However, a comprehensive architectural analysis of the PM has not been published. Moreover, length-tension and passive mechanical properties of the muscle have never been reported. The purposes of this study were to:

a) determine the PM architectural properties in a relatively young population,
b) measure in vivo sarcomere length operating range, and
c) determine the passive mechanical properties of the human psoas muscle.

We hypothesized that due to the PM’s role as a hip flexor, its architecture would be characterized by long fibers and a small physiological cross-sectional area compared to posterior paraspinal muscles, and that its sarcomere length operating range would be similar to muscles in the lower extremity.

Methods: The lower one half (T12 to toes) of thirteen cadaveric specimens was harvested. The PM was isolated from each vertebral level, permitting architectural measurements of mass, normalized fiber length (Lf), physiological cross-sectional area (PCSA), and fiber length-to-muscle length ratio (Lf/Lm). Separately, to determine PM sarcomere length operating range, sarcomere lengths were measured in vivo from intraoperative biopsies taken with the hip joint in flexed and extended positions. Additionally, single fiber and fiber bundle tensile properties as well as the molecular weight of the PM titin protein were measured from the intraoperative biopsies.

Results: Average muscle mass was 249.79 ± 18.43g and average normalized Lf of 12.70 ± 2cm, yielded an average PCSA of 18.45±1.32cm2, and an average Lf/Lm of 0.48 ± 0.06. Intraoperative sarcomere length measurements revealed that the muscle operates from 3.18 ± 0.20 µm with hip flexed at 10.7±13.9° to 3.03 ± 0.22 µm with hip flexed at 55.9±21.4°. Passive mechanical data demonstrated that the elastic modulus of the PM muscle fibers (37.44 ± 9.11 kPa) and bundles (55.3 ± 11.8 kPa) were similar to those of the erector spinae muscles.

Conclusions: The architectural design of the PM demonstrates that its’ average fiber length and passive...
biomechanical properties resemble those of the lumbar erector spinae muscles. The PCSA of the PM was larger compared to the longissimus and iliocostalis and smaller compared to multifidus. Additionally, PM sarcomere lengths were confined to the descending portion of the length-tension curve allowing the muscle to become stronger as the hip is flexed and the spine assumes a forward leaning posture. These findings suggest that the human PM has architectural and physiologic features that support its role as both a flexor of the hip and as a dynamic stabilizer of the lumbar spine.

**CLINICAL: CERVICAL NEW MOTION PRESERVATION TECHNOLOGIES**

**172**

**Will an Advanced Generation Artificial Cervical Disc Provide Normal Post-operative Kinematics?**


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**Introduction:** The M6-C artificial cervical disc (Spinal Kinetics, Sunnyvale, CA) is an advanced generation artificial disc intended to treat degenerative cervical radiculopathy. It is designed to replicate the anatomic structure of a natural disc by incorporating an artificial nucleus and annulus. The compressible polymer nucleus of the M6-C is designed to simulate the function of the native nucleus, while the surrounding multi-layer high tensile strength fiber annulus is intended to provide controlled range of motion. This unique design allows the M6-C device to have all 6 degrees of freedom to include angular motion in flexion-extension, lateral bending and axial rotation as well as allowing independent translations along the 3 anatomic planes (anterior-posterior, side-to-side and axial compression). The hypothesis of the study is that the novel design of the M6-C device will provide normal post-operative kinematics.

**Methods:** The M6-C US IDE feasibility study and the M6-C German Post-Market Registry were single-arm, prospective studies intended to evaluate the initial safety and clinical performance of the M6-C artificial cervical disc for the treatment of intractable cervical radiculopathy at one or two levels. Patients were evaluated pre- and post-operatively at predetermined intervals through 24 months. Radiographic images included AP, Lateral, Flexion-Extension and, in the US, Left-Right Bending. Validated, computer-assisted methods (QMA®: Medical Metrics, Inc., Houston, TX) were used to quantify intervertebral motion in the sagittal and coronal planes, including center-of-rotation (COR).

**Results:** Radiographic analysis was performed in 72 patients from nine clinical sites with a mean age of 45 years. Fifty patients were treated at one level and 22 at two levels for a total of 94 implanted levels. Intervertebral motion from flexion to extension at the index level at 2 years (7.3 ± 5.1 deg) was not significantly different than at pre-op (9.2 ± 4.5 deg, P=0.13). There was also no significant difference between 1-level and 2-level patients (P=0.76). Intervertebral translation averaged 1.0 ± 0.7 mm at pre-op and 0.7 ± 0.6 mm at 2 years (P=0.052). Intervertebral rotation in left-right bending averaged 5.8 ± 3.9 deg at pre-op and 5.0 ± 3.8 deg at 2 years (P>0.99). In flexion-extension, the anterior-posterior position of the COR did not change significantly from pre-op (P>0.99). The cephalo-caudal position of the sagittal plane COR shifted cranially by approximately 2 mm (P< 0.001) but remained within or below the disc in all patients. In left-right bending, there was a trend for the COR to shift caudally between pre-op and 2 years (P=0.21), but the COR remained within or above the disc in most patients. Post-operatively, the index level COR in the sagittal and coronal planes significantly overlapped the 95% confidence intervals for asymptomatic populations.

**Conclusion:** Two years following implantation of the M6-C, the quantity of intervertebral motion is preserved in most patients. The M6-C also generally appears to provide for a quality of motion that is within previously established limits for asymptomatic volunteers. The ability of the implant to support a COR that is below the disc in the sagittal plane and above the disc in the coronal plane suggests that it may support a helical axis of motion consistent with true, 6 degree-of-freedom kinematics.

**CLINICAL: POSTERIOR DYNAMIC PEDIKULAR STABILIZATION**

**175**

**Patient Satisfaction Following Lumbar DSS Surgery**

(Dynamic Spine Stabilization System, Paradigm Spine)

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**Objective:** To evaluate the satisfaction of patients who were surgically treated with Dynamic Stabilisation System (DSS) for lumbar degenerative disorders at our unit.

**Summary of background data:** Various forms of lumbar instability require surgical stabilization. As an alternative to fusion, a mobile, dynamic stabilization restricting segmental motion would be advantageous in various indications, allowing greater physiological function and reducing the inherent disadvantages of rigid instrumentation and fusion. The DSS system is a pedicle-screw based, implantable dynamic spine stabilization system indicated for degenerative disc disease of the lumbar spine. The range of motion is controlled by a combined spring and damper unit allowing approximately 50% range of motion in flexion...
and extension. The system allows controlled dynamic stabilisation while allowing control of rotation and the modularity allows combination of fusion and dynamic stabilisation.

**Method:** 28 consecutive patients underwent DSS fixation from July 2008 to July 2010 in our spine unit by one consultant surgeon (IMS). The patient group consisted of 17 females and 11 males with an age range of 36 to 86 years. The range of follow-up period is 3-27 months. Indications for surgery were lumbar canal stenosis, grade I or II spondylolisthesis and degenerative lumbar disc disease. 25 patients had single level DSS fixation, two had 2 levels and one had 3 level fixation. 16 patients had decompression with DSS alone (group A) and 12 had hybrid DSS and posterior lumbar interbody fusion (group B). The patient satisfaction scored according to the Odom criteria. The scoring was carried out by the author who was not involved in the surgery. Pre operative scores were collated of Visual Analogue Scale, Oswestry Disability Index and Centre for epidemiology studies-depression scale. Follow-up scores continue to be collated.

**Results:** At one year follow up, results of 23 cases according to Odom criteria showed 9 cases to be rated excellent (39%), 7 good (31%), 4 fair (17%) and 3 poor (13%). Overall results of the 28 patient at their last visit showed that 10 cases (36%) were categorized as excellent, 8 (29%) good, 6 (21%) fair and 4 (14%) poor. Looking at the two groups the outcomes are: Group A; 7 cases rated excellent (44%), 2 good (12%), 4 fair (25%) and poor 3 (19%). Group B; 3 cases scored excellent (25%), 6 good (50%), 3 fair (25%) with no poor results. We had no implant or screw related failures.

**Conclusion:** Early data indicates that there were improvements in outcomes of majority of patients who underwent DSS surgery. Majority had improved after surgery by one year and those who had been followed up for two years have maintained the same level of their Odom scoring. Overall 86% were satisfied with the surgical outcome at their last visit.

DSS is a new, safe, reliable device and gives promising outcome at their last visit.

Early results in patient satisfaction at this early stage. Early results are encouraging and more research is required in this field.

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Early results are encouraging and more research is required in this field.

**METHOD:**

**Basic Science: Cervical New Motion Preservation Technologies**

**Biomechanical Evaluation of the Titanica Cervical Intervertebral Disc Prosthesis**

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**Introduction:** In vitro nondestructive flexibility testing of a constrained, semi-mobile total disc replacement (TDR) was performed (Titania disc; Meteor Medical, Istanbul, Turkey). It was hypothesized that the TDR would not significantly alter biomechanics relative to normal, whereas rigid fixation would cause significant changes. Biomechanical assessment included a wide array of kinematic parameters for thorough characterization of the device.

**Methods:** Eight unembalmed human cadaveric C3-T1 specimens were tested intact, after TDR, and after anterior plating. Flexion, extension, lateral bending and axial rotation were induced by pure moments; flexion-extension was then induced by a simplified muscle force model with 70-N follower load and dead weight representing the head. Finally, 70N, 110N, and 150N were applied to specimens in static upright posture. Optical markers measured 3D vertebral motion and 8 points of laminar surface strain were recorded for assessing C5-C6 facet loads. Biomechanical parameters studied included Range of Motion (ROM), Lax Zone (LZ), angular coupling pattern, sagittal Instantaneous Axis of Rotation (IAR), and facet loads normal to the facet joint plane. Mean values of parameters were compared statistically using RM-ANOVA/Holm-Sidak tests.

**Results:** TDR reduced ROM during all loading modes to an average of 52% of intact (p<0.001) while plating reduced ROM to an average of 35% of intact (p<0.001, Figure 1). Similarly, TDR reduced LZ during all loading modes to an average of 27% of intact (p<0.001) while plating reduced LZ to an average of 18% of intact (p<0.001, Figure 1).

After TDR, sagittal IAR shifted insignificantly relative to normal by 4.7 mm (Figure 2, p>0.18). However, after plating, IAR shifted 9.4 mm relative to the intact position, which represented a significant rostral shift (p=0.008).

Coupled axial rotation per degree lateral bending was 69% of normal after TDR (p=0.027), but 22% of normal after plating (p=0.001). Coupled lateral bending per degree axial rotation was 76% of normal after TDR (p=0.029), but 62% of normal after plating (p=0.002). According to output from strain gauge arrays, neither TDR nor plating significantly altered facet loads during bending or twisting; loads were significantly reduced relative to normal by both constructs in the upright posture with 70N, 110N, or 150N applied (p<0.03).

**Conclusions:** Although this TDR is not as mobile as other commercial cervical TDRs, with regard to ROM, LZ, IAR, and coupling, deviations from normal biomechanics were less substantial after TDR than after plating. Facet load alterations were minimal with either construct. Our results show that this particular TDR permits moderate mobility and maintains some desirable kinematic patterns in a cadaver model.
CLINICAL: EVALUATION OF NEW BIOLOGIC TREATMENT

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Minimally Invasive Lumbar Fusion (XLIF) Using a βTCP-HA Bone Graft Substitute (FormaGraft): Fusion Rates out to 2 Years
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Summary: The use of a beta-tricalcium phosphate/hydroxyapatite (FormaGraft) with bone marrow aspirate (BMA) was prospectively studied in 57 consecutive 1- and 2-level XLIF procedures. Outcomes were encouraging; XLIF has proven to be a safe and effective procedure, and now 24-month results using βTCP-HA bone graft substitute confirm fusion, maintenance of improvements, and overall patient satisfaction.

Introduction: Good short-term outcomes after XLIF have been shown, however, no reports to date have focused specifically on fusion rates associated with XLIF, or on the graft materials used in XLIF. Issues related to early resorption and hospital cost with bone morphogenic protein in lumbar fusions have fueled continued evaluation of other bone graft substitutes.

Methods: The use of a beta-tricalcium phosphate/hydroxyapatite (FormaGraft) with bone marrow aspirate (BMA) was prospectively studied in 57 consecutive 1- and 2-level XLIF procedures. Radiographic outcomes were evaluated to demonstrate fusion and were compared with clinical results.

Results: Patient age ranged from 25-79yrs (average: 55.9yrs). Primary diagnoses included stenosis(31), DDD(12), spondylolisthesis(8), and HNP(6). Comorbid conditions included previous spine surgery(47.4%); smokers(40.35%); diabetes(22.81%); chronic steroid use(8.77%); obesity/morbid obesity(52.6%). 64 levels were treated: 50=1-level, 7=2-level; 1@T8-9, 4@L1-2, 6@L2-3, 16@L3-4, 37@L4-5. Graft included equal amounts by volume FormaGraft and BMA, aspirated from the adjacent vertebral body under lateral exposure. All included supplemental fixation. Hgb change and hospital stay averaged 1.20g and 1.04days. Complications included one iatrogenic HNP requiring secondary decompression. One patient died at 10months post-op, unrelated to his surgery. Average disk height improved from 6.35mm to 10.86mm, and was maintained at 10.0mm at 24 months. Fusion by Lenke score=1 and 2 was 90.0% at 24 months. Average VAS pain scores decreased from 9.0 at pre-op to 3.2 and 3.6 at 12 and 24 months respectively. 89% expressed satisfaction with their procedures at 12months, and 89% said they would do it again.

Conclusion: XLIF has proven to be a safe and effective procedure, and now 24-month results using βTCP-HA bone graft substitute confirm fusion, improvements, and overall patient satisfaction.

CLINICAL: LUMBAR FUSION (I.E. MIS, TLIF, XLIF, AXIAL LIF, ALIF)

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Minimally Invasive Far Lateral Lumbar Interbody Fusion: A Review of the Technique, Indications and Preliminary Outcomes
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The current study was designed to describe the technique and to evaluate the efficacy of lumbar interbody fusion achieved due minimally invasive intertransverse process...
approach. This surgical via avoids the need for either intraabdominal dissection or violation of the spinal canal in accessing the disc space and it is indicated in selected lumbar pathologies as symptomatic degenerative disc disease or low grade of spinal instability that may require interbody fusion without spinal canal decompression. Twenty-three patients with single-level spinal instability or degenerative disc disease were identified and treated by this method. Visual analogue Scale (VAS) and Oswestry disability index (ODI) were used to assess back pain and functional outcome. Fusion was evaluated by CT scan achieved 6 months after surgery. The average follow-up period was 13 months. Clinical outcome was satisfactory in all patients; mean improvement of 5.7 points in VAS scores and 23.7% in the ODI was observed. Evidence of fusion was observed in all patients. In our experience far lateral lumbar interbody fusion technique achieved due minimally invasive intertransverse approach has shown the potential to reduce the rate of complications, the amount of intra-operative blood loss, the intensity of postoperative pain, and the duration of hospital stays. This kind of extraforaminal approach, when used in selected lumbar pathologies that do not require spinal canal decompression, allows to achieve a satisfactory results and it is a valid alternative to other fusion techniques.

**BASIC SCIENCE: POSTERIOR DYNAMIC PEDICULAR STABILIZATION**

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**Design Optimization of a Posterior Dynamic Stabilization Concept for Restoring the Intact Biomechanics of Lumbar Spine after Facetectomy**  
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**Background:** Concept of posterior dynamic stabilization (PDS) is a recent alternative to traditional fusion surgery, and for stabilization after decompression surgery in treatment of spinal stenosis. PDS systems often include combination of various mechanical joints; however which combination would provide the most intact like biomechanics while having the least loads going through implant components is not yet known. We undertook finite element analyses to evaluate the effects of design variables on biomechanics of spine following facetectomy and stabilization using a screw-based PDS system.

**Methods:** A nonlinear 3D, experimentally validated L3-S1 FEM was used. A total bilateral facetectomy was simulated at L4-L5 prior to placement of PDS. The PDS included a pair of curved male-female CoCr sliding components with a base radius of 45mm and its center of rotation (COR) matched that of intact disc. The radii of PDS were 30, 40, 50 and 55mm and a BS joint was attached bilaterally to either end of each PDS via a cross connector. A total of 15 implanted scenarios which included 5 radius variations each with three BS joint settings (NJ: no joint, BJ: joint at bottom and TJ: joint at top) were simulated.

All models were loaded with 400N of pre-compressive load and 10Nm of moment to simulate flexion:Flex, extension:Ext, lateral bending:LB and lateral rotation:LR. The segmental motion and load sharing at discs and implants were computed for intact and implanted cases.

**Results:** The intact segment had motion of 2.7°, 5.0°, 4.5° and 2.4° in Ext, Flex, LB and LR respectively. At implanted level the motion varied between 2° to 3.9°, 3.3° to 5.2°, 1.3° to 4.5° and 0.7° to 2.4° for different PDS settings for the same loadings. When the ball joints were placed at caudal side, the motion was closest to intact. Also variation of curvature of PDS affected the segmental kinematics in each loading; the PDS with R45 (base) had motion closest to intact. Among all cases, PDS-R45 with joint at caudal side had intact like motion in all loadings. At adjacent segments, all implanted models had kinematics close to intact, L3L4: 2.4°, 5.0°, 4.7° and 2.6°; L5S1: 3.5°, 5.2°, 3.5° and 2.2° in Ext, Flex, LB and LR respectively.

The intradiscal pressure across segments predicted similar changes as kinematics for all implanted cases versus intact. The axial pullout load on screws increased (45 to 72N) in NJ cases and decreased (78 to 54N) in BS cases when radius of PDS increased. However in BJ models, the loads remained close to 60N independent of variations in the radius. The bending moment on screws didn’t change much when the curvature varied in NJ (~2.1Nm) and BJ (~2.2Nm) cases. However it decreased as the radius increased in TJ cases (1.8 to 1.2Nm).

**Discussion:** Our results suggest that a design which has a matched COR with disc will provide the segment with kinematics similar to intact. Having the BS at the caudal end helps to keep the COR close to inferior endplate much like the intact. This would reduce the loads on screws thus lesser risk of implant failure in the long run.

**CLINICAL: POSTERIOR DYNAMIC PEDICULAR STABILIZATION**

**198**

**Dynamic Stabilization of the Lumbar Spine with Isobar**  
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**Introduction:** The occurrence of symptomatic adjacent segment disc degeneration (ASD) has paralleled the use of rigid instrumentation placed to facilitate spinal arthrodesis. It is thought that the rigid metal implants place supra-physiological strain on the neighboring intervertebral disc space and facet joints, thus leading to segmental hypermobility, facet deterioration, instability, and ultimately advanced segmental degeneration in a domino-type effect. The occurrence rate of adjacent segment degeneration (ASD) has been reported by numerous authors and ranges up to 82.6%. Dynamic stabilization aims to reduce the strain placed on adjacent levels through semi-rigid implants. The Isobar, by Scientx Corporation, is a pedicle screw based system that utilizes a dynamic rod. The device can be used to provide dynamic support to a single spinal level, or it can be used to top off a rigid fusion. We describe our experience with 76 consecutive patients undergoing dynamic stabilization procedures at a single institution by senior author, DQM.

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Methods: Seventy-six consecutive patients undergoing dynamic stabilization procedures at a single institution are presented. Radiographic follow-up and outcome measures with the Oswestry Disability Index, and SF-36 were gathered. Results: Patient follow-up ranges from 4-50 months. A total of 36 patients had completed an Oswestry Disability Index at the time of their last follow-up (range 6-43 months). Excellent outcomes were conferred in 51.7% of patients, while 20% had a good outcome, 20% had a fair outcome, and only 8.6% had a poor outcome. There was no evidence pedicle screw failure on radiographic follow-up, and in only one case there was a hardware failure that consisted of a set-screw backing out. This, however, was asymptomatic and did not require further intervention.

Conclusion: In our experience with seventy-six patients, we have found the Isobar dynamic stabilization system to be a safe and effective means of offering patients a spinal stabilization procedure while mitigating the incidence of symptomatic adjacent level degeneration. It is clear that further longitudinal evaluation will be required to determine the long-term benefit of this device. In addition, a randomized, prospective study comparing similar cohorts undergoing stabilization with Isobar dynamic rod or rigid fusion would be useful in determining the Isobar’s effectiveness in preventing SASD.

BASIC SCIENCE: BIOMECHANICS / BASIC SCIENCE

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Micro-CT Based, Structural Analysis of the Facet Joint, Comparing L4/5 to C6/7
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Introduction: It is known that the facet joints carry approximately 20% of the spinal loads in upright position. Therefore, they play an important role in the biomechanics of the vertebral column. Facet degeneration is present in up to 80% of older adults. Facet joint arthrosis can be a severe source for back pain. Knowledge of the morphology and its changes is a prerequisite for the development of new facet joint implants that address degenerative changes with age. Therefore, the goal of this study was to investigate the anatomy of cervical and lumbar facet joints using microcomputer tomography (μCT).

Methods: Cervical and lumbar spinal segments (C6/7, L4/5) of 23 formalin fixed donors (12 female, 11 male) aged 43-98 y (median 68 y) were used. This yielded a total number of 197 single joints (C6 - 40, C7 - 38, L4 - 58, L5 - 61). First, the vertebral bodies were dissected from the posterior structures. Subsequently, all soft tissue was removed. Lumbar superior and inferior facet joints were divided anatomically. A cylinder of 11 mm diameter was drilled from the centre of the articulating surface through the whole joint using a custom made core drill. This cylinder was scanned with a μCT using a 30 μm resolution. Due to the smaller size, both cervical facets were scanned together at a resolution of 35 μm and divided after scanning.

Volumes of interest were defined to investigate the morphology of the endplates and the underlying trabecular structure seperately. Furthermore, the segments were subdivided into five equally spaced slices to investigate regional variations. Thresholding of each single image was done using an adaptive threshold. Each subgroup was morphologically analysed with a view to age and gender. Due to equal variances we performed an ANOVA using a significance level of p=0.05.

Results: In contrast to the bony endplates of the vertebral bodies, the facet endplates are much thicker. Statistically significant difference of 8% in trabecular thickness (Tb.Th) between males and females was found. Tb.Th in the superior and inferior facets was equal. No statistically significant difference was found between the segments C6/7 and L4/5. No difference in Tb.Th could be found with respect to age for both male and female. Porosity in the endplates was on average 85% and equal amongst the segments.

Conclusion: This study presents a detailed insight into the internal structure of the facet joints. This could help to understand the load flow in the fact joints. Understanding the morphology is a prerequisite for the design of new treatment strategies.

BASIC SCIENCE: PROSTHESIS

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Effect of Multilevel Lumbar Disc Arthroplasty on Spine Kinematics and Facet Joint Loads
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Total disc arthroplasty (TDA) has been successfully used for monosegmental treatment in the last few years. Therefore, more and more surgeons started to use artificial discs for multisegmental approaches. However, already two-level lumbar TDA led to controversial clinical results. Therefore, the application of three or even four-level TDA is under heated debate. We hypothesize that:
(1) the more artificial discs are implanted, the stronger the increases in spinal mobility and facet joint forces;
(2) deviations from the optimal implant position lead to strong instabilities. Therefore, we investigated these hypotheses in finite element analyses.

A three-dimensional non-linear finite element model of the intact L1-L5 human lumbar spine was created. Additionally, finite element models of the L1-L5 region implanted with multiple Charité artificial discs at different levels were created. The models represented different possible clinical conditions ranging from two to four-level TDA, and took into account possible misalignments in the antero-posterior direction of the artificial discs. All these models were exposed to an axial compression preload of 500 N. Pure unconstrained moments of 7.5 Nm were subsequently applied to simulate flexion and extension.

For central implant positions and the loading case extension, a strong increase of the range of motion (from 51% for two
implants to 91% for four implants) and a marginal increase of the facet joint forces (from 24% for two implants to 38% for four implants) were calculated after multilevel TDA. In flexion, the models predicted a motion decrease of 5% for two implants, 11% for three implants and 8% for four implants compared to the intact lumbar spine. Some of the artificial disc models led also in flexion to small facet joint forces with a maximum value of 17 N. For both flexion and extension, the motion and the facet force alterations between the intact model and all instrumented lumbar spines occurred mainly at the implanted segments. Generally, posteriorly placed implants led to a better representation of the range of motion calculated for the intact lumbar spine. However, lift-off phenomena between the core and the implant endplates were observed in some extension simulations in which the artificial discs were anteriorly or posteriorly implanted.

From this study, it can be concluded that multilevel TDA leads to significant increase of both spinal mobility and facet joint forces. The more artificial discs are implanted, the stronger these increases can be expected. Deviations from the optimal implant position lead to unfavorable kinematics, to high facet joint forces and even to lift-off phenomena. Therefore, multilevel TDA should, if at all, only be performed in appropriate patients with good muscular conditions and by surgeons that can ensure optimal implant positions.

**CLINICAL: CERVICAL NEW MOTION PRESERVATION TECHNOLOGIES**

**206**

**PEEK on PEEK Cervical Disc Replacement (POPCDR): Clinical and Radiological Results of 36 Patients with More than One Year Follow up**

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**Background:** In the recent years, anterior cervical disc replacement (ACDR) has gained popularity as the treatment for patients with cervical radiculopathy and myelopathy. The superiority of ACDR over anterior cervical decompression and fusion (ACDF) in obtaining optimum clinical and radiological results has been reported by several authors. We present the results of a single centre, prospective study to evaluate the clinical and radiographic outcomes of ACDR using the NuNec™ Cervical Arthroplasty System (Pioneer Surgical Technology, Marquette, Mich., USA), a novel PEEK on PEEK articulating disc.

**Materials & methods:** All patients with radiculopathy/myelopathy caused by degenerative disc disease at C3-7 levels, who failed to respond to conservative measures, were included. Pain and function were evaluated by Visual Analogue score for Neck pain (VAS-NP) and Arm pain (VAS-AP), Neck disability index (NDI) and SF-36 questionnaires; these were completed pre-operatively and at final follow up. Radiological outcomes include anterior and posterior disc height and range of movement (ROM); these were measured pre and post-operatively. Statistical analysis was completed using SPSS 16.0 statistical package (SPSS Inc, Chicago, IL). A paired t-test was used after confirming the normal distribution of the data (NDI scores). In cases where data (SF 36 Bodily pain, VAS-NP, VAS-AP) was non-parametric, Wilcoxon signed-rank test was used.

**Results:** 36 patients received the ACDR at 78 levels. There were 22 male patients with an average age at operation of 51 years (range 35 - 77 years). 33 patients had pure cervical arthroplasty whereas three had ACDR + ACDF. The level distributions were C3-4 (7), C4-5(12), C5-6 (32), and C6-7 (24). 8 patients received ACDR at one-level, 15 had 2-level surgery, 12 had 3-level surgery and 1 had a 4-level surgery. At the time of final follow-up (Mean 14.25 months, Range 12-22.5 months) the mean NDI improved from 49.35; to 33.78 ([p< 0.001, 95% confidence interval (9.60, 21.53)]). The mean post-operative VAS -NP and VAS-AP scores were reduced to: 3, (Pre-op: 8, p< 0.001) and 3 (Pre-op: 7, P< 0.001) respectively. The average improvement in SF-36 bodily pain component was 8.03 (pre-op BP: 29.15, post-op:37.18, p=0.002). Anterior disc height improvement at C3/4, C4/5, C5/6 and C6/7 were 82, 78%, 102% and 181% respectively. Posterior disc height improved to 95%, 98%, 104% and 140% at C3/4, C4/5, and C5/6 and C6/7 levels. The pre-op ROM was 46.80 ±10.52 and there were no significant changes noted at the final follow-up (Mean 45.04±11.53).

**Conclusion:** Our results of ACDR using the NuNec™ disc show statistically significant improvement in the clinical and radiological outcomes that are comparable to other types of ACDR reported in literature. In addition, our results show preservation of global cervical spine ROM despite single or multiple levels ACDR. This may be attributed to preservation of ROM at the adjacent segments. Furthermore, NuNec™ ACDR has the added advantage of safe use of MRI during follow-ups with excellent image quality. In all the patients who underwent post-operative MRI clear visualization of cord, canal and foramen was possible. In our preliminary results, we report that NuNec™ ACDR device is safe, effective and has added design benefits.

**CLINICAL: DEFORMITY**

**216**

**Hospital Cost Analysis of Adult Scoliosis Surgery in 120 Consecutive Cases**

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**Summary:** This retrospective review is designed to determine the surgical and hospitalization costs, charges, and reimbursements for adult scoliosis correction at one institution. Identification of specific contributors to cost will enable a targeted approach to cost reduction and resource allocation. We report a mean total cost of $47,127. Implants remain the largest individual contributor to overall cost. Age, operative time, and number of screws used predicted increased cost.

**Introduction:** Achieving clinical success is the primary goal of surgical treatment for adult scoliosis. Socioeconomic pressures due to rising health care costs have made it imperative to do so in the most cost-effective manner possible. This study sets out to determine the surgical and hospitalization costs,
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A Novel Minimally Invasive Technique to Avoid Injury during the Implantation of the Trans1 Axial Lumbar Interbody Fusion Device
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Aims: A series of patients were prospectively studied to determine the efficacy and feasibility of performing an axial lumbar interbody fusion through a 10-mm endoscopic balloon cannula in the minimally invasive approach to axial lumbar interbody fusion using the Trans1 AxiaLIF device.

Methods: The presacral space is free of neurovascular and intra-abdominal structures and has proved to be an ideal approach for the Trans1 axial lumbar interbody fusion (AxiaLIF). In some patients however, the use of the Trans1 AxiaLIF device is contraindicated due to the possibility of anatomic anomalies caused by previous surgery, pelvic inflammatory conditions and inflammatory bowel diseases. The use of endoscopic balloon cannulas and the laparoscope allow the surgeon to visualize the surgical site and avoid injury to the patient. A standard presacral approach utilizing a 10-mm endoscopic balloon cannula and 10-mm laparoscope is described. One hundred patients treated with this method were evaluated with respect to intraoperative blood loss, operating time, intraoperative and postoperative complications and fusion results.

Results: There were no complications, either general or technique related in any of the 100 patients studied. The use of endoscopic equipment did not increase blood loss or complications and did not decrease fusion rates. In every case clear, unobstructed visualization of the sacrum and Retroperitoneum allowed for implantation without injury to the patient.

Conclusions: The use of a 10-mm endoscopic balloon cannula and endoscope during the implantation of the Trans1 AxialLIF device is a safe and effective way to decrease the risk of injury to the patient by mechanically retracting critical anatomic structures away from the operative site. The technique shows little to no effect on blood loss, surgical complications or fusion results with a negligible increase in operative time.

BASIC SCIENCE: BIOMECHANICS / BASIC SCIENCE

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Static Evaluation of Shear Loading Associated with Extension/Compression of the CerviCore Intervertebral Disc
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Introduction: Migration of intervertebral devices is a multifaceted phenomenon which includes mechanical factors such as disc loading and transfer of motion. Clinical factors such as bone quality, site preparation and sizing also play a role. The purpose of this study was to measure compressive and shear loading transfer within the CerviCore Intervertebral Disc under neutral and extension conditions. (Investigational Device Limited by USA Law to Investigational Use. Not for sale in the USA. CE marked in EU)

Material and methods: Six caprine FSUs were implanted with a CerviCore intervertebral disc. Pressure sensitive film was placed between the superior and inferior components of the device. Wedges were fabricated to provide extension angles of 0°, 5°, 10° and 15° between the superior and inferior vertebral body. For each angle, a compressive load of 100N was applied to the FSU and maintained for 30 seconds to permit pressure film exposure. Pressure film analysis was performed using a Topaq system. (Figure 1) For each extension condition, peak and mean values for contact stress, force and area were computed. The neutral or 0° extension condition was used as the control condition. The remaining extension conditions were subjected to computation of shear stress and force through the relationships:

Shear Stress = TAN(Extension angle) x Compressive Stress
Shear Force = TAN(Extension angle) x Compressive Force

Results: Compression: A significant increase in contact
area was detected at 15° of extension as compared to both the neutral (0°) and 5° of extension. The mean and maximum compressive force was significantly increased at 15° of extension as compare to both the neutral (0°) and 5° condition. No significant difference was detected in maximum compressive pressure or mean compressive pressure regardless of extension angle.

Shear: The mean and maximum shear pressure was significantly increased at all extension angles. The mean and maximum shear force was significantly increased at 15° of extension as compare to both the neutral and 5° condition. Mean and maximum shear force was significantly increased at 15° of extension as compared to both the neutral (0°) and 5° condition.

Discussion: The resulting compressive contact area and forces were increased in a similar manner at the various extension angles. Since both parameters increase at comparable rates the contact pressure (defines as force/area) remains essentially constant. Shear loading can be viewed as the force indicative of tendencies for migration. Though statistically significant increases in both mean and maximum shear pressure were observed at all extension angles, the maximum shear force computed was 41N and is considerably lower than the value determined for pullout the device in the neutral position. [(226±6.2)N] The low shear force denotes a low propensity to migration of the device based on mechanical factors alone. Based on this data, the CerviCore disc displays a low tendency to migrate anteriorly due to forces generated under extension.

CLINICAL: BIOMECHANICS / BASIC SCIENCE

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Static Evaluation of Distraction Associated with Axial Rotation of the CerviCore Disc
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Introduction: With respect to the cervical spine, coupled motion may be attributed in part to the oncovertebral joints which act as rails to guide the vertebral bodies. Under axial rotation, vertical distraction is observed and increased until additional anatomical structures are engaged to restrain motion. The purpose of this study was to compare the axial distraction manifested by the CerviCore® Intervertebral Disc under axial rotation in comparison to the native intact disc.

Material and methods: Six caprine FSUs with excess tissue removed were utilized in the test. A deflecting transducer was secured with an adhesive to the lateral aspect to the FSU so as to span the intervertebral disc space. The FSU was placed in a materials testing machine where a 100N compressive load was applied to the superior FSU followed by axial rotation relative to the inferior vertebral body. At rotation angles 0°, 3°, 6° and 9° the axial displacement between the vertebral bodies of the FSU was recorded using the transducer. The FSU was then returned to the 0° condition with surgical implantation of the CerviCore® disc performed. The testing sequence of axial rotation to 0°, 3°, 6° and 9° was repeated. The transducer was not removed during insertion of the device. Subsequent FSUs were tested in an identical manner.

Statistical comparisons between the intact and implanted conditions were conducted with a repeated measures ANOVA and employed a Tukey post-hoc test for comparisons between angle configurations. Further, comparisons between the intact and implanted conditions at specific angle orientations were performed using a paired t-test.

Results: No statistically significant differences were found between the intact and CerviCore® implanted conditions regardless of rotation angle (P>0.4 for all). With respect to the effect of rotation angle upon distraction, a significant difference between the neutral and 6° and 9° rotation (P<0.05 for both) was found for the intact condition. In the case of the CerviCore implanted condition a significant difference was found between the neutral (0°) and 9° condition (P<0.05). A comparison of the rate (regression slope) of vertical distraction as well as the initial distraction (regression intercept) to applied rotation did not result in a significant difference between the intact and implanted condition (P>0.08)

Discussion: No statistically significant differences were detected in a side by side comparison of distraction height at rotation angles of 0°, 3°, 6° and 9° under intact and implanted conditions. In addition, a linear regression of axial distraction versus rotation angle indicated that implantation of the CerviCore® disc did not alter the FSU response as compared to the native disc. Based on this in-vitro data, the CerviCore® disc displayed performance characteristics of coupled motion for distraction under rotation equal to the intact disc.

BASIC SCIENCE: BIOMECHANICS / BASIC SCIENCE

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The Influence of Contact Stress on Total Disc Arthroplasty Baseplate Design under Static and Fatigue Loading
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Introduction: All total disc replacement (TDR) designs, irrespective of kinematic philosophy, require device contact with the vertebral endplate. The purpose of this study was to determine the contact stress of various TDR baseplate designs upon the vertebral body endplate.

Materials and methods: Three baseplate designs were used; the first design possesses a short central keel (SK), the second design encompasses a longer central tapered keel (LK) and the third design contains a domed shaped (DM) baseplate comprised of layered ellipses. For each design, six bovine lumbar endplates were contoured to accept a randomly assigned baseplate design. The cortical rims were not violated and a light press fit of the keel geometries was performed so as to simulate a healed condition. Prior to device implantation, strips of pressure film were placed on the inferior surface of the baseplates. Vertebral bodies were mounted to a load cell and subjected to a static load of -100N for 30s to permit film exposure. Using new pressure...
for patients with moderate lumbar spinal stenosis referring to the current studies. The different options of surgery, stand alone, combination with posterolateral or midline endoscopic decompression will be discussed.

**Methods:** There will be a consideration on our retrospective experience with interspinous implants. The patients now were treated with an novel interspinous implant, which is a minimally invasive spinal device that limits back extension at the symptomatic level.

For the study there was a prospective evaluation of 121 patients treated at the Emma Klinik (Seligenstadt, Germany) in the years 2008/2009. The follow up points were at 1, 3, 6, and 12 months. The outcome measurement was done by ODI, VAS, health related quality of life with Physical Component Summary (PCS) and Mental Component Summary (MCS) scores from the SF-36. Adverse events have been collected.

**Results:** Interspinous implants improve the situation of patients with lumbar stenosis and radicular pain as well as claudication significantly. Additional minimal invasive procedures can assist this without severe approach damage. In the study back function improved as more than 30% from pretreatment in 76% for axial pain and 86% for extremity pain. The statistical analysis of the other scores demonstrated a comparable improvement. Four (3.3%) explants were performed, although 3 were not related to the device. Eight procedure related adverse events, observed in 6 patients, included superficial seroma, minor wound pain and infection.

**Discussion:** The minimally invasive Implant with an expandable interspinous device is an effective and safe treatment option for patients with moderate LSS who are unresponsive to conservative care. The addition of additional minimal invasive procedures can give an assistance for improvement.

**CLINICAL: INTERSPINOUS AND LIGAMENTOPLASTY**

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**Interspinous Distraction and Stabilisation with the Superion Implant for Effective Minimally Invasive Treatment of Moderate Spinal Stenosis**

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**Background:** Lumbar spinal stenosis with caudicatio becomes more and more a problem in our aging society. Meanwhile a lot of these older patient have been left without optimal treatment caused by comorbidity and refusal of open surgeries, the field of minimal invasive procedures opens a new window to improve their situations. The use of the effects of ligamentoplasty by slight distraction sometimes combined with endoscopic decompression fills the gap between a failed conservative treatment and the more aggressive laminectomy or fusion. The used and presented interspineous implant Superion allows a less destructive placement by interspineous ligament splitting and midline insertion.

**Purpose:** There will be presented the preliminary effectiveness and safety of a novel interspineous implant.

**CLINICAL: LUMBAR NON-FUSION (I.E. MIS DISCECTOMY, PERCUTANEOUS DISCECTOMY)**

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**Disc-FX - A New Combination Procedure for Disc Surgery - Basics and 2 Years Results of a Prospective Study**

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Chemonucleolysis and percutaneous discectomy as well as laser decompression and discectomy are used methods besides the rapidly developing endoscopic techniques as minimal aggressive techniques for discal pain syndromes. In recent years, the use of different radiofrequency energy was added to this spectrum. Every technique from thermocoagulation for annuloplasty to the “coblation” must be considered as unique procedure. A new minimally invasive technology for the treatment of discal diseases of the lumbar spine with high radiofrequency based on the extensive use of the percutaneous RF-techniques and and positive experiences with use in endoscopic spine surgery has been developed to recombine the advantages of the different methods in one minimal invasive surgery. The purpose of the presentation is to assess the the feasibility and the potential of this radiofrequency based combination procedure. First we will...
discuss basic investigations for the efficacy and safety of this procedure. Then we will present our first clinical results after 2 years.

**Methods:** For this first prospective outcome study patients with radicular pain syndromes and simple neurological deficits as well as contained disc extrusions or protrusions has been included. We did the procedures in two different centers by different surgeons in different cultures and investigated the outcome postoperatively, after 6 weeks, 6 months and 2 years by a standardized protocol partly by independent investigators. Beside the clinical results two scores has been observed.

**Results:** Limited temperature rise was demonstrated at the site of high frequency radiowave application. There was no effect on epidural structures. The average ablation of the nucleus was 0.8 g and the average annular shrinkage was 30 percent by simultaneous demonstrations in surgery. Clinically VAS scores improved from 8.6 to 1.9 two days postoperatively. At six weeks and 6 months VAS scores were 3.5 and 3.3, respectively. The current investigation for the 2 years follow up shows no significant change of the results with a VAS of 2.1. The McNab index, and Andrews and Lavyene score showed excellent outcomes in the immediate postoperative period and good outcomes after six weeks and six months. After 2 Years we got excellent and good results in 82.2% There were no complications in the study.

**Conclusion:** The results after 2 years encourage us to implicate this procedure into the algorithm of disc surgery and seem to be comparable to the other minimal invasive procedures avoiding an open surgery and to fill the gap in the cascade of treatment of discal disorders. The combination of different techniques in one procedure with the use of special radiowave mark an advantage and seems to be superior to a single technique. The risk of a complication especially epidural scar is diminished by this technique. Cause of the instruments there are further optional opportunities and it is less invasive than an fullendoscopic procedure, but an endoscopic assisted control is possible.

**CLINICAL: LUMBAR NON-FUSION (I.E. MIS DISCECTOMY, PERCUTANEOUS DISCECTOMY)**

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**Endoscopic Dorsal Rhizotomy, a New Anatomically Guided MIS Procedure, Is More Effective than Traditional Pulsed Radiofrequency Lesioning for Non-discogenic Axial Back Pain**

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**Introduction:** Radiofrequency lesioning of the medial branch of the lumbar dorsal ramus is the standard interventionalist's method to treat facet joint mediated axial back pain. Its effectiveness is less predictable because of the inability to confirm complete surgical lesioning of the medial branch with dependence on fluoroscopic guidance of electrode placement in locating the targeted nerve. A more effective endoscopically visualized guided technique is introduced.

**Method:** A prospective non-randomized pilot feasibility study of 50 patients was initiated in 2006-2007 to assess the effect of endoscopic radiofrequency lesioning of the medial branch. A 90% Excellent/Good result was obtained, VAS 6.2-2.5, and ODI 48-28 with a one year follow-up. The endoscopic procedure also provided the capability to expose and target the intermediate and lateral branch of the lumbar dorsal ramus. Patients with lumbar spondylosis and facet arthrosis on MRI presented with predominant axial back pain and had at least 50% pain relief by medial branch blocks met the inclusion criteria. The study was extended to this updated report, while modifications of the surgical technique evolved, based on continued study of cadaver dissections identifying variable anatomy of the branches of the dorsal ramus. The study sample now total 205 patients.

**Results:** All patients experiencing relief of back pain with medial branch blocks had equal or greater pain relief with dorsal endoscopic rhizotomy. Patients selected for repeat endoscopic lesioning who had minimal relief with radiofrequency lesioning were also satisfactory. Pre-and post-op VAS decreased an average of 4 points and Oswestry scores decreased 30%. No patient was worse. No permanent complications, although a few patients experienced mild temporary dysesthesia. At 1-3 year follow-up, 6 patients experiencing partial return of their axial back pain requested requested repeat rhizotomy. They experienced similar, but lesser improvement from the index procedure. Rhizotomy of the upper lumbar facets were not as consistent nor better than relief received from medial branch blocks at the lower lumbar spine from L3-S1.

**Discussion:** Modification of the original surgical technique since 2006 was instituted after cadaver dissection of 5 specimens, offering 10 additional levels for study, demonstrated considerable variability in different cadaver specimens. In the upper lumbar spine, especially from L1 and L2, the standard anatomic relationships did not hold up. We were not able to find the medial branch to the facet as consistently as explained in the spine literature. The nerve to the facet joint, because it is more cephalad to the transverse process, did not traverse the transverse process as it would in the lower lumbar spine. Nerve Ablation at these two levels may require lesioning of the dorsal ramus or targeting the medial branch on the facet capsule. The side firing laser provides ready access to the lateral facet capsule. A newly designed bi-tip bipolar probe for facilitated soft tissue ablation.

**Conclusion:** Endoscopically guided rhizotomy provides more consistent ablation of the medial and lateral branches of the lumbar dorsal ramus. A more consistent and surgically effective technique provides more surgical options and better, longer lasting results. The variations in the location of facet innervation as demonstrated in cadaver dissections dictates a need for visually guided endoscopic MIS surgery.
**BASIC SCIENCE: BIOMECHANICS / BASIC SCIENCE**

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Prophylactic Usage of Interspinous Spacer in Rigid Lumbar Fusion Surgery, Does it Work for Prevention of Adjacent Level Disc Degeneration?

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**Introduction:** Posterior spinal instrumentation is used extensively in the treatment of spinal disorders, such as fractures, disc disorders, and scoliosis correction, etc. Complications and problems of fusion surgery, e.g., the adjacent segment disease (ASD), have been frequently reported. Abnormal loading and increased mobility in the adjacent segments may be the causes of ASD. Recently, the interspinous spacer was developed to constrain the excessive motion of motion segment. The purpose of this study is to check if the interspinous spacer can biomechanically reduce the motion and intradiscal pressure of adjacent level to prevent the ASD following spinal fusion.

**Methods:** Four 4-level lumbar motion segments were dissected from 6-month-old pigs. All soft tissues except the surrounding ligaments and facet capsule were carefully removed. Specimens were wrapped in saline-soaked gauze and stored in the freezer until the experiment. Four pedicle screws, with 6 mm in diameter and 40 mm in length, were inserted into two segments of lumbar vertebra. Coflex-“interspinous U” with 8 mm in width was used in cranial adjacent interspinous space of instrumentation level. Four groups of experimental setup were examined. The four groups are; Group A: intact vertebra as control group; Group B: injury group with bilateral facetectomy and excision of interspinous ligament over intended instrumentation level, Group C: the fusion group, instrumentation group with four pedicle screws insertion for Group B, Group D: fusion group C with Coflex insertion over cranial adjacent interspinous space. A needle pressure sensor was prepared for measuring intradiscal pressure under meticulous investigation. Two pressure sensors were inserted into the center of the cranial adjacent disc and implant level disc. Range of motion (ROM) and intradiscal pressure were recorded by CCD image and pressure transducer. Both flexion and extension of intact and post-instrumentation spinal column were recorded only in this study. Intradiscal pressures of instrumentation and cranial adjacent level were recorded.

**Results:** In extension test, the IDP of cranial adjacent level of Group C was 1.4(0.7) bar, and the IDP of cranial adjacent level of Group D was 1.4(1.6) bar. In flexion test, the IDP of cranial adjacent level of Group C was 6.2(2.1) bar, and the IDP of cranial adjacent level of Group D was 5.6(2.3) bar. The IDP of cranial adjacent level of Group C is not different from the one of group D. However, the ROM restriction was noted after Coflex insertion, especially in extension test (3.5(1.6) degree vs. 1.4(0.7) degree).

**Discussion:** In our preliminary study, the intradiscal pressure of cranial adjacent disc level has no significant change before and after inserting Coflex under rigid instrumentation. The current results show that the prophylactic usage of Coflex in prevention of adjacent level disease may not be effective. Some limitations about this study should be addressed. This study use porcine lumber instead of the human cadaver. The porcine lumber is usually stronger than the degenerated human one. Hence, the degree of deformation may be smaller than the one of human cadaver. In conclusion, the prophylactic implantation of interspinous device may help the hyper extension of adjacent level, but cannot reduce the IDP of the constrained level.

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**CLINICAL: DEFORMITY**

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Segmental Correction of Adult Focal Sagittal Plane Deformation Using a Novel Lateral Interbody Approach with Anterior Longitudinal Ligament Release

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**Objectives:** To present the surgical technique and preliminary results of minimally invasive far lateral approach (LIF) with anterior longitudinal ligament (ALL) release to accomplish focal sagittal plane deformity correction.

**Introduction:** Correction of sagittal plane malalignment has been increasingly recognized as a critical component to successful treatment of adult spinal deformity. The traditional surgical methods of posteriorly-based osteotomies are technically demanding procedures with significant peri- and post operative morbidity. Minimally invasive procedures, such as LIF, combined with ALL release have not been reported for the treatment of focal sagittal plane deformity.

**Methods:** Surgical and radiographic records of five patients with adult spinal deformity who had significant sagittal imbalance and focal deformity were retrospectively reviewed. All underwent single level LIF with ALL release. The pre- and post-op segmental sagittal malalignment and global lumbar lordosis were measured and compared to final results.

**Results:** There were 2 males and 3 females. Mean age at surgery was 50±4 (34±9 to 64±9). The mean follow-up was 36 m (8 to 57). The single level intervention was done at L1-2 in one, L2-3 in two and L4-5 in two patients. The mean pre operative segmental Cobb was +8.4 that corrected to -23.1 and 20.5 in immediate post operative and final visits, respectively. Similarly, the mean pre operative lumbar lordosis was -20 that changed to -39.8 in post operative and to -41.6 in final F/U. The mean correction achieved with one level LIF and ALL release was -30.2 for segmental sagittal deformity and -21.6 for lumbar lordosis. No peri- operative vascular or neurologic injury was observed. One patient had severe metallic allergic reaction that required surgical drainage and one had vertebral body fracture at the upper level of posterior instrumentation that did not
required revision.

**Conclusion:** Our preliminary experience shows that the results of minimally invasive lateral approach combined with ALL release are comparable to traditional posterior open approach using osteotomies in correcting focal sagittal alignment and restoring lumbar lordosis. Moreover, this technique may benefit patients having a lower peri-operative risks and complications. It is important to adhere to surgical detail to avoid complications especially neurovascular injuries.

**CLINICAL: DEFORMITY**

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**Isolating the Effect of the Lateral Approach in Combined Anterior and Posterior Surgery for Adult Spinal Deformity:**

*A Radiographic Analysis*

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**Summary:** Adult spinal deformities frequently require anterior and posterior procedures to achieve desired correction. Acceptable (40%) deformity correction can be seen in patients with advanced adult lumbar scoliosis with the use of XLIF. Even greater correction (66%) can be achieved using combined XLIF + posterior spinal fusion.

**Introduction:** Adult patients with significant spinal deformities frequently require combined anterior and posterior procedures to achieve desired correction. The use of XLIF has recently become a surgical alternative to the traditional anterior approach; however, quantifying the degree of deformity correction after the XLIF procedure has not yet been performed. The purpose of this study was to examine the isolated radiographic results immediately after XLIF in combined anterior and posterior surgery.

**Methods:** Radiographs and chart review was conducted at single institution on all patients who underwent multilevel XLIFs for adult lumbar deformity. Only patients who had full length scoliosis radiographs immediately following the XLIF procedure were included. All patients had the posterior procedure performed as a second stage 3-5 days later.

**Results:** Fifteen patients were included in the study. 10 had combined XLIF and posterior spinal fusion while 5 were staged alone. For all patients, average age was 63 years (range 24 to 82) and average number of XLIF levels was 3.6 (3-5). Mean pre-op Cobb angle was corrected from 48˚ (range 22˚ to 92˚) to 27˚ (range 14˚ to 53˚) immediate post XLIF (43%). Mean lumbar lordosis was corrected from 36˚ (range 6˚ to 62˚) to 44˚ (range 15˚ to 63˚) immediate post XLIF. Mean pre-op Cobb angle within the XLIF levels was reduced from 40˚ to 21˚ (47%) and mean pre-op lordosis within the XLIF levels was restored from 17˚ to 28˚. The second stage posterior fusion (PSF) reduced the Cobb angle an additional 26%.

**Conclusion:** Multilevel XLIFs alone can provide acceptable immediate post-operative radiographic correction (40%) in advanced adult lumbar scoliosis. Using a combination of XLIF and PSF procedures provides an average immediate post-op Cobb angle correction of 66%.

**Significance:** Acceptable deformity correction (40%) is seen in patients with advanced lumbar adult scoliosis with the use of XLIF. Even greater correction can be achieved with combined XLIF/posterior spinal fusion (66%). These results show XLIF combined with PSF can successfully correct lumbar scoliosis and is similar to previously reported results with traditional open anterior and posterior surgery.

**CLINICAL: TRAUMA: FRACTURES AND SPINAL CORD REPAIR**

**257**

**Variant Jefferson Fractures: Diagnosis and Treatment**

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**Objective:** To investigate the diagnosis and treatment of variant Jefferson fracture.

**Methods:** A total of 23 patients from 2002 to 2008, male 18 cases, female 5 cases, with a mean age of 45 years (24-65 years) and a mean follow-up of 17 months (5-35 months), were included in this study conducted at The First Affiliated Hospital of Soochow University, Suzhou, China. Lateral and anteroposterior open-mouth radiograph and Computed Tomography (CT) scan of cervical spine were used to classify the fractures, determine therapy selection and fracture union. 19 patients were treated with collar or plaster immobilization for 3 months after traction for 3-4 weeks, 2 patients were treated with posterior occipital fusion and 2 patients were treated with anterior decompression internal fixation procedure.

**Results:** There were a total of 13 patients with 3-part fracture of atlas, 6 patients with 2-part fracture and 4 patients with 1-part fracture. 5 patients presented with neurologic deficits caused by spinal cord injury, 11 patients were found to have associated spinal or other fractures. Follow-up evaluation indicated that all fractures progressed to union, without aggravated neurological defect. In 19 nonoperative treatment patients, there were no complication such as local pain, tardive atlas dislocation or tetraplegia. In 4 operative treatment patients, there were no complication such as infection, leakage of cerebrospinal fluid, or implant failure (loosening, bending, or breakage of screws).

**Conclusion:** Lateral and anteroposterior open-mouth radiograph combine with CT scan of cervical spine are helpful to diagnose and classify variant Jefferson fracture. In most of variant Jefferson fracture, collar or plaster immobilization after traction reduction is an effective method of management.

**Keywords:** Atlas, Fracture, Computed tomography scan
**CLINICAL: FUSION**

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**Occipitocervical Fusion with Transpedicular Fixtion System**

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**Objective:** To evaluate the long-term clinical results after occipitocervical fusion with transpedicular fixation system in a large and diverse patient population, the authors prospectively studied a consecutive group of 43 patients.

**Methods:** From 2004 to 2008, occipitocervical fusion was performed in 43 patients (32 male, 11 female, mean age 46.5 years) with transpedicular internal fixation system (Sofamor Danek Company). Out of them, there were 24 with upper cervical tumor, 10 with cervical congenital malformation and 9 with dens axis fracture association with atlantoaxial dislocation. The clinical outcomes were investigated by clinical observations, radiologic studies and statistical analysis.

**Results:** All the patients were followed up for 6 to 60 months with an average of 26 months. The result of X-ray showed that bony fusion was successful in 34 patients at 3 months and 9 patients at 6 months of follow-ups. There was no deterioration of spinal cord injury. The JOA scores of neurofunction increased from 5-17 points (mean 12.6 points) to 8-17 points (mean 15.8 points), with the improvement of 72%.

**Conclusion:** Transpedicular internal fixation system has multiaxial screw of three-column fixation and plastic rods, which offer strong fixtion and good fusion. It can also benefit the maintenance of cervical curve. It is an effective and reliable method for reconstruction of upper cervical stability.

**CLINICAL: TRAUMA: FRACTURES AND SPINAL CORD REPAIR**

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**The Use of Cervical Transpedicular Fixation for the Treatment of Fracture and Dislocation of Lower Cervical Spine**

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**Objective:** To investigate the method and effect of treating fracture and dislocation of lower cervical spine utilizing cervical transpedicular fixation.

**Methods:** The case of fracture and dislocation of cervical treated from June 2002 to June 2008 were retrospectively analyzed, 27 males and 11 females aged from 22 to 63 years (mean 44.25 years),of which 6 cases with unilateral small articular fracture and dislocation, 13 cases with bilateral small articular fracture and dislocation, 14 cases with bilateral small articular fracture and dislocation combined with compression fracture of vertebral body, 5 cases with cervical burst fracture and dislocation, all of which spinal injury at different grade. According to American Spinal Injury Association grades: 18 cases were in A grade, 12 cases in B grade, 6 cases in C grade, 2 cases in D grade.

**Results:** Six months after the operation, all patients had achieved solid bony fusion and stable fixation of the related segments. Twenty patients with incomplete spinal cord injury improved their ASIA Impairment Scale classification by 1 to 2 grades after the operation. Eighteen patients with complete spinal cord injury had no improvement in neural function. However, nerveroot symptoms such as pain and numbness were alleviated to some extent.

**Conclusions:** The cervical pedicle screw system is an effective and reliable method for the restoration of cervical stability. Sufficient pre-operative imaging studies of the pedicles and strict screw insertion technique should be emphasised.

**CLINICAL: LUMBAR FUSION (I.E. MIS, TLIF, XLIF, AXIAL LIF, ALIF)**

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**Percutaneous Axial Lumbosacral Interbody Fusion: Preliminary Clinical and Radiological Results**

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**Background:** Minimally invasive spine surgery continues to be a growing trend for orthopedic and neurosurgical spinal surgeries. Generally, anterior and posterior approaches are chosen for direct exposure of the lumbosacral spine. Anterior access to the L5-S1 disc space for interbody fusion can be technically challenging, frequently requiring the use of an approach surgeon for adequate exposure. We reviewed our experience with a novel minimally invasive technique for L5-S1 interbody fusion (Trans1) that exploits the pre-sacral space and its relative dearth of critical structures.

**Materials and methods:** 8 patients were included in this analysis. Average follow-up was 6 months. Back pain was secondary to lumbar degenerative disc disease (DDD) in 2 cases, failed-back surgery syndrome in 1 case and lytic spondylolisthesis grade I in another 1 case. All patients had radiographic evidence of L5-S1 degeneration and underwent percutaneous interbody fusion with Trans1 cage. Trans1 was followed by percutaneous pedicle screw-rod fixation in 2 patients; in the remaining patients facet joint screw fixation devices were implanted. Clinical evaluation was performed using a visual analogue scale (VAS) and Oswestry disability index (ODI).

**Results:** Mean operative time for the Trans1 procedure was 55 minutes. All patients had radiographic evidence of stable L5-S1 interbody cage placement and fusion at last follow-up. The VAS scores assessing back pain improved significantly from 7.20 to 2.65. The mean Oswestry score improved significantly from 58.3% to 31.5%. No device related complications were identified.

**Conclusion:** The percutaneous paracoccygeal approach to the L5-S1 intervertebral disc space provides a minimally invasive corridor through which discectomy and interbody fusion can safely be performed. It can be used alone or in combination with minimally invasive posterior screw fixation. It may provide an alternative route of access to the L5-S1 intervertebral disc in those patients who may have unfavourable anatomy for or contraindication to traditional open approach to this level.
CLINICAL: LUMBAR FUSION (I.E. MIS, TLIF, XLIF, AXIAL LIF, ALIF)

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Minimally Invasive Lumbar Interbody Fusion Access through Extreme Lateral Approach: Analysis of Medium-term Results
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Background: The interbody fusion by extreme lateral approach (XLIF), is performed through a percutaneous allowing passage through the retroperitoneal space. All the procedure needs the help of a retractor which is neuromonitored. The exposure allows the direct visualization of the lateral side of the disc, facilitating discectomy and the placement of implants. The surgical results of this procedure have shown that it is a safe and reproducible technique. It has demonstrated the benefits of a minimally invasive procedure, with quick recovery and improvements in pain and function scales.

Objective: Analysis of the clinical and radiographic results of a homogeneous series made during two years in two Italian Orthopaedic Departments for the treatment of spinal diseases.

Materials and methods: From January 2008 to January 2009, 22 patients were underwent lumbar fusion by XLIF. In all the cases, the pre-operative diagnosis was degenerative disc disease with instability and radiculopathy. The levels treated were L2-L3 in 7 cases, L3-L4 and L4-L5 in 4 cases. In 11 patients a stand-alone interbody fusion was performed whereas in remaining cases other techniques of spinal fixation were used. Evaluation criteria considered the clinical and radiographic results with the help of pre-and postoperative Visual analogue scale (VAS) and Oswestry Disability Index (ODI).

Results: Patients were evaluated at a mean follow-up of 18 months (range 14-24 months). In one case we observed the subsidence of the cage in the lower vertebral body and in one case the cage was placed too back. About half of patients we found a postoperative temporary cruralgia recovered spontaneously. We observed an improvement on the VAS and ODI scale. The post-operative radiographs made at a distance of 3,6 and 12 months showed an excellent fusion.

Conclusion: The lumbar interbody fusion through XLIF is a minimally invasive technique and also very safe. This technique requires a long learning curve. It’s a valid alternative technique preferable to use in elderly patients who could not deal with surgery heavy blood loss.

CLINICAL: TRAUMA: FRACTURES AND SPINAL CORD REPAIR

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Three Different Surgical Approaches and Treatment Options for Thoracolumbar Burst Fractures
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Objective: To explore the advantages, disadvantages and indications of anterior, posterior and paraspinal(wiltse) approach in the treatment of thoracolumbar fracture, provide the treatment options for thoracolumbar fractures.

Methods: From March 2008 to September 2010, 64 patients were selected with thoracolumbar fractures (all cases were single Vertebral fractures ), in which 36 males and 28 females, aged 18 to 77 years, average 44 years old. 22cases were selected by anterior resection with titanium mesh plate and Z-plate fixation, 28cases with Median posterior reduction and pedicle screw fixation. The average follow-up was 18 months.Clinical effects were compared by blood loss, after bed time, vertebral body height restoration, preoperative and postoperative JOA scores and other indicators were statistically analyzed.

Results: Average Blood loss in paraspinal(wiltse) approach was 91.6±16.9ml, incision length was 7.6±0.8cm ,operation time was 94.1±13.7min. Average Blood loss in traditional posterior approach was 218.7±32.3ml, incision length was 17.4±2.1cm, operation time was 141.8±19.6min Average Blood loss in anterior approach was 225.1±38.4ml, incision length was 18.6±2.4cm, operation time was 156.3±20.7min .all the difference was statistically significant (P< 0.05). And no significant differences were found in cobb angle and Vertebral body height restoration ( P >0.05).

Conclusion: Anterior approach fits for severe vertebral fractures of AO classification of C class, which will help vertebral height restoration and reconstruction, but requires relatively complicated procedure and large side-injury. The traditional surgical approach is applicable to most of the thoracolumbar fractures, which help restore vertebral fractures and retain the structures, especially for intra-spinal occupation to facilitate decompression. By wiltse approach, the facet joints can be explored easily and completely, and a clear surgical field will be provided for the placement of pedicle screws. As a minimally invasive approach with less bleeding and op-time, it can be widely used on thoracolumbar fractures with no decompression

Keywords: Thoracolumbar fractures; Surgical approach; Treatment methods

BASIC SCIENCE: NUCLEOPLASTY AND INTRADISCAL THERAPIES

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Biomechanical Effects of Nucleus Augmentation with an Injectable in situ Cured Hydrogel
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Introduction: With the appropriate device design, maintaining the form and function of a compromised disc would potentially enable biomechanical attributes for the entire functional spinal unit (FSU) to be preserved. In order to gauge the efficacy of hydrogel augmented nucleus pulposus relying on the otherwise plenary intervertebral disc, tests isolating the performance of the treatments were conducted. The biomechanical flexibility or stability of the functional spinal units (FSU) was established with in vitro human lumbar FSU specimen. Additionally, each FSU was modified through posterior column resection in order to quantify and compare the anterior column kinematic contributions with and without nucleus augmentation.

Materials and methods: Sixteen fresh frozen human lumbar cadaveric specimens were processed with the intent of sparing the native osteoligamentous structures. Based on the radiographic grading of each level by the surgeon, severely degenerated FSU were excluded, leaving 25 qualified levels. Each of the lumbar segments was separated into individual FSU and then subjected to ±5.0Nm for flexion extension, lateral bending, and axial torsion. Each FSU was tested sequentially in the intact condition, with posterior column removed and with a polymer augmented nucleus. An analysis of variance (ANOVA) statistical model was used to detect differences amongst the treatment groups with a Bonferroni post hoc test to specify the different treatment groups.

Results: The mean±stdev ROM, shown in the figure, for the intact flexion extension bending was 9.30±2.33°, 13.40±4.28°, and 12.00±6.58° for the intact, posterior column removed and with nucleus augmented treatments. The mean ROM for lateral bending was 8.03±2.57°, 8.85±3.37° and 7.92±3.42° for the same treatment order. Similarly, for axial torsion, the mean ROM was 4.03±2.70°, 8.23±5.01°, and 7.13±5.35°. The ROM was statistically greater with the posterior element removal exhibiting the largest ROM and the nucleus augmentation of the anterior column of the FSU have a statistically significantly reduced ROM. In conclusion, nucleus augmentation may have a significant effect on the intervertebral disc and the corresponding vertebral bodies, particularly in the axial torsion mode of loading.

Discussion: Clearly, removal of the posterior facets destabilized the FSU in flexion extension as measured by the ROM. The role of the facets cannot be underestimated particularly in this mode of loading. In order to capture the contributions specifically from the intervertebral disc, the

CLINICAL: COMPLICATIONS

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Single Extrafascial Lumbar Incision or Modified Muscle-sparing Paraspinal Approach? A Review of the Rate of Subcutaneous Lumbar Seromas in Patients Treated with a Lumbar Motion Preservation System
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Several surgical approaches exist as standard of care in spinal surgery. With regard to the posterior lumbar spine, we present the post-operative rate of lumbar seromas in 27 patients who underwent lumbar decompression and dynamic spinal stabilization. This paper presents the results obtained from a prospective randomized clinical IDE research trial, and the rate of post-operative lumbar seromas at two clinical trial sites. Each site performed implantation of the same dynamic device using a single midline extrafascial (SME) lumbar incision or a modified muscle-sparing paraspinal (MMSP) lumbar incision as described in SAS Journal article, Winter 2008.2:40-42, Anand N. et al. Cosmetically and historically the SME has been preferred. We have indentified a higher post-operative rate of lumbar seromas with a SME incision and thus prefer MMSP incision.

Methods and materials: Each clinical site reported the number of lumbar seromas encountered in post-operative randomized dynamic stabilization patients. Seromas were considered significant when their persistent protuberance (approximately 30cc) impacted activities of daily living or clothing/brace wear and remained or enlarged on subsequent examination. 27 patients were reviewed, 16 SME incision and 11 MMSP incision. Site A used an SME incision while Site B used an MMSP incision. Total postoperative follow-up was 2 years.

Results: The total number of sterile lumbar seromas was 4 out of 27 patients or 15%. Of those patients, none required removal of the implant. 3 required percutaneous drainage, and 1 required irrigation and debridement with wound vac application.

There were no seromas in the MMSP group B. In the SME incision group A 4 had seromas or 25%. Of those patients, none required removal of the implant. 3 required percutaneous drainage. While these findings are not statistically significant, we believe they are clinically relevant.
Conclusions: The authors believe that the MMSP incision is superior compared to SME incision for placement of dynamic stabilization devices. Incision length is longer with the SME to achieve lateral retraction, creating a large extrafascial subcutaneous pocket. Percutaneous Arrow® catheter drainage is one method that can be used in the management of SME related seromas (Figure 1). However, the MMSP incision allows for less aggressive dissection laterally thereby lessening the risk of post-operative seroma formation. Further, the MMSP incision follows a natural cleavage plane through paraspinal musculature allowing for less muscle damage.

CLINICAL: MIS FUSION-STABILIZATION

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Dynamic EMG Testing for the Placement of Lumbar Pedicle Screws
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Introduction: Evoked EMG has been shown to be a sensitive tool for assessing pedicle integrity after the placement of pedicle screws. This post-hoc “Basic” testing allows for identification of breach intraoperatively and repositioning of screws if necessary, but with additional time, trauma, and limited correction ability. A prospective, IRB-approved study was undertaken to evaluate the effectiveness of “Dynamic” EMG testing, which enables active monitoring during pedicle preparation and screw insertion, enabling changes in pedicle trajectory to be made before a breach occurs.

Methods: Lumbar pedicle screws were placed using Dynamic testing where EMG feedback was provided to the surgeon on a randomized basis among screws in each patient. EMG thresholds were collected during cannulation, tapping, and placement of each screw. Final screw positioning was confirmed with a Basic screw test after placement. Intraoperative redirections based on EMG feedback were documented. A neural exam and VAS pain assessment were performed pre-op, post-op, and 4-6 weeks after surgery. A post-op CT scan was obtained and was evaluated for screw placement accuracy by an independent spine surgeon.

Results: A total of 44 levels were treated with instrumented XLIF and/or TLIF with 137 screws placed. 8 (6%) breaches were identified by post-op CT: 6 (4%) medial, 1 (1%) lateral, and 1 (1%) inferior. All breached the pedicle by less than 2mm, were without sequelae, and no revisions were required. Low EMG thresholds during pilot hole formation led to a significant number of redirections (p=0.014) with no correlation to incidence of breach. There was a significant correlation between thresholds during tapping and screw placement and incidence of breach (p< 0.001), suggesting that once a redirection was made and threshold values continued to be low, the surgeon was less likely to redirect and more likely to breach, or that pedicle wall integrity had already been compromised and screw path could not be changed once prepared.

Conclusion: Dynamic EMG testing provides safe, real-time predictive feedback during pilot hole formation and placement of pedicle screws. Earlier warning of low thresholds provides greater opportunity for redirection.

BASIC SCIENCE: BIOMECHANICS / BASIC SCIENCE

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Quantifying the Load-bearing Characteristics of the Whole Lumbar Spine: A Finite Element Method Study
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Objective: The purpose of this study is to quantify the load-distribution patterns of the intact whole lumbar spine and its structural components (ligaments, discs and facets) under the different loading conditions (flexion, extension, axial rotation and lateral bending).

Methods: Finite element analysis was performed to investigate the load-bearing characteristics of whole lumbar spine and its elements. The follower load was used to apply the effects of muscle activities. Under a 500 N follower load, 7.5 Nm was applied for flexion/extension and 5 Nm for lateral bending/axial rotation. The individual forces of the three components were summarized respectively from each Cartesian coordinates (x-, y-, and z-axis). The resultant forces were calculated from the summarized forces on the x-, y-, and z-ordinates of ligaments, discs, and facets respectively.

Results: In flexion, ligament and disc proportion in load-bearing contribution were similar (ligaments: 210.29 N, 46.6 % vs. discs: 218.11 N, 48.3 %) whereas, in extension, ligament and facet showed similar proportion (ligaments: 106.49 N, 25.7 % vs. facets: 92.09 N, 22.2 %). In lateral bending, disc proportion was highest (103.72 N, 68.9 %) when compared to those in other loading conditions, whereas, in axial rotation, disc proportion was lowest (11.17 N, 17.1 %).

Conclusions: In this study, we could clearly determine the quantified load-sharing patterns of the whole lumbar spine and its three components. Load-bearing activities of the three components were complementary to each other, and each component has its own load-bearing contributions in the four load conditions.

Keywords: Load-bearing contribution, load-sharing ratio, lumbar spine, ligament, disc, facet
Successful Revision of an L5-S1 AxialLIF Rod Using a Minimally Invasive Presacral Approach: A Case Report
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Aims: To describe procedural details of a minimally invasive presacral approach for revision of an L5-S1 AxialLIF rod.
Methods: A 70-year-old male presented with marked thoracolumbar scoliosis, osteoarthritic changes characterized by high grade osteophytes, and significant intervertebral disc collapse and calcification. The patient required crutches during ambulation and reported intractable axial and radicular pain. Multi-level reconstruction of L1-4 was accomplished with extreme lateral interbody fusion although focal lumbosacral symptoms persisted due to disc space collapse at L5-S1. Lumbosacral interbody distraction and stabilization was achieved with the AxialLIF System (TranS1 Inc., Wilmington, NC) and rod implantation via an axial presacral approach. Despite symptom resolution following this procedure, the patient suffered a fall 7 months later with direct sacral impaction resulting in symptom recurrence and loss of L5-S1 distraction. The revision of the AxialLIF rod utilized the same presacral approach with an experimentally approved larger cannula. Minimal adhesions were encountered upon presacral reentry. Precise operative trajectory to the base of the previously implanted rod was achieved using fluoroscopic guidance. Surgical removal of the implant was successful with minimal bone resection required. A larger diameter AxialLIF rod was then implanted and joint distraction was reestablished.

Results: Symptoms resolved following revision surgery. No adverse events occurred and the patient is ambulating without assistance.

Conclusions: The AxialLIF interbody distraction rod may be revised and replaced with a larger diameter rod using the same presacral approach. Technical and clinical success was achieved in this challenging case.

Choice of Indication for Kyphoplasty
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Objectives: To retrospectively analyze the efficacy of kyphoplasty for treatment of spinal tuberculosis, probe the indication of kyphoplasty.
Methods: From April, 2002 to June, 2008, 14 vertebral bodies in 7 patients with spinal tuberculosis were treated by kyphoplasty because of misdiagnosis as osteoporotic vertebral compressional fracture. There were six female and 1 male for average 61.8 years (from 43 to 71). All pathological changes occurred in thoracic vertebra, among which one case is in T9/10, 2 in T10/11, 3 in T11/12 and 1 in T12/L1. All these patients felt pains in thorax and back to different degrees, showing no typical symptoms or physical signs of spinal tuberculosis. Vertebral bodies above or below those with pathological changes showed stenosis to different degrees. MRI showed low signal on T1, high signal on T2 and STIR series.

Results: Through 9-38 months' follow-up on the 14 vertebral bodies, we found that the original symptoms and physical signs had improved to different degrees after the operations. 5 of the 7 patients underwent biopsy during the operation and we diagnosed spinal tuberculosis one week after the operation, so they received regular anti-tuberculosis treatment immediately. Their symptoms and physical signs are effectively controlled. Among the two whose biopsy failed to lead to right diagnosis, one patient suffered from lupus sebaceus at the same time and had taken hormone for a long time. This patient had a high fever with 40 centigrade one month after the operation and then felt pains in thorax and back again. MRI reexamination showed more severe destruction of vertebral body and symptoms of dysesthesia and hypokinesise. We finally diagnosed spinal tuberculosis after laminectomy, trans-vertebral pedicle internal fixation and biopsy were performed. The vein finally recovered after anti-tuberculosis treatment. CT reexamination and reconstruction in one month showed severely destruction in vertebral body, suquestrum, paravertebral abscess and sinus. Currently the patient's condition is effectively controlled and obviously improved. The patients also shows incomplete paralysis. Another patient felt pains in thorax and back again two months after the operation and MRI reexamination showed destruction in vertebral body and paravertebral abscess. Regular anti-tuberculosis treatment effectively controlled the patient's condition.

Conclusions: Differences between symptoms of osteoporotic vertebral compressional fracture and spinal tuberculosis are difficult to distinguish. Those patients who suffer from pathological changes between two adjacent segments and will undergo kyphoplasty should undergo MRI and CT examinations firstly. We should observe carefully changes on interval between adjacent vertebra. As for patients with untypical osteoporotic vertebral compressional fracture, we should examine ESR, PPD, C-RP, chest radiograph and tuberculosis antibody to exclude the possibility of spinal tuberculosis.

Combination of Minimally Invasive Surgical Techniques (XLIF and TLIF) for the Treatment of Two-level Disc Disease in the Lumbar Spine. Radiological and Clinical Outcomes out to 20 Months
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Background context: Spine surgical procedures are often referred to as an open procedure or minimally invasive. Open procedures require larger incisions, muscle stripping, more anesthesia, operating time, and hospitalization. Consequently, the patient usually needs more time to recuperate. Minimally invasive surgical techniques utilize
portals or small incisions made in the skin (percutaneous). The purpose of this study was to assess the benefits of combining two different minimally invasive techniques in the treatment of two-level lumbar disc disease.

**Purpose:** To assess the clinical and radiographic outcomes in combining two different minimally invasive techniques in the treatment of two-level lumbar disc disease (XLIF L4-L5 and MIS TLIF L5-S1).

**Study design/setting:** Prospective clinical study.

**Patient sample:** 17 patients

**Outcome measures:** Visual analog pain score (VAS) and Oswestry disability index (ODI) were evaluated preoperatively and at various time-points postoperatively. VAS included the assessment of both back pain and leg pain.

**Methods:** 17 patients underwent XLIF L4-L5 and MIS TLIF L5-S1 for the treatment of two-level symptomatic low back and/or leg pain or dysfunction. The interbody graft used in both levels was a PEEK interbody implant filled with DBM in a lipid carrier mixed with autograft bone in the TLIF implant and DBM in a lipid carrier mixed with hydroxyapatite and tri-calcium phosphate granules in XLIF devices. TLIF levels were supplemented with pedicle screw fixation by a percutaneous approach. Patients were followed clinically and radiographically for up to 20 months postoperatively.

**Results:** 17 patients with symptomatic two-level lumbar disc disease were included. Mean patient age was 47 yrs (range: 24-68 yrs). All patients had a two-level disease L4-L5 and L5-S1. Mean combined operative time was 180 minutes and in all cases measured blood loss was less than 75 cc. Patients were typically out of bed, ambulating and advanced to regular diet on the day of surgery, and discharged home the following 48 to 72 hours. Mean back pain VAS decreased from 7.4 at pre-op to 3.6 at 3 months, 3.4 at 6 months, and 2.8 at 2 years. Mean leg pain VAS was decreased from 6.8 at pre-op, to 1.8 at 3 months, 3.4 at 6 months, and 0 at 2 years. Mean ODI improved from 52.3 at pre-op to 12 at 3 months, 9.3 at 6 months, and 0 at 2 years. Mean back pain ODI decreased from 6.8 at pre-op, to 1.8 at 3 months, 3.4 at 6 months, and 0 at 2 years. Mean ODI improved from 52.3 at pre-op to 12 at 3 months, 9.3 at 6 months, and 11 at 2 years. [NuVasive1]

**Conclusions:** This study showed that the combination of XLIF and MIS TLIF is an effective surgical treatment for two-level lumbar disc disease at L4-L5 and L5-S1. Multilevel fusion at the lumbosacral junction can be achieved using this combination. Postoperative recovery is notably faster than traditional open procedures.

**CLINICAL: LUMBAR FUSION (I.E. MIS, TLIF, XLIF, AXIAL LIF, ALIF)**

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**Mini-open Lateral Approach for Anterior Lumbar Interbody Fusion**

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**Introduction:** Recently, minimally invasive lateral approach is revived and getting popularity under the name of XLIF or DLIF by modification of miniopen method using sequential tubular dilator and special expandable retractor system.

**Purposes:** The purposes of this study were to introduce the mini-open lateral approach for the anterior lumbar interbody fusion (ALIF), and to investigate the advantages, technical pitfalls and complications & to provide basic knowledge on XLIF or DLIF.

**Materials and methods:** Seventy-four patients who underwent surgery by the mini-open lateral approach from September 2000 to April 2008 with various disease entities were included. Blood loss, operation time, incision size, postoperative time to mobilization, length of hospital stay, technical problems and complications were analyzed.

**Results:** With this approach, we can reach form T12 to L5 subdiaphragmatically. The blood loss and operation time of patients who underwent simple ALIF were 61.2 ml and 86 minutes for one level, 107 ml and 106 minutes for two levels, 250 ml and 142.8 minutes for three levels, and 400 ml and 190 minutes for four levels of fusion, respectively. The incision sizes were on average 4.5 cm for one level, 6.3 cm for two levels, 8.5 cm for three levels and 10.0 cm for four levels of fusion. The complications were retroperitoneal hematoma in two cases, pneumonia in one case and transient lumbosacral plexus palsy in three cases.

**Conclusion:** The mini-open lateral approach is simpler & safer than XLIF or DLIF with very short learning curve. However, in long level fusion, XLIF or DLIF would be more advantageous. Trial of miniopen lateral approach would be helpful before trial of XLIF or DLIF.

**Keywords:** Lumbaropen lateral approach, Interbody fusion

**CLINICAL: PROSTHESIS**

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**Artificial Lumbar Disc Replacement in the Treatment to Recurrent Lumbar Disc Herniation**

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**Objective:** To evaluate the clinical result of Artificial Lumbar Disc Replacement in the Treatment to Recurrent Lumbar Disc Herniation by assessing the retaining of the segmental intervertebral disc’s motion, the retaining of the lumbar spinal physical assignment and its clinical curative effect.

**Method:** From January 2001 to June 2008, 14 patients suffered Recurrent Lumbar Disc Herniation underwent artificial lumbar intervertebral disc replacement with SB Charite-III disc prostheses. Among these patients, 13 (15 prostheses) were followed up for average 6.8 years (from 1.5 to 9.5 years). There were 8 males and 5 females with an average age of 44 years old (from 40 to 58 years old). The average visual analogue scales score for pain was 9.40 before operation. Meanwhile, the average Oswestry Disability Index was 50.8 before operation. All patients underwent standard Artificial Lumbar Disc Replacement under general anesthesia via anterior approach. One level replacement was done in 11 patients (L4-5:9 cases, L5-S1:2 cases). And 2 patients were treated with two 1 levels (L4-5 and L5-S1) replacements.
Clinical and radiographic results of these patients were evaluated at each follow-up time (1, 3, 6, 12, 24 months after operation and the latest follow-up).

**Result:** The average visual analogue scales score for pain at 1, 6, 12, 24 months after operation and latest follow-up were 4.3, 4.3, 3.7, 3.1, 2.7 respectively. Meanwhile, the average Oswestry Disability Index at 1, 24 months after operation and latest follow-up were 29.6, 13.5 and 9.2 respectively. Motion: the motion was reserved at the latest follow-up, average 5.3°. There were no translocation, loosening and subsidence of the prostheses in all the patients. The satisfied rate was 96%.

**Conclusion:** The artificial lumbar disc replacement is on of the effective method for the treatment to Recurrent Lumbar Disc Herniation. The patients’ selection for the surgical indication is critical. And its long-time outcome remains to be verified.

**CLINICAL: DEFORMITY**

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Revision Surgery for Severe Kyphoscoliosis

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**Objective:** To investigate the revision surgery for severe kyphoscoliosis after the failure of one stage surgical fusion and evaluate the effect and risk of this surgery.

**Methods:** From October 2006 to June 2009, 32 patients with severe kyphoscoliosis after failure of one stage surgical fusion were treated with revision surgery. There were 7 male and 25 female with an average age of 23.8 years (19-31 years old). The average interval after past surgery was 11.3 years (7-21 years). The average number of times was 2.3 (1-7 times). The pre-operative scoliosis Cobb angle was 123.2° (83°-156°) and kyphosis Cobb angle was 87° (53°-129°). Trunk shifts in the coronal plane was found in 17 patients, about 2.7cm (2.1-6.1 cm). 3 patients suffered the injury of spinal cord. Asia classification: C: 1 case, D: 2 cases. Among the 32 patients, instrument was fixed in 12 patients’ spine. The materials were taken out at the one stage surgery. And the revision surgery was done at the second stage. The other 20 patient were treated with the revision surgery at the one stage. The structure of the spine and the state of the spinal cord were pre-operative measured by CT photograph, 3D reconstruction and the MRI photograph. All patients underwent total vertebral osteotomy on the apex vertebra, trans-pedieular fixation combined with supporting of Ti cage. Autogenous bone and Allogenic bone were used for Bone grafting. Spinal canal bony mediatinum occurred in one patient. And Tethered Cord syndrome occurred in 4 cases. The neurosurgeons did the spinosustomy and loosing of the tethered cord at the same time. The operation time, blood loss, complication of perioperation, the reconstruction to the scoliosis and kyphosis, trunk shift and the patients’ satisfied degree were evaluated.

**Results:** There was no major complication of neurological injury and hardware failure. The average surgery time was 260 mins and average blood loss volumn of 1875ml (960-8200ml). The post-operative average kyphosis and scoliosis curve was 37.1° (correction rate: 57.4%) and 58.4° (correction rate: 52.6%), respectively. The average trunk shift was 1.3 cm (correction: 51.9%). The Asia C case before the operation became Asia D after the operation. one of the two Asia D cases before the operation became Asia E after the operation, the other was still Asia D. The complication rate was about 40.2%. Impairment of inferior extremities nerve: 2 cases. Hyperalgesia of inferior extremities: 1 case. These 3 cases were recovered after surgery. Hemopneumothorax: 1 case. Pleural effusion: 2 cases. Superior mesenteric artery syndrome: 3 cases. Stress Digestive Ulcer: 1 case. Superficial skin necrosis: 3 cases, cured after treatment. The average follow-up was 2.2 years (1-3 years). No pseudarthrosis and collapse of interal fixation. At the latest follow-up, 27 patients were satisfied with the revision surgery.

**Conclusion:** The revision surgery for severe kyphoscoliosis after the failure of one stage surgical fusion has the characteristic of difficulty to reconstruction, high risk and complication. Satisfied clinical effect would be achieved by the complete measurement before operation, total vertebral osteotomy on the apex vertebra and trans-pedieular fixation. The serve complication rate was also decreased.

**BASIC SCIENCE: POSTERIOR DYNAMIC PECULAR STABILIZATION**

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**Study design:** Biomechanical effect of implantation of pedicle based dynamic stabilization systems (PBDS) were investigated using the nonlinear three-dimensional finite element model of L3-L4. The NFlex, Dynesys, and PEEK rod were chosen as the representative PBDS and compared with the intact and rigid rod fixation model of functional spinal unit.

**Objective:** To investigate the effect of implantation of PBDSs to spinal functional unit and to evaluate the differences in biomechanical characteristics according to PBDS materials and design.

**Methods:** Intact osteoligamentous L3-L4 finite element model was created with 1-mm computed tomography scan of a cadaveric spine and known material property of each element. Three models implanted with non-metallic (Dynesys and PEEK) and metallic with variable interpedicular distance (NFlex), were developed. The implanted model predictions were compared with that of the intact and rigid fixation model. Range of motion, force on the spinal ligaments, force on the facet joint, stress on the vertebral body and vertebral endplate with flexion/extension, lateral bending, and axial rotation under 400 N compressive preload were compared among the models.

**Results:** The PBDS implanted models showed decreased range of motion in flexion/extension, lateral bending, and axial rotation compared with that of the intact. Under 6-Nm moment, the range of motion was decreased in order of rigid fixation, PEEK rod, Dynesys, and NFlex except axial rotation. Decrease in flexion ROM is more than extension ROM. In case of NFlex, ROM was 32% in flexion and 38% in extension of intact spine. Instantaneous axis of rotation (IAR) was moved posteriorly over posterior bodyline in rigid and...
Disc arthroplasty, especially cervical disc arthroplasty, has gained more popularity in recent years as a surgical treatment option for disc degenerative disease. The main advantage of disc arthroplasty over fusion, which has been a gold standard for many years, is preserving the segment motion and therefore, at least conceptually, preventing the acceleration of disc degeneration at adjacent levels. A novel cervical disc arthroplasty device, NuNec, has been developed recently and its early clinical experience on this device will be presented.

**Method and material:** NuNec has an inner ball/socket articulation which allows physiological range of motion in all three major directions. However, differing from other disc arthroplasty devices, NuNec is made of PEEK OPTIMA, which has been widely used as spinal implants with proven biocompatibility and history, and has a unique CAM lock mechanism. The benefits of using PEEK for artificial cervical disc includes its superb wear resistant and radiolucency. Most other cervical artificial discs either are made of all metals or contain two metal plates which are fixed to the adjacent vertebrae. The metals have a strong artifact on CT and MRI images which prohibit accurate diagnosis on the index level with these imaging methods. It is to our knowledge that NuNec is the first radiolucent articulating artificial cervical disc. Another unique design feature of NuNec is its CAM locking mechanism. In order to fix the endplates of artificial disc to the adjacent vertebrae, most other devices use either keels or flange/screw. Keel fixation requires cutting keel slots in the vertebrae during the procedure and can be dangerous if the cutter move too posteriorly. Also, for multi-level disc arthroplasty, the keel design adds another risk of splitting the vertebra. The CAM design of NuNec avoids the step of cutting keels and fixes the endplates through interference CAMs (screws), while has zero profile on the surface. The bench-top pullout testing showed that this CAM design has fixation force higher than most other keel and flange-screw designs. In addition, NuNec has HA coating on the outer surfaces to enhance both short term friction and long term bony ingrowth. This study reports our early clinical experience on our first 11 Chinese patients using NuNec artificial cervical disc at 12 levels. There were 6 males and 5 females. The patient age ranged from 23 to 67 years old. The level distributions are C4/5 (1), C5/6 (8) and C6/7 (3). An anterior approach was used to implant the NuNec device. 

**Result:** There was no major intra-op and post-op complication occurred in this series. In the follow-ups ranged from 3 to 12 months, patients experienced significant pain reduction and functional as measured by Neck Disability Index (NDI) and Visual Analog Score (VAS). Radiograph images showed no dislocation of the implant and maintaining of the normal range of motion. In the post-op MRI and CT images, there was none to little artifact from the implant.

**Conclusion:** This early clinical experience on NuNec suggested that the device is safe and effective. Many of the design benefits have been demonstrated through this early clinical study. This warrants further expansion of clinical study with more patients and longer follow-ups.

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**CLINICAL: CERVICAL NEW MOTION PRESERVATION TECHNOLOGIES**

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Early Clinical Experience of NuNec Artificial Cervical Disc

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**Objective:** Disc arthroplasty, especially cervical disc arthroplasty, has gained more popularity in recent years as a surgical treatment option for disc degenerative disease. The main advantage of disc arthroplasty over fusion, which has been a gold standard for many years, is preserving the segment motion and therefore, at least conceptually,
**Introduction:** In degenerative lumbar spondylolysis with spinal stenosis, decompression and fusion have been widely recommended; however, possible adjacent disc degeneration and pain at the bone donor site are the main drawbacks of this method. More recently, dynamic stabilization with Dynesys system have shown encouraging results. We present our experience in a series of 22 patients with degenerative lumbar spondylolysis with spinal stenosis who were treated using new stabilization systems.

**Materials & methods:** There were 22 patients who underwent central decompression and dynamic stabilization for degenerative lumbar spondylolysis with spinal stenosis in our Spinal unit; we used the Scient’s IsoBar TTL Dynamic Rod Stabilization and the Inlign™ Multi-Axial Screws (Disc Motion Technologies - DMT) stabilization systems. The pain intensity was evaluated using the Visual Analogue Score for back pain (VAS-BP) and leg pain (VAS-LP) and functional outcomes were measured with Oswestry Disability Score (ODS). To assess the overall general patients’ health the Bodily Pain component of the SF -36 questionnaire was used (SF36-BP). Data was analysed with the SPSS 16.0 for Windows (SPSS Inc, Chicago, IL). Paired sample t-test for normally distributed data and Wilcoxon signed-rank test for non-parametric data were used. Statistical significance was designated at p < 0.05.

**Results:** There were 3 male and 19 female patients; the average age at operation was 68.95 years (Range 57-79 years). The average duration of follow up was 16.18 months (Range 8-37 months). Mean duration of symptoms prior to surgery was 61.45 months (Range: 12-410 months). Most common level of spondylolysis was L4/5 (18 cases), followed by L5/S1 (2 cases) and L3/4 (2 cases). 21 cases presented with grade I spondylolysis and in 1 case the lysthesis was grade II. Decompression and instrumentation involved 1 level (7 cases), 2 levels (9 cases), 3 levels (1 case) and 4 levels (5 cases). All patients underwent conservative treatment (spinal rehabilitation programme, regular analgesia, sacral epidural injections) for at least 6 months before the surgical intervention. Our results show a statistically significant improvement in clinical outcomes following central decompression and dynamic stabilization for degenerative spondylolysis. ODS improved from 49.45 (SD=14.35) to 22.91 (SD=16.38), p< 0.001. There was also significant improvement in VAS-BP (p< 0.001), VAS-LP (p< 0.001) and SF36-BP (p=0.002).

**Conclusion:** In our study, we conclude that central decompression and dynamic stabilization using the new systems (TTL/DMT) for degenerative lumbar spondylolysis is a reliable method and offers good clinical outcomes. Comparing to the standard decompression and fusion, this method has the advantage of an absent bone donor site pain and possibly less adjacent level degeneration due to the motion allowed by the stabilization system.

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**CLINICAL: PROSTHESIS**

**353**

**Cervical Alignment Changes after Single Level ProDisc-C Replacement**

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**Objective:** To study the changes of spinal alignments after single level ProDisc-C replacement.

**Method:** 53 cases with single level ProDisc-C replacement in one center were reviewed. ROM of operative level, FSU(Functional Spinal Unit)angle, Cobb angle of C2-C7 were measured and compared on dynamic X-rays from PACS (Picture Archiving & Communication System).

**Result:**

1) The follow-up averaged 13.8 months and there were 7 cases of C34, 10 cases of C45, 27 cases of C56 and 9 cases of C67.
2) The preoperative segmental ROM averaged 8.6° and postoperative ROM averaged 9.7° with statistical significance;
3) The preoperative FSU angle averaged 1.8° and postoperative FSU angle averaged 3.6° with statistical significance;
4) The preoperative Cobb angle of C2-C7 averaged 8.0° and postoperative Cobb angle of C2-C7 averaged 8.0° without statistical significance.

**Conclusion:** After the ProDisc-C replacements, the segmental ROM was preserved and the FSU lordosis was restored. The ProDisc-C will be a better choice for the patients with preoperative FSU kyphosis.

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**CLINICAL: PROSTHESIS**

**355**

**Clinical Outcome of Lumbar Total Disc Replacement Using ProDisc-L in Degenerative Disc Diseases: Minimum 5-year Follow-up Results**

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**Objective:** The purpose of this retrospective study is to determine the clinical outcome of the patients with degenerative disc diseases (DDD) following lumbar total disc replacement (TDR) using ProDisc-L in a minimum 5-year-follow-up.

**Methods:** Among 42 consecutive patients undergoing lumbar TDR by a single surgeon (C.K.P) between 2003 and 2005, 32 patients who agreed to be followed up and could be interviewed were enrolled in this cohort study. The remaining 10 patients couldn’t be reached due to wrong address or phone number. Mean age was 48.84±11.31 years (range: 29–70) at the interview. Mean follow up period was 77.19±10.79 months (6.4 years) (range: 60–94). Twenty-three patients underwent one-level TDR and 9 patients two-level. The clinical outcome was assessed using VAS (visual analogue scale) score and ODI (Oswestry disability index), and compared between preoperative and last follow-up results. At the last follow up, the patients were also evaluated with a 4-point scale to assess overall satisfaction and with another 5-point scale to assess ‘choose the same treatment again’. In addition, sporting activity was evaluated using ‘modified Cincinnati sports activity scale (0-100)’ and SF (Short-form)-36 was evaluated.

**Results:** At the last follow-up, mean VAS score was considerably low (1.28±1.71) and the decrease was statistically significant compared to preoperative mean VAS score (7.27±2.89) (p< 0.05). Mean ODI score was also low (16.94±15.88) and significantly decreased from the preoperative value (37.06±17.82) (p< 0.05). Twenty patients responded as ‘satisfied’ with the treatment (62.5%), 11 did as ‘somewhat satisfied’ (34.3%), and 1 did as ‘somewhat dissatisfied’ (3.1%). As for ‘choose again’ question, 19 responded as ‘definitely yes’ or ‘probably yes’ (59.4%), and 6 ‘not sure’ (18.8%), 1 ‘probably not’ (3.1%), and 6 ‘definitely not’ (18.8%). Mean sports activity scale score was significantly much higher at the final follow-up (52.97±17.64) compared to...
the preoperative one (6.87±9.65) (p< 0.05).
Analysis of the SF-36 revealed significant differences between preoperative and last follow-up results. Physical and mental summary scores at the last follow up (PCS: 38.87±13.47, MCS; 52.24±11.08) were significantly higher than the preoperative value (PCS; 33.95±8.78, MCS; 36.49±13.88), respectively (p< 0.05).

Conclusions: The study demonstrates that lumbar TDR using ProDisc-L in the treatment of degenerative lumbar disc diseases provides with considerably better clinical outcome compared to the preoperative state. Not only therapeutic effects of lumbar TDR on back pain, mental and physical functions and sports activity but the patients' satisfaction and friendly feeling toward TDR treatment also appear to maintain until more than 5 years postoperatively.

CLINICAL: PROSTHESIS

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Sagittal Alignment and Ranges of Motion 30 Months after Cervical Disc Replacement with a Semi-constrained Cervical Prosthesis
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Background: Motion preserving techniques were developed in last decades, in order to avoid some complications of anterior cervical interbody fusion (ACIF) ; several clinical trials investigating the existing cervical disc prostheses are currently running. However there is little information available on quantitative analysis of symptoms relief, sagittal alignment and ranges of motion with more than 2 years follow-up.

Purpose: To evaluate the 30 months clinical and radiological outcomes in patients treated by TDR with Discocerv® semi-constrained cervical mobile prosthesis.

Methods: 53 consecutive patients (31m/22w: mean age 44.8 ± 8 yrs [28-65]) with single-level cervical arthroplasty and a minimum follow-up of 2 years were included in this prospective observational study (average FU 30 months [24-46 mths]).

Outcome measures: Clinical criteria: VAS (1-100) self-reported cervical and radicular pain, Neck Disability Index (1-50 scale) and symptoms evolution (ODOM score). Radiographic evaluation: flexion-extension mobility, mean centers of rotation (MCR) for treated and adjacent levels, cervical (C1C7) and local lordosis.

Results: Clinical outcomes highlighted symptoms relief: pre- and postoperative cervical and radicular pain decreased from an average VAS value of 64.2[4-100] and respectively 67.3 [0-100] (before surgery BS) to 22.5[0-81] and 14.2[0-70] in early exams and further to 14.5[0-70] and 11.2[0-74] at 2 years follow-up. NDI improved from 26/50 (BS) to 7/ 50 (at 1 and 2 years FU) and results as per ODOM criteria were excellent (79%), good (25%) or unsatisfactory (4%) at 24 months. Complications were observed in 7/53 cases and 92% of patients were satisfied with their treatment.

Quantitative radiographic analysis showed an average cervical mobility at the treated levels (mostly C5C6) of 6.7±4° (0-15°) in early exams and of 8.2±4° (4-19°) at 24 months follow-up, except for 6 patients for whom ranges of motion were inferior to 3° at FU. These values are comparable to preoperative mobility of treated level i.e. 9.2[4-24]°, though inferior to the average mobility of asymptomatic subjects (12 [6-24]° for treated level). MCRs had a normal location in half of patients, most of the abnormal locations being
projected on the upper plate of the prosthesis. The adjacent level mobility was found within normal ranges post-operatively: i.e. 12.2 ± 5° [4-21] in early exams and 14.2 ± 5° [4-29] at 24 months follow-up, with mean centers of rotation normal in 90% of cases. Ten patients presented an abnormal sagittal alignment before surgery which was restored after TDR. Lordosis was stable and within normal ranges after surgery in all cases; however, C1C7 lordosis marked a progressive increase from 48±10° before surgery to 55±10° at last follow-up which need to be further monitored in time.

Conclusions: Intermediate clinical and radiological results in TDR with Discocerv® prosthesis highlight a satisfying level of symptoms relief associated to mobility in 88% of cases and postoperatively stable sagittal alignment at 30 mths FU. However, a longer term analysis is required to validate these outcomes of cervical TDR with a semi-constrained prosthesis.

CLINICAL: DEFORMITY

359 Comparative Analysis of Surgical Approaches and Osteotomies for the Correction of Sagittal Plane Spinal Deformity in Adults
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Study design: A retrospective review.
Objective: To compare the radiographic and clinical profile between two surgical approaches for the correction of sagittal plane spinal deformity.
Summary of background data: Sagittal plane decompensation is the radiographic parameter that carries the greatest impact on adverse outcomes. Surgical correction methods are heterogeneous, and opposing views pervade the spine community in consideration of the most effective approach and techniques to achieve correction.
Methods: A total of 33 cases with sagittal spinal deformity were assessed according to their surgical approach, posterior only vs. combined anterior-posterior group. Comparison was based on demographic data and radiographic parameters included: pelvic tilt (PT), pelvic incidence, sacral slope, lumbar lordosis, thoracic kyphosis and sagittal vertical axis (SVA).
Results: 22 subjects were identified for the posterior only and 11 subjects for the antero-posterior group. Average age was 58.7 years in the posterior only and 55.7 years for the combined approach. Preoperative mean SVA was 186.6mm and 147.7mm, for the posterior only and combined approach, respectively (p=0.1). Preoperative mean PT was 34.2° for the posterior group and 36.9° for the combined approach group (p=0.5). A greater operative time for the combined approach was significant, 535 vs. 333 minutes (p< 0.001). 8/22 patients in the posterior only group and 7/11 patients in the combined approach cohort experienced a post-operative complication, (p=0.16). The average follow up was 41.8 and 47.7 months for the posterior only and combined approaches, respectively (p=0.4).
Conclusions: A posterior only or combined surgical approach had comparable radiographic outcomes. Higher morbidity was significant in regards to operative time in the combined approach group. Deciding on the approach best suited for achieving correction in the sagittal plane, likely resides on the surgeon’s experience and expertise.

CLINICAL: PROSTHESIS

361 Clinical Outcomes, Complications and Ranges of Motion 2 Years after Total Cervical Disc Replacement
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Background context: Given the possible complications of anterior cervical interbody fusion in young and active populations, motion preserving techniques are developing with various materials and designs for cervical mobile disc prostheses. As clinical trials investigating these prostheses are still running, a mid and long term quantitative analysis of symptoms relief, sagittal alignment and ranges of motion is required.
Purpose: To evaluate the intermediate clinical and functional outcome in patients operated with Discocerv® semi-constrained cervical mobile prosthesis.
Study design/setting: Prospective observational study
PATIENT SAMPLE: 35 consecutive patients with single-level arthroplasty were enrolled in the study. 20 patients (14m/6w: mean age 42.5 ± 7 years [28-53]) had follow-up superior to 24 months, clinical and radiological data being available for this group with an average follow-up of 27.3 [24-35] months.
Outcome measures: Clinical evaluation was based on following criteria: complications rate, pre- and post-operative VAS (1-100) self-reported cervical and radicular pain, Neck Disability Index (1-50 scale), symptoms evolution (ODOM score) and return to work rate. Radiographic evaluation provided flexion-extension mobility of the treated and adjacent levels, cervical (C1C7) and local lordosis.
Methods: All patients underwent single-level cervical arthroplasty with Discocerv for degenerative disc diseases. Results: Surgery duration was 57±20 min, corresponding to an average blood loss of 65.8 ml; there was one case of per-operative minor vascular complication. In the active population, 75% of patients resumed work within 6 months after surgery and all but 2 patients (invalid) resumed their work within the first year. At 24 months FU, the ODOM score showed 70 % excellent and 30 % good results and 90% of patients were fully satisfied with their treatment. Mean cervical and radicular VAS decreased from 61 [10-95] and 65 [12-96] pre-operatively to 16[0-65] and 11[0-70] at last follow-up. Values of neck Disability Index decreased from 23/50 before surgery to 12/50 in early postoperative exams and to 8/50 at FU.
Quantitative radiographic analysis showed preservation of cervical mobility at the operated levels with mean flexion-extension ranges of 6.7±2° (4-10°) at 24 months follow-up, except for 3 patients for whom ranges of motion were inferior to 3°. The adjacent level mobility was found within normal ranges and stable post-operatively: i.e. 14.1 ± 4° in early exams (3-6 months) and 14.4 ± 3° at FU (24 months). Five patients presented an abnormal sagittal alignment before surgery that was restored afterwards. Local lordosis was stable postoperatively and C1C7 lordosis marked a progressive increase from 45±10° before surgery to 49±9° at last follow-up.
Conclusions: The two years clinical and radiological results in TDR with Discocerv® prosthesis highlight a satisfying level of symptoms relief and return to work, associated to preserved mobility and normal sagittal alignment.
CLINICAL: POSTERIOR DYNAMIC PEDICULAR STABILIZATION

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Posterior Lumbar Inter-laminar Dynamic Stabilization Combined with Fusion for the Treatment of Multiple Level Lumbar Stenosis
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Objective: To Evaluate the efficacy and safety of posterior lumbar inter-laminar dynamic stabilization combined with fusion for the treatment of multiple level lumbar stenosis.

Methods: From September 2007 to January 2010, 14 patients with multiple level lumbar stenosis were treated with posterior lumbar inter-laminar dynamic stabilization combined with fusion in our hospital. There were 6 male and 8 female with an average age of 58.7 years (53-71 years old). The diagnosis included degenerative stenosis with instability in 6 cases, degenerative stenosis with spondylolisthesis in 4 cases, simple degenerative stenosis in 4 cases. All patients in this group had lower back pain, neurological symptom and neurological claudication. Plain and dynamic X-ray, CT scan and MRI test were performed for all the patients to rule out the symptomatic levels pre-operatively. All the cases had two levels procedures. All patients underwent posterior selective decompression, transpedicular instrumentation system fixation and interbody fusion or pesterolateral fusion combined with selective decompression, disc excision and inter-lumbar Coflex implantation under general anesthesia. Interbody fusion: 11 cases. Pesterolateral fusion: 3 cases. The VAS scale and Oswestry Disability Index were evaluated pre-operatively and post-operatively for clinical outcome. Plain and flexion-extension X-ray were taken for radiographic evaluation. Patient’s satisfaction for the treatment was reported at the latest follow-up.

Results: All patients underwent the procedure safely and the average operating time was 165 minutes (140-190) with an average blood loss of 340 ml (300-400). There was no nerve injury, extensive bleeding and infection occurred in this group. All patients were mobilized with soft brace five days post-operatively and discharged 7-10 days post-operatively. All patients were followed at 1, 3, 6, 12, 24 months post-operatively for clinical and radiographic evaluation. The average follow up time was 5.7 months (3-9). The average VAS scale was from 8.1 pre-operatively to 3.2 post-operatively and 2.7 at the latest follow-up. The average Oswestry Disability Index was from 55.3 pre-operatively to 23.9 post-operatively and 24.5 at the latest follow-up. There were significant differences between the index of preoperation and postoperation. The fusion segment is solid fused and the non-fusion segment had acceptable motion range in follow-up. The average range of motion of the operated lumbar segment was 3.6 degree (2-6). There was no implant migration found at the follow up. At the latest follow up, the patient’s satisfaction was 92.9% (13/14).

Conclusion: The posterior lumbar inter-laminar dynamic stabilization combined with fusion for the treatment of multiple level lumbar stenosis, especially for degenerative stenosis is a minimal invasive procedure which can achieve adequate decompression to improve the neurological symptoms while maintaining the motion of the operated segment. Short term follow up results showed that it is a safe and effective procedure for the surgical treatment of degenerative lumbar Stenosis. The long term outcome of this procedure is to be evaluated.

CLINICAL: DEFORMITY

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The Incidence of Transitional Vertebra in the Lumbar Spine
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Lumbosacral transitional vertebra (LSTV) is a congenital vertebral anomaly of the L5-S1 junction in the spine. The prevalence of transitional level changes has not been well studied in the non-back pain American population. This study reviewed abdominal roentgenograms from normal subjects and categorized the transitional level changes according to the Castellvi system. 1100 abdominal films from the past 2 years (2008-2009) were reviewed, and 211 x-rays were identified as being adequate for measurement of the desired parameters. Of these 211 subjects, 107 (50.7%) were male and 104 (49.3%) female, with an average age at the time of the kidney-urinary-bladder (KUB) x-ray of 59.8 years. 93.4% of subjects (197) presented five lumbar vertebrae and only fourteen (6.6%) had six lumbar vertebrae. 75 subjects (35.5%) were identified with transitional vertebrae, the most common anatomical variant was the Castellvi type IA (14.7%), followed by type IB (8.53%), type IIA (4.3%), type IIB (3.8%), type IIIA (1.9%), type IIIIB (1.4%), and type IV (0.9%). For all types, the third lumbar vertebra had the longest transverse process (TP) present in 55% of cases. The mean length of last rib for the sample was 12.11 cm and average height for TP was 15.9mm. This study establishes the rates of transitional level changes and the distribution of the various pathologic anatomical variants in a non-back pain American population.

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Minimally Invasive Spine Surgery in Adult Deformity Correction: A Prospective Case Series of 37 Patients
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Purpose: Adult spinal deformity is a complex musculoskeletal problem in the aged patient. Spinal alignment analysis has come to the forefront the spinal surgeon’s pre and post operative considerations. One of the drawbacks of conventional open correction is the morbidity associated with the extensive soft tissue dissection that is associated with traditional deformity correction. Minimally invasive spine surgery (MISS) techniques can be employed in conjunction with modern surgical solutions to restore sagittal balance and spinal alignment in cases of degenerative spinal deformity. This study evaluates the safety, efficacy, and outcomes of MISS for complex de novo degenerative scoliosis.

Methods:
Study design: A prospective study including 37 patients with degenerative spinal deformity were treated by MISS techniques. The patients received MISS, anterior lumbar inter body fusion (ALIF), direct lateral inter body fusion (DLIF) and percutaneous and minimal access technology in conjunction with biological solutions such as bone morphogenic proteins (BMP2). Diagnosis was based on history, examination, MRI, CT discography, AP lateral whole spine, and electrophysiological
studies. Minimum follow-up of the 37 patients was 12 months. Ten patients were male and 27 patients female, with an average age of 66.51 yrs (range=44-82 yrs). The average operation duration was 146.73min (range 75-300min) with an average blood loss of 338.0mls (range 0-910.0).

**Outcome measures:** Clinical outcomes were measured using Oswestry Disability Index (ODI), Visual Analogue Score (VAS) back and leg, Roland Morris Disability Questionnaire (RMDQ), and SF-36 questionnaires. Patients were assessed preoperatively and at 3, 6 and 12 months. Radiological assessment consisted of AP lateral whole spine, flexion/extension standing films, and fine cut CT at 6 months. Cobb analysis of sagittal and coronal balance was performed.

**Results:** Analysis of results at latest follow-up versus baseline included mean reduction in mean back VAS back scores reduced from 77.08±17.85 to 22.11±20.79 (-71.3%); mean right VAS leg score reduced from 44.0±32.50 to 16.84±22.13 (-61.7%), while mean left VAS leg scores reduced from 41.73±32.89 to 27.32±27.76 (-34.5%). Mean RMDQ reduced from 16.50±4.23 to 7.44±5.59 (-54.9%). Mean ODI reduced from 46.54±17.08 to 25.46±17.89 (-54.3%); SF-36 PCS increased from 29.47±5.56 to 39.26±8.58 (+24.9%) and SF-36 MCS increased from 40.13±11.38 to 48.19±13.12 (+16.7%). Patient satisfaction surveys indicated that 77.78% patients rated their satisfaction with the surgery as "excellent" or "good" 3 months following their operation. All patients had greater than 50% correction of the preoperative coronal and sagittal Cobb angles. Complications included one vascular injury and one reoperation, and one L4 nerve root dysfunction. No infections, no transfusions and no pseudoarthrosis were detected.

**Conclusions:** Technological and biological innovations appear to enhance the safety and efficacy of MISS in elderly patients with adult spinal deformity. This study has shown comparable clinical and functional outcomes with traditional open techniques, as well as reduced complications. Improvement in pre to post operative sagittal and coronal balanced was achieved. The results of this preliminary study suggest there is a role for MISS in the care of degenerative spinal deformity. Confirmation through a controlled randomised prospective study would be desirable.

**CLINICAL: POSTERIOR DYNAMIC PEDICULAR STABILIZATION**

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**Functional Pedicle Based Posterior Dynamic Stabilization System (DSS®) - First Results**
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**Introduction:** Pedicle based posterior dynamic stabilization systems are designed to stop degenerative processes and control intersegmental motion. Optimal biomechanical control is achieved when the center of rotation is close to the natural point, when facet joints are unloaded, hyper mobility in extension/flexion is avoided, shock absorption is provided and rotational movements are limited in spondylolisthesis. The motion remains in the neutral zone. Stiffness parameters were determined in a finite element model and combined with clinical and safety aspects for the final design (Wilke et al Spine 34 (3) 255-261 (2009). Indications are patients degenerative disc disease at one or more levels including grade 1 spondylolisthesis. This modular system (Paradigm Spine GmbH) uses flexible spacers (DSS motion) and rigid spacers (DSS Fusion) to combine fusion with stabilization to protect adjacent levels (topping off) or stabilize existing total disc prostheses. If a later fusion should become necessary only the spacer is exchanged.

**Material and methods:** The purpose of this prospective, consecutive controlled study of 94 patients is to investigate the safety and efficacy the DSS® system. Employed parameters were VAS and ODI. Patients are assessed pre and postoperatively 3, 6, 12, 24 and 36 month.

**Results:** 53 males (mean age 51 range 29 - 71) and 41 female patients (mean age 54 range 33 - 88) received single or multi level surgeries between Th9 and S1. In a total of 39 motion cases the single level (stand alone or in combination with a previous total disc replacement in the same or neighboring segment) L4/L5 was the most frequent (70%). There are 6 two level, 1 four and 2 five level cases. For 12 fusion cases in the single level (alone or in combination with TDR) L5/S1 is most frequent (66,6%) followed by L4/L5. There are 2 two level cases and 1 three level.

43 Patients received hybrid multilevel implantations (fusion combined with motion or vive versa) including 6 in combination with TDR. The most frequent two level construct (n=15) was L3-L5 (61,5%) followed by L2-L4 and in three level constructs (n=15) L3/S1 (40%) followed by L2-L5 (33%). In four level cases (n=8) L2-S1 predominates (75%); there are 3 five level and each 1 7 and 8 level cases. VAS, NDI values decreased significantly at 3 month postoperative and were maintained throughout the follow up.

VAS scores decreased from a mean score of 6.8 ± 1.2 baseline to 4.1 ± 2.4 at 3 months; 4.0 ± 2.2 at 6 months; 4.1 ± 2.3 at 1yr; 3.9 ± 3.1 at 2 yrs. and 4.0 ± 3.3 at 3 yrs. ODI scores (in %) were reduced from 52.2 ± 17.5 baseline to 44.2 ± 17.6 at 3 months, 46.4 ± 16.8 at 6 months; 42.4 ± 17.2 at 1yr; 43.2 ± 15.3 at 2yrs and 37.2 ± 15.7 at 3 yrs.

**Conclusion:** Apart from ease of implantation and the modularity of the system there are indications that other products with different biomechanics show differences in clinically relevant parameters. These results of the small patient group needs to be completed by long term data.

**CLINICAL: DEFORMITY**

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**Clinical Characteristics of Adolescent Idiopathic Scoliosis (AIS) Patients who Were Lost to Follow up**
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**Introduction:** Long term outcome studies are influenced by extreme difficulties in obtaining a high follow up rate. We hypothesize that one reason for patients not following up with their orthopaedic surgeon is poor clinical outcome. If correct, studies with high dropout rates potentially...
provide skewed results.

**Methods:** 271 members of one of the largest scoliosis specific internet community in Germany submitted an online questionnaire, including several demographic and treatment related questions as well as the SRS-22 questionnaire. Patients were then divided into two groups; those that changed their orthopedist were considered as being lost to follow up (LTF) and were compared to patients who did follow up with their orthopedist (FU). The LTF and FU groups were compared in regards to age at surgery, surgical approach, number of fused levels, amount of major curve correction, average number of years post surgery, and revisions. The groups were then matched in terms of years since surgery for SRS-22 data sub-analysis.

**Results:** Of the 81 included patients, 39 (48%) were grouped as “FU” and 42 (52%) as “LTF”. No significant difference was found for age at surgery, surgical approach, number of fused levels, or revision rate, whereas time since surgery and major curve correction showed a significant difference between the two groups (p< 0.001 and p=0.006, respectively). The matched cohort analysis of both groups based on years since surgery included 58 patients and revealed significant differences for the SRS-22 domains: function (p=0.002), pain (p=0.02), mental health (p=0.03), and total score (p=0.009).

**Conclusion:** Patients who have changed their orthopedist after surgical treatment for AIS and who therefore can be considered as being lost to follow up scored significantly lower in the SRS-22 categories function, pain, mental health, and total score compared to patients who have not changed their orthopaedic surgeon. The nature of the German demographic and health system minimizes many reasons for doctor-changes.

### BASIC SCIENCE: BIOMECHANICS / BASIC SCIENCE

**381** Characterizing Disc Bulge in Three Different Regions of the Outer Annulus Subjected to Biomechanical Testing Including Pure Moment Protocols  
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**Introduction:** Due to the proximity of the neural elements, the occlusion potentially created by the outer annulus is an important clinical attribute to characterize. Isolating the effects on the anterior column from the posterior column would allow direct comparisons between native and treated conditions. Moreover, nucleus augmentation devices would have more exacting performance parameters to meet. In order to gage the efficacy of hydrogel augmented nucleus pulposus relying on the otherwise plenary intervertebral disc, the disc bulge at the outer annulus of functional spinal units (FSU) with resected posterior columns was measured in vitro using human lumbar specimen.

**Materials and methods:** Based on the radiographic grading of over 30 lumbar levels by the surgeon, severely degenerated FSU were excluded, leaving 25 qualified levels. Individual FSU with the posterior columns removed, were subjected to ±5.0Nm in pure moment flexion extension bending, lateral bending, and axial torsion. Both the native and polymer augmented nucleus treatments were tested. Disc bulge was measured in three distinct regions on the surface of the annulus. In the figure shown below, the hollow circles indicate the approximate locations of each of the LED in the neutral position at the beginning of each test cycle. The method to determine disc bulge was calculated from the neutral position at three separate locations on the outer annulus with the posterior marked as region I, the posterolateral as region II, and the lateral marked as region III. An analysis of variance (ANOVA) statistical model was used to detect differences amongst the treatment groups with a Bonferroni post hoc test to specify the different groups.

**Results:** The mean±stdev disc bulge for the native anterior column in flexion extension bending was 0.55±0.32mm, 0.84±0.60mm, and 0.58±0.40mm at the posterior, posterolateral and lateral regions respectively. Similarly, the mean±stdev disc bulge for the augmented condition was 0.55±0.46mm, 0.60±0.44mm, and 0.47±0.34mm in the same regions. The mean bulge for the native condition in lateral bending was 0.37±0.30mm, 0.59±0.34mm and 0.87±0.45mm while the nucleus augmented condition measured 0.22±0.30mm, 0.46±0.30mm, and 0.65±0.30mm. The mean disc bulge for the native condition in axial torsion was 0.27±0.33mm, 0.16±0.34mm and 0.09±0.40mm compared to 0.13±0.16mm, 0.08±0.25mm, and 0.25±0.57mm in the augmented condition. The disc bulge was statistically reduced at all three measured regions of the outer annulus (p=0.008 for posterior, p=0.021 for posterolateral, p=0.017 in lateral) only in lateral bending.

**Discussion:** Nucleus augmentation appears to dramatically reduce the disc bulge in all three measured regions of the outer annulus in lateral bending. Significant influences on disc bulge in any location in flexion extension bending and axial torsion were not detected. In conclusion, nucleus augmentation may have a significant effect on the disc bulge in lateral bending however other modes of loading did not exhibit significant reductions in bulge.

### CLINICAL: LUMBAR FUSION (I.E. MIS, TLIF, XLIF, AXIAL LIF, ALIF)

**389** Mini-open Standalone PLIF Using the VariLift Expandable Interbody Fusion System: Early-term Clinical Results for 500 Patients  
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Questions? (866) 423-9440 (U.S.) +1(630) 995-9994 (Int’l)
**Introduction:** Conventional open PLIF involves an incision extending well above and below the affected levels and extensive soft tissue dissection and retraction for placement of instrumentation, leading to increased post-operative pain and recovery time and loss of some physiologic function. Here we present the results for 500 patients undergoing mini-open PLIF with stand-alone, expandable, titanium-alloy interbody fusion devices. The expanded wedge shape and grooved surface of this device provide stability, precluding the need for supplemental fixation. This minimally-invasive procedure maintains biomechanically important structures of the posterior spine, allows a quick recovery, and yields excellent clinical results.

**Materials/methods:** This retrospective study includes a series of 500 consecutive patients undergoing PLIF using stand-alone VariLift-L devices (Figure 1) from 2005 to 2009. Clinical data was compiled via third-party chart review. In this procedure, the spinous process is removed, and bilateral laminotomies are performed, providing access to the disc space with minimal nerve retraction via a minimally-invasive midline incision (approximate length 2”). The articular facets are left intact. The disc is removed in a standard bi-lateral fashion, completely removing the cartilaginous plates from the vertebral body surfaces. The small pre-expanded VariLift is grooved and screws easily into position in the disc space, thus avoiding impaction. After the device is positioned, an inner locking expansion washer is advanced anteriorly, opening the device into a wedge shape locking the device into position and providing immediate stability and disc space restoration. The devices are then packed with autograft for interbody fusion.

**Results:** The 500 patients included 780 operated levels (L1-S1). Mean EBL was 423 ml, mean hospital stay 4.03 days. At 2 months, 97% of working patients had returned to work. Complications included 1 (0.2%) deep infection in a diabetic patient. No patients were returned to OR for supplemental fixation or revision surgery. Pain scores improved significantly post-operatively. Before fusion, 473 patients (99.8%) rated their pain as “high or medium”. After 6 weeks, 442 patients (89.5%) rated their pain as “low or none”. At 12-month follow-up, 98.6% (365/370) of patients showed solid fusion, and 1.8% (10/563) operated levels showed migration or subsidence over 2 mm.

**Conclusions:** Early-term follow-up of this series of patients found significantly improved pain scores, a high rate of bony interbody fusion, and remarkably low rates of subsidence or migration. This technique achieves stability with stand-alone interbody devices, avoiding the need for supplemental pedicle screw fixation while preserving facet articulation. This technique further offers the benefits of an open exposure; i.e. a bilateral view of the disc space after decompression allowing bilateral disc removal and ease of device insertion with minimal retraction of the neural elements using minimal incision.

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**Biomechanical Evaluation of the Verteloc™ Facet Stabilization System - An in vitro Study**

**Introduction:** Spinal stenosis is one of the major causes of back pain. The treatment options for low back pain may range from conservative treatment to instrumented fusion. Allograft-based facet stabilization system (FSS), as an alternative to posterior pedicle screw instrumentation, is currently being explored by clinicians. The dual geometric dowel implant is placed in between the facets while they are distracted. This allows for compression fit of the implant when the surgical instruments are removed. The purpose of this study is to demonstrate the biomechanical stability of the facet stabilization system (FSS) compared to pedicle screw system (PSS).

**Material and methods:** Six fresh-frozen ligamentous motion segments (3 L2-3 and 3 L4-5) were procured. The cranial (L2 or L4) and caudal (L3 or L5) ends of each motion segment were potted using bondo (a 2-part epoxy resin). Loads were applied at the cranial end while the caudal end was fixed to the base of the testing apparatus. Specimens were subjected to pure moments (up to 8Nm) in flexion (flex), extension (ext), right and left lateral bending (rb & lb), and right and left axial rotation (rr & lr). Motion (ROM) of L2 or L4 vertebral body with respect to the fixed vertebra was tracked using the Optotrac motion measurement system (NDI, Waterlo, Canada).

**Results:** The 500 patients included 780 operated levels (L1-S1). Mean EBL was 423 ml, mean hospital stay 4.03 days. At 2 months, 97% of working patients had returned to work. Complications included 1 (0.2%) deep infection in a diabetic patient. No patients were returned to OR for supplemental fixation or revision surgery. Pain scores improved significantly post-operatively. Before fusion, 473 patients (99.8%) rated their pain as “high or medium”. After 6 weeks, 442 patients (89.5%) rated their pain as “low or none”. At 12-month follow-up, 98.6% (365/370) of patients showed solid fusion, and 1.8% (10/563) operated levels showed migration or subsidence over 2 mm.

**Conclusions:** Early-term follow-up of this series of patients found significantly improved pain scores, a high rate of bony interbody fusion, and remarkably low rates of subsidence or migration. This technique achieves stability with stand-alone interbody devices, avoiding the need for supplemental pedicle screw fixation while preserving facet articulation. This technique further offers the benefits of an open exposure; i.e. a bilateral view of the disc space after decompression allowing bilateral disc removal and ease of device insertion with minimal retraction of the neural elements using minimal incision.
Following the biomechanical testing of the intact specimens, dual geometric facet allografts (VG Innovations, Inc., Winston-Salem, NC) of appropriate sizes were inserted (Figure 1A) as per the recommended surgical procedure and the test was repeated (FSS). The facet allografts were removed and the pedicle screw system was implanted (Figure 1B) and the test was repeated.

Results: In comparison to intact, the motion of the spine stabilized with FSS reduced in ext (59%), flex (55%), lb (42%), rb (31%), lr (12%) and rr (22%), Figure 2. The corresponding values for spine stabilized with PSS were: ext (59%), flex (63%), lb (47%), rb (32%), lr (31%) and rr (48%).

Figure 2: Mean and SD motion at 8 Nm for the Intact, Facet Stabilization System (FSS) and Pedicle Screw System (PSS) [Figure 2]

The data demonstrates FSS provides comparable stabilization in flexion/extension, lateral bending and axial rotation to traditional methods (i.e., PSS). Stabilization was significant in all modes, except axial rotation. Statistically, there was no significant difference between the two stabilization systems evaluated in this study.

Discussion: The FSS is effective in restricting facet joint movement and thereby decreases the motion across segment. This method may provide stabilization and fixation for minor instabilities, which can allow the joint to fuse through integration with the allograft. This study demonstrates that the load-displacement responses of the FSS are similar to existing methods of stabilization.

CLINICAL: CERVICAL NEW MOTION PRESERVATION TECHNOLOGIES

393
Posterior Cervical Microscopic Foraminotomy and Discectomy Using CO2 Laser in Unilateral Cervical Radiculopathy

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Purpose: To evaluate the feasibility of using CO2 laser in posterior foraminotomy and discectomy. We report several operative experiences of unilateral cervical foraminal stenosis cases by using microscope and CO2 laser.

Materials and methods: 12 patients were treated by posterior foraminotomy & discectomy with microscope and CO2 laser at our hospital between 2006 and 2008. We confirmed symptomatic unilateral cervical foraminal stenosis by preoperative MRI & CT. 10 patients had been done single level foraminotomy and 2 patients had been done two level foraminotomies. In annulotomy and discectomy, we used about 300 jouls of CO2 laser energy.

Results: All patients had improved or resolved previous radicular symptoms. We confirmed that ventral foraminal lesion was removed and foraminal space was widened by postoperative MRI in all cases. Two patients had transient axial neck pain. No surgical related complications were happened in our cases.

Conclusion: In selective limited cases for unilateral cervical foraminal stenosis, the posterior foraminotomy and discectomy by using microscope and CO2 laser can be alternative useful method.

BASIC SCIENCE: BIOMECHANICS / BASIC SCIENCE

394
Performance of Cervical TDRs for Both Center of Balance and Center of Rotation in a Cadaveric Model

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Introduction: Few Cervical Total Disc Replacement (TDR) devices are engineered to address both the Center of Balance (COB) and the Center of Rotation (COR) of the cervical motion segments. The COB is the axis in the intervertebral disc through which the axial compressive load is transmitted. TDRs placed posterior of this point tend to fall into kyphosis while devices placed anterior of this point tend to fall into lordosis. Thus from a “balancing” point of view the ideal placement would be at the COB. However, the COR position has been shown to be posterior and inferior to the disc space. It has also been shown that constrained devices tend to lose motion when there is a mismatch between device and anatomic centers. Mobile core devices may be placed at the COB since their unconstrained rotations and translations allow for the device COR to follow the anatomic COR, but they rely heavily on the facet joints and other anatomic features to resist the paradoxical motion.

A new cervical TDR was introduced at SAS London that was engineered for both the COB and COR. The purpose of this study was to compare the 3D kinematic and biomechanical performance of the TriLobe to a ball and trough(BT) cervical TDR in an augmented pure moment cadaveric study to find the ideal AP implant placement.

Materials and methods: Specimen were CT imaged for three-dimensional reconstruction. Visual, CT, and DEXA screening was utilized to verify that specimens are free from any defects. Specimens were prepared by resecting all nonligamentous soft tissue leaving the facet joint capsules and spinal ligaments intact. C2 and T1 were potted to facilitate mounting in the testing apparatus (7-axis Spine Tester, Univ. of Utah, Salt Lake City, UT). OptoTRAK motion tracking flags were attached to each vertebra including C2/C3 and T1 to track the 3D motion of each vertebra.

- Specimens C2-T1.

Questions? (866) 423-9440 (U.S.) +1(630) 995-9994 (Int‘l)
• Treatment Level C5-C6.
• Insertion of fixture pins under fluoro.
• Load Control Testing to 2.5Nm in FE, LB, AR.
• 15 Pre-cycles in load control in FE / LB / AR (2.5Nm).
• Test implants in load control in FE / LB / AR to 2.5Nm for 4 cycles with data recorded for all cycles.

Results:

<table>
<thead>
<tr>
<th>Range of Motion (deg)</th>
<th>Neutral Zone Stiffness (deg/Nm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>FE</td>
</tr>
<tr>
<td>Intact</td>
<td>15.5±4.3</td>
</tr>
<tr>
<td>TriLobe - 2mm</td>
<td>25.3±1.1</td>
</tr>
<tr>
<td>TriLobe - 3mm</td>
<td>23.7±1.1</td>
</tr>
<tr>
<td>TriLobe - 4mm</td>
<td>22.1±1.4</td>
</tr>
<tr>
<td>BT - 2mm</td>
<td>24.6±2.8</td>
</tr>
<tr>
<td>BT - 3mm</td>
<td>26.6±1.4</td>
</tr>
<tr>
<td>BT - 4mm</td>
<td>24.6±1.7</td>
</tr>
</tbody>
</table>

Discussion: This study showed that the TriLobe had better control of motion compared to the ball and trough both in ROM and variability for FE, LB, and AR. The TriLobe had better control of limiting kyphosis over the ball and trough by 41% of the flexion motion. The neutral zone slope, an measure for device stability, showed that the TriLobe was 51% more stable than the BT. AP placement of devices showed there was a general trend of decreasing stability from anterior to posterior placement; however, statistical significance was not established.

CLINICAL: INNOVATIONS NON-CONVENTIONAL

398 Surgical Excision with Preoperative Embolization for Primary Sacral Tumors

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Surgical excision of sacral tumor is challenging, with multiple complications due to its uncontrollable intraoperative hemorrhage. Preoperative embolization of hypervascular spinal tumors has been known to be helpful for completing tumor resection, but few studies have reported in sacral tumor. We sought to investigate the value of surgical excision with preoperative transarterial embolization for primary sacral tumors and evaluate the outcomes. Data were obtained from a consecutive series of 60 patients with sacral tumor underwent surgical excision assisting by arterial embolization between 1992 and 2007. Evaluation parameters included intraoperative blood loss, transfusion, treatment, local recurrence, and complications associated with surgery. Of sixty patients, thirty-three were female and twenty-seven were male. All tumor masses were resected without intraoperative shock or death cases. The mean intraoperative blood loss was 1168.3 ml (200 to 5700 ml) and the mean transfusion was 5.2 units (0 to 35 units). Radical wide excision was performed in eight cases, marginal excision was performed in thirty-four cases and intralesional excision in the remaining eighteen cases. Mean follow-up was 75.2 months (range, 15 to 180 months). Nineteen (31.7%) patients developed local recurrences. Of the patients with at least second sacral roots and unilateral S3 preserved, 33 (84.6%) had normal bladder and 34 (87.2%) had normal bowel control. Preoperative arterial embolization may significantly reduce intraoperative hemorrhage and has the potential to assist surgeons in completing resection and improving outcomes of these patients.

CLINICAL: LUMBAR FUSION (I.E. MIS, TLIF, XLIF, AXIAL LIF, ALIF)

399 The Coflex F™ - A New Minimally Invasive Device for the PLIF Procedure

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Since the PLIF procedure is a very good and well established technique for the treatment of lumbar instability in combination with an additional narrowing of the spinal channel a rather big or an additional approach for the implantation of the pedicle screw based posterior part of this fusion technique is needed. With the Coflex F™ the approach is limited to the small incision that is needed for the decompression, discectomy and implantation of the intervertebral cages. From 2008 to 2010 more than 31 patients (22 male, 9 female) from 50 to 86 years were operated with discectomy, decompression, intervertebral cages (either PEEK or Titanium) and the Coflex F™. The pathologies were instability up to Meyerding 1° in combination with lumbar spinal stenosis caused by hypertrophic changes of the ligaments and/or the facet joints. The follow up period varies between 6 to 24 month. ODI, VAS and whether the patients are satisfied or not were registered for follow up after 6 weeks, 3 month, 6 month, 12 month and 24 month. A neurological examination and x-ray control were performed. There is an evidence of bridging bone even in the 6 month follow up. The clinical results are very good and good in 83% and fair in 17 % after 24 month. Even if the amount of patients is very limited the results are very encouraging. Further investigation also with a bigger amount of patients is necessary.

CLINICAL: PROSTHESIS

400 Prospective Randomized Series Comparing Maverick™ Lumbar Total Disc Replacement (TDR) with Anterior Lumbar Interbody Fusion (ALIF): Five Year Follow up

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Introduction: The data reported in this abstract is from an IDE clinical trial with a minimum five-year follow-up comparing the Maverick (25 patients) with an ALIF utilizing an LT-CAGE® with INFUSE® Bone Graft (11 patients). Methods: Patients were blindly randomized 2:1 (Maverick:ALIF). Indications for surgery were similar to lumbar fusion. Inclusion/Exclusion criteria will be discussed. All surgeries were one-level L4-5 (7) or L5-S1 (29). Average...
Patient age was 43 in both groups (range 21-55), with an average BMI of 24 (range 21-27). Surgical technique will be discussed.

Average operating time was 99 minutes (range 68-118) for the Maverick and 60 minutes (range 53-112) for the ALIF. Blood loss averaged 20cc for Maverick and 78cc for ALIF. Average hospital stay for both groups was 1.6 days (range 1-4).

Time to unrestricted activity averaged six weeks in the Maverick group and six months in the ALIF group.

Results: All 25 Maverick patients had two-year follow-up and 19 patients had five-year follow-up. Ten of the 11 ALIF patients had two-year follow-up and seven patients had five-year follow-up.

Maverick pre-op Oswestry Disability Index (ODI) was 56; One-year ODI was 15; Two-year ODI was 15 for an average improvement of 74% (P< 0.001). The five-year ODI average was 9.6 (P< 0.001). ALIF pre-op ODI mean was 58; One-year ODI was 35; Two-year ODI was 41 for an average improvement of 29% (P< 0.05). The five-year ODI average was 38.3.

Maverick pre-op mean Visual Analog Scale (VAS) was 7; One-year VAS was 3; Two-year VAS was 2 for an average improvement of 71% (P< 0.001). The five-year VAS was 1.5 (P< 0.001). ALIF pre-op VAS was 8; One-year VAS was 5; Two-year VAS was 6 for an average improvement of 25% (P< 0.04). The five-year VAS was 6.

Fourteen of the 19 Maverick patients had an ODI less than 10 and a VAS less than two at five-year follow-up. FDA definition of clinical success was achieved in 84% of the Maverick patients and 55% of the ALIF patients.

One Maverick patient required reoperation for an infection 18 months post op. Three of the 11 patients in the ALIF group required posterior fusion for pseudoarthrosis (27%). One additional patient is awaiting posterior fusion.

Overall patient satisfaction, based on FDA criteria, was 95% for the Maverick TDR and 78% for the ALIF group.

Conclusions: These Maverick TDR results are similar to those reported by six other IDE sites at two-year follow-up. The combined results of 173 Maverick patients from seven IDE sites indicate statistical superior clinical outcomes compared to ALIF at one-year, and two-year follow-up (P< 0.001). This class I data reporting five-year follow-up results indicates no change from the two year results.

**BASIC SCIENCE: POSTERIOR DYNAMIC PEDICULAR STABILIZATION**

408

A Comparison of Anterior Column Load-sharing and Load Distribution Following Rigid and Semi-rigid Fixation Techniques: Material, Implant Design and Biomechanics

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Load-sharing through the anterior column is an important biomechanical factor which may directly affect fusion success and future disease progression following spine surgery. It has implications as to the longevity of implants, directly through screw loosening and breakage, and indirectly through altered biomechanics associated with stress shielding of that level. It has been postulated that semi-rigid or dynamic fixation provides more load-sharing in the anterior spinal column, a potentially advantageous benefit for both fusion and reduction of adjacent level stresses. In this study, the authors evaluated load-sharing of a novel posterior dynamic stabilization (PDS) system, TRANSITION®.

The regional load distribution on an interbody spacer was compared between rigid, semi-rigid PEEK, and semi-rigid dynamic posterior instrumentation (Figure 1). Load-sharing was quantified through a digital pressure film positioned on the spacer. The mechanical test fixtures, and instrumentation complex underwent simulated flexion of 12.8 Nm through three cycles of neutral-flexion-neutral. The pressure at maximum flexion of the last cycle was used for data analysis.

The force through the entire spacer was used to determine the percentage of anterior and posterior column loading as a fraction of the applied load. Load not passing through the pressure film (located in the anterior column) was considered to pass through the posterior instrumentation. The anterior column load-sharing was 55%, 59%, and 75%, for rigid rods, PEEK rods, and posterior dynamic stabilization, respectively. The posterior dynamic stabilization system transferred statistically more load to the anterior column than rigid or PEEK rods. Rigid and PEEK rods did not statistically differ in their ability to transfer load through the anterior column.

The load distribution across the interbody spacer area proved...
to be more uniform with posterior dynamic stabilization when compared to semi-rigid PEEK or rigid fixation as evidenced by Figure 2. Due to the predefined clearance of 400µm between the upper text block and sensing pad, load was first transmitted into the anterior portion of the spacer. With rigid and PEEK rods, minimal load was transferred to the posterior aspects of the spacer. Dynamic stabilization and rigid rods have similar pressures on the anterior region of the spacer, but differ dramatically in the posterior, left, and right portions of the spacer, which are much more uniform, and statistically higher for PDS when compared to rigid rods. One difference between the PDS device in this study and conventional designs is a cord imbedded within titanium spools which allow some travel or sliding to compress and engage the soft bumper. This effect may have helped to redistribute the loads.

**BASIC SCIENCE: BIOMECHANICS / BASIC SCIENCE**

**409**

**Tolerance and Shape Selection in Patient-specific Drilling Templates**


1The Howard Hughes Medical Institute through the Undergraduate Science Education Program and from the Arizona State University School of Life Sciences, Tempe, AZ, USA, 2Barrow Neurological Institute, Spinal Biomechanics Laboratory, Phoenix, AZ, USA

**Introduction:** With recent development of modern technology for easily converting CT images to computerized and physical models, researchers and clinicians have introduced patient-and site-specific drill templates for placement of pedicle screws and other bone screws. The use of a physical site-specific drill guide during surgery helps decrease the intraoperative pedicle screw trajectory error rate, as well as operating time and fluoroscopic exposure to the patient and medical staff. For optimal accuracy, the apposing three-dimensional model with embedded drill guide must conform to the intended bone uniformly and unambiguously. The purpose of this study was to measure and optimize the contact between three-dimensional models created to appose lumbar vertebrae, and to compare 4 template designs to determine the minimum bone contact area that still allows unambiguous positioning.

**Methods:** Axial computerized tomography (CT) images of a human cadaveric (Male, 39 years-old) L5 vertebra were obtained and 3D physical models that conformed to the area around the pedicle screw entry region were created using CT conversion software (ScanIP, Simpleware, Exeter, UK), computer aided design software (SolidWorks, Concord, MA) and a 3D printer (Spectrum Z510, ZCorporation 3D technologies, Burlington, MA). Four template shapes were devised and a series of four 3D models of each shape were created with varying offsets to measure their tangency. Offset was adjusted by altering conversion threshold and applying software filtering to subtract volume from the tool surface. The L5 soft tissue was removed to determine the closest intersection between bone and template surfaces of varying offsets. The best junction was measured by placing a fixed amount (2.0g - 4.0g) of plasticine between the tool and the bone, then manually pressing the tool and bone together with a consistent force. It was determined that the least amount of plasticine left on the formed conjuncture (Δ plasticine weight before and after tool articulation) demonstrated the most contact between the offset of the tool and the pedicle screw entry point on L5.

**Results:** Comparison of 20 3D models with 4 shapes and varying offsets (0.125mm - 0.750mm) revealed that the model with the most anatomically advantageous shape (Fig. 1C) achieved the highest plasticine displacement (mean±standard deviation 85±6%) at an offset of 0.125mm.

**Conclusion:** A unique method used for assessing tangency between 3D models intended to appose a cadaveric lumbar vertebra is described. Using this method, a patient-specific template shape that is appropriate for unilateral pedicle screw insertion and has optimal bone gripping properties was identified. Future research will incorporate this template design in experiments to assess ease and accuracy of template-assisted pedicle screw insertion.

**Fig. 1. 4 Template shapes that were tested.**

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**BASIC SCIENCE: CERVICAL NEW MOTION PRESERVATION TECHNOLOGIES**

**412**

**Dynamic Cervical Stabilization: A Novel, Motion-preserving Alternative to Fusion and Articulating Total Disc Replacement**

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**Intro:** Fusion may contribute to adjacent segment disc degeneration while motion preserving alternatives, such as total disc replacement(TDR) are associated with index level facet arthrosis. Dynamic cervical stabilization with...
the Dynamic Cervical Implant (DCI) is a novel motion-preserving concept that facilitates controlled, limited flexion and extension, with restriction of axial rotation and lateral bending motions. The objective of the current study was to evaluate loading at the index and adjacent levels after fusion, TDR, and implantation of the DCI (Paradigm Spine) under both load and displacement control scenarios. We hypothesized that the DCI would reduce or maintain index level facet contact forces compared with the intact condition and TDR, while affording relative protection of the adjacent levels compared with fusion.

**Methods:** An intact finite element model of C4-C7 was utilized. The C5-C6 level was altered to include an intact spine, ideal fusion, DCI, and TDR(Fig1). Fusion was simulated by setting the disc material properties to match the bony endplate. Models of DCI and TDR devices were virtually implanted at C5-C6. Displacement-controlled hybrid loading was applied to the implanted models. Additionally, a 100 N compressive follower load with 2.5 Nm pure moments in flexion, extension, lateral bending, and axial rotation was applied. Rotational range of motion(RoM), facet contact force, and adjacent segment disc resultant forces were determined.

**Results:** In general, TDR resulted in increased mobility at the index level during both load and displacement-controlled scenarios. The increased rotational RoM after TDR observed for extension, axial rotation, and lateral bending was associated with increased facet contact loading(Fig2). Conversely, DCI maintained limited RoM at the index level compared with TDR but prevented facet contact in all loading modes. Displacement control indicated increased loading at the adjacent segments for fusion when compared to both DCI and TDR(Fig2).

**Discussion:** Our results demonstrate that by providing limited subaxial motion in the sagittal plane (flexion and extension) but limiting axial rotation and lateral bending, the DCI facilitates protection of the index level facet joints, while at the same time protecting the adjacent levels from excessive stresses. We submit that from a biomechanical perspective, the DCI serves as a compromise between rigid fixation with ACDF, and the potential hypermobility demonstrated with TDR. By protecting the facet joints the DCI may serve as an alternative to TDR, and further, may provide a motion-preserving alternative to patients with pre-existing facet arthrosis who are currently contra-indicated for TDR.
was +2.1° preoperatively and -8.4° postoperatively. Mean postoperative evaluation the good positioning of the was possible and pain was controlled in every cases. On Results:

vertebral body height. Measurement of local sagittal deformity and restitution of postoperative evaluation was clinical and radiological with complementary anterior access for intervertebral grafting. treated by a two-step procedure. Firstly a posterior percutaneous osteosynthesis, completed by a

Discussion: The results demonstrate that a pedicle invasive method for deformity correction and spinal fixation in septic conditions in association with a anterior graft provides satisfactory clinical and radiographic results. It provides an interesting alternative for deformity correction and spinal stabilization with a minimal invasive access in patients with comorbidities.

Discussion: The results demonstrate that a pedicle screw-based SRSS mitigates strain maxima near the screws when compared with PEEK or Titanium rods, while also reducing the presence of bone resorption signal(stress shielding) in the anterior vertebral body. We conclude that compared with PEEK and Ti rod systems, SRSS may provide a “soft landing” in osteoporotic spines, thereby reducing the likelihood of screw pullout and fracture in this patient cohort, while at the same time minimizing stresses transferred to the adjacent levels by facilitating motion at the operative level.

CLINICAL: MIS FUSION-STABILIZATION

Minimal Invasive Spinal Fixation in Septic Conditions

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Background and purpose: Management of pyogenic spondylodiscitis in adults is still controversial at the moment. The aim of this study is to evaluate the results of a minimal invasive method for deformity correction and stabilization of these lesions by a percutaneous osteosynthesis.

Methods: Ten patients were included in this study and treated by a two-step procedure. Firstly a posterior percutaneous osteosynthesis, completed by a complementary anterior access for intervertebral grafting. Postoperative evaluation was clinical and radiological with measurement of local sagittal deformity and restitution of vertebral body height.

Results: On the whole series, bacteriologic identification was possible and pain was controlled in every cases. On postoperative evaluation the good positioning of the implants was always verified. Mean local sagittal deformation was +2.1° preoperatively and -8.4° postoperatively. Mean increase of the vertebral body height was measured at 8mm postoperatively. At last follow-up a moderate loss of correction was noticed (with a mean of 2° and 3mm) and all patients but one showed a solid bony fusion..

Conclusion: The realization of a percutaneous osteosynthesis in septic conditions in association with a anterior graft provides satisfactory clinical and radiographic results. It provides an interesting alternative for deformity correction and spinal stabilization with a minimal invasive access in patients with comorbidities.

CLINICAL: PROSTHESIS

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Clinical Performance of an Elastomeric Lumbar Disc Replacement 24 Months Following Surgery
L. Oliveira1, L. Marchi1, E. Coutinho1, L. Pimenta1,2

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Aim: Elastomeric lumbar disc replacements have been developed as a means to restore the normal shock absorption properties and physiologic center of rotation of the involved level. The Physio-L® is an elastomeric lumbar disc prosthesis which uses compliant polycarbonate polyurethane as the core material and has been designed to have enhanced endurance properties. A multi-center clinical trial is underway to determine the safety of the device in-vivo and the present study reports the 24 month clinical results.

Methods: Eighteen patients presenting with degenerative disc disease were treated by one of two surgeons at two clinical sites. Thirteen patients received treatment at a single level (L5-S1) while five patients received treatment at two levels (L3-L4/L5-S1, or L4-L5/L5-S1). All patients were assessed pre-operatively, and at 6 weeks, 3, 6, 12 and 24 months. Clinical outcome measurements included patient self assessment scores forVAS and ODI. Adverse events were monitored intra-operatively and at all follow up evaluations.

Results: Of the 18 patients, 14 were male and 4 were female. The patients had an average age of 39.2 years (range 25-55) and an average BMI of 25.4 (range 19.4-31.6).

Clinical outcomes: At the 24 month follow up evaluation, the VAS back pain score improved 65% and ODI scores improved 68% when compared to baseline. At the 24 month follow up evaluation, the VAS back pain score improved 80% and ODI scores improved 78% when compared to baseline. Statistically significant differences were observed at all follow-up intervals when compared to the preoperative scores.

Radiographic outcomes: There were no failures or migration of the implanted devices and all of the prostheses are mobile in flexion/extension. One patient has experienced caudal subsidence greater than 2mm.

Adverse events: During the surgical procedure, two patients lost greater than 1500ccs of blood requiring transfusion and one patient experienced vascular damage at L4-L5 that required further surgery to repair. These events were resolved without further incident and did not result in any adverse clinical effect post-operatively. At the six month follow up evaluation, one patient experienced retrograde ejaculation.
which was resolved at 12 months.

**Conclusions:** This study is the first to report 24 month clinical results on the next generation of total disc prostheses. While a longer term follow up of these patients is necessary, the initial two-year clinical data for the Physio-L lumbar disc suggests that elastomeric discs may provide a superior approach to treating degenerative disc disease.

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**CLINICAL: DEFORMITY**

432  
Common Mathematical Formulas Fail to Predict Postoperative Sagittal Alignment: Confirmation of a Need for More Advanced Equations  

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**Introduction:** Failure to achieve optimal sagittal alignment after spinal fusion correlates strongly with poor clinical outcomes. Mathematical models have been proposed to predict optimal postoperative sagittal vertical axis (SVA) following pedicle subtraction osteotomy (PSO). Most formulas fail to evaluate pelvic tilt and the compensatory interplay between the spine and pelvis in response to regional alignment changes. The purpose of this study is to provide a comparative evaluation of mathematical formulas in predicting good/bad postoperative spinopelvic alignment following PSO surgery.

**Methods:** Multicenter, radiographic evaluation of a large consecutive series of PSO procedures. The ability of 5 mathematical models to predict postoperative SVA category (poor / good, cutoff=5cm) following PSO was evaluated by comparing predicted categories to post-operative radiographic measurements.

**Results:** 147 patients, mean age 52 yrs (SD, 15 yrs) received 147 PSO (42 thoracic, 105 lumbar). Mean number of levels fused was 12.6 (SD, 3.8 levels). Mean pre and postoperative SVA were 108 mm (SD 95 mm) and 30 mm (SD 60 mm; p< 0.001). 47 patients had postoperative SVA>5cm. Each mathematical formula provided unique prediction for postoperative spinal alignment and adjusted for the interplay between spine and pelvis based upon regional alignment changes leading to optimal prediction of post-operative SVA.

<table>
<thead>
<tr>
<th>Equation</th>
<th>Correct prediction (%)</th>
<th>Correct prediction of poor SVA (%)</th>
<th>Correct prediction of good SVA (%)</th>
<th>Spine score</th>
<th>Mean SVA prediction</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) LL ≥ TK + 20</td>
<td>62</td>
<td>63</td>
<td>51</td>
<td>0.37</td>
<td>NA</td>
</tr>
<tr>
<td>(2) PSO angle &gt; 20°</td>
<td>72</td>
<td>98</td>
<td>59</td>
<td>0.75</td>
<td>11mm</td>
</tr>
<tr>
<td>(3) LL = TK ≥ 40</td>
<td>74</td>
<td>78</td>
<td>97</td>
<td>0.97</td>
<td>NA</td>
</tr>
<tr>
<td>(4) LL = TK ≥ 30</td>
<td>78</td>
<td>79</td>
<td>78</td>
<td>0.95</td>
<td>NA</td>
</tr>
<tr>
<td>(5) TK ≥ 42.5° or 5.00-PR &lt; 4.11•LPM - 6.89•PR &lt; 2.09•LPM +</td>
<td>109</td>
<td>70</td>
<td>98</td>
<td>0.75</td>
<td>35mm</td>
</tr>
</tbody>
</table>

**Conclusion:** Preoperative planning is essential to optimize postoperative spinal alignment. Mathematical models that do not account for pelvic geometry and orientation poorly predict postoperative alignment and may predispose to poor clinical outcome. Formula 5 incorporated spinopelvic parameters and adjusted for the interchange between spine and pelvis based upon regional alignment changes leading to optimal prediction of post-operative SVA.

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**BASIC SCIENCE: FUSION**

433  
A Novel, Simple Method to Salvage Stripped Lateral Mass Screws in the Subaxial Cervical Spine Using the Screw Sock™  
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Lateral mass screws are the gold standard for achieving spinal fixation in the subaxial posterior cervical spine (C3-C7) for spinal fusion constructs. In the setting of a failed or stripped lateral mass screw, the limited amount of local host bone often precludes redirecting the screw using an alternate trajectory in order to gain satisfactory screw purchase. Further, the use of a larger “salvage” screw, a technique commonly employed in stripped thoracic and lumbar pedicle screws, is of limited utility in the posterior cervical spine as a result of loss of local bone during the initial attempt at screw insertion. Therefore, the search continues for optimal lateral mass screw salvage strategies that do not require use of a larger screw. The objective of this study was to evaluate the biomechanical performance profile of the Screw Sock™, a combination mono- and multifilament polyethylene terephthalate (PET) device that is placed between the screw and the stripped hole in an attempt to increase the interference fit and screw pullout forces.

Six female cadaveric spines (ages: 46-60; BMI: 23.9-32.3) were procured and imaged with quantitative CT to assess bone density (range: 314-433mg/cm²). C3-C7 lateral mass screw holes were prepared using the Magerl technique by a fellowship-trained spinal surgeon. Test A compared the pullout force of a stripped 3.5mm screw and a stripped 3.5mm screw augmented with Screw Sock™. Test B compared a 4.0mm screw and stripped 3.5mm screw augmented with Screw Sock™. Test C compared an intact 3.5mm screw and a 3.5mm screw augmented with Screw Sock™. Using a servohydraulic load frame, each screw was removed at a rate of 5mm/min per ASTM F543-07 and and

Questions? (866) 423-9440 (U.S.) +1(630) 995-9994 (Int’l)
the maximum axial force was reported. A total of 56 fixation points were available for evaluation. For Test A, the Screw Sock™ increased pullout strength compared with the stripped screw by 49.5%(102.3N vs. 152.9N, Figure 1). For Test B, Screw Sock™ achieved 84% of the pullout force of a larger 4.0mm rescue screw (86.6N vs 103.3N). When the data from Test A and B were pooled, however, Screw Sock™ increased pullout forces compared with the rescue screw by 15.8%(119.8N vs. 103.3N). In Test C, Screw Sock™ increased pullout forces compared with the intact 3.5mm screw by 14.7%(229.0N vs 199.6N, Figure 2). This simple, efficient device warrants further study as a cost-effective and highly versatile means to salvage stripped screws in the spine without needing to convert to a larger screw, or potentially as a primary screw augmentation device in patients with compromised bone quality (i.e. osteoporosis).


Materials and methods: Fifteen health adult sheep were divided into three experimental groups and tested:
(a) control group: Intact (n=5);
(b) injury group: destabilized by means of complete resection of the cervical spine ligament complex of C3-4(n=5);
(c) tendon reconstruction group: stabilization with heterograft bio-derived freeze-dried tendon, which were cross-fixed with “8” shaped in the 3-4 cervical bilateral facet joints(n=5). The sheep were euthanized at 12 months after surgery. The biomechanical testing mainly evaluate the range of motion (ROM) under series of pure moments cycled from 0.75 to 3.5 Newton-meter for flexion, extension, right and left lateral bending, and axial rotation on a test apparatus. Statistical analysis was performed respectively (P< 0.05, ANOVA). In histological evaluation, HE, Masson and Immunohistochemical staining were performed. This study protocol has been approved by the Animal Experiment Ethics Committee of West China Hospital, Sichuan University in Chengdu, China.

Results: Biomechanics observation indicated that, compared with injury group, the novel fixation in tendon reconstruction group can provide enough stability in flexion motion, and do not limit the lateral bending and axial rotation motion. The values of ROM in tendon reconstruction group were closed to control group (P>0.05). On histological observation, in the tendon reconstruction group, the healing tissue showed regeneration of neovascularization. The bone-tendon interface had developed into dense connective tissue with little inflammatory cell infiltration. The transition zones of collagen fibers, fibrocartilage and bone occurred in the local region of tendon-bone interface. The collagen fibers were formed in abundance and regularly arranged.

Discussion: This novel fixation may provide enough stability and motion preservation. The bio-derived frozen dried tendon showed a good biocompatibility and ability of regeneration in animal model. Further study is needed to determine whether the cervical posterior fixation with other material may prove more promising for cervical dynamic stability reconstruction.

Keywords: Cervical posterior fixation; ligament complex; bio-derived tendon; histology; biomechanics

BASIC SCIENCE: INNOVATIONS NON-CONVENTIONAL

437
Long Term Study: A Novel Cervical Spine Posterior Fixation Using Bio-derived Tendon in the Goat Cervical Ligament Complex Injury Model
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¹West China Hospital, Sichuan University, Department of Orthopedics, Chengdu, China, ²No.363 Hospital, Chengdu, China
Purpose: A prospective, randomized IDE clinical trial is being conducted to assess the safety and effectiveness of the FLEXUS™ Interspinous Spacer for the treatment of lumbar spinal stenosis. This IDE study compares the clinical results of patients treated with the investigational FLEXUS™ device as compared to patients treated with the PMA-approved XSTOP device. Pooled data from the four top enrolling centers are presented.

Methods: The clinical trial is being conducted at up to 20 sites across the United States. Patients are randomized 1:1 to either the investigational FLEXUS™ device or the control XSTOP treatment. Patients suffering from lumbar spinal stenosis as defined by leg, buttock or groin pain, with or without back pain, that relieves during flexion, at one or two contiguous levels, were enrolled in the study. Zurich Claudication Questionnaire (ZCQ) scores, Visual Analog Scale (VAS) back and leg pain, SF-36 Health Status Survey, Owestry Disability Index (ODI) scores and patient satisfaction are collected pre-operatively and at 6 weeks, 3 months, 6 months, 1 year and 2 years post-operatively. A total of 89 patients have reached the 12 month follow-up visit, 43 treated with FLEXUS™ and 46 with XSTOP. Outcome data from these patients are presented.

Results Summary: Both treatment groups demonstrated an improvement in ZCQ scores at 12 months postoperatively. Average ZCQ (symptom severity) for FLEXUS™ patients was 3.0 (±0.6) preoperatively, reduced to 1.9 (±0.9) at 12 months, compared to XSTOP patients with average scores of 3.2 (±0.6) at preop and 2.0 (±0.7) at 12 months. Average ZCQ (physical function) for FLEXUS™ was 2.5 (±0.4) preoperatively and 1.6 (±0.7) at 12 months, compared to 2.5 (±0.6) preoperatively and 1.5 (±0.5) at 12 months for XSTOP. Average ZCQ (satisfaction) at 12 months was 1.8 (±0.9) for FLEXUS™ and 1.6 (±0.7) for XSTOP. VAS back and leg pain scores showed improvement in both cohorts. Average VAS back pain scores for FLEXUS™ were 54 (±30.8) preoperatively, reduced to 24.5 (±32.7) at 12 months, in comparison with XSTOP with 50 (±30.8) and 17.8 (±25.9), respectively. Average VAS left leg pain scores for FLEXUS™ were 49 (±33.2) preoperatively, reduced to 14.7 (±24.3) at 12 months, in comparison with XSTOP with 46 (±34.3) and 10.4 (±20.2), respectively. Average VAS right leg pain scores for FLEXUS™ were 48 (±33.0) preoperatively, reduced to 16.8 (±28.5) at 12 months, in comparison with XSTOP with 51 (±31.7) and 9.8 (±17.2), respectively. Similarly, ODI and SF-36 MCS improved for both groups at 12 months compared to baseline. Six investigational FLEXUS™ patients underwent device removals; five of these removals were due to ongoing or recurrent back and/or leg pain and one as a result of a spinous process fracture. Two XSTOP devices were removed due to ongoing or recurrent back and leg pain. Two FLEXUS™ patients received supplemental fixation at the treated level due to radiculopathy and continued back pain.

Conclusion: The FLEXUS™ and XSTOP treatment groups experienced improvement in both pain and function at 12 months as compared to the pre-operative baseline. Interspinous distraction appears to be a viable alternative for the treatment of spinal stenosis. Continued follow-up data is needed to determine long-term safety and efficacy of the FLEXUS™ Interspinous Spacer.
At 12 months, Barricaid patients exhibited lower VAS back scores (13.2 vs. 23.8, p=0.019), lower VAS ipsilateral leg scores (3.9 vs. 16.3, p=0.002), and similar ODI scores (15.6 vs. 19.3, p=0.317). Defining clinical significance as a reduction of at least 20 points in VAS or at least 15 points in ODI, all implanted patients exhibited clinically significant reductions in VAS ipsilateral leg (vs. 82% control) and ODI (vs. 80% control). 93% demonstrated a clinically significant reduction in VAS back (vs. 54% control).

These trends continued at 24 months post-op. Barricaid patients exhibited lower VAS back scores (9.1 vs. 19.2, p=0.1294), lower VAS ipsilateral leg scores (6.9 vs. 20.8, p=0.0063), and lower ODI scores (9.6 vs. 18.9, p=0.0711). All implanted patients exhibited clinically significant reductions in VAS ipsilateral leg (vs. 74% control), ODI (vs. 79% control), and VAS back (vs. 66% control).

Control patients have lost an average of 13.5% of their preop disc height by 12 months, compared to 9.6% for Barricaid patients. At 24 months, control patients lost 15.8% of their preop disc height vs. 10.3% for Barricaid patients.

**Discussion:** Implantation of the Barricaid has been shown to be safe and easy, with no implantation failures, and no device-related adverse events at any timepoint. To date, the device is performing its function of retaining nuclear material within the disc, and the implanted patients have experienced excellent clinical outcomes superior to control, particularly in VAS back scores.

**CLINICAL: DEFORMITY**

442 Thoracic Pedicle Subtraction Osteotomy for Adult Spinal Deformity Improves Regional Spinal Deformity and Pelvic Tilt


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**Introduction:** Thoracic pedicle subtraction osteotomy (TPSO) can correct rigid thoracic deformity with significant focal correction. However, little data exists on the impact of TPSO upon global spinopelvic parameters. The purpose of this study was to evaluate the radiographic outcome of TPSO on regional and global spinopelvic alignment.

**Methods:** This was a multicenter, retrospective radiographic analysis of adult spinal deformity (ASD) patients receiving TPSO. Analysis included focal and regional measures (kyphosis and scoliosis at TPSO site) thoracic kyphosis (TK), thoracolumbar kyphosis (TLK), lumbar lordosis (LL), global measures: sagittal vertical axis (SVA), T1 and T9 spinopelvic inclination (SPI), and pelvic measures: pelvic tilt (PT), pelvic incidence (PI) and sacral slope (SS).

**Results:** Between 2003-2009, 41 patients received TPSO for ASD. Deformities included; primarily sagittal (n=21), coronal (n=13), and multiaxial (n=7) deformities. Resection levels ranged from T2 to T12; T8 was most common level (n=9). Mean sagittal correction for primary sagittal deformities was 34 degrees. Mean coronal correction for primary coronal deformity was 43 degrees. Mean total angular correction (sagittal + coronal correction) for multiaxial deformities was 76 degrees. Postoperative TK, TLK and SVA were significantly less than preoperative values (Table). Mean SVA correction was 26 mm. Postoperative TK improvement generated favorable PT correction (Table).

**Conclusion:** TPSO corrects regional and global spinal deformities. Total angular correction for all patients was 54 degrees, SVA correction was 26mm. Focal thoracic correction generated improved pelvic parameters including improved PT. Regional improvements in spinal balance following TPSO favorably impact the pelvis allowing postoperative normalization of pelvic parameters. Normalization of pelvic parameters, especially PT, has been shown to correlate with improved clinical outcome.

<table>
<thead>
<tr>
<th></th>
<th>Pre-op</th>
<th>Post-op</th>
<th>Change</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thoracic kyphosis</td>
<td>62</td>
<td>37</td>
<td>-25</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Thoracolumbar kyphosis</td>
<td>15</td>
<td>6</td>
<td>-9</td>
<td>0.006</td>
</tr>
<tr>
<td>Lumbar Lordosis</td>
<td>-63</td>
<td>-60</td>
<td>-3</td>
<td>NS</td>
</tr>
<tr>
<td>SVA (mm)</td>
<td>24</td>
<td>-2</td>
<td>-26</td>
<td>0.002</td>
</tr>
<tr>
<td>T1 SPI</td>
<td>-16</td>
<td>-10</td>
<td>5</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>T9 SPI</td>
<td>-16</td>
<td>-10</td>
<td>5</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Sacral Slope</td>
<td>36</td>
<td>40</td>
<td>4</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Pelvic Tilt</td>
<td>15</td>
<td>11</td>
<td>-4</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Pelvic Incidence</td>
<td>51</td>
<td>51</td>
<td>0</td>
<td>NS</td>
</tr>
<tr>
<td>Max Cobb angle</td>
<td>56</td>
<td>54</td>
<td>-2</td>
<td>&lt; 0.001</td>
</tr>
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</table>

[Pre- and Post-Op Parameters]

**CLINICAL: FUSION**

444 The Use of rh-BMP2 in Standalone eXtreme Lateral Interbody Fusion (XLIF) Clinical and Radiological Results after 24 Months Follow-up

L. Oliveira¹, L. Marchi², E. Coutinho³, L. Pimenta¹,²

¹Instituto de Patologia de Coluna, São Paulo, Brazil, ²University of California - San Diego, San Diego, CA, USA

**Introduction:** The eXtreme Lateral Interbody Fusion technique (XLIF®) is a safe and effective procedure for minimally invasive treatment of various spinal conditions. The XLIF allows for easier, less invasive true lateral access to the disc space. Lateral implantation also preserves the stabilizing ligaments, and the footprint of the device capitalizes on the biomechanical support of the ring apophysis, allowing its use without the need of additional supplementation. Due the emphasis on
minimizing the invasiveness of the technique and for being considered as good as autograft, rh-BMP2 was used as bone graft to achieve fusion

**Methods:** A prospective, non-randomized study was conducted in a single center site. 15 patients underwent spinal fusion for single level DDD (L4-L5). None of the patients presented major osteoporosis condition or previous fusion surgery at L4-L5. Within the cases, 7 patients were male and 8 female, with a mean age of 45.7 (26-69 years). All patients completed two years follow up. Radiological exams, such as X-ray and CT scans, neurological examination, and clinical outcome assessment using Oswestry Disability Index and VAS scores were performed at the preoperative and 1, 6 week, 3, 6, 12 and 24 months after surgery. The XLIF® procedure was done through the retroperitoneal space and through the Psoas muscle to access the anterior spine, avoiding vascular lesions, and avoiding neural damages using nerve avoidance monitoring system (NeuroVision®). A partial discectomy was done and the end-plates were cleaned preserving the spinal ligaments, keeping the spine more stable than the traditional anterior surgery. A large peek cage was filled with synthetic bone graft containing rh-BMP2 (Infuse®) and inserted into the disc space. All procedures were standalone constructions without the need of supplementation

**Results:** The procedures were performed without major complications in an average 67.3 minutes and with less than 50cc blood loss. VAS and Oswestry scores statistically improved from preoperative to postoperative assessments. After surgery, was possible to observe 1 case (6.7%) of subsidence. Two patients had additional surgery (13.4%), one direct decompression due congenital small pedicle screws and other due excessive bone formation that compressed the nerve root. All patients presented some source of bone formation 12 months after surgery, showing the efficacy of the stand alone procedure

**Discussion and conclusion:** Using the stand alone XLIF® procedure we were able to treat single level DDD in a minimal invasive way, targeting the disc space without the risks and morbidity associated with other fusion techniques. The technique provided pain relief and improvement in physical disability assessments. The study revealed that it is possible to treat DDD with standalone anterior spine fusion via lateral approach, which allowed rapid and efficient spine fusion with the use of a biological bone graft. The use of this technique improves patient’s recovery and allows bone formation, reducing surgery costs due to a shorter hospital stay, less material implanted and the needless presence of an access surgeon.

**CLINICAL: FUSION**

**447**

**Standalone Anterior Interbody Fusion Procedure for the Treatment of Low Grade Spondylolisthesis**

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**Background:** Spondylolisthesis may cause local instability, facet distraction, and central and foraminal stenosis. The most used surgical option is a posterior slippage reduction and stabilization by pedicle screws and rods, but the literature reports increased postoperative complications on these techniques. Here, we propose an anterior one-stage approach for the treatment of spondylolisthesis without the need of direct decompression of the neural structures and posterior supplementation.

**Methods:** Five patients and six lumbar levels were treated by one-stage anterior approach, through a mini-ALIF procedure. It was utilized a special interbody cage, which has two screws that fixes at the upper vertebral body and one fenestrated screw that reaches the lower vertebral body. All screws pass through the device. Pre, intra and postoperative early, 6 weeks, 3 and 6 months data were collected, including radiological and clinical outcomes.

**Results:** Three patients were enrolled in this series, and four lumbar levels were treated (3 were L5S1 and one L4L5). The average surgical time was 110 minutes and no intraoperative complications occurred. In all cases were achieved the surgical objectives: disc height gain, vertebra slippage correction, spine level stabilization, axial and/or radicular pain reduce.

**Conclusion:** Low grade spondylolisthesis was treated using stand alone anterior interbody fusion device without posterior decompression and supplementation. Good clinical and radiological results were achieved, providing the efficacy of the procedure in the treatment of different spondylolisthesis etiologies. Long term follow up evaluation is still needed to testify the efficacy of the proposed treatment.

**CLINICAL: CERVICAL NEW MOTION PRESERVATION TECHNOLOGIES**

**451**

**Image Friendly Peek-ceramic Cervical Total Disc Replacement: One Year Experience**

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2University of California - San Diego, San Diego, CA, USA

**Introduction:** Many surgical options are available for the treatment the cervical spine disease. Total disc replacement has been reported to restore motion in the cervical spine, avoiding some complications of fusion like adjacent level disease. The disc incorporates a ceramic-on-ceramic design that it is believed to increase durability and eliminates the potential problems of wear debris from other bearing surfaces such as polyethylene. And this ceramic ball and socket in a peek core reduces MRI artifacts, improving postoperative radiological analysis. In pre-clinical testing, this TDR was favorably compared to other artificial discs currently in FDA clinical studies. It is also designed to ensure proper placement because of its “self-centering” feature. The purpose of this study is to evaluate the indications, pain relief, radiographics, surgical technique and outcomes of the cervical disc replacement utilizing the novel peek-cervical system.
Methods: 15 patients with moderate forms of cervical disc degeneration underwent a total of 16 cervical total disc replacements from C4-C5 to C7-T1. The mean age was 43 years old (28 to 60 years). 13 patients presented with degenerative disc disease and 2 patients with adjacent level disease, with one Klippel Feil case. Neural decompression was performed in standard Smith-Robinson technique. Radiographic and clinical outcomes were collected preoperatively, at 1 week, at 1, 3, 6 and 12 months postoperatively. The Neck Disability Index (NDI) and Visual Analog Scale (VAS), TIGT questionnaires and EuroQol (EQ-5D) were used to access pain and functional outcomes.

Results: At twelve months follow-up, the ROM was not statistically different from preoperative evaluations. The sagittal alignment was satisfactory maintained. Mean blood loss was 118 cc (range < 50 to 550 cc). Mean length of surgery was 106 minutes (range 80 to 210 min). No intraoperative complications occurred. All outcomes assessment showed statistically differences during all the postoperative follow-up periods.

Conclusions: Following cervical arthroplasty with the image-friendly peek ceramic disc, radiographic and clinical outcome measures were encouraging. We are able to say that this cervical artificial disc is a good and effective option for the treatment of painful cervical disc disease associated or not with radiculopathy. This is the first report about a ceramic prosthesis option for total disc replacement, providing to be a valuable alternative to other metal discs, generating better postoperative image control and good clinical outcomes.

CLINICAL: COMPLICATIONS

456
Complications on Lumbar Arthroplasty - What Can Be Done to Improve Results?
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Introduction: The lumbar degenerative disc disease has been treated over the years with methods of stabilization and it has presented good results, but the completely lost of motion in a fused segment leads to overload the adjacent segments, pseudoarthrosis, and a long recovery time. Looking for reducing the adjacent disc degeneration incidence and the long recovery in post-op period; the artificial discs have been developed as an alternative for fusion to keep the range of motion of the spine attempt to decrease the adjacent disc degeneration. Charité prothesis has over than 20.000 patients worldwide and has been implanted since the early 1980's. Over these years, new prostheses have been developed, differing in disc materials, biomechanical features, indications and implantation approaches. Nowadays we can be supported by literature and clinical experience, what have directed lumbar technology to better developing strategies and results.

Methods: We have evaluated the pitfalls in the lumbar arthroplasty history and how is possible to minimize this problems. Along with surgical and basic science literature, Dr. Pimenta's wide clinical experience was analyzed, which covers more than 300 single or multi-level implanted prostheses with up to 8 years follow up. The clinical experience lay on different prostheses, including charité, prodisc, mobidisc, triumph, maverick, physio-L, active-L and lateral disc. Patients had been prospectively monitored, using the clinical and imagining outcomes assessment. Complications and success have been recorded and related to pre-existing conditions, prostheses design, approaches and indications.

Results: Overall clinical outcomes testify TDR benefits, but point out to long term complications appearance. Complications type depends on the prosthesis model, covering facet join pain, subsidence, bad positioning, core fracture, pedicle fracture, istrogenic scoliosis, heterotopic ossification and CrCo allergy.

Conclusions: Our analyses can point out various lumbar arthroplasty aspects, including its pros: better biomechanical results, better clinical results, restoration of global motion, no month follow up, prevalence that continues up to the last point. Radiolucency cases were illustrated by slight bone damage around the rod, up to cases with upper vertebral body and disc violation by the rod. One revision surgery was performed due to rod loosening and collapse.

Conclusions: The clinical data to date indicate that subjects being treated with AxiaLIF two levels device and procedure have on average improved since their pre-treatment condition. The presence of radiolucency was seen in 80% of cases. The fusion analysis depends on considering the radiolucency or not. Longer follow up is required to better understand the radiolucency influence in fusion status and surgery success.
bone graft needed; and its cons: expensive technology, short follow up in comparison to fusion, important adverse events, ideal prosthesis yet nonexistent. Constant patient monitoring, data sharing, concept and technology adapting are essential for achieve crescent success.

**CLINICAL: DEFORMITY**

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Alignment Failures Following Thoracic Pedicle Subtraction Osteotomies

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**Introduction:** Thoracic pedicle subtraction osteotomy (TPSO) is utilized to correct rigid thoracic deformities. TPSO planning often focuses upon regional correction at the osteotomy site. Failure to consider global spino-pelvic alignment (SPA) may result in sub-optimal correction and poor spinal balance. The purpose of this study was to evaluate risk factors for failure to achieve ideal SPA following TPSO.

**Methods:** This was a multicenter, retrospective radiographic analysis of adult spinal deformity (ASD) patients receiving TPSO. Analysis included correction at the osteotomy site, thoracic kyphosis (TK), lumbar lordosis (LL), sagittal vertical axis (SVA), pelvic tilt (PT), and pelvic incidence (PI). Radiographic measures were defined as focal (osteotomy site) or global (TK, LL, SVA, PT, PI). Final SPA and PT were assessed to determine if ideal SPA (SVA < 4cm, PI < 25°) was achieved. Differences between ideal SPA were analyzed with a paired t-test.

**Results:** 41 consecutive ASD patients (mean age 42yrs) received TPSO. Average focal correction was 14° in the sagittal plane and 9.9° in the coronal plane. TPSO significantly decreased TK, max Cobb angle, SVA and PT (p< 0.05). Ideal SPA was achieved in 32 pts (78%) and failed in 9 patients (22%). Ideal and FAIL had similar number of spine levels fused (IDEAL=7.4; FAIL=7.3), similar percentage of patients fused to the sacrum (IDEAL = 87.5%, FAIL=66.7%, p=0.1), had similar focal correction, and had similar SVA and PT correction (Table). FAIL had larger preop SVA, PT and PI and a smaller LL than IDEAL (Table; p< 0.05).

**Conclusion:** TPSO corrects rigid focal thoracic deformities. Poor final SPA occurred in 22% patients despite similar operative procedures and regional correction as IDEAL. Preop PT and SVA predicted failed postop SPA. Additional or alternative correction procedures should be considered when planning TPSO for patients with large global imbalance otherwise patients are at risk for suboptimal correction and poor outcomes.

**CLINICAL: FUSION**

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Extreme Lateral Interbody Fusion (XLIF) for the Treatment of Degenerative Spondylolisthesis

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**Introduction:** The optimal surgical treatment for lumbar spondylolisthesis remains unclear. This work shows our clinical and radiological experience in treating degenerative spondylolisthesis in a lateral minimal invasive way. Satisfactory clinical outcomes for the treatment of degenerative spondylolisthesis have been reported, but its optimal surgical treatment still remains unclear.

**Methods:** Prospective, non randomized single center clinical trial with 66 levels. Patients were treated for low grade degenerative spondylolisthesis at lumbar levels. Lateral, A-P, and flexion-extension X-rays, neurological examination, and clinical outcome assessment using Oswestry and VAS scores were performed at the preoperative, 1, 6 week, 3, 6, 12 and 24 months postoperative intervals. Also, radiological outcomes were accessed at same f.u. points. The extreme lateral approach was done through the retroperitoneal space and through psoas muscle avoiding neurological and vascular lesions. A discectomy was done and the end-plate cleaned, a cage settled with graft and the ALL and PLL were preserved, adding more stability, thus the ligamentotaxis. Two groups were compared - standalone and suplemented XLIF procedures.

**Results:** The procedures were performed without complication in an average 171 minutes and with less than 50cc blood loss. Global VAS pain scores improved from the average 8.84 at pre-op to 3.2 at 2 years, standard deviation 1.75 and 1.16 respectively. Oswestry scores improved from an average 58.44 at pre-op to 20.75 at 2 years with standard deviation of 12.79 and 9.32 respectively. In the two groups, stand alone or supplemented with pedicle screws, occurred fusion, with no difference of consolidation time. We observed similar cage subsidence prevalence in both groups, but only on standalone group occurred cases of total disc collapse. L4L5 was the level that presented most of the subsidence occurrences, and severe cases appeared on elderly women. These results are proven to be statically significant.

**Discussion and conclusion:** Using the XLIF technique we were able to treat the deformity, improving pain, providing stabilization and fusion. The XLIF technique has shown to be a safe and reproducible technique to treat spondylolisthesis.
deformity thought a minimally invasive way. On elderly women fusion supplementation may be considered to avoid cage subsidence.

**CLINICAL: PROSTHESIS**

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Controlled ROM of a New Metal on Metal Lumbar TDR Placed by Lateral Approach

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**Introduction:** Current lumbar total disc replacement (TDR) devices require an anterior approach for implantation. The anterior approach to place lumbar TDR devices has inherent biomechanical limitations and surgical risks. Within the possible intraoperative issues are: the damage to various abdominal structures, such to the grand vessels, to bowel components and to the sympathetic neural plexus, without mentioning the long discharge and rehabilitation time. Besides the surgical riks, there is resection of the anterior longitudinal ligament (ALL). Placement of a TDR device from a true lateral (XLIF) approach allows for easier, less invasive access to the disc space, as has been shown in reports of XLIF for fusion procedures. Lateral implantation of TDR also preserves the stabilizing ligaments, which are a natural restraint to excessive rotations and translations, and thereby help to minimize facet stresses. Importantly, implantation from a lateral approach leaves greater opportunity for safer revision surgery, if necessary, by avoiding scarring of anterior vasculature. Additionally, the footprint of the lateral TDR device capitalizes on the biomechanical support of the ring apophysis.

**Methods:** Prospective, non randomized clinical trial to evaluate the safety and effective of the lateral total disc replacement implanted by the XLIF approach. Patients included 16 males and 20 females, average age 43 yrs (24-60). A TDR device designed for implantation through a true lateral, retroperitoneal, transpsoas approach (XLIF) was implanted in 36 patients with discography-confirmed 1- or 2-level DDD. Clinical and radiographic outcomes assessments were prospectively collected.

**Results:** Surgeries included 14 1-level, 3 2-level, and 19 hybrid TDR/ALIF cases. The surgery was performed through a 4cm lateral incision in an average of 134 minutes (90-300) and with an average 58cc blood loss (30-150). There was no intra-op or post-op complications. Postoperative x-rays showed good device placement, with restoration of disc height, foraminal volume, and sagittal balance. All patients were up and walking within 12 hours of surgery. VAS pain scores improved from an average of 9.3 at pre-op to 2.27 after 3 years. Oswestry Disability Index improved from an average of 57 at pre-op to 16.5 after 3 years.

**Discussion and conclusion:** Mid-term results of a laterally placed TDR device demonstrate maintenance of pain relief and functional improvement. The benefits of this technique -- minimal morbidity, avoiding mobilization of the great vessels, preserving the anterior longitudinal ligament, biomechanically table orientation, and broader revision options II suggest a promising new direction for TDR procedures.

**CLINICAL: FUSION**

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Why Lumbar Artificial Disc Replacements (A.D.R.) Fail

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**Purpose:** To determine why A.D.R.’s fail by examining results of 91 patients in F.D.A. studies performed at a single I.D.E. site with minimum two-year follow-up.

**Methods:** To minimize variables, every patient undergoing A.D.R. at one I.D.E. site by two surgeons were evaluated for clinical success. Failure was defined as less than 50% improvement in O.D.I. and V.A.S. or any additional surgery at index or adjacent spine motion segment. This criterion for success was more stringent than F.D.A. guidelines, which require only a 25% improvement in O.D.I. and V.A.S. for clinical success.

Three A.D.R.’s were evaluated: Maverick™ (M) 25 patients, Charité™ (C) 31 patients, Kinflex™ (K) 35 patients. All procedures were one level performed at L4-5 or L5-S1. Demographics and inclusion/exclusion criteria were similar and will be discussed. Face pain was diagnosed by facet block and significant clinical improvement after facet rhizotomy.

**Results:** Overall clinical failure occurred in 26%, (24 of 91 patients) at two-year follow up. Clinical failure occurred in: (M) 28%, (7 of 25 patients); (C) 39%, (12 of 31 patients); (K) 14%, (5 of 35 patients). The type of A.D.R. makes a difference. Causes of failure included: facet pathology 46% of failure patients, (11 of 24). Implant complications occurred in 6% of the total patients and 25% of the failure patients, (6 of 24). Patients with additional orthopedic or medical pathology or disability/narcotic issues making them unable or unwilling to fill out follow-up forms specific to their A.D.R. occurred in 29% (7 of 24), of the failure group. Despite the fact these patients were considered failures based on O.D.I. and V.A.S., they reported a 92% satisfaction with the A.D.R. and would repeat the surgery for the same result. Interestingly, A.D.R. patients are often either a clinical success at three-month follow-up (home run) or a possible failure (strike out). Only five patients went from a success to failure after three months. One was an infection one year after A.D.R. and four patients developed additional pathology unrelated to their A.D.R. Only one patient went from a failure to success after a facet rhizotomy one year after A.D.R.

**Conclusions:** Seventy-four percent of patients after A.D.R. met strict clinical success after two-year follow-up. The clinical success verses failure rate did not change from their three-month follow-up in 85 of the 91 patients (93%). Home run verse strike out can be determined early. Failures occurred due to: facet pain, 46% of the time; implant complications in 25%; and additional unrelated pathology or disability/narcotic issues resulting in form filling not specific to their ADR in 29% of patients. Implant type appears to impact clinical success. These results indicate overall clinical success can be improved most by patient selection and implant type. Patients with a B.M.I. over 34, multiple orthopedic and/or medical pathology, facet pain, or disability/narcotic issues have a higher failure rate with A.D.R.
Purpose: To educate spine surgeons how the FDA has impacted innovation and its detrimental impact to our patients.

Methods: Metanalysis of discussions with Spine company CEO’s, venture capitalists, and product managers. Venture Capitalists typically invest in a start up spine company with a 5 to 7 year exit strategy either through an IPO or an acquisition. They expect a 2.5 to 3 time return. If $100 million is invested, an acquisition would require $250-300 million as a sale price. The numbers do not work anymore. An FDA IDE study to obtain a PMA costs $30-40 million. Because of the current climate at the FDA, approval for an IDE is more than a 5-7 year timeframe. The numbers for VC money into an IDE simply no longer exist. There is no VC funding for new technologies for start-up companies and a big exit of VC money is expected for any medical or surgical device company. Another FDA detriment to VC investment is FDA unpredictability. It costs $2 million and two years to enter the E.U. while it costs $70 million and 7 years to enter the US market.

The 510(k) approval process has a long history. The vast majority of US products are predicate devices. The FDA has a database of all device complications for the last 10 years. The 510(k) process has resulted in very few device complications. 510(k) allows innovation without harm. Despite this the FDA has made the 510(k) process difficult if not impossible. Companies which typically received 25 to 510(k)’s a year and within an average 44 days now get 2 per year averaging 210 days. Products 510(k)’d 8 to 10 years ago are being challenged. Companies are being required to conduct IDE type studies for a 510(k). In the last year, there has been 1/3 less 510(k) approvals, all requiring three times longer. The Menaflex story will be presented. Explanations for the change in the FDA include the new administration, new people at FDA and directions from congress to audit everything.

Conclusion: Many CEO’s do not anticipate any new FDA IDE spine studies secondary to cost and FDA unpredictability of ever receiving approval. Venture Capitalists cannot deal with this environment of unpredictability. The first question asked to any company is whether this is a 510(k) product, a 510(k) product requiring data or an IDE and what are the possibilities of the product ever being reimbursed. In the current environment, ideas are not getting funded. There is a major shift of investment capital and jobs to outside the U.S. The current FDA does not have our patients’ best interest as a priority. Future innovative spine surgery will be performed only outside the U.S.
Conclusions: Lumbar disc arthroplasty can dramatically improve global ROM, although this improvement may take several years in some patients. There is also a significant negative association between global ROM and pain scores post-operatively, although this association can explain only a small part of the improvement in clinical outcomes.

CLINICAL: MIS DECOMPRESSION

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At Two Years: One Institutions Experience with Transforaminal Decompression
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Transforaminal decompression was first popularized by Kambin and has been had many reiterations. This surgical experience utilizes a method of decompression popularized in Germany and the Netherlands in which an endoscope is placed targeting the specific pathology (ie: the herniated nucleus pulposus) sparing the remainder of the disk. The authors utilized this technique for multiple compressive pathologies. It became clear that despite a steep learning curve successful outcomes with this procedure were achievable. With review of the outcomes it also became clear that certain pathologies were better treated by these physicians than others. The classic disk herniation with subsequent LE radiculitis and LBP secondary was the presentation that was most successfully delt with by utilizing this procedure. It also was advantageous in patients who had primary LBP with disk herniations and LE radiculitis who would also need fusion, or total disk replacement. The outcome at two years exceeded the success of long quoted outcomes with this procedure. It also was advantageous in patients who had primary LBP with disk herniations and LE radiculitis who would also need fusion, or total disk replacement. The outcome at two years exceeded the success of long quoted success with classic microdiscectomy as described by Caspar and others. The posterior compressive lesions could be delt with in this minimally invasive fashion and then the less invasive anterior surgical technique of total disk replacement or anterior stand alone arthrodesis and internal stabilization could be performed. This subgroup also did very well at two years. Further clinical experience and follow-up is necessary as is a prospective multi-center study to help bring this technique to the mainstream in the USA, and establish it as the "gold standard".

BASIC SCIENCE: INTERSPINOUS AND LIGAMENTOPLASTY

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Restoration of Lumbar Spine Stability with an Interospinous Implant: An in vivo Biomechanical Study
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Introduction: Interspinous implants are used in non-fusion surgical techniques to treat lumbar spinal disorders. Little research has investigated their effect on lumbar spinal stability and stiffness. The objective of this in vivo biomechanical animal study was to determine the effect of an interspinous implant on lumbar spine stability and stiffness during exposure to posteroanterior (PA) loading.

Methods: Merino lambs (n=12, 6-8 months old, 25 kg) were mechanically tested in vivo using a validated computer controlled force application apparatus designed to quantify PA stiffness. Load and displacement at L2 were collected at a sampling rate 2500 Hz. To quantify intersegmental displacements, tri-axial accelerometers were attached to intraosseous pins rigidly fixed to the L3 and L4 lumbar spinous processes under fluoroscopic guidance and general anesthesia. Oscillatory (2 Hz) loads (~5% of body weight) were applied to the L2 spinous process under load control and with the animals lying prone on an operating table. PA Lumbar spine stiffness (load/deformation, N/mm) at L2 were determined over six trials of 20 cycles of loading, and averaged. PA and Axial (AX) acceleration responses at L3 and L4 were recorded at 5000 Hz. Peak-peak segmental accelerations at L3, L4 and L3-L4 were computed from the acceleration-time recordings and displacements subsequently calculated.

Four spinal conditions were examined:
1) the initial intact condition,
2) following a destabilisation procedure at the L3-L4 level simulating a stenotic degenerative spondylolisthesis,
3) following the insertion of an 8 mm InSwing® interspinous device at L3-L4, and
4) again with the implant secured by means of a tension band tightened to 1 N/m around the L3 and L4 spinous processes.

Stiffness and displacement comparisons for each condition were performed using a one-way analysis of variance (ANOVA) with repeated measures. Post-hoc analysis with Bonferroni correction was used when significant differences were observed.

Results: The mean stiffness (± standard deviation) for the intact, destabilization, InSwing®, and InSwing® with tension band conditions were 4.20 (±0.94) N/mm, 4.07 (±0.92) N/mm, 4.10 (±1.04) N/mm, and 4.25 (±1.16) N/mm, respectively. Compared to the intact condition, the destabilization condition
significantly decreased L2 stiffness (P=.000) which was only recovered by the InSwing® with tension band intervention. AX Displacements of L4 significantly increased from 4.09 (±1.73) mm in the intact condition to 4.47 (±1.40) mm in the destabilized condition (P=.038). L4 AX displacements were significantly reduced by the InSwing® and InSwing® with tension band to 3.70 (±1.15) mm (P=.038) and 3.12 (±0.96) mm (P=.001), respectively. The addition of the tension band to the InSwing® condition significantly reduced L4 AX displacements (P=.005). Likewise, intersegmental AX displacements of L3-L4 were significantly reduced by both InSwing® (P=.01) and InSwing® with tension band (P=.001) interventions.

Conclusions: The ovine model used in the current study provided objective biomechanical evidence of restoration of lumbar stability and stiffness by means of an interspinous device during PA spinal loading. The addition of a tension band had a marked effect on stability in several biomechanical outcomes. To our knowledge, this is the first in vivo biomechanical study showing the advantage of using an interspinous device to stabilize the spine in response to PA forces. These results may be useful when considering non-fusion devices for unstable degenerative spondylolisthesis patients.

BASIC SCIENCE: COMPLICATIONS

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Effectiveness of a Polyvinyl Alcohol Barrier to Reduce Risk of Tissue Damage during Anterior Spine Surgery
P. Jeffords

Introduction: Postoperative adhesions and scar tissue are a significant problem in anterior spine surgery. Involvement of overlying structures can create pain and neurovascular complications. Adhesions also create a difficult surgical environment at revision surgery.

Purpose: To evaluate the safety and efficacy of a permanent polyvinyl alcohol (PVA) hydrogel barrier in reducing the risk of potential postoperative vessel damage during anterior lumbar revision surgery and creating a plane of dissection at revision surgery.

Methods: The PVA devices were implanted onto the ventral surface of exposed lumbar intervertebral discs in sheep using an anterolateral approach. Discs at two levels adjacent to the study site were also exposed in each sheep to serve as controls. Periodic sampling was undertaken to evaluate gross anatomic, micropathological and biochemical environments and physical properties of the shields at necropsy at up to 120 days.

Results: The properties and visual appearance of the device remained intact. The material remained flexible, hydrophilic, and soft. The material showed no resorption or decomposition at necropsy. The material was well tolerated by the animal, with histological studies showing minimal sign of acute or chronic inflammation or rejection. Tissue planes were easily able to be localized, presenting a “landing zone” to the surgeon attempting to locate the prior surgical site.

Discussion and conclusion: The PVA vessel shield effectively protected the structures overlying the sheep spine after initial surgery, and provided a clear dissection plane for resection at repeat surgery. The device allowed for easy separation of the overlying structures with no adhesion.

CLINICAL: PROSTHESIS

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Total Lumbar Disc Replacement with SB Charite-III Prosthesis: Chinese Experience with 2-10 Years Follow-up
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Objective: To determine the med-term and long-term clinical results, radiographic results, and incidence of complications in a large patient cohort with lumbar total disc replacement (TDR).

Methods: Between January 1998 and August 2008, 82 patients with lumbar DDD and failing nonoperative treatment were treated with lumbar arthroplasty. Among these patients, 68 patients (72 prosthesis) were followed-up for more than 2 years (2-10 years). There were 37 females and 32 males, and the mean age at the time of surgery was 43.6 years (range, 34-56 years). The primary diagnosis was discogenic low back pain with radiculopathy in 46 patients, discogenic low back pain without a radicular component in 13 patients and failed lumbar disc surgery in 10 patients. All patients had a minimum of 6 months of treatment with physiotherapy and medication. All patients had a minimum of 6 months of treatment with physiotherapy and medication. All patients underwent standard anterior procedure under general anesthesia. There were 65 patients with one level replacement (L34 in 6 patients, L45 in 33 patients and L5S1 in 26 patients) and 4 patients with two level procedures (L34/L45 in 1 patient and L45/L5S1 in 3 patients). Clinical and radiographic results of these patients were evaluated during follow up period (1, 3, 6, 12, 24 and latest follow up).

Results: 69 patient were followed for more than two years (2-10 years). The average VAS score was 9.2 preoperatively, 4.1one month postoperatively, 2.5 two years postoperatively and 1.8 at the latest follow up evaluation. The average Oswestry Disability Index was 46.2 preoperatively, 29.4one month postoperatively, 12.9 two years postoperatively and 8.8 at the latest follow up evaluation. All operated levels but 5 maintained mobile and There were 3 cases (%) of postoperative facet arthrosis, 2 cases (2.8%) of subsidence, 5 cases (2.8%) of adjacent-level degeneration, 1 case need reoperation because of adjacent-level disease. All patients returned to work (38 returned to previous work and 10 for modified work). All patients but one (99%) were satisfied with the surgery at the latest follow up evaluation.

Conclusion: This is the largest series of lumbar total disc replacement with SB Charite III prosthesis in China for the treatment of degenerative lumbar disc disorders. The clinical and radiographic results at more than two years follow up showed that all patients benefited from the procedure and satisfied with their outcome. Lumbar total disc replacement is effective for the treatment of degenerative disc disorders.

Keywords: Intervertebral disk; Lumbar; Proseses and implants; Treatment outcome
CLINICAL: NAVIGATION, IMAGE GUIDED SURGERY AND ROBOTIC ASSISTANCE

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Relationship between Changes in Lumbar Lordosis and Clinical Outcomes Following Lumbar Disc Arthroplasty
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Introduction: Sagittal plane alignment of the lumbar spine is generally accepted as a clinically relevant parameter, although specific guidelines for good or bad lordosis are poorly developed. This is particularly true with LDA, where the device may affect both segmental and overall lordosis. This study investigates the relationship between lumbar segmental and overall lordosis and clinical outcomes following LDA, and evaluates the ability of LDA to restore patients to normal lordotic curvature.

Methods: Analysis of monocentric data from 96 investigational patients from the prospective randomized IDE, the continued access, and the continued access metal ion studies for Maverick® (Medtronic, Memphis, TN). Follow up to 5 years is ongoing. Lordosis (disc angle), ODI and numeric leg and back pain scores were collected. The angle between the L1 and S1 endplates (global lordosis) was measured at pre-op, 2 and 5 years (N=36) using validated, computer-assisted methods from standing neutral-lateral x-rays. The change in this angle was also calculated on a per-patient basis. Standard statistical methods were used.

Results: Relative to pre-op, global lordosis increased approximately 4 degrees on average following surgery, but this change was not significant (P=0.2). A similar magnitude of change was also seen in the measured angle between adjacent endplates at the treated level and this was significant (P=0.01, Figure 1). However, it was also noted that although significant (P=0.007), there was only a weak (R²) relationship between the change that occurred in segmental disc angle and the change that occurred in overall lordosis, suggesting that factors other than local disc angle control global lordosis.

Discussion: This study builds on the findings from the IDE study, which showed that LDA restores patients to normal lumbosacral lordosis. The current study extends these findings by examining the relationship between changes in both segmental and overall lordosis and clinical outcomes following LDA. The results suggest that while LDA is effective at restoring global lordosis, factors other than local disc angle may also influence overall lordosis. Further research is needed to better understand the relationship between changes in lordosis and clinical outcomes following LDA.

CLINICAL: PROSTHESIS

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Percutaneous Pedicle Screw Placement Using Intraoperative CT Navigation Is Safe and Accurate
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Purpose: Pedicle screws are widely used in the treatment of various spine disorders. Intra-operative CT-guided navigation systems are available which facilitate percutaneous pedicle screw placement. This study reports the accuracy of percutaneous pedicle screw insertion using an intra-operative CT-guided navigation system, and compares accuracy rates to previous reports.

Methods: Between August 2008 and September 2010, 33 patients underwent percutaneous pedicle screw fixation for the treatment of various spinal disorders. Intraoperative CT was performed to generate images that were used for navigation. A navigated Jamshidi needle was used to cannulate the pedicles. Intra-operative CT scans were performed after placement of the K-wires. Cannulated screws were then placed after demonstration of good position of the K-wire within the pedicle on CT images. K-wire revision and screw revision rates were determined as the primary measures in this study.

Results: Mean patient age was 53.5 years (range 13 to 87 years). There were 10 male and 23 female patients. Underlying diagnoses included degenerative disc disease (24), spinal stenosis (8), spondylolisthesis (7), degenerative scoliosis (2) and pseudoarthrosis (2). A total of 166 pedicle screws were placed using real-time navigation, with a mean of 5 screws per patient (range 2 to 12). Following K-wire placement, a CT was obtained intraoperatively. 9 K-wires (5.4 %) were revised intraoperatively due to suboptimal position. In 8 cases, the K-wire was successfully redirected, and in 1 case, the K-wire was removed. None of the screws were revised after insertion for a 0% screw revision rate. At latest follow-up, no patients had returned to the OR due to screw malposition. There were no major neurovascular complications.

Conclusion: We found a 95 % accuracy for navigated K-wire placement, and 100% accuracy in percutaneous pedicle screw placement using an image-based navigation system. This is more accurate than the 95% accuracy rate for image-guided insertion from a previous meta-analysis (Kosmopoulos, 2007). Using CT-imaging, malpositioned K-wires were identified prior to screw insertion, and were either removed or redirected. Percutaneous pedicle screw placement in using CT navigation resulted in no identified complications and is a promising technique for improving the safety of pedicle screw placement. Screw accuracy was comparable to other techniques.
Disability Index improved significantly from 58.3 before surgery to 14.9 after surgery and the mean of VAS improved significantly from 8.2 to 1.9 after surgery.

Conclusions: Percutaneous pedicle screw for degenerative spinal disorders is a reliable method of minimal invasive fixation with very low rate of operative complications. Guided by intraoperative fluoroscopic imaging and anatomic landmarks, thoracic pedicle screws can be placed safely. Percutaneous TLIF is an alternate of treatment choosed for thoracic spinal lesion.

[Fig. 1: Change in Average Disc Angle]

Conclusion: The results suggest that global lordosis can partially explain some of the variabiliy in clinical outcome scores following lumbar disc arthroplasty. Treatment using the Maverick Disc reduced the proportion of patients with too little lordosis from 15% preoperatively to 5% post-operatively. This treatment effect on overall lordosis is largely controlled by factors other than the direct effect of the surgery on disc angle at the index level. The results also support a significant but weak relationship between global lordosis and clinical outcomes, but it remains unclear whether lordosis influences outcomes or symptoms influence lordosis.

CLINICAL: LUMBAR FUSION (I.E. MIS, TLIF, XLIF, AXIAL LIF, ALIF)

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Percutaneous TLIF for Thoracic Spine Lesion
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Objectives: Thoracic spine is least mobile region of spine, lateral bending evenly distributed between vertebral segments, more axial rotation in upper thoracic spine, and more flexion/extension in lower thoracic spine. Minimally incision techniques, the use of bone graft substitutes and extenders, and computerized navigation strategies have contributed to enhance the safety, decreasing morbidity and generally improving outcomes.

Methods: This is a retrospective study to assess clinical outcome 23 patients thoracic spine disorder treated with thoracic spine fusion from Nov. 2006 to Jan. 2010. The diagnosis was thoracic spine disorders with HIVD, scoliosis, spinal tumor and fracture et al. We compared the pre- and post-operative Oswestry Disability Index, pain score (VAS), fusion rate and post-operative analgesic usage of those patients. It have good fusion rate (100%, 23/23).

Results: Of the 119 cases reviewed, 12 (10.1%) had postoperative wound infections and 22 (18.5%) had durotomies requiring repair. Wound infections were aggressively treated with irrigation and debridement and IV antibiotic therapy followed by a course of oral antibiotics. No patients had to have any further surgeries to manage chronic wound infections or osteomyelitis. Durotomies were repaired primarily. Patients did not have any long term sequelae fistulas form as a result of the durotomies. Patients who had wound infections and durotomies treated had equivalent outcomes and did not have worse outcomes 5 years post operatively.

Conclusions: Despite a higher rate of post-operative wound infections and durotomies, revision spine surgery still has the potential for good outcomes. If wound infections are treated with aggressive debridement and antibiotic therapy and durotomies are treated with good primary closures, they have a good chance of having equivalent outcomes as patients who did not have a post-operative wound infection or durotomy.

Introduction: Revision spine surgery is sometimes necessary due to adjacent segment degeneration, recurrent stenosis, and . The purpose of this study was to review our revision spine procedures to determine the rate and nature of complications, such as infections and dural tears and their rate on reoperation and outcome.

Methods: A retrospective chart review of 119 consecutive revision spine cases performed by our single senior surgeon from August of 2003 to November of 2007 was done and all complications, adverse events, reoperations and presence of intraoperative pseudoarthroses were noted. The mean patient age was 58 years. Revision procedures included lumbar laminectomy, foraminotomy, microdiscectomy and instrumented fusion. Inclusion criteria were any patient who underwent revision surgery at the same level or adjacent level as a previous procedure.

Results: Of the 119 cases reviewed, 12 (10.1%) had postoperative wound infections and 22 (18.5%) had durotomies requiring repair. Wound infections were aggressively treated with irrigation and debridement and IV antibiotic therapy followed by a course of oral antibiotics. No patients had to have any further surgeries to manage chronic wound infections or osteomyelitis. Durotomies were repaired primarily. Patients did not have any long term sequelae fistulas form as a result of the durotomies. Patients who had wound infections and durotomies treated had equivalent outcomes and did not have worse outcomes 5 years post operatively.

Conclusions: Despite a higher rate of post-operative wound infections and durotomies, revision spine surgery still has the potential for good outcomes. If wound infections are treated with aggressive debridement and antibiotic therapy and durotomies are treated with good primary closures, they have a good chance of having equivalent outcomes as patients who did not have a post-operative wound infection or durotomy.
We describe our experience with CT guided Real Time Plasma Energy Discoplasty (PED) for symptomatic Cervical Disc Degeneration. The primary purpose was to evaluate the role of percutaneous plasma energy delivery as a less invasive option of disc decompression than open surgical disectomy with the additional advantage of disc preservation (Discoplasty). The secondary purpose was to evaluate the advantage of high quality real time multi-slice CT for needle guidance over routine X-ray fluoroscopy in accuracy and complication avoidance.

50 patients with symptomatic Cervical Disc Degeneration and disc protrusions as defined by clinical findings correlated with MRI were treated. All patients were assessed to have contained disc protrusions. 30 patients had predominantly radicular symptoms and 20 patients had predominantly axial pain. The procedure was carried out in an outpatient setting under local anesthesia with intravenous sedation in an interventional CT suite under sterile conditions. A percutaneous puncture and needle placement into the symptomatic disc was carried out in real time CT. Either an anterior or a lateral approach was carried out to avoid critical vascular and neck structures based on CT with contrast (CT angio). A wand was then placed into the nucleus and 2-3 lesions done for 8-12s duration. The average procedure time was 55 minutes. There were no intra-procedure complications. One patient had a vaso-vagal episode during the procedure. Patient satisfaction was measured by using Visual Analog Scale before surgery and one and six months post procedure.

Most patients were discharged from hospital an average of 2 hours after the procedure. 28 of 30 patients with radicular symptoms had significant relief (VAS mean pre-op: 8.2; VAS mean post-op: 2.1). 15 of 20 patients with axial pain had significant relief (VAS mean pre-op: 8.5; VAS mean post-op: 2.3). 5 patients had recurrent symptoms (mean follow-up: 12 months; range 6-18 months). In conclusion, PED is a less invasive option than open surgery in selected patients with a reasonably good success rate of symptom relief (86%) and with minimal morbidity. There were no intra-procedure complications including inadvertent vascular puncture or incorrect needle placement and lesioning outside the nucleus with real time CT guidance. Further long term studies are needed to assess recurrence rates and conversion to open surgery including TDR. However this procedure does not preclude the patients receiving TDR in the future.

**CLINICAL: LUMBAR FUSION (I.E. MIS, TLIF, XLIF, AXIAL LIF, ALIF)**

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Minimally Invasive TifLIF (Trans Foraminal Inferior Facet Lumbar Interbody Fusion). A Technical Modification to the Traditional MIS TLIF: Surgical Anatomy and Prospective Case Series Study

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**Study design:** Description of a new surgical technique and a prospective preliminary case series review of 57 patients.

**Methods:** From July 2008 to April 2010, 57 patients were treated with lumbar spinal fusion using the minimally invasive TifLIF technique, with posterior pedicular screw fixation supplementation. Diagnoses included degenerative disc disease, degenerative spondylolisthesis and facet cysts. 3 cm paramedian incisions, 5 cms from the midline where used. Using fluoroscopic guidance, a non-traumatic dissection was used to separate de lumbar musculature and through the use of tubular and self fixing separators, the corresponding facet joint was exposed; a selective inferior facet osteotomy was performed. The medial border of the medial intertransverse muscle was laterally dissected along with the intertransverse membrane, in that way protecting the dorsal root ganglion and the exiting root. Using this technique, we gained access to the Kambin’s safety triangle with sufficient space to perform the discectomy and placement of the intervertebral cage. In all cases, the manipulation of the exiting nerve root was minimal and there was no need to visualize the traversing root. All cases were supplemented by using pedicular screw fixations by way of minimally invasive techniques. Clinical evaluation was performed by using the Oswestry Disability Index and the Visual Analog Scale before surgery and one and six months after the procedure. Patient satisfaction was measured by using the Odom Scale.

**Results:** Over 90% of patients showed an improvement in the evaluated parameters after their first post operative month. The improvement rates remained close to 80% at six months. There were no major complications or serious neurologic injuries. The average surgical time was less than that reported for the traditional minimally invasive TLIF, and in hospital stay was less than 24 hours in all cases.

**Conclusions:** The new TifLIF technique allows us to perform a safe and effective interbody fusion, with minimal and less bone removal, low morbidity, short in - hospital stay and similar clinical outcomes when compared to the conventional minimally invasive TLIF technique.

**Keywords:** Minimally Invasive Surgery, TLIF, Transforaminal Lumbar Interbody Fusion, Degenerative Disc Disease
Spatial Correlation between Uncovertebral Joint and Intervertebral Foramen Considered when Performing Anterior Cervical Foraminotomy

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Purpose: It is challenging for surgeons to decide types of surgery in decompression without fusion, fusion and total disc arthroplasty for the cervical foraminal stenosis demanding uncovertebral process resection. Because the biomechanical function of uncovertebral joint (UVJ) is to stabilize the cervical segment. However, the parts of uncovertebral process involved in the articulation of UVJs are different in cervical levels and the spatial correlation with intervertebral foramen are not clear enough when using the conventional radiographs. The 3D image processing software (Aquarius, TeraRecon, Inc., San Mateo, CA) using MDCT enables to visualize the precise morphology of each vertebra and each interface between adjacent vertebrae. This study is to evaluate the morphometry of UVJ and intervertebral foramen in each cervical level and gender and to determine the spatial correlation of those for each level using Aquarius program.

Methods: Forty patients (35.8±9 yrs, 20/20 males/females) were randomly selected in population who underwent C-spine CT in our institute with excluding levels developed foraminal stenosis. CT images obtained in 0.625mm or 0.75mm increments were reconstructed at 0.15mm intervals and reformatted into 3D planes. Parameters for UVJ [Inter-UVJ Distance (IUVD), Inter-UVJ Angle (IUVJA), UVJ Length (UVJL)] and for intervertebral foramen [Inter-Foraminal Distance (IFD), Foraminal Angle (FA), Foraminal Length (FL)] were evaluated with the axial plane that demonstrated the uncovertebral articulations simultaneously at anterior and posterior margins while the other planes pointing the lowermost margin of inferior endplate of upper vertebra. Each parameter was statistically compared for gender and cervical level. Pair-wise comparisons were performed for IUVD-IFD, UVJA-FA and UVJL-FL to determine spatial correlation between UVJ and intervertebral foramen.

Results: The UVJL, IFD, and FL of males were significantly greater than those of female, while UVJA, UVJL, IFD and FA demonstrated significant differences for cervical levels (Table 1). For comparison of IUVD-IFD, IUVD was significantly greater than IFD in C3 (P=0.011) while IFDs were significantly greater than IUVDs in C6 (P=0.029) and C7 (P=0.011). The parts of UVJ were involved in intervertebral foraminas of C6 and C7, while least was in C3. The UVJLs were significantly greater than FLs in all levels. The difference was minimal in C7. The FAs were significantly greater than UVJAs in all levels. The difference was minimal in C7. The difference was least in C7.

Conclusion: In C6-7 UVJ, the articulation started most medially, the length is shortest and the axis is closest to those of intervertebral foramen. In C2-3 UVJ, the articulation is at the most lateral corner and is most laterally placed to the intervertebral foramen. The part of uncinate process resection in lower cervical levels (C7, C6) may impair the stability of UVJ while posterolateral decompression in upper and middle cervical levels (C3, C4 and C5) may maintain the mechanical function of UVJ. Thus, the amount of uncinate process resection and surgical level should be considered when selecting type of surgery following cervical foraminotomy.

<table>
<thead>
<tr>
<th>Level</th>
<th>IUVD (mm)</th>
<th>IFD (mm)</th>
<th>UVJA (°)</th>
<th>UVJL (mm)</th>
<th>FA (°)</th>
<th>FL (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>C6</td>
<td>17.4 (7.4)</td>
<td>14.8 (7.9)</td>
<td>15.0 (5.2)</td>
<td>11.5 (3.1)</td>
<td>18.0 (7.5)</td>
<td>12.0 (5.3)</td>
</tr>
<tr>
<td>C7</td>
<td>17.4 (7.4)</td>
<td>14.8 (7.9)</td>
<td>15.0 (5.2)</td>
<td>11.5 (3.1)</td>
<td>18.0 (7.5)</td>
<td>12.0 (5.3)</td>
</tr>
</tbody>
</table>

* a: significantly different with C3, b: significantly different with C4, c: significantly different with C5, d: significantly different with C6, e: significantly different with C7

[Table 1]
patients developed adjacent level disease requiring another operation. Mean operative time was 90 minutes (range 35-175 minutes). One patient experienced dysphagia that resolved by the 3-month timepoint.

**Conclusion:** Although the follow-up period is short, it is our conclusion that the STALIF C™ integrated interbody system is a safe, effective, and reproducible device for fusion in the cervical spine. The overall patient success rates were notable in not only the adjacent level disease patients, for whom the device was initially targeted, but also the many virgin, stand-alone cases for which the device was used. The clear benefits over the standard plate/screw systems are less overall hardware, no risk for disruption of adjacent levels with hardware (i.e., cervical plate), and shorter operative times (as compared to patients with adjacent level disease and needing removal of hardware, etc.).

**CLINICAL: MIS FUSION-STABILIZATION**

**512**

**Clinical Outcome of Two-level Percutaneous Pedicle Screw Fixation in Lumbar Degenerative Disease: A Preliminary Report**

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**Objective:** The evolution of minimally invasive techniques should reduce or minimize the destructive aspects of the open techniques but preserve the operative goals of neural decompression and spine fusion. The purpose of this study was to report the clinical experiences for percutaneous posterior fixation of the lumbar spine.

**Methods:** A total of 24 patients with two-level lumbar degenerative disease underwent neural decompression, discectomy, and interbody cage insertion via small midline incision with percutaneous pedicle screw fixation. Clinical outcome was measured by Odom's criteria, Visual Analogue Scale (VAS), and Oswestry Disability Index (ODI). Operative results were assessed by total operating time, intraoperative blood loss volume, change of total lumbar lordotic angle (TLA) and segmental lordotic angle (SLA), accuracy of pedicle screws, and rate of bone fusion.

**Results:** “Excellent” or “good” clinical results were obtained in 19 patients (79.2%). VAS scores prior to surgery to alleviate back and leg pain were 6.67 and 7.17 and 4.75 and 5.00 immediately postoperative and 3.83 and 3.63 at the last follow-up visit, respectively. Preoperative ODI was 66.08%. ODI was 51.83% immediately postoperative and 35.54% at the last follow-up visit. The total procedure required a mean of 4.17 hours. Estimated blood loss was 521 ml, and transfusion was needed in 4 patients during the surgery. There was no statistical significance in the change of TLA and SLA for the preoperative, postoperative, and follow-up period, and the bone fusion rate was 91.6%. Of the 144 screws placed, 6 (4%) screws were malpositioned, and two cases involved performing a conventional, open procedure in the earlier stage, since it was difficult to insert screws, due to their pedicle alignment.

**Conclusion:** Two-level percutaneous pedicle screw fixation can be safely and effectively performed using minimally invasive techniques, thereby reducing pain, operating time, and blood loss. Pedicle alignment is a critical factor in multilevel percutaneous pedicle screw fixation.

**CLINICAL: PROSTHESIS**

**514**

**Three-level Lumbar Total Disc Replacement**

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**Introduction:** Some patients present with the challenge of multi-level painful disc degeneration unresponsive to non-operative care. While three-level fusion may be considered, it is not typically desirable due to the chance of pseudoarthrosis and the potential for future problems at adjacent segments. The purpose of this study was to evaluate the outcomes of three-level total disc replacement (TDR).

**Methods:** Six patients with three-level painful degenerative disc disease underwent TDR. None of the patients had significant facet joint degenerative changes. There were 3 males and 3 females with a mean age of 35.4 years, ranging from 25 to 55 years. The mean body mass index was 23.2 (range 25.1 to 26.8). Five patients were operated from L3 to S1 and the remaining patient from L2 to L5. The mean follow-up was 28.4 months, ranging from 9 to 60 months. ProDisc-L was used in five patients and Charite in one patient. Outcome measures used were visual analog scales (VAS) separately assessing back and leg pain. The Oswestry Disability Index was used to assess physical function.

**Results:** The mean VAS back pain scores improved significantly (Figure 1; p < 0.025) and there was a trend for significant improvement in leg pain (0.05 < p < 0.07). Oswestry scores also improved significantly from a pre-operative mean of 48.4 to a mean of 28.4 at the most recent follow-up.

One patient had early subsidence at all three levels, but his clinical results were satisfactory so that no additional surgery was undertaken. There were no re-operations or complications.

**Conclusion:** This study found that patients with three-level painful degenerative disc disease improved significantly following TDR. These patients present a treatment challenge and need to be carefully evaluated for bone quality and facet joint problems. If a patient fulfills the selection criteria for TDR, multi-level replacement may be considered.
CLINICAL: POSTERIOR DYNAMIC PEDIcular STABILIZATION

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2 Year Results from a US IDE Trial Evaluating a Lumbar Posterior Dynamic Stabilization (PDS) System
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Introduction: Pedicle screw based Posterior Dynamic Systems (PDS) are intended to offer stability and are used in conjunction with decompression to treat patients with degenerative lumbar stenosis as an alternative to traditional decompression and fusion when indicated. This study compares clinical outcomes at 2 years with preop findings of patients treated with the Stabilimax* system at 1 or 2 levels from 2 sites of the US IDE trial.

Methods: Patients with leg/back pain due to degenerative spinal stenosis were enrolled in a prospective, randomized clinical trial, and results from 2 of the 20 sites were evaluated. Decompression and stabilization with the PDS system was performed at index level(s). Patients were evaluated preop and at 6 weeks, 3, 6, 12, 18 and 24 months postop. Outcomes included: ZCQ-SS (Zurich Claudication Questionnaire - Symptom Severity), ZCQ-PF (Physical Function), ODI (Oswestry Disability Index), VAS-R (Visual Analogue Scale - Right Leg Pain), VAS-L (Left Leg Pain) and VAS-B (Back Pain).

Results: 28 consecutive patients (17 females, 11 males) with mean age of 55 years were enrolled in 2 sites. There were 17 one-level patients and 11 two-level patients. Patient data was available for 24 patients completing 12 month follow-up, with 17 of those patients completing 18 month follow-up and 14 patients completing 24 month follow-up. Preoperatively, patients had significant disability (Figure 1). There was significant improvement in all outcome measures in comparison to preop (p<0.11) at all time intervals (Figure 1).

Conclusion: The data shows that the combination of decompression coupled with a PDS device designed to allow near normal Range of Motion (ROM) and Inter-Pedicular Travel (IPT) results in a significant improvement in patient based pain and functional outcomes at 2 year follow-up in this case series.

Significance: PDS may be a viable alternative to fusion in patients with lumbar stenosis requiring decompression and stabilization.

CLINICAL: INNOVATIONS NON-CONVENTIONAL

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Report of Surgery Patients with Degenerative Disease of the Lumbar or Cervical Spine Treated at an Ambulatory Surgery Center
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Introduction: The evidence-based literature broadly supports the safety, effectiveness and efficiency of many types of orthopedic surgery in an outpatient setting. Microlumbar discectomy, and more recently anterior cervical discectomy and fusion (ACDF), have been reported as safe and feasible on an outpatient basis. With continuing advances in intraoperative imaging and visualization technology, minimally invasive instrumentation, and improved anesthesia and surgical techniques, there is growing interest in other outpatient spinal surgery procedures, including interspinous process distraction, disc arthroplasty and lumbar arthrodensis. In this study we report on a large series of spine patients operated at a single outpatient surgery center.

Methods: This is a case series report of 632 surgeries at a single center from December 2007 to October 2010 by two fellowship-trained spine surgeons, for patients operated at one or more levels for symptomatic lumbar or cervical degenerative disease unresponsive to nonoperative care. Intraoperative measures including operative time and blood loss, and postoperative observations including complications, readmissions, revisions and reoperations were reviewed. Patient satisfaction surveys related to the outpatient setting were also reviewed.

Results: There were 406 lumbar spine surgeries, including: 18 decompressions; 110 disc replacements; 90 anterior lumbar fusions; 86 posterior or posterior lateral fusions; 54 spinous process distractor insertions; 28 microdiscectomies; 10 hardware removals; and one nucleus replacement and nine other procedures. In addition, there were 226 cervical spine surgeries performed, including: 3 decompressions; 175 disc replacements; 24 anterior fusions; 4 posterior fusions; and 20 hybrids combining disc replacement and fusion at adjacent levels. Mean operative time and EBL for lumbar/cervical surgeries was 99.9/100.0 minutes and 59.9/58.0 cc respectively. A total of 30 (7.4%) secondary surgical procedures (8 cervical) were performed, including: 13 reoperations for additional decompression or adjacent surgery.

Significance: The data shows the safety, effectiveness and efficiency of many types of orthopedic surgery in an outpatient setting.
level disease, 5 revisions for displaced hardware/subsidence, 5 reoperations due to failed fusion, and 7 wound-related procedures. There were no readmissions/transfers to hospital following an index procedure. Patient satisfaction with the care provided in this outpatient center exceeded 95% on all measures, 99% recommending this center overall for procedures of the lumbar and cervical spine.

**Conclusions:** Appropriately selected patients with lumbar or cervical degenerative disease unresponsive to conservative measures may be safely treated on an outpatient basis with a variety of surgical interventions. Compared with complication rates reported in the literature for lumbar and cervical degenerative disease surgeries in a traditional hospital setting, these outpatient center spinal surgeries may be considered both feasible and safe. As evidence of the safety and effectiveness of outpatient spine surgery continues to grow, and as pressure to reduce unnecessary costs in the health care system increases, the evolution away from traditional hospitals for selected procedures will continue.

**CLINICAL: COMPLICATIONS**

534 Complication Risks of the Transforaminal Approach to the Lumbar Spine: An Anatomic and Patho-anatomic Risk Assessment

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**Purpose:** The paramedian and lateral trans-foraminal approach to the lumbar spine has known pitfalls from operating near the dorsal root ganglion. With foraminal endoscopic surgery, however, documentation and visualization of patho-anatomy has identified additional, but lesser known causes of sciatica and post-operative dysesthesia.

**Method:** Patients with minor and major adverse effects undergoing endoscopic foraminal surgery are prospectively studied and retrospectively reviewed. Inflammatory conditions and patho-anatomy identified with the endoscope recorded in vivo serve as the data base for study.

**Findings:** Post-operative dysesthesia occurred an average of 8-15% of the time in a review spanning over 1000 consecutive procedures for herniated lumbar discs and painful degenerative conditions of the lumbar spine. Findings of “anomalous” nerves, synovial cysts, and inflammatory membranes are routinely seen, but has not been cited in the literature as a complication risk. Furcal (forked) nerves contribute significantly to the pre-and post-operative symptom complex. Furcal nerves may be difficult to differentiate from the foraminal ligament. Autonomic nerves confirmed by endoscopic excisional biopsy, have also been identified. The most common pathologic endoscopic finding was inflammatory and granulation tissue in the foram, annulus, and disc. The presence of inflammation in normal tissue is correlated with pain. This endoscopic finding correlated well with severe back pain and sciatica produced by low pressure low volume discography. Its severity post-operatively may be correlated with the extent of thermal ablation on the outer annulus and the presence of anomalous and furcal nerves in the foramen.

**Discussion:** Dysesthesia is a “complication” that is an unavoidable consequence of surgical access through the foramen, even when no adverse event is anticipated and when the surgery goes well. Surgeons working in the foramen through a paramedian posterior approach encounters the same surgical risk. Working near the Dorsal Root Ganglion is a Known risk by itself, in all transforminal surgery. Ablation or removal of nerves in the inflammatory membrane, however, results in a satisfactory surgical outcome of overall pain relief of axial back pain and sciatica, but may also produce a temporary side effect of dysesthesia of varied severity. Furcal nerves, when identified, but are correlated with temporary dysesthesia if ablated and small in size. Dysesthesia is usually mild, self-limited, and temporary, but a major concern to patients who get it severely post-operatively. Permanent residuals are rare, but may result in residual numbness and extremity weakness. Post-operative dysesthesia responds well to Lyrica or Neurontin, foraminal nerve blocks, and lumbar sympathetic blocks. Co-morbidities such as peripheral neuropathy, and seizure disorders are additional risk factors.

**Conclusion:** Post Operative neuropathic pain staying the same or worsening may not be able to be completely eliminated, and is a risk of the endoscopic procedure. Pre-operative Consent should include neuropathic pain, usually transient, but with a possibility of permanent numbness or weakness. A thorough discussion of the risks associated with foraminal surgery must be explained to any patient undergoing open or endoscopic foraminal surgery. Knowledge of the effect of foraminal epidural injections intra-operatively, post-operatively, and in the management of post-operative dysesthesia will decrease this adverse side effect of foraminal surgery. The overall risks and surgical morbidity are still less than posterior trans-canal surgery.

**CLINICAL: PROSTHESIS**

536 ProDisc®-C Nova Total Disc Replacement - First Results

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**Introduction:** Cervical total disc replacement (TDR) is intended to address discogenic pain, restore disc height, and preserve functional motion between two vertebral bodies in patients with symptomatic cervical disc disease. Thus, TDR may prevent subsequent adjacent disc degeneration. The ProDisc®-C Nova (Synthes Gmbh) TDR, is the next-generation ProDisc®-C. It has an updated keel design, better enabling multi-level implantation, and updated materials to allow for improved MRI imaging. The purpose of this study was to evaluate the preliminary clinical results of the ProDisc®-C Nova TDR.

**Methods:** Beginning in 2009, a prospective, controlled, consecutive case series of 60 patients have received cervical arthroplasty using the ProDisc®-C Nova TDR (132 devices). To
date, patients have been assessed pre-operatively and post-operatively at 3, 6 months and 12 months. Evaluations included the Neck Disability Index (NDI), Visual Analog Scales (VAS), satisfaction and SF-36 patient self-assessments, physical and neurological exams, and radiographic evaluation. **Results:** 28 were males with a 51 yrs. average ranging from 36 - 84 yrs. and 32 were females 52 yrs. average ranging from 36 - 69 yrs.). Of the 60 patients, 23.3% underwent single-level (C3/C4 = 1; C4/C5 = 2; C5/C6 = 7; C6/C7 4); 41.6% two-level (C3-C5 = 6; C4-C6 = 7; C5-C7 10; C3/C4+C5/C7 = 1; C4/C5 +C6/ C7 =1); 26.6% three-level (C3-6= 1; C4-C7 = 13; C3-C5+C6/C7= 1; C3/C4 + C6 Th1) and 8.3% four-level surgery (C3 - C7 = 4; C3/ C4+C5-C7+Th1/Th2=1). At 3 months, the mean NDI score improved significantly and maintained this improvement out to 12 months (baseline: 44.7 ± 20.3 %; 3 months: 27.9 ± 18.9 %; 6 months 34.0 ± 21.7 %; 12 months 35.7 ± 22.6 %). Similarly, the average VAS pain intensity score showed significant improvement at 3 months, from baseline, and maintained improvement out to 12 months (baseline: 6.0 ± 3.0mm; 3 months: 3.1 ± 2.7mm; 6 months: 3.1 ± ; 12 months: 4.4 ± 3.2 ). The SF 36 physical / mental component and total was baseline P 39 ± 9,2 M 25,9 ± 10,8 T 81,3 ± 18,7; 3 month P 42,6 ± 10,8 M 26,1 ± 9,1 T 83,8 ± 17,2; 6 month P 42,4 ± 14,6 M 30,3 ± 8,7 T 91,3 ± 21,7 and at 12 month P 41 ± 12,11 M 31,3 ± 4,4 T 88,6 ± 15,6; At 3 month all patients were satisfied or very satisfied at 6 months 8,1 % of patients reported being unsatisfied and at 12 month none of the patient was unsatisfied with their surgery. Radiographic evaluation demonstrated that functional range of motion was being maintained. One patient required a re-operation due to subsidence, because of an infection, at 6 months. **Conclusions:** Since the majority of the affected patients require multi-level surgery, the design of the ProDisc®-C Nova is optimal for these cases, and allows for superior imaging. The early results of this study provide evidence that ProDisc®-C Nova is a safe and efficacious TDR surgical treatment for patients with disabling disc disease in both single and multi vertebral levels. Longer follow up is required to confirm these findings.

**CLINICAL: IDENTIFYING AND TREATING THE PAIN GENERATOR**

538

**In-vivo Endoscopic Visualization of Patho-anatomy in Painful Degenerative Conditions of the Lumbar Spine**

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**Introduction:** The patho-anatomy and degenerative processes in an aging spine have been defined by Wolfgang Rauschning’s anatomic cryosections of cadaveric specimens. Theories of pain generation are suggested by close examination of these specimens. If the visualized patho-anatomy can be studied in-vivo by spinal probing, rational treatment options can be developed, and the pathophysiology of spinal pain can be better understood. This study is made possible by evaluating painful tissue and structures in vivo in a conscious, partially sedated patient. **Method:** Endoscopic spinal endoscopy is studied as a method capable of clearly visualizing the patho-anatomy in the spine. An IRB approved study of 56 patients in 1997 provided evidence that endoscopic transfominal surgery was feasible for a diagnosis and treatment of a wide spectrum of degenerative conditions. Discography was also a critical tool to help correlate pain production with the patho-anatomy visualized, and correlated with in-vivo probing. An intra-operative chromo-discogram was used to evoke concordant pain. Dilute Indigocarmine stained the degenerated nucleus and annulus. Foraminal normal and patho-anatomy was probed under local anesthesia. **Results:** Patho-anatomy ranging from annular tears to synovial cysts and spinal stenosis provided evidence that foraminal decompression, ablation, and irrigation was a minimally invasive surgical technique that could treat painful conditions with minimal morbidity. It provided evidence that even instability from spondylolisthesis can be successfully treated. Intradiscally, the most common endoscopic finding was inflammatory tissue in the disc and annulus. Inflammation was correlated with the presence of painful annular tears. Inflammation may affect all tissues in the foramen. Lateral recess stenosis was more accurately assessed by observing lack of foraminal and peri-neuro fat. Neo-angiogenesis and neurogenesis and “Anomalous” furcal and autonomic nerves identified pain generators that have not been reported in the surgical literature.

**Discussion:** The ability to visualize patho-anatomy and correlate it with surgical results addressing the patho-anatomy resulted in a better understanding of the pain generators in the lumbar spine. The study also provided better understanding of pain generation in spinal instability and stenosis. Findings also served to advance and evolve endoscopic transfominal technique ranging from intradiscal disc therapy to foraminal lateral recess decompression and intradiscal artificial nucleus implantation and fusion. The endoscopic foraminal approach to the spine and disc is a technique that can meet the goal of sparing normal anatomy, but allowing access to degenerative patho-anatomy in the spine. **Conclusion:** The foraminal endoscopic approach to the spine offers the delivery system for minimally invasive spine surgery that is tissue sparing, and effective in selected patients. The learning curve may be high, but results are also good, concomitant with the surgeon overcoming the learning curve, visualization of patho-anatomy, and with the continued evolution of the endoscopic approach to the spine.

**CLINICAL: INTERSPINOUS AND LIGAMENTOPLASTY**

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**Dynamic Inter Spinous Stabilization in Lumbar Discectomy. 4 Years of Follow up**

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**Introduction:** Using entrenched subsequent stabilization is a different, avoiding Arthrodesis in operated segments resulting in the need for a dynamic stabilization to allow a stable feature segment alternative.

**Methods:** Study prospective, by autocontrol, longitudinal, of deliberate intervention, 46 patients with dynamic stabilization interspinous type Dallos 1997-2004 with 4 year follow-up analysis was performed clinical and radiographic preoperative and 4 years, evaluating: lumbar disability, pain, disc height, disc angle in neutral, flexion, extension; the results be parsed. He was the descriptive statistics and applied the test ranges with Wilcoxon sign. Statistical significance was taken when p 0.05.

**Results:** 39 of 46 patients completed a 4-year follow-up. They were included in the study 9 women, 30 men, with an average age of 30.74 years. Affected levels were: 21 patients L4 and L5; 17-L5/S1; 1-L3/L4; an improvement in the 80.3 per cent in the level of Oswestry (P = 0.0001) preoperative pain decreased 6.8 points VAS; disc height decreased 0.1mm average without significance; disc angle in neutral increased 1.13° without presenting statistical difference; in flexion increased 2.641° (P = 0.0002) extension decreased 0.817° average without statistical significance; the range of mobility decreased 3.416° (P = 0.004).

**Conclusions:** The ligamentoplasty interspinous improves segmental stability, allowing a mobility within normal ranges, preserving the disc height 4 years of follow-up, offering greater dynamic stability. Success clinical improvement was been.

**CLINICAL: TRAUMA: FRACTURES AND SPINAL CORD REPAIR**

**551 Transpedicular Lag-screwing Fixation for Unstable Hangman Fractures**

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**Objective:** To evaluate the efficacy of transpedicular lag-screwing fixation for unstable hangman fractures.

**Methods:** Between March 2008 and April 2010, 10 cases with unstable Hangman fractures were treated using transpedicular lag-screw fixation in our Orthopedic Department, which included 8 males and 2 females. Their ages range from 31 to 62 years with an average of 43.5 years. The etiology involved 6 cases with traffic accident, and 4 cases of falling injury. There were 2 multiple-trauma cases, which included one splenic rupture case and another with multiple rib fractures and hemopneumothorax. The average interval between injury and operation was 8.8 days (range, 5 to 30 days). According to Levine-Edward's classification, there were 7 cases with type B and 3 cases with type A. Preoperatively, we made a neurological evaluation of all cases by Frankel scale, which showed 3 cases with grade D and 7 cases of grade E. All the cases had fractures reduced by skull traction prior to surgery. The operation was performed under local anaesthesia for all cases. The middle part of C2 lateral mass was chosen as the entrance point for screw; taking a cephalic angle of 15°-20° and 25°-30° angle on sagittal plane. The lengths of screws as used in this study ranged from 28-34mm with a diameter of 4.0 mm. 9 cases had bilateral screws fixation and one case underwent unilateral screwing due to the comminuted fragments. All procedures were performed under monitoring of “C”-arm fluoroscopy.

**Results:** All the procedures achieved success with an average length of 100 minutes (range, 80 to 130 minutes). The average blood loss was 290 ml (range, 210 to 400 ml) during operation. Postoperatively, all patients were followed up from 3 to 14 months, with an average of 8.5 months. Based on Frankel scale, 2 cases with grade D improved to E and one case remained as grade D. The evaluation made by Mayo (McGrory) scoring showed an marked increase from 58 preoperatively to 96 after procedure. Bony fusion was achieved in all cases at an average of 3.5 months (range, 3 to 5 m). All cases showed preservation of neck motion. No spinal cord or vertebral artery injury was witnessed in the procedure. During follow-up, there were no screw loosening or breakage, no cervical malformation or instability.

**Conclusion:** The transpedicular lag Screwing fixation is a less invasive, but most effective surgical method for unstable Hangman fractures. This method can provide immediate stability of cervical spine following operation. Additionally, it is able to preserve the physiological motion of upper cervical spine with little interference of adjacent segments.

**CLINICAL: NAVIGATION, IMAGE GUIDED SURGERY AND ROBOTIC ASSISTANCE**

**553 Diagnostic Efficacy of Myelo-CT for Surgical Confirmation in Degenerative Lumbar Spine Diseases; Comparison with MRI**

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**Purpose:** Since MRI was introduced in clinical practice, the diagnostic usefulness of myelo-CT has been overlooked. In the present retrospective study, the authors tried to elucidate diagnostic value of myelo-CT compared to that of MRI in a patient, who had clinically significant radiculopathy and needed a surgical management.

**Methods:** The study included retrospectively 100 consecutive patients in an average age of 58 years (range 20-81 years) presenting with intractable unilateral radicular leg pain caused by degenerative lumbar spinal disease between March and September 2010. The authors preformed preoperative MRI and CT-myelography concurrently, and confirmed a nerve root compromise by the disc or stenosis during operation in all cases. The root shadows on preoperative MRI (T2 axial images) and CT-myelography (axial scans) of symptomatic side at the pathologic level were classified into four grades: Grade 0: no root compression (root shadow is well visualized), Grade 1: nerve root is just abutted or contacted, Grade 2: nerve root is displaced by compression, Grade 3: definite root compression.
and completely non-visualized (flattened or obliterated) root shadow. The results of each imaging modality were compared and assessed by two different observers in relation to the grades, and the inter-observer difference was also assessed.

Results: The study included 165 individual nerve roots. Diagnoses were 49 cases of herniated disc, 39 of lateral recess stenosis caused by hypertrophied facet joints, 10 of spondylolisthesis and 2 of foraminal stenosis. The main offending lesions observed during the operation were herniated disc in 49 cases, facet or ligamentum flavum in 48, and combined in 3. The distribution of the grade observed on MRI was 1.2% of Grade 0; 27.2% of Grade 1; 26.6% of Grade 2; 44.8% of Grade 3. Meanwhile, the distribution of the grade observed on myelo-CT was 1.2% of Grade 0; 13.3% of grade 1; 26.6% of Grade 2, and 58.7% of Grade 3. In comparison study between two diagnostic procedures, the cases, in which an identical patient has different grade in either myelo-CT or MRI, account for 29%, and this difference was statistically different (P< 0.05). And it was observed that 2/3 of patients in Grade 1 on MRI demonstrated higher grades on myelo-CT, whereas only less than 1/10 of the patients in Grade 1 on myelo-CT revealed higher grades on MRI; 39% of the patient in Grade 2 on MRI demonstrated Grade 3 on myelo-CT, whereas 10% of patient in Grade 2 on myelo-CT revealed Grade 3 on MRI (P< 0.001). Myelo-CT brought about 2% of intracranial hypotension and 22% of temporary back pain, but no infection or arachnoiditis.

Conclusion: The present study demonstrates that myelo-CT would be more sensitive to define nerve root compromising lesions in the lumbar spine than MRI. Myelo-CT can be considered to be a useful supplementary study for a confirmative diagnosis when MRI study does not provide enough information in a patient with lumbar radiculopathy.

CLINICAL: PROSTHESIS

564 Radiological Analysis of a New Cervical Disc Prosthesis: 2-years Follow-up
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Introduction: Cervical total disc replacement is an alternative to fusion in patients with herniation or disc degeneration disease. The aim of this study is to report 2-years follow-up results with the Baguera cervical disc prosthesis.

Material and methods: 51 patients were included in this multicentric study with a mean age of 42 years (24-65) and underwent a single level total replacement between C3 and C7. During the follow-up period, systematic X-rays were obtained 3, 6, 12 and 24 months postoperatively. Measurements were including the global and local sagittal balance, the range of motion of the treated level, the positioning of the implant. The presence of heterotopic calcifications was also noted.

Results: At final follow-up, 46 patients were analyzed. Compared with the preoperative evaluation, disc height of the treated level was improved by 37%. Mean global cervical lordosis changed from 9° to 18° and evaluation of the treated level showed a mean variation from 0° to 3° of lordosis at final follow-up. Local range of motion of the treated level improved from an average of 3° to 8° at last follow-up. One implant was too posterior on the control X-ray and a second procedure was necessary. Concerning heterotopic calcifications, at two-years of follow-up, two patients had a bony bridge in front of the implant, an incomplete bridge was noticed in two more cases.

Discussion: At two years of follow-up, the Baguera implant showed satisfactory clinical and radiological results with a preserved range of motion. A restoration of the normal sagittal cervical lordosis was also noticed. On the whole series, no implant failure was reported and no technical difficulties for insertion were reported. Such cervical disc prosthesis leads to a postoperative sagittal adaptation of the cervical spine with satisfactory results. Presences of heterotopic calcifications are imprevisible but seem to be without significant clinical consequences. Longer term follow-up of these patients will be necessary in order to confirm the good result of this series.

BASIC SCIENCE: BIOMECHANICS / BASIC SCIENCE

566 The Effects of Nonenzymatic Glycation on Invertebral Disc Material Behavior and Tissue Hydration
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Introduction: Degenerative disc disease (DDD) is a debilitating disease characterized by the degeneration of the intervertebral disc (IVD) that results in reduced mobility and is often associated with increased pain. The IVD is an avascular tissue whose ability to resist deformation is dependent on the interactions of the matrix constituents, consisting a network of type 2 collagen and proteoglycans that work together to imbibe cationic fluids. The proper mechanical and structural function of the the IVD is highly dependent on its tissue material properties. Post-translational modification of long-lived proteins through the process of nonenzymatic glycation (NEG) occurs under the presence of oxidizing sugars in the extra-cellular space and results in the increased crosslinking due to the formation of Advanced Glycation End-products (AGEs). The accumulation of AGEs has been shown to adversely affect the tissue material properties of orthopedic tissues including bone and cartilage. Due to its lack of vascularity with little turnover of proteins, the IVD is susceptible to the accumulation of AGEs, and degenerated IVDs have been shown to have increased elevated levels of AGEs.

Hypothesis: The accumulation of advanced glycation end-products may alter the ability of the IVD tissues to retain water and affect the tissue material behavior.

Methods: 40 lumbar/thoracic intervertebral discs were removed from 4 sheep lumbar-thoracic spines for a total of 80 tissue samples. Using a previously established in vitro ribosylation procedure, the tissues were matched by location to undergo a 0, 2, 4, 6, 8-day incubation period in a
After the respective incubation times, they were mechanically assessed and analyzed for water composition, and the extent of nonenzymatic glycation. One-way ANOVA was used to determine the effects of NEG incubation period on mechanical properties and water content. Multiple regression analyses were used to determine relationships between AGES, disc tissue material properties, and water content.

**Results & discussion:** Water content in both tissue types decreased significantly with incubation time in both the AF (p< 0.001) and NP (p< 0.05) tissues. Regression analyses showed a significant inverse relationship between decreasing water content and increasing AGES. Furthermore, the decrease in water content in the NP tissue is more susceptible to losses in water content due to increases in AGES than in AF tissues. The increase of AGES in the tissue also resulted in a stiffening of the tissue as indicated by the indentation modulus. The accumulation of AGES in collagenous tissues has been previously shown to deteriorate its energy dissipation capability and disrupt the tissue's structure-function relationship. We demonstrate for the first time that the loss of tissue water content can be induced in a dose-dependent manner through nonenzymatic glycation. Furthermore, the loss of water content directly modulates the tissue material properties of the IVD tissues. The resulting biochemical behavior reduced the tissue's ability to retain its viscous component. It is possible that the accumulation of AGES could alter the charge-density characteristics of the tissue that further contributes to the loss tissue water content. The alterations in both the elastic and viscoelastic properties at the tissue level may be directly related to the decreasing disc height observed in discs with elevated AGES.

**CLINICAL: FUSION**

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“Adjacent” Disc Degeneration of L3/4 after Fusion of L5/S1. A Matched-cohort Analysis

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**Introduction:** Symptomatic degeneration of a disc adjacent to a fusion (ASD) is one of the main issues in spinal surgery of the degenerative lumbar spine. There is controversy about influencing factors and about the question if and to which extend adjacent disc degeneration due to biomechanical reasons exists at all.

**Materials and methods:** The present study is a matched-cohort case-control analysis of patients with prospectively collected data.

From all patients that underwent monosegmental lumbar fusion (PLIF) between 2002 and 2006, 70 patients could be matched into two groups according to demographic parameters, diagnosis and preoperative signs of degeneration: 35 patients underwent surgery at L4/5, 35 patients at L5/S1. We excluded patients who underwent surgery due to infections, tumor and trauma, as well as revision surgeries, and all patients with incomplete preoperative datasets.

Preoperatively, and at last follow-up (mean follow-up: 38 months), standing x-ray films of the lumbar spine were analysed for disc degeneration of L3/4 in both groups and L4/5 in the group with PLIF L5/S1, using the grading system proposed by Wilke et al. in 2006.

A multiple regression model was developed to evaluate the impact of different variables like age, length of follow up, diagnosis, preoperative disc status and the presence of an adjacent fusion.

Moreover, to clarify clinical significance, SF36 and Oswestry-Disability-Index scores were collected preoperatively and at last follow-up and correlated with signs of adjacent segment degeneration.

**Results:** Progredient degeneration of L3/4 occurred in 48.6% after PLIF at L4/5 and in 11.4% after PLIF L5/S1. Moreover, the segment L4/5 showed signs of degeneration in 25.7% after PLIF L5/S1.

There was a trend towards patients with a diagnosis of a degenerative disease (DDD and degenerative spondylolisthesis) having a higher risk for developing ASD than patients treated for lytic spondylolisthesis.

No significant difference was found concerning the clinical outcome variables.

Multiple regression analysis showed a statistical significant odd’s radio (OR) of 5 for the presence of an adjacent fusion to be the main risk factor for the development of ASD. Less important co-factors were age and length of follow-up.

**Conclusions:** This study suggests that there is appreciable data that supports the hypothesis of biomechanically induced adjacent disc degeneration in the lumbar spine. Patient’s age and length of follow-up seem to be relevant co-factors.

**CLINICAL: MIS DECOMPRESSION**

574

The Muscular Injury Makes a Difference. A Study with 36 Months of Follow up

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**Introduction:** The minimally invasive techniques in spinal surgery has many advantages such a little postoperative pain, short surgical time, less bleeding, without muscular injury, traduced on early return to normal activities.

**Materials and methods:** We present sixty patients with radicular pain secondary to extruded lumbar disc herniation, whose underwent surgery with minimally invasive platform (MAXCESS RETRACTOR), we report the Visual Analogue Scale and Oswestry on Preop, Discharge, 6 weeks, 3, 6, 12, 24, 36 and 72 months, surgical time, bleeding, time to discharge and return to normal activities.

**Results:** Mean age 40.3 y/o, Visual Analogue Scale preop 8.3, 1.9 on discharge, 1.8 6 weeks, 1.4 3 months, 1.2 on 6 and 12 weeks and 1 24months and 0 on 36 months, Oswestry 54 preop, 10 on discharge, 9 on 6 weeks, 8 on 3 months and 3
on 6, 12 and 24 and 36 months. the mean surgical time was 62 minutes, stay hospitalization: mean 5.4 hours and time to return to work mean 7.6 days. Complications: one patient had LCR fistula with medical management successfully.

**Conclusion:** The minimally invasive spine surgery allow to reduce a muscular injury and is a good option improving the pain as a short staying and return to normal activities and optimal follow up on 36 months.

**CLINICAL: POSTERIOR DYNAMIC PEDICULAR STABILIZATION**

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Novel Indication for Posterior Dynamic Stabilization Device: Correction of Rotational Instability after Total Disc Replacement

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**Background:** The increase in total disc replacement (TDR) procedures performed over the last five years has yielded more postoperative presentations of rotational instability anteriorly or laterally. The proposed treatment for this complication has been TDR device retrieval followed by ALIF versus posterior fusion. In the present technical note, we propose a novel approach for the correction of rotational instability after TDR using the Dynesys posterior dynamic stabilization (PDS) system (Zimmer Spine, Minneapolis, MN).

**Methods:** Operative Technique. Pedicle screws are inserted using standard techniques under fluoroscopic guidance with electrodiagnostic positional confirmation. We address the collapsed side of the TDR device first. We proceed with Dynesys installation by placing the pedicle distance gauge between screw heads and applying sufficient distraction force to create parallel endplates. Spacers are placed, with the spacer on the contralateral side being shorter by 2-3 mm. The spacers are threaded and pulled into place with the tensioning instrument. The collapsed side is distracted with the spacer and the contralateral side is compressed with tension from the cord. The fascia and skin are closed using standard techniques.

**Results:** Two patients with tilted TDR devices (Figures 1 and 2) underwent corrective procedures with the Dynesys PDS system. Radiographs confirmed correction of deformity in both cases.

**Conclusions/level of evidence:** This technical note presents a novel indication for PDS and describes how a PDS device could be used for the correction of rotational instability after TDR.

[Figure 1]

[Figure 2]

**Keywords:** Total Disc Replacement, Dynesys, Posterior Dynamic Stabilization, Disc Tilt, Disc Collapse.

**Figure legends.**
Figure 1: Case 1 anterior-posterior standing radiographs showing the TDR device in its original position (A), the collapsed/tilted TDR device (B), and the TDR device after Dynesys correction of rotational instability (C).
Figure 2: Case 2 anterior-posterior standing radiographs showing the TDR device in its original position (A), the collapsed/tilted TDR device (B), and the TDR device after Dynesys correction of rotational instability (C).

**CLINICAL: FUSION**

586
Early Results of the NuNec Cervical Disc Replacement

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**Object:** The object of this study is to evaluate clinical effectiveness of cervical disc replacement using the NuNec system.

**Methods:** Ten patients (seven male and three female) with a mean age of 47.3 years were enrolled. They presented with cervical radiculopathy and/or myelopathy with or without neck pain. After failure of conservative management, a standard anterior cervical discectomy was carried out and a NuNec disc was implanted in the affected level.
The involved level was C3/4, C4/5 and C6/7 in one patient respectively and C5/6 in seven. Neck score of Japanese orthopedic association (JOA score) and pain in the neck and upper extremities by Visual analogue scale (VAS, range: 0 to 100) were evaluated. Segmental ROM and height between two vertebrae were measured. The follow-up period was average 6 months (3 to12). Adverse effect during and after surgery was also checked
Result: JOA score improved from 21.2/29 to 26.3/29. VAS improved from 70.4 to 21.0 in the neck and from 75.3 to 15.2 in the arm. Segmental motion was 4.5 degrees preoperatively. It increased to 6.8 degrees postoperatively. The vertebral height also increased 7.6mm. No adverse effect was observed. One case showed slight migration of the implant (2mm to front), but settled in six months. She had no clinical symptom.
Conclusion: Although it is an early result, total disc replacement with the NuNec showed clinical improvement. It also increased segmental ROM and height slightly.
Six cases showed neck pain.
Patients presented clinically with cervical radiculopathy and/ or myelopathy with or without neck pain. A standard anterior cervical discectomy was carried out and a Bryan disc was implanted in the affected levels. A total of 59 prosthetic discs were implanted, in 49 patients at a single level and in 5 at two adjacent levels. The neurological status was evaluated preoperatively and at one and two years thereafter. Plain X-rays, CT, and MRI were used for pre-operative diagnostics. Post-operative follow-up was done by X-rays.

Findings: All patients had an excellent or good neurological outcome according to the Odom criteria. Loss of function (motion range < 3 degrees) was found in 7 (12%) out of 59 Bryan discs at two years after surgery. Heterotopic ossification (HO) of the McCaffee grades 1-4 was seen in a total of 17 (29%) segments. There were no implant dislocations or migrations.

Conclusions: Implantation of the Bryan disc resulted in excellent or good neurological outcome in all patients. The surgical technique was safe and without complications. Twelve percent of the implanted Bryan discs lost mobility at two years, mainly due to HO. A trend was seen towards development of HO in the operated segments. Further investigations with longer follow-up periods and with a control group (e.g. fusion with intervertebral cage) will be necessary for a definitive assessment of the long-term functionality and benefits of artificial cervical discs. Mean VAS in the neck decreased from 56.8 preoperatively to 11.8 postoperatively and arm pain decreased from 68.1 to 18.0.

**CLINICAL: IDENTIFYING AND TREATING THE PAIN GENERATOR**

**587 Innovation in Spine Surgery: Miracles of MMG**

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**Introduction:** Transmission of signals between the entire body & the brain is carried out by the ‘Spinal Cord’. This transmission to the remotest parts in the body is done by neurons. Neurons are of two types: motor neurons & association neurons. The association neurons work within the same segment of the spinal cord; with a segment being the horizontal section of the cord that gives rise to a pair of spinal nerves. These second order lower motor neurons - the spinal nerves, form part of the final common pathway for information traveling from the central nervous system to the periphery. Recently, recurrent nerve monitoring has become increasingly frequent, as studies show decreased incidence of postoperative vocal paralysis in monitored cases.

**Electromyography (EMG):** Conventionally, EMG is used during spine surgery to monitor spinal nerves. By monitoring the muscles that are stimulated by these nerves, technologists determine if a nerve root is being disturbed during the procedure. If disturbed in any way (bumping, stretching, etc.), the nerve will depolarize, causing an action potential, which causes the corresponding muscle to twitch. Electrodes record this twitch & immediate feedback is sent on the monitor, alerting the surgeon.

**Disadvantages of EMG:**
- EMG fails on patients administering medication affecting nervous system.
- Even though an EMG provides real-time feedback of nerve root irritation, sometimes the damage has already been done. Therefore, determining that a nerve was affected does not necessarily mean that it will lead to a more positive post-operative outcome.
- Electrical stimulus like electrocardiogram (ECG) and from other hospital machinery may be picked as noise.

**Mechanomyography (MMG):**

MMG is the epidural measurement of the mechanical activity (“muscular sound”) of contracting muscles; i.e. MMG non-invasively records and quantifies the oscillations generated by dimensional changes of the active skeletal muscle fibers. MMG v/s EMG:

- Study Purpose: To compare the effectiveness of MMG with EMG in detecting nerves.

Study Design:
- EMG muscle electrodes were placed into muscles of the hindquarters of adult sheep where insulation was confirmed. MMG sensors were placed adjacent to the EMG electrodes onto the surface of skin. Their clocks were synchronized.
- Through a lateral exposure, a grid was placed over the psoas muscles.
- The current ramp was turned “ON” & binary O/P recorded.
- This was repeated for remaining 65 holes locations with 4160 trails in total.

Results:
- Overall Agreement: 94%
- Positive Agreement: 98%
- Negative Agreement: 71% MMG detected nerves up to 7s before EMG. On an average MMG detected presence of a nerve 1.2s earlier than EMG.

Analysis of Detection Time for MMG v/s EMG:

<table>
<thead>
<tr>
<th>Time</th>
<th>S a m e</th>
<th>1s</th>
<th>2s</th>
<th>3s</th>
<th>4s</th>
<th>5s</th>
<th>6s</th>
<th>7s</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nerves</td>
<td>1021</td>
<td>1337</td>
<td>603</td>
<td>245</td>
<td>112</td>
<td>58</td>
<td>18</td>
<td>6</td>
<td>1.2</td>
</tr>
</tbody>
</table>

**Conclusion:**
- Even though both use electrical events as stimulus (same pulse duration & waveforms), their sensor designs are different: MMG detects motor response, EMG detects electrical current.
- **Remarkable observations:**
  - High positive agreement: 98%
  - MMG sensors have increased sensitivity compared to EMG sensors.
  - MMG sensors detected nerves on average 1.2s and as much as 7s faster than EMG.
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Abram, Leon - available onsite
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Berdugo, M - (c)-NuVasive, Inc; (e)-Bacterin International, Inc
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Bhattacharya, Sanghita - (g) nothing to disclose
Bhatti, Harvinder - (c,d,f)-Globus Medical
Bilys, James - (c)-NuVasive; (d)-Safewire; (e)-Trans1, NuVasive; (f)-Trans1, Medronic, ANS
Blaskiewicz, Donald - available onsite
Blondel, Benjamin - (g) - nothing to disclose
Blumenthal, Scott - available onsite
Brücher, Dirk - (e,f)-Aesculap AG
Büettner-Janz, Karin - (a) Smith & Nephew; (d) SpineWave
Burger, Evalina - (g) - nothing to disclose
Bucic, Josip - (d)-Minimus Spine
Butterworth, Kimberly - (e)-Orthokinematics
Cappuccino, Andrew - (c)-NUVA, Centinellel; (d)-Pioneer, K2M, NUVA, Implant, Therall; (f)-NUVA, Globus, Centinellel
Cardoso, Mario - (g) - Nothing to Disclose
Castelli, Antonio - (c)-Scient;x; (e)-Alphatec; (f)-Globus
Chay, Edward - (g)-Nothing to Disclose
Chen, Xi - available onsite
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Cheng, Boyle - (c)-Laix; (d)-Exactech, Medtronic; (e)-Alphatec Spine, Scient’x; (f)-Medtronic, Alphatec Spine; Cheng, Wayne - (e) DePuy Spine, Lank, Aesculap
Christensen, Finn - (d, e) FBC Device
Cohen, Anders - - available onsite
Collignon, Frederic - (e,f)-Medtronic, Alphatec
Cook, Daniel - (g) nothing to disclose
Coric, Domagoj - (c,d,e) SpineWave; (d,e)Pioneer Surgical, Spinal Motion; (e) DePuy Spine
Crawford, Neil - (f) Trans1; (e) Laxn; (d) Sparteck SDRI
Davis, Reginald - (e,f) Zimmer Spine
Delamarter, Rick - available onsite
Demakakos, Jason - (g)-Nothing to Disclose
DiAngelo, Denis - (d) Cagenix, Inc
Diaz, Roberto - (e) DePuy Spine; (f) Orthofix Spinal Implants, Synthes
Ding, Chen - (g) -Nothing to Disclose
Dipp, Juan - (d)-I-spine, Magellan Spine, Venbenny Medical; (f)-Interventional Spine, Venbenny Medical
Diwan, Ashish - (e)-J&J-ATRM;
Domyahn, Mark - (d, e)-Zimmer, Inc
Donald, Gordon - (c, f)-K2M; (e)-K2M, Orthoco; (f)Orthovita;
Doria, Carlo - (g) -Nothing to Disclose
Dwyer, Jim - available onsite
Elf, Marcus - available onsite
Elshihabi, Said - (e) Spine Wave, Centinel, DePuy; (f) Spine Wave, Centinel Spine
Fabrizi, Anthony - (g) nothing to disclose
Fayyazi, Amir - (d)-Bonovo, Surgitech, Exactech, Titan, Alphatec, IS0I; (e)-Kuros; (f)-Synthes
Feifei, Zhou - (g) nothing to disclose
Feng, Frank - (e)-NuVasive
Ferrara, Lisa - (e) fee for service only consultant and test facility
Field, Justin - (e)-NuVasive, Globus, Stryker; (f)NuVasive, Globus, Stryker
Fogel, Guy - (g) nothing to disclose
Foley, Kevin - available onsite
Frankel, Bruce - (c) Zimmer Spine, Orthofix Spine; (d) Spine Align Medical, Minimae Spine, Advanced Spinal Research; (e) Orthofix Spine, Synthes Spine, DePuy Spine, Spine Align Medical, Aloka Ultrasound; (f) Orthofix Spine
Freeman, Andrew - (g) nothing to disclose
Garcia, Rolando - (e)-Aesculap; (f)-Aesculap & Stryker Spine
Geisler, Fred - -available onsite
Gille, Olivier - available onsite
Gimbel, Jonathan - (d, e)-Flexuspine, Inc;
Gornet, Matthew - (c) -Stryker, Medtronic, Pioneer; (d) -BioAssets Development, Bonovo, Disc Motion Technologies, K2M, Orthobones
Mehler, Hans - (c)-Medtronic, Aesculap, Fehling, Synthes; (e)-Codon
Messer, Julie - (d,e)-Anulex Technologies
Mekar, Umesh - (a)-AOSpine - financial support for attending conference
Mihalko, Mark - available onsite
Miz, George - (c,d,e,f) K2M; (f) Synthes
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Moumene, Missoum - (d)-Johnson & Johnson; (e)-DePuy Spine Inc.
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Neely, Warren - available onsite
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Nicol, Hazem - (g) nothing to disclose
Noriega, David - (e,f)-Vexim SAS;
Nunley, Pierce - (c) BioMet, Osprey BioMedical, LDR Spine; (d) Amedica, K2M, Paradigm Spine, Spineology; (e) K2M, NuVasive
Oggiano, Leonardo - available onsite
Oh, Jong Yang - available onsite
Ohnmeiss, Donna - (a) Employed by a non-profit foundation that has received research and/or educational support from OREF, AO Spine, Medtronic Neurological, NuVasive, Orthofix, Mazor Robotics, Stryker Spine, and TranS1
Osborn, Brett - available onsite
Osman, Said - (c)-Zimmer Spine
Ozer, Fahir - (g) Nothing to Disclose
Palepu, Vivek - (g) nothing to disclose
Park, Chun-Kun - (a)-Synthes, Medtronic; (f)-Janssens Korea, Medtronic, Synthes Korea, Depuy Korea;
Park, Soo-An - (d)-L&K biomedical
Patel, Ashish - available onsite
Patwardhan, Avinash - (f) Aesculap Academy; (e) Simpircia Spine; (d) Spinal Kinetics, Axiomed, Orthokinetamics
Peppelman, Walter - (c)-Globus, Aesculap, zimmer; (d, e)-Globus, Annulex;
Pettine, Kenneth - (c)-Medtronic,(d)-Mesoblast;(e)-DePuy; (d,e,f)-NuVasive;Paradigm
Pflugmacher, Robert - (e,f)-Medtronic, Dfine
Phillips, Frank - (c)-NuVasive, DePuy; (d)-Baxano, Feeluspine, Axiomed, Bonovo, Crossstreets, Spinal Motion, Spinal Kinetics, SI-Bone, BioAssets; (e)-Kyphon, K2M, NuVasive
Pillay, Prem - (d)-Roche; (f)-Pfizer
Pimenta, Luiz - (c,f)-XLIF-NuVasive, Inc; (e)-NuVasive, Inc; Zyla; (d)-NuVasive, Inc;
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Polly, Jr., David - (e,f) Medtronic
Pumberger, Matthias - (g) Nothing to Disclose
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Reyes-Sánchez, Alejandro - (g) Nothing to Disclose
Ricart-Hoffiz, Pedro (g) Nothing to Disclose
Rischke, Burkhard - (d, e)-Axiomed spine Corp.
Robertson, Peter - (a) travel costs; (e)-Medtronic, DePuy;(f)-Medtronic, DePuy JJ.
Rodgers, Blake - (c, d, e, f) NuVasive; (d) Alphatech; (e, f) Exactech; (e, f) SpineArt; (e) VTI; (f) Trans1
Rousseau, Marc-Antoine - (g) nothing to disclose
Ryu, Kyeong-Sik - (g) Nothing to Disclose
Samdani, Amer - (e,f)-DePuy Spine, Synthes Spine, SpineGuard;
Saoud, Abdelfattah - (g) Nothing to Disclose
Sawa, Anna - (g) Nothing to Disclose
Schaeft, Christoph - (d)-Bayer; (e)-Spinal Kinetics; Stryker; Kroenet; (f)- Spinal Kinetics
Schmidt, Hendrik - available onsite
Scott-Young, Matthew - (d)-Johnson & Johnson, Medtronic; (e)-FDA trial investigator-DePuy spine
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Serhan, Hassan - (a, d, f) DePuy Spine
Shah, Neil - (g) nothing to disclose
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Shi, Qin - (g) Nothing to Disclose
Shibayama, Motoshi - available onsite
Sibata, Motohide - available onsite
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Smith, Zachary - (e)-Orthokinetamics
Soroceanu, Alex - (g) Nothing to Disclose
Souchome, Petr - (c, e, f)-Aesculap AG, Germany
Suetson, Futoshi - (g) Nothing to Disclose
Sullivan, Humbert - (g) Nothing to Disclose
Sumpio, Bauer - (e, f)-Replication Medical
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Sun, Zhi-Yong - (g) Nothing to Disclose
Szpalski, Marek - (d) Orthovita; (e) Orthofix, Scient’x
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Voronov, Leonard - (g) Nothing to Disclose
Wang, Beiyu - (g) Nothing to Disclose
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Wardlaw, Douglas - (e)-Medtronic
Wilke, Hans-Joachim - (e)-Spinetech, Ulrich Medical; (f) Lutriusis, Surgil
White, Andrew - (e)-Globus, DePuy, Biomet; (f)-Globus Medical
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Wong, David - (a)-Neurotech/Cerviom, Greenwood ASC, Dll; (d)-Neurotech/Cerviom, Greenwood ASC, Colorado Orthopaedic and Surgical Hospital, Denver Integrated Imaging; (e) - Stryker, Allosource, United Healthcare; (e, f)-Synthes
Wong, Wendy - (g) Nothing to Disclose
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Yang, Hui Lin - (g) Nothing to Disclose
Yeung, Anthony - (c, f)-Richard Wolf Surgical Instrument Co., Eliquence; (d)-Surgitech, Ovro Bros, Bonovo
Yi, Seong - (g) Nothing to Disclose
Youssef, Jim - (c)-Nuvasive, SeaSpine, DePuy, Aesculap/B. Braun, Osprey, Amedica; (d)-Amedica, Pioneer, Vertiflex; (e)-Aesculap/B.Braun, NuVasive, SeaSpine
Yuan, Hansen - (c) Stryker, DePuy Spine, Pioneer Surgical; (d) NuVasive; (e) Pioneer Surgical
Yue, James - (c, d, e, f)Alphatec Spine; (e)-RMI
Zhou, Lijin - available onsite
Zhu, Xuesong - (g) Nothing to Disclose
Zigler, Jack - (c)-Zimmer Spine, Osprey, Kzar, (d)-Options in Fiopuspine, Expanding Orthopedics; (e)-Synthes Spine; (f)-Stryker Spine
Zou, Jun - (g) Nothing to Disclose
Zou, Dewei - (g) Nothing to Disclose

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