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Clinical Outcomes of Extreme Lateral Interbody Fusion (XLIF) in the Treatment of Degenerative Conditions of the Lumbar Spine  
A.G. Tohmeh¹, W.D. Smith²  
¹Northwest Orthopaedic Specialists, Spokane, WA, USA, ²University Medical Center, Neurosurgery, Las Vegas, NV, USA  

Background context: Minimally-disruptive techniques for lumbar spine procedures continue to gain prevalence as both patients and surgeons aim to decrease morbidities associated with conventional, open procedures. One such procedure is extreme lateral interbody fusion (XLIF). The purpose of this study was to examine mid-term outcomes in a consecutive series of XLIF patients.  

Methods: 95 patients were treated with XLIF for degenerative conditions at one institution and were followed through a prospective registry. Of those, 70 (74%) were available for at least 12 month follow-up. Mean age was 60.7 years (range 22-85 years) with a body mass index of 29.8 and 52.9% of patients were male. 14.9% of patients were smokers, 19.4% had diabetes mellitus, 13.6% had coronary artery disease, and prior spine surgery had occurred in 54.3% of patients. Of the prior surgery patients, 41% had undergone laminectomies, 25.6% had received posterolateral fusion, 15.5% had undergone interbody fusions and 12.8% had undergone microdiscectomies. Cumulative diagnoses (secondary diagnoses were present in a majority of cases) included spondylolisthesis (31.7%), postlaminectomy syndrome (29.8%), stenosis (14.9%), adjacent segment disease (15.9%), and degenerative disc disease (70.4%). Number of levels treated ranged from one to four, with an average of 1.5 levels per patient. The most common levels treated were L4-5 (70.0%) and L3-4 (32.9%), with L5-S1 treated in 14.3% of cases through a transforaminal lumbar interbody fusion approach (TLIF). Supplemental internal fixation was used in all but one case. Anterolateral plating was used in 41.4% and pedicle screw fixation was used in 57.1% of cases. A direct decompresion was performed in 22.6% of cases. Outcome measures included the Oswestry disability index (ODI), visual analogue scale (VAS) for back and leg pain, quality of life (SF-36), patient satisfaction, and self-reported willingness to re-do the procedure had their outcome been known preoperatively. Statistical analysis included frequency testing and paired-samples t-tests, with significance measured at p< 0.05.  

Results: Mean anesthesia time was 145 mins (range 58-262), with mean operating (ORT)(skin-to-skin) time being 93.3 mins (62 mins per level, range 24-187). Mean blood loss (EBL) was 101.8cc per case (including supplemental instrumentation), and length of hospital stay (LOS) was 2.8 days (range 1-6 days) with one (1.4%) intraoperative complication (dural tear). One (1.4%) patient experienced breakage of a pedicle screw rod, which required revision. Mild thigh pain and/or weakness was observed in 6 (8.6%) patients, with symptoms resolving without additional intervention. VAS back pain improved 62.2% at last follow-up from 7.6 preoperatively to 2.9. Leg pain (VAS) similarly improved from 5.8 preoperatively to 2.4 at last follow-up, a 59.1% decrease. ODI improved 44.8% from 50.4 preoperatively to 27.8 at last follow-up. Quality of life (SF-36) improved from 40.7 preoperative to 62.3 at last follow-up, a 53.1% increase. All pre- to postoperative clinical outcomes were statistically significant at p< 0.001.  

Conclusions: Carefully selected patients with degenerative conditions can be treated safely and effectively with XLIF. In this series, VAS back pain, VAS leg pain, ODI, and SF-36 improved by 62.2%, 59.1%, 44.8%, and 53.1%, respectively. These outcomes rates are substantially equivalent to reports of conventional approaches for anterior or posterior interbody fusion, with less ORT, EBL, LOS, and fewer complications.
Discussion: Hip flexion was weakened immediately following the LIF procedure, which may be attributed to the psoas muscle injury during the procedure. However, this damage is temporary, with almost complete return to baseline values after 2 weeks.

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Minimally Invasive Lateral Interbody Fusion in the Morbidly Obese
W.B. Rodgers¹, E.J. Gerber¹, J.A. Lehmen¹, J.A. Rodgers¹
¹Spine Midwest, Inc., Research, Jefferson City, MO, USA

Summary: This study demonstrates outcomes of a large series of Minimally Invasive Lateral Interbody Fusion (MI-LIF) procedures in obese or morbidly obese patients and presents a safe and effective minimally invasive alternative for spinal fusion for this challenging patient group.

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 MI-LIF 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 1093 MI-LIF patients, 576 were identified as obese (BMI>30) and 192 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 morbidly obese 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. Age ranged from 22-83yrs. Comorbidities included smoking (34%), prior spine surgery (47%), diabetes (41%), CAD (37%), COPD (3%). 244 levels were treated in these 192 patients: 150 1-levels, 33 2-levels, 8 3-levels and 1 4-level; the majority at L4-5. All but 2 surgeries included supplemental fixation. There were 3 transfusions and no infections. Complications included 2 MI’s at 4 and 6 wks, 3 atrial fibrillation, pneumonia requiring intubation for 5 days, one other respiratory distress requiring reintubation, one pulmonary embolism, two posterior hardware failure/rod fracture at 6 and 18 mos, and one fracture of vertebral osteophytes and a vertebral body fracture at 2 months requiring reoperation. Hospital stay averaged 1.54 days. From pre-op to 24 month follow-up: disk height increased an average 3.0mm; slip decreased an average 3.6mm in spondylolisthesis patients; and VAS pain scores decreased from 8.7 preop to 3.1 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 MI-LIF technique in treating morbidly obese patients minimally invasively. Complications are minimal, procedures timely, and outcomes similar to non-obese patients.

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Learning Curve of a Complex Surgical Technique: Minimally Invasive Transforaminal Interbody Fusion
K.H. Lee¹, W. Yeo¹, H. Soeharno¹, W.M. Yue¹
¹Singapore General Hospital, Orthopaedics, Singapore, Singapore

Purpose: The purpose of this study is to evaluate the learning curve of minimally invasive transforaminal lumbar interbody fusion (MIS TLIF). Very few studies have evaluated the learning curve of this technically demanding surgery, and those available have small sample sizes and mainly evaluated learning based on operative time. We intend to evaluate the learning curve of MIS TLIF with a larger sample size and assess surgical competence based not only on operative time, but with peri-operative variables, clinical and radiological outcomes, incidence of complications, and patient satisfaction.

Methods: From June 2005 to July 2008, the first 80 single-level MIS TLIF, which utilized a consistent technique and spinal instrumentation, performed by a single surgeon at our tertiary institution were studied. Prior to performing the first MIS TLIF, this surgeon had performed 25 single-level open TLIF, observed the MIS TLIF procedure performed by 2 spine surgeons and practiced the technique on 3 cadavers.

Variables studied included operative time, peri-operative variables, clinical (Visual Analogue Scores for back and leg pain, Oswestry Disability Index, North American Spine Society Scores for neurogenic symptoms) and radiological outcomes, incidence of complications and patient rating of overall result of surgery. The data were collected prospectively by independent assessors. All patient outcomes and variables, with a minimum follow up of 2 years, were analyzed in eight sequential groups of 10 patients.

Results: The eight groups of 10 patients were similar in age, race, gender distribution and spinal levels operated (p>0.05). Of all the variables utilised in the assessment of learning curve, only three variables showed difference between the early and later phase of learning. They were mean operative time, mean fluorooscopy time and mean usage of patient controlled analgesia. The mean operative time for the first ten cases was 227.5 ± 86.3min, decreasing significantly and reaching a steady state after 40 cases with a mean operative time of 133.5 ± 20.0min (p< 0.05). The mean fluorooscopy time was 95.2 ± 21.9sec for the first ten cases, and decreased to a mean of 29.8 ± 8.8sec after 50 cases (p< 0.05). The mean usage of patient controlled analgesia (morphine) was 14.9 ± 20.0mg for the first ten cases, and decreased to a mean of 0.82 ± 2.2mg after 20 cases (p< 0.05).

All other peri-operative variables, clinical and radiological outcomes, incidence of complications and patient rating of overall result of surgery were good and similar across the eight groups. None of the MIS TLIF cases in this series were converted to open TLIF.

Conclusion: Shorter operating and fluoroscopy times do not necessarily equate surgical competence. To portray a more comprehensive picture of the learning curve of MIS TLIF, clinical and radiological outcomes were included in this study. Based on our surgeon’s experience, MIS TLIF is a technically demanding surgery, but with prior experience in open TLIF, good outcomes can be
achieved even in the early phase of adopting the MIS TLIF technique. However to perform MIS TLIF more efficiently, the asymptote of the learning curve can be achieved after performing about 40 cases.

A comparison of Open versus MIS TLIFs in a Worker’s Compensation Patient Population

F.M. Phillips1, K. Singh1, M.A. Pelton1
1Rush University Medical Center, Orthopaedic Surgery, Chicago, IL, USA

Background context: Recent data has shown that MIS (Minimally Invasive Surgery) TLIFs (Transforaminal Lumbar Interbody Fusion) may have significant short and long-term clinical benefits versus open fusions. Very few studies have analyzed outcomes in a worker’s compensation (WC) population.

Purpose: The purpose of this study was to analyze intraoperative, immediate post-operative and financial outcomes in worker’s compensation and non-worker’s compensation patients undergoing either an open or MIS TLIF.

Study design: This study was a non-randomized, non-blinded prospective review.

Patient sample: 66 consecutive patients undergoing a single-level TLIF (open/MIS) were analyzed (33 open, 33 MIS). From this series, 24 total workers compensation patients were identified (11 MIS, 13 open). Patients in either cohort (MIS/Open) were matched according to insurance status (WC) and medical co-morbidities (Charleston disability index). Every patient in this study had a diagnosis of either degenerative disc disease or spondylolisthesis and stenosis.

Outcomes measures: Operative time (minutes), Length of stay (LOS, days), estimated blood loss (EBL, cc), anesthesia time (minutes), and hospital cost/payment amount were assessed.

Methods: Patients were matched in either group (MIS/open and Work-Comp versus Non-Work Comp) according to demographics (race, age, gender, smoking status, co-morbidities, diagnosis). Statistical analysis was conducted using SPSS Statistics version 17.0.

Results: There were no statistically significant differences between MIS WC and non-WC TLIFs with respect to surgical time, LOS, EBL, and Anesthesia time (Table 1). There were no statistically significant differences between Open WC and non-WC TLIF patients in all of the same above-mentioned parameters. However, there were significant differences between MIS WC and Open WC TLIFs with regards to surgical time, LOS, anesthesia time, and EBL (Table 1). There were statistically significant differences in total costs amounts between MIS TLIF and Open TLIF groups ($28,060 vs $33,862 respectively; p=0.0311). Total payment amounts were significantly increased in both WC groups vs $33,862 respectively; p=0.0311). Total payment amount to the hospital with similar resource utilization as their non-WC counterparts.

| Table 1 |

345 Minimum 2-year Follow-up Results and Complications after AxiaLIF 2 Levels

L. Marchi1,2, L. Oliveira1, R. Amaral1, C. Castro1, T. Coutinho1, E. Coutinho1, L. Pimenta1,2
1Instituto de Patologia da Coluna, São Paulo, Brazil; 2Unifesp, DDI, São Paulo, Brazil; 3University of California San Diego, Neurosurgery, San Diego, CA, USA

Purpose: Axial lumbar interbody fusion (axiaLIF) is a minimally invasive presacral surgical technique providing damage neither to the annulus fibrosus nor to the anterior and posterior longitudinal ligaments. It was initially designed and utilized for L5-S1 interbody fusion and recently was extended for 2-level fusion (L4-L5 and L5-S1). Up to now, only biomechanical and radiological studies have discussed the feasibility of the technique and no report on a clinical study is available. The purpose of this article is to report results and complications of axiaLIF 2-level with a minimum of 24-month follow-up.

Methods: This is a prospective, non-randomized, single-center study. Twenty-seven patients underwent AxiaLIF surgery for L4-L5 and L5-S1 fusion and were eligible for enrollment. Clinical outcomes were collected with VAS for back and leg symptoms and with ODI, preoperatively and postoperatively at 1 week, 6 weeks, 3 months, 6 months, 12 months and annually. Radiographic parameters such as disc height, segmental lordosis and bone fusion were analyzed with x-rays and computed tomography. Complications and revision surgeries were also recorded. The minimum follow-up was 24 months (up to 72 months).

Results: There were no intraoperative complications. One major complication was observed: a patient evolved on septicemia. Clinical questionnaires scores showed overall improvement in pain and in physical function.
During follow-up were observed complications in the construction: screw breakage (14.8%), proximal/distal transsacral rod detachment (11.1%), radiolucentency around transsacral rod (52%) and cephalic rod migration (24%). Disc height gain was testified early after surgery, but at 24-month follow-up the disc space was seen to be diminished in comparison to preoperative status. Compared to preop values, after 24 months the studied group had experienced lost in segmental lordosis. Only 22% of total treated levels were considered to have solid fusion at 24-month radiological evaluation.

Conclusions: Cases undergoing axialLIF 2-level have experienced satisfactory short-term clinical outcomes. Yet vast radiological complications compromised surgery goals after 24 months. Additional studies are required to better understand 2-level indication for this technique.

Discussion and conclusion: The retrieval rate in our series is very high. It shows that the end-plate reaction in a long period of time happens, resulting in important subsidence and mechanic back pain. The device expulsion was another cause of pain and second surgery, as shown in literature. Patients must be frequently monitored to guard against significant complications that sometimes are unnoticed in the clinical routine in order to prevent the reproduction of these disastrous results.

Endoscopic Transforaminal Discectomy (ETD)
M. Schubert

Background: Microscopic dorsal lumbar discectomy is the gold standard treatment for lumbar symptomatic disc herniation. To reduce the complication rate and to eliminate the risks of general anaesthesia, more minimal invasive procedures gain significant interest in patients and spine surgeons.

Purpose: Of this study is to evaluate the effectiveness and complication rate of the endoscopic transforaminal discectomy (ETD).

Study design: A prospective clinical study.
Patient sample: 252 consecutive patients over a four year period with a MRI proven disc herniation in the lumbar spine with radicular symptoms, positive Lasegue (< 45°), or neurological symptoms that did not respond satisfactory to conservative treatment off at least two months.

Outcome measures: The patients had a clinical evaluation 3 months after surgery and returned at two years an extensive questionnaire including VAS scores, Mac Nab score as well as subjective satisfaction

Methods: All patients were treated under local anaesthesia and could be discharged the day after surgery. From a lateral approach first the intervertebral foram was enlarged and a working cannula was inserted in the spinal canal. The prolapsed or extruded part was removed under endoscopic vision with special...
forceps, curettes and with an awl and a special reamer the inferior endplate was perforated, abraded and all loose intradiscal fragments were removed.

**Results:** At the two year follow-up 96.4% of the patients reported an excellent or good result, 2.8% a fair and 0.8% unsatisfactory result. Patients reported a significant improvement in leg and back pain according to the VAS scale. According to MacNab criteria: 44.8% of the patients felt fully regenerated, 48.8% felt their capacity slightly restricted, 5.6% felt they were noticeably restricted and 0.8% felt unchanged. In 6 (2.4%) cases an early recurrent disc herniation (<3 months) appeared. 3 patients (1.2%) had a temporary paraesthesia and foot weakness (which disappeared after 3 months). There were no cases of discitis.

13 patients (5.2%) were treated for recurrent disc herniation (between 3 months and 2 years). 10 of those patients where treated endoscopically again, 3 had a microdiscectomy. 10 patients were very satisfied or satisfied after second surgery, one was unchanged and two were unsatisfied.

**Conclusion:** The endoscopic transforaminal discectomy appears to be a safe, effective procedure without significant complications and is an alternative to open microdiscectomy.

**Cervical Transfacet Fixation: Safety and Accuracy of Open versus Percutaneous Approaches**


Loma Linda University Medical Center, Orthopaedic Surgery, Loma Linda, CA, USA, Loma Linda University School of Science and Technology, Psychology, Loma Linda, CA, USA

**Purpose:** Cervical transfacet fixation has been shown to be biomechanically and clinically comparable to lateral mass screw-rod fixation. Nonetheless, surgical technique descriptions and safety evaluations of open and percutaneous cervical transfacet screw placement remain scarce in the literature. The purpose of this study was to compare open and percutaneous approaches to placing cervical transfacet screws in terms of safety in avoidance of neurovascular structures and accuracy of screw placement.

**Methods:** Eighty cervical facet joints from 8 cadaveric spines were used. A percutaneous technique was used on one side and an open technique was used contralaterally. Cannulated screws (4.0 mm diameter, 16 mm length) were placed over guide wires across each facet joint from C3-4 to C7-T1. Screw position was later evaluated for accuracy and safety by fine cut computed tomography and cadaveric dissection.

**Findings:** No screws penetrated into the spinal canal. Three percutaneously-placed screws violated the vertebral artery. Two of those same screws violated nerve roots. Mean distance from the screw to the vertebral artery was 5.1 mm in the percutaneous group and 5.9 mm in the open group (p = 0.1). Mean distance from the screw to the nerve root was 2.8 mm in the percutaneous group and 3.9 mm in the open group (p = 0.012). Mean distance from the screw to the spinal canal was 6.4 mm in the percutaneous group and 8.5 mm in the open group (p < 0.001). Mean angle of the screw to the center of the spine in the axial plane was 21.7 degrees in the percutaneous group and 23.4 degrees in the open group (p = 0.035). Seventy-nine percent of all screws had ideal facet capture. Eight screws (9.1%) had less than 15% purchase of the facet joint, six of which were from the percutaneous technique.

**Results:** The open technique resulted in a significantly greater distance from the screw to spinal cord than the percutaneous technique. The surgical techniques did not statistically differ in distance from the screw to the vertebral artery, distance from the screw to the nerve root, screw purchase ratio and angle of screw in the axial plane.

**Conclusions:** For the experienced spine surgeon, percutaneous transfacet fixation may provide a clinically feasible, minimally-invasive alternative to posterior cervical fixation. Reducing screw size from 16 to 14 mm will reduce the risk to neurovascular structures.
systemic or local complications and no neurological deterioration were reported; one CSF leak was identified and successfully repaired during surgery.

**Discussion:** The trans-foraminal approach enables sufficient access to the midline of the spinal canal without extensive resection of the facet joint or the adjacent pedicle. Since most of the osseous and ligamentous structures are preserved, no additional instrumentation is required to prevent post-operative instability. Partial drilling of the cephalic aspect of the caudal pedicle may be required in order to get good access to the disc annulus. This might be encountered especially in cases where the foramen is relatively small, such as in the upper thoracic level in smaller patients, or when the disc protrusion extends to the spinal canal above or below the disc space. In these cases the minimally invasive extra-cavitary approach may be used. However, in our series, drilling of the pedicle was not needed. Patients showed no clinical or radiological signs of spinal instability.

**Study design: Meta-analysis and systematic review**

**Objective:** The purpose of this meta-analysis is to determine if differences in safety or efficacy exist between balloon kyphoplasty (BKP), vertebroplasty (VP) and nonsurgical management (NSM) for the treatment of vertebral compression fractures (VCFs).

**Summary of background data:** While class I evidence supports the superiority of vertebral augmentation procedures (VAPs) over NSM for reducing pain and disability, a few recent randomized trials claimed no difference between VP and NSM.

**Methods:** As of February 1, 2011, a PubMed search (key words: kyphoplasty, vertebroplasty) resulted in 1587 articles- 27 met basic selection criteria (prospective multiple-arm studies with cohorts of ≥20 patients). This meta-analysis adheres to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

**Results:** Both BKP (-5.07/10 points, P < .01) and VP (-4.55/10, P < .01) performed better than NSM (-2.17/10) in reducing pain, while no difference was found between procedures (P = .35). Subsequent fractures occurred more frequently in the NSM group (22%) compared with VP (11%, P = .04) and BKP (11%, P = .01). BKP resulted in greater kyphosis reduction than VP (4.8° vs 1.7°, P < .01). Quality of life (QOL) improvement showed superiority of BKP over VP (P = .04), along with a trend for disability improvement (P = .08). Cement extravasation was less frequent in the BKP (P = .01). VAPs within the first 7 weeks yielded greater pain reduction.

**Conclusions:** VAPs provided greater pain relief and fewer subsequent fractures than NSM in patients with osteoporotic VCFs. BKP is marginally favored over VP in disability improvement, and significantly favored in QOL improvement. BKP had a lower risk of cement extravasation and resulted in greater kyphosis correction and height restoration. Despite this analysis being restricted to Level I and II studies, significant heterogeneity suggests that the literature currently does not present a consistent picture of the safety and effectiveness of VAPs.

**Keywords:** Vertebral compression fractures; Osteoporosis; Balloon kyphoplasty; Vertebroplasty; Meta-analysis.

**Background:** Vertebral fractures (VCF) are often painful and lead to reduced quality of life (QOL). We compared the efficacy and safety of balloon kyphoplasty (BKP) to non-surgical management (NSM) over 24 months in patients with acute painful fractures.

**Methods:** Adults with one to three VCF were randomized within 3 months from onset of pain to undergo bilateral BKP (n=149) or NSM (n=151). Subjective QOL assessments (e.g., SF-36 PCS) and objective functional (Timed up and go [TUG]) and vertebral body kyphotic angulation (KA), were assessed over 24 months; we also report surgical parameters and adverse events temporally related to surgery (i.e., within 30-days).

**Results:** Kyphoplasty was associated with greater improvements in SF-36 PCS scores when averaged across the 24-month follow-up period, compared with NSM (overall treatment effect 3.24 points, 95% CI, 1.47-5.01; p = 0.0004). Kyphoplasty also resulted in greater functionality by assessing TUG (overall treatment effect -3.00 seconds, 95% CI, −1.0 to −5.1; p < 0.0043). At 24 months, the change from baseline in KA was statistically significantly improved in the kyphoplasty group (average 3.1° of correction for BKP versus 0.8° for NSM, p=0.003). On average, IBT inflation pressures were 178 (left) and 180 (right) psi; IBT inflation volumes were consistent with cement volumes at 2.4 cc per side. The most common adverse events within 30-days were back pain (20 BKP, 10 NSM) new vertebral fracture (11 BKP, 7 NSM), nausea/vomiting (12 BKP, 4 NSM) and UTI (10 BKP, 3 NSM). There were two device-related serious adverse events in the second year that occurred...
Lumbar Therapies

Analyzing the Relationships between Pain, Patient Expectations, and Satisfaction Following Spine Surgery

**Aims:** Clinical outcomes of spine surgery may be related to many factors including patient expectations prior to the intervention. The purpose of this study was to investigate the relationships between patient expectations, changes in pain levels, and satisfaction with treatment outcome.

**Methods:** Data were collected prospectively for 160 patients as part of a presurgical psychosocial screening study. Pre-operatively, patients completed a 0 to 10 numerical rating scale (NRS) asking what was their current pain intensity, and on another NRS rated what they expected their pain to be after surgery. Post-operatively, patients completed NRSs indicating their current pain level, how well their outcome met their expectations, and their level of satisfaction with surgery.

**Results:** There were statistically significant differences between patients’ pre-operative pain level and their expected post-operative pain level (p< 0.01; see table; indicating they expected their pain to be significantly lower after surgery). Post-operatively, the median current pain level was significantly greater than the expected levels (p< 0.05) although the current pain was significantly improved from the pre-operative value (p< 0.05; suggesting that patients’ pain improved significantly, but did not improve to the level expected pre-operatively).

**Conclusions:** In this population of spine surgery patients, pain levels improved significantly after surgery, but did not improve to the level patients indicated they expected based on a pre-operative NRS. There was a high rate of agreement when comparing responses to a post-operative question asking if expectations were met and the values produced by comparing the pre-operative expected pain level and the actual post-operative pain score. Meeting expectations is highly related to a high satisfaction rate; however, failure to meet expectations did not preclude being satisfied as more than half of patients whose expectations were not met were satisfied.

**Low-grade Spondylolisthesis Can Be Effectively Treated by Either Coflex® Interlaminar Stabilization or Laminectomy and Posterior Spinal Fusion: Two-year Clinical and Radiographic Results from the US IDE Trial**

**Introduction:** The gold standard treatment for low-grade degenerative spondylolisthesis with spinal stenosis remains laminectomy and posterior spinal fusion (PSF) with pedicle screw implants. The potential for substantial perioperative morbidity and adjacent segment degeneration has led to the search for motion-preserving alternatives that still allow for direct neurologic decompression and stabilization. The US IDE trial compares coflex® interlaminar stabilization with laminectomy and PSF for the treatment of the following conditions:

1. low-grade spondylolisthesis, and
2. spinal stenosis with disabling low back pain. In the current study, we report exclusively on the subset of patients at 2 years from this IDE trial with low-grade spondylolisthesis.

**Methods:** This is a prospective, randomized, multicenter FDA IDE trial comparing coflex® interlaminar stabilization (n=140) with laminectomy and PSF (n=72) to treat 1- and 2-level spinal stenosis with low back pain or up to Grade I degenerative spondylolisthesis. In the spondylolisthesis subset there were 64 coflex® and 34 PSF patients with complete data at 2 years. Study inclusion consisted of moderate to severe spinal stenosis with significant low back pain (VAS Back Pain ≥50/100) and significant disability (ODI ≥40%), with Grade I spondylolisthesis, at 7 or greater on the 10-point scale assessing satisfaction, indicating they were quite satisfied with results. Of note, there were only two patients whose pre-operative expected pain value was met or exceeded, but who were not satisfied. Among patients whose expectations were not met (based on the difference between pre-op expected pain level and the actual post-op pain level), 62.2% of them indicated that they were satisfied with their results. This was significantly lower than the satisfaction rate (96.0%) among patients whose expectations were met.

**Conclusions:** In this population of spine surgery patients, pain levels improved significantly after surgery, but did not improve to the level patients indicated they expected based on a pre-operative NRS. There was a high rate of agreement when comparing responses to a post-operative question asking if expectations were met and the values produced by comparing the pre-operative expected pain level and the actual post-operative pain score. Meeting expectations is highly related to a high satisfaction rate; however, failure to meet expectations did not preclude being satisfied as more than half of patients whose expectations were not met were satisfied.
spinal segments from L1-L5.

**Results:** Follow-up for the entire cohort at 24 months was 96.6% and 98.6% for coflex® and PSF groups, respectively. There were no group differences at baseline. Coflex® patients experienced significantly shorter operative times (p<0.001), EBL (p<0.001), and length of stay (p<0.001). ODI scores were lower at all post-operative timepoints with coflex®, with significant improvement at 3months (p=0.034) and a trend at 6months (p=0.033). Despite equivalence at baseline, 2 year coflex® ODI scores averaged 19.6 compared with 26.0 for PSF (p=0.141). The proportion of coflex® patients achieving a 15-point ODI reduction at 24months was 88.0%(44/50) compared with 76.7% with PSF(23/30). ZCQ outcomes were significantly improved with coflex® at 2 years in Symptom Severity (p=0.041), Physical Function (p=0.048), and Satisfaction (p=0.015). SF-12 outcomes revealed no group differences except at 24 months where the coflex® cohort trended towards greater improvement in the Mental Health Component (p=0.086). VAS Back and Leg scores revealed equivalent improvement with either coflex® or PSF. Based on the stringent FDA composite for overall success including ODI improvement ≥15 points, no device-related complications, no reoperations, and no epidural injections, 67.2%(41/61) of coflex® and 63.6%(21/33) of PSF with spondylolisthesis succeeded, respectively. Finally, PSF exhibited significantly greater angulation (3.77 vs 6.38°, p=0.0003) and translation (0.78 vs 1.15mm, p=0.049) at the cranial adjacent level (Figure) at 2 years.

![Figure: Angulation (Top) and Translation (Bottom)]

**Conclusions:** Low-grade spondylolisthesis can be effectively treated by decompression and coflex® interlaminar stabilization with equivalent or superior results at 2 years when compared with laminectomy and PSF. The reduced perioperative morbidity, shorter hospital length of stay, equivalent or superior clinical outcomes, and significantly reduced adjacent segment stresses supports the use of coflex® as a viable alternative to PSF in low-grade spondylolisthesis.

**499 Coflex® Interlaminar Stabilization Compared to Posterior Spinal Fusion for Spinal Stenosis and Spondylolisthesis: Two-year Results from the Prospective, Randomized, Multicenter Food and Drug Administration IDE Trial**

R.J. Davis\(^1\), T.J. Errico\(^2\), H. Bae\(^3\), J.D. Auerbach\(^4\)

\(^1\)Greater Baltimore Neurosurgical Associates, Towson, MD, USA, \(^2\)Hospital for Joint Diseases-NYU, New York, NY, USA, \(^3\)The Spine Institute, Santa Monica, CA, USA, \(^4\)Bronx-Lebanon Hospital Center, Department of Orthopaedics, Bronx, NY, USA

**Introduction:** Lumbar laminectomy and posterior spinal fusion are commonly performed for patients with degenerative spondylolisthesis and spinal stenosis with significant low back pain. Long-term untoward sequelae of lumbar fusion have led to the search for motion-preserving, less-invasive alternatives. The purpose of the current study is to evaluate the safety and efficacy of the coflex® interlaminar device compared to posterior spinal fusion in the treatment of 1- and 2-level spinal stenosis and degenerative spondylolisthesis.

**Methods:** Prospective, randomized, multicenter FDA IDE trial comparing direct decompression and coflex® interlaminar stabilization with laminectomy and posterior spinal fusion. Study inclusion consisted of moderate spinal stenosis with significant low back pain (VAS Back Pain ≥50/100) and significant disability (ODI ≥40%), with up to Grade I spondylolisthesis, at spinal segments from L1-L5. Two hundred nineteen patients (146 coflex® and 73 fusion controls) were randomized and treated from 21 sites in the USA to receive direct decompression and coflex® interlaminar stabilization or laminectomy and posterolateral spinal fusion with spinal instrumentation in a 2:1 ratio. Perioperative data, ODI, VAS Back, VAS (worse) Leg, SF-12, ZCQ, and radiographic outcomes at minimum 2 years were evaluated. Overall device success was a composite of >15-point reduction in ODI, no reoperations, no major device-related complications, and no post-operative epidural injections.

**Results:** Patient follow-up at a minimum of 2 years was 96.6% and 98.6% for coflex® and fusion control groups, respectively. There were no group differences at baseline in any demographic, clinical, or radiographic parameter. Coflex® patients experienced significantly shorter operative times (p<0.0001), estimated blood loss (p<0.0001), and length of stay (p<0.0001) compared with to fusion controls. At 2 years, mean ODI scores were significantly better in the coflex® cohort (p=0.021) with a trend towards a greater proportion achieving a 15-point reduction in ODI (p=0.06). Both groups demonstrated significant improvement in all VAS Back and Leg parameters. Coflex® patients had significantly greater improvement in SF-12 Physical Health outcomes (p=0.027) and similar Mental Health outcomes. Coflex® subjects had greater improvement in all ZCQ outcomes compared with fusion (Symptom Severity (p=0.013); Physical Function (p=0.013); Satisfaction (p=0.025)). Based on the stringent FDA composite for overall success, 66.4% of coflex® and 59.7% of fusions succeeded, respectively. The overall complication rate was similar between the groups. At 2 years fusion controls exhibited significantly increased sagittal plane translation (p=0.05) and angulation (p<0.0001) at the superior adjacent level, while coflex® maintained normal operative and adjacent level motion.

**Conclusions:** Our results demonstrate safety, efficacy, and non-inferiority of decompression followed by coflex® interlaminar stabilization compared to fusion in the treatment of spinal stenosis and degenerative spondylolisthesis. Coflex® stabilization led to significantly improved perioperative outcomes, multiple clinical outcomes measures, and maintenance of motion at operative and adjacent levels compared with fusion at 2 years. Coflex® interlaminar stabilization is a safe and efficacious alternative, and provides several distinct advantages over lumbar spinal fusion with pedicle screw instrumentation.

**112 Lumbar Spinal Stenosis: How Much Can You Decompress without Destabilizing the Spine?**

C. Hoelscher\(^1\), A. Peters\(^2\), E. Edusei\(^3\), W. Skalli\(^4\), B. Moal\(^2\), T. Errico\(^1\)

\(^1\)NYU Hospital for Joint Disease, Division of Spine Surgery, New York, NY, USA, \(^2\)Laboratoire de Biomecanique, Department of Biomechanics, Paris, France

Questions? (866) 423-9440 (U.S.) +1(630) 995-9994 (Int’l)
Summary: Direct and digital measurements were recorded for the distance between the left and right pars interarticularis (PI) at each level of the lumbar spine, allowing for an appreciation of the window available for executing a stable canal decompression. An increase in PI distance was revealed when descending from L2 to L5 level; similarly, canal width and the ratio of PI-to-canal-width increased at caudal lumbar levels.

Background context: With advanced imaging modalities leading to higher rates of diagnosis of spinal stenosis, a more precise understanding of the window for stable decompression is critical. Clinically iatrogenic violation of the PI is more common in decompressions of the upper lumbar spine compared to the lower lumbar spine. Current data characterizing the PI level-by-level is lacking. This study analyzed the average distance between the left and right PI at each level of the lumbar spine.

Purpose: To determine the window available for lumbar canal decompression while maintaining stability.

Study design/setting: Direct measurements on dried lumbar spine specimens, and digital measurements via a database of CT images.

Methods: The interpars distance was defined as the narrowest distance between the lateral edges of the left and right PI. Direct measurements were recorded using a digital caliper accurate to 0.1mm on 53 complete lumbar specimens. A database of CT images provided an additional 30 sets of lumbar vertebrae. For both methods, the mean interpars distances were compared moving down the lumbar spine. Additionally, a level-to-level comparison was performed between direct and digital measurements.

Results: (See Table 1)

For direct measurements, the average (SD) interpars distances increased from L2 to L5. ANOVA with tukey post hoc analysis revealed significant differences (p< 0.05) across L2-L3, L3-L4, and L4-L5 levels. No significant differences were noted when male and female vertebrae were compared level-to-level. For digital measurements, the average interpars distances similarly increased from L3 to L5. An increase in spinal canal width was observed only across L4-L5 and an increase in the interpars-to-spinal-canal-width ratio was noted at the L3-L4 level. Comparing direct and digital measurements level-to-level revealed no significant differences.

275 Low-grade Isthmic vs. Degenerative Spondylolisthesis: Complications and Outcomes Following Reduction and Posterior Instrumented Fusion with TLIF

D.G. Crandall1, M. Gebhardt1, J. Revella1, J. Datta1, D. Revella1, M.S. Chang1, T. Crowder1, R. Mclemore1
1Sonoran Spine Center, Mesa, AZ, USA, 2Banner Orthopaedic Residency Program, Phoenix, AZ, USA

Purpose: Instrumented fusion after decompression is a well-established treatment for symptomatic low-grade spondylolisthesis. Additionally, reduction of the slip has theoretical advantages of indirect foraminal decompression, improved sagittal balance, and more room for an interbody cage. Disc distraction alone often improves the slip for degenerative spondylolisthesis (DS), but not isthmic spondylolisthesis (IS). For cases where reduction is advantageous (collapsed disc and foramina, grade 2 listhesis), achieving both slip reduction and TLIF can be technically demanding. This is the largest series of complications and outcomes for the surgical treatment of low-grade spondylolisthesis, comparing IS to DS after single and multilevel arthrodesis.

Methods: This is a retrospective review of prospective clinical and radiographic outcomes on 249 consecutive adults with grade 1-2 spondylolisthesis (DS-199, IS-50) undergoing decompression, reduction (grade 2 slips only, 1/3 of the series), and instrumented fusion with or without TLIF. Excluded: high-grade slips, retro or rotational listhesis, spondylolisthesis at the end of a long deformity (>4 levels). Age: DS 65.4 years (34-85 years); IS 50.5 years (14-82 years). Prior surgery was common: laminectomy-36, fusion-37. Thirty-one were smokers. Posterior arthrodesis averaged 2.6 levels (1-4 levels); DS averaged 2.8 levels, IS averaged 2.5 levels. TLIF was performed in 165 at average 1.6 levels. Clinical outcomes: VAS, Oswestry (ODI), and pain medication records recorded pre-op, 1 and 2 years post-op. Radiographs were obtained pre-op, 1 and 2 years. Arthrodesis was defined as bridging bone across the interspace, no motion on flexion/extension, and no sign of screw or cage loosening at 2 years.

Results: Follow-up averaged 57 months (12-114 months). The complications that were similar between DS and IS included wound infection (2%), nonunion (1 each), painful hardware, and persistent radiculopathy. DS had more degeneration related complications: adjacent level degeneration (DS-43%, IS-2%), herniated disc (DS-6%, IS-0%), footdrop (3 vs. 0) and additional surgery for any reason (DS-9%, IS-2%). These differences were not statistically significant. Both
single (DS-72, IS-28) and multi-level (DS-127, IS-22) fusions improved clinically. Single-level: VAS for IS: 6.01 pre-op, 2.4 at 2 years (p=0.001); DS:6.1 pre-op to 2.4 at 2 years (p=0.001). ODI for IS: 46.8 pre-op to 26 at 2 years (p=0.057); DS ODI improved from 47.3 pre-op to 22 at 2 years (p=0.002). Multi-level: VAS for IS: 5.7 pre-op to 2.4 at 2 years (p< 0.001); DS: 6.0 pre-op, 2.8 at 2 years (p=0.038). ODI for IS: 45 pre-op, 29 at 2 years (p=0.008); DS ODI improved from 46 pre-op to 26 (p< 0.001) at 2 years.

Conclusions: Decompression, slip reduction and TLIF when advantageous, and instrumented fusion in low-grade DS and IS results in similar long-term clinical outcomes for single and multi-level constructs. The differences in complications appear related to degenerative disease. DS patients were 15 years older on average, had much more adjacent level disease, and underwent more revision surgery over nearly 5 years follow-up than did patients treated for IS.

Five Year Adjacent Level Degenerative Changes Comparing Lumbar Total Disc Replacement to Circumferential Fusion in Patients with Single-level Disease in a Prospective Randomized Cohort Analysis

J.E. Zigler, R. Delamarter, J. Glenn

Aim: The authors report the five year results of radiographic adjacent level degenerative changes seen in patients enrolled in a prospective multicenter study in which they were randomized to either total disc replacement or circumferential fusion for single-level lumbar degenerative disc disease.

Methods: Two hundred thirty six patients with single-level lumbar degenerative disc disease were enrolled and randomly assigned to two treatment groups: 161 in the total disc replacement (TDR) group were treated with the ProDisc-L (Synthes Spine) and 75 were treated with circumferential fusion. Complete radiographic follow-up at five years was available for 123 TDR patients and 43 fusion patients. To characterize adjacent level degeneration (ALD), radiographic films were read by radiologists at an independent facility. ALD was characterized by a composite score comprised of disc height loss, endplate sclerosis, osteophytes and spondylolisthesis. At five years, changes in ALD (ΔALD) were compared to the pre-operative assessment and are reported.

Results: In all patients at five years, no change in adjacent level degeneration was observed in 90.8% of the TDR patients compared to 71.4% of the Fusion patients (p=0.004). For patients with no adjacent level disease pre-operatively, new findings of ALD at five years were found in 6.7% of the TDR patients and in 23.8% of the Fusion patients. Adjacent level surgery leading to secondary surgery was reported for 2.9% of the TDR patients and 4.0% of the Fusion patients (p=0.6819).

TDR patients had a mean pre-operative, index level range of motion (ROM) of 7.2° that was maintained at five years. Neither treatment group had significant changes at five years in either ROM or translation at the superior level.

Conclusion: At five years following index surgery, the arthroplasty device maintained ROM and was associated with a significantly higher rate of no ΔALD compared to results in prospectively randomized patients treated with circumferential fusion. The Fusion patients had a 4.5 times higher rate of ΔALD compared to TDR patients. Even in the relatively short follow-up window of five years, there is a significant radiographic protective effect of ProDisc-L on the adjacent lumbar segment, particularly in those patients with no adjacent level disease at the time of their index surgery. It is anticipated that, over time, this will be reflected in a lower rate of secondary surgery.

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patients. Clinical outcomes were improved (p< 0.05) from baseline to 24 months (Figure 1). At 24 months, 85% of patients stated that they were satisfied with their procedure and 85% stated that they would repeat their procedure. Major perioperative complications occurred in 13 patients (12.1%). Additional complications to date include 1 posterior revision for painful hardware and 1 cage failure without revision.

**Conclusion:** This prospective study represents the largest report of patients treated with XLIF for adult scoliosis. This study supports XLIF as a valuable adjunct in the treatment of adult scoliosis. Despite advanced age and co morbidities, patient-reported clinical outcomes from this study reflect promising clinical outcomes, low revision rates, and high patient satisfaction.

**29 Repair Surgery for Pars Defects in Symptomatic Lumbar Spondylolysis Using Two Different Surgical Methods; Pedicle Screw with Universal Hook System and Direct Pars Screw Fixation**

K.-S. Ryu, M.-H. Shin, C.-K. Park

1Seoul St. Mary’s Hospital, The Catholic University, Seoul, Korea, Republic of

**Objectives:** The authors performed a retrospective study to assess the clinical and radiological outcome in symptomatic lumbar spondylolysis patients who were confirmed with pars defects block and underwent a direct pars repair surgery using two different surgical methods; pedicle screw with universal hook system (PSUH) and direct pars screw fixation (DPSF), and compare the results between two different treated groups.

**Methods:** Forty-seven consecutive patients (PSUH; 23, DPSF; 15) with symptomatic lumbar spondylolysis who underwent a repair surgery for the pars defect were included. The average follow-up period was 37 months in the PSUK group, and 28 months in the DPSF group. The clinical outcome was measured using visual analogue pain scale (VAS) and Oswestry disability index (ODI). The length of operation time, the amount of blood loss, the duration of hospital stay, surgical complications, and fusion status were also assessed.

**Results:** In comparison with PSUH, DPSF presented larger degree of decrease in average VAS and ODI scores at the last follow-up. (Figure 1) (Figure 2) The average operation time was 174.9 minutes in the PSUK group, and 141.7 minutes in the DPSF group. The average blood loss during operation was 476.8cc in the PSUH group, and 298.8cc in the DPSF group. The average hospital stay after operation was 8.9 days in the PSUK group, and 7 days in the DPSF group.

In the PSUH group, there was one case of a screw misplacement requiring revision surgery. In the DPSF group, one patient suffered from transient leg pain. The successful bone fusion rate was 78.3% in the PSUH group, and 93.3% in the DPSF group.

**Conclusion:** The present study suggests that the surgical repair of the pars defects using direct pars screw appears to be more effective than the method using pedicle screw with lamina hook system, in most of clinical variables observed including decreased operation time, amount of blood loss, hospital stay, fusion success rate, and clinical outcome.

**Figure 1.** Bar graphs demonstrating the clinical outcomes based on VAS and ODI scores. Mean VAS and ODI scores were significantly lower at final follow-up visits in both groups. However, the PSUK group shows less degree of clinical improvements than the DPSF group.

**Figure 2.** Bar graphs showing the clinical outcomes of each subgroup in relation to fusion success in the PSUK group. Fusion failure group showed less clinical improvement compared to fusion success group.
The ACADIA™ Facet Replacement System IDE Clinical Trial: One Year Outcomes

1D.I.S.C Sports and Spine Center, Beverly Hills, CA, USA, 2Central Texas Spine Institute, LLP, Austin, TX, USA, 3Springfield Neurological & Spine Institute, LLC, Springfield, MO, USA, 4Durango Orthopedic Associates/Spine Colorado, Durango, CO, USA, 5Neuro-Spine Solutions, Bristol, TN, USA, 6Desert Orthopedic Center, Rancho Mirage, CA, USA, 7Albany Medical Center, Albany, NY, USA, 8Globus Medical, Inc., Audubon, PA, USA

Purpose: Decompression and arthrodesis is a preferred method to treat lumbar spinal stenosis with instability. Alterations in lumbar biomechanics resulting from fusion may accelerate degenerative changes at adjacent levels. The ACADIA™ Facet Replacement System is designed to mimic the natural facet in form and function and may provide stability while preserving lumbar biomechanics, thereby decreasing the risk of accelerated degeneration. A prospective, randomized IDE study is being conducted to determine the safety and efficacy of this new motion sparing technology.

Methods: Patients enrolled into the ACADIA IDE pivotal study are randomized 2:1 to either the investigational ACADIA™ device or the control instrumented posterolateral fusion (PLF). Outcome measures are collected pre-operatively and at 6 weeks, 3 months, 6 months, 12 months, and 24 months post-operatively. Outcome variables include Oswestry Disability Index (ODI), Zurich Claudication Questionnaire (ZCQ), and Visual Analog Scale (VAS) measurements of back and leg pain.

Results: One hundred twelve (112) patients have been randomized to ACADIA™ and 39 to the control PLF. The mean age, operative time, blood loss and hospital stay for the ACADIA™ vs. PLF cohorts are: 60 vs. 61 years, 165 vs. 127 minutes, 372 vs. 316mL, and 2.65 vs. 2.75 days. Mean ODI was 47 ±15 at pre-op and 13 ±14 at 12 months for ACADIA™ patients, as compared to 45 ±15 at pre-op and 16 ±16 at 12 months for PLF patients. For ACADIA patients, the ZCQ Symptom Severity (SS) score improved from 3.63 ±0.57 at pre-op to 1.83 ±0.67 at 12 months, compared to 3.58 ±0.56 at pre-op and 1.92 ±0.00 at 12 months for control patients. ZCQ Physical Function (PF) scores improved from 2.77 ±0.46 at pre-op to 1.49 ±0.50 at 12 months for the ACADIA cohort, versus improvement from 2.74 ±0.47 at pre-op to 1.46 ±1.00 at 12 months for the PLF cohort. The mean ZCQ patient satisfaction score at 12 months was 1.37 ±0.60 for ACADIA™ patients as compared to 1.57 ±1.00 for PLF patients. Mean VAS back pain score for ACADIA™ patients was 67.9 ±23 at pre-op, reduced to 13.9 ±23 at 12 months, while PLF patients reported 63.8 ±24 at pre-op and 27.1 ±30 at 12 months. Mean VAS right leg pain scores for ACADIA™ patients were 57.3 ±32 at pre-op and 8.0 ±16 at 12 months, versus 56.9 ±29 at pre-op and 13.9 ±25 at 12 months for PLF patients. Mean VAS left leg pain score for ACADIA™ patients was 55.6 ±31 at pre-op and 9.7 ±18 at 12 months versus 51.6 ±33 at pre-op and 7.8 ±16 at 12 months for PLF patients. The investigational ACADIA™ treatment may represent a viable alternative to lumbar fusion. Improvements in all function and pain outcome measures were seen at 12 months for both treatment cohorts and high levels of patient satisfaction have been recorded for the investigational ACADIA™ and control PLF groups. Continued follow-ups is required to determine the long term safety and efficacy of the ACADIA™ Facet Replacement System.

Total Disc Replacement Compared to Lumbar Fusion: A Randomised Controlled Trial with Five-year Follow-up

C. Nyqvist1, S. Berg2, H. Tropp2
1Linköping University, Faculty of Health Sciences, Department of Clinical and Experimental Medicine, Linköping, Sweden, 2Stockholm Spine Center, Stockholm, Sweden

Purpose: The main objective of this study is long-term evaluation of clinical outcome of total disc replacement (TDR) compared to posterior fusion in surgical treatment at chronic low back pain (CLBP) due to degenerative disc disease.

Methods: The study is a prospective randomised controlled trial comprising 152 patients; 80 were randomised to TDR and 72 to fusion. Mean age was 40 years (21-55) and 59 % were women. All patients suffered from CLBP with varying degrees of leg pain and had not responded to a non-surgical treatment program. Diagnosis was based on clinical examination, radiographs and MRI. Primary outcome measure was Global Assessment of Back Pain (GA) and secondary outcome measures were back and leg pain, Oswestry Disability Index (ODI), EQ-5D and SF-36. All measures were collected from SweSpine, the Swedish national register for spinal surgery, at one, two and five years. Follow-up rate at five years was 99,3 % with no crossover.

Results: Both groups showed clinical improvement at five year follow up. There was no deterioration over time. Regarding GA 38% (30/80) in the TDR group was totally pain free vs. 15% (11/71) in the fusion group (p< 0.003). Back pain and improvement of back pain were better in the TDR group (23±29 vs. 31± 27, p=0,008). ODI and improvement in ODI were also better in the TDR group (ODI at 5yrs 17±19 vs. 23+ 17, p=0,016,)(ODIdiff5yrs 25±18 vs. 18±19 (p = 0,019). EQ-5D and VAS leg pain also showed significantly better improvement in the TDR group.

Achievement of surgical goal (non-mobile fusions) at two years was not related to clinical outcome neither at two nor five years. Achievement of surgical goal (mobile disc arthroplasties) at two years was related to greater improvement in back pain at five years. There was no difference in complications between the two groups. A difference was registered between the two groups in numbers of reoperation. 16 % (13/80) in the TDR group had undergone one or more reoperation compared to 31% (22/72) in the fusion group (p=0,365).

Conclusions: Global assessment of back differed between the two surgical groups at all follow-up
occasions. The difference between groups concerning back pain, pain improvement and ODI had been present at one year, disappeared after two years but reappeared at the five-year follow-up. There is no deterioration of results over time.

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Midline Anterior Approach from the Right Side to the Lumbar Spine for Interbody Fusion and Total Disc Replacement. A New Mobilization Technique of the Vena Cava
G. Edgard-Rosa1, G. Geneste1, G. Negre1, T. Marnay1
1Clinique du Parc, Centre de Chirurgie Vertébrale, Castelnau le Lez, France

Study design: Prospective study
Purpose of the study: To describe a midline anterior approach to the lumbar spine from the right side, below the aortic bifurcation to L5S1 and by mobilizing the vena cava from right to left between L2 and L5. Feasibility and complication rate related to the approach have been studied.

Summary of background data: Midline anterior approach to the lumbar spine has developed during these last years, mainly for interbody fusion and disc arthroplasty surgery. This retroperitoneal approach is well described in publications and classically made from the left side. Major complications associated with the approach are known: retrograde ejaculation, venous injuries and arterial thrombosis.

Methods: A total of 469 patients were included in a prospective study between August 2003 and November 2010, either for interbody fusion by anterior approach or for total disc replacement, on one or several levels between L2-L3 and L5-S1.

Results: On the 154 patients who had a mobilization of the vena cava, no injury occurred. Only four major venous injuries occurred among the 469 approaches. There was no arterial complication and the oxygen saturation signal, which was monitored for all procedures, was interrupted in only one case. No case of retrograde ejaculation was found.

Conclusions: The midline anterior retroperitoneal approach from the right side is a safe alternative compared to the classical approach from the left side. The low rate of venous injury is explained by the sidewall thickness of the vena cava compared to the left iliac vein sidewall. Contrary to what happens by left sided approach, the vascular retraction required for access to L4-L5 and above does not lead to arterial occlusion and therefore diminishes the risk in atheromatous patients. The absence of retrograde ejaculation confirms previous studies made on the left anastomosis of the superior hypogastric plexus suggesting that its approach and mobilization by the left side is delicate. This right sided approach should also be beneficial in second surgery by anterior route alternatively to the left route, thereby providing a virgin access.

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Clinical Results of Two-level Lumbar Disc Replacement vs. Combined Arthroplasty & Fusion (Hybrid Procedure) in 200 Patients with a Minimum of 4 Years Follow-up
M. Scott-Young1, A. Kasis1, C. Magno1, D. Nielsen1, E. Mitchell1, N. Blanch1
1Gold Coast Spine, Gold Coast, QLD, Australia

Introduction: The majority of patients with multi-level discogenic low back pain present with symptoms originating from either degenerative disc disease (DDD)
or internal disc disruption (IDD). The pathology at any one functional spinal structure dictates the technology to be applied at that level. Favorable outcomes have been reported using anterior lumbar interbody fusion (ALIF) and total disc replacement (TDR). It is considered that outcomes are dependent on a precision diagnosis and strict adherence to indications and contraindications. A hybrid construct (HYB) combines TDR and ALIF and is considered, over 2-level TDR, when the posterior structures contraindicate 2-level TDR (2TDR). This study represents a retrospective review of prospective data comparing 2TDR with HYB treatment for 2-level DDD/IDD.

Materials/methods: Between July 1998 and February 2007, n=200 consecutive patients underwent either a HYB or 2TDR for DDD/IDD with/without radicular pain. The HYB construct was performed using an ALIF (PEEK™ /Carbon Fiber cage with cancellous allograft and rhBMP-2) at one level and TDR (CHARITÉ®, Depuy Spine) at the other. 2TDR was performed using the CHARITÉ® at both levels. All patients completed self-assessment questionnaires preoperatively and at 3, 6 and 12 months postoperatively; with annual follow up thereafter, assessing Oswestry Disability Index (ODI), Roland-Morris Disability Questionnaire (RMDQ) and Visual Analogue Score (VAS) for back and leg pain.

Results: There were 93 patients in the HYB group and 107 patients in the 2TDR group. The mean age at surgery was (HYB 52.3±1.01 vs. 2TDR 48.4±0.82). The mean follow-up in months was (HYB 57.7±1.06 vs. 2TDR 87.14±2.16). Comparing pre and post-operative outcome scores of both groups individually showed significant statistical improvement at all follow-up points for VAS back and leg pain and RMDQ (p<0.001 for all). When comparing the outcome between the two groups: VAS back pain scores showed no statistically significant difference in the mean scores (p>0.1),

- pre-operatively (HYB 74.27±2.36 vs. 2TDR 78.9±1.7),
- 4 years (HYB 22.7±2.6 vs. 2TDR 22.67±3.33)
- improvement in the scores (HYB 51.7±3.7 vs. 2TDR 57.4±2.9)

VAS leg pain showed statistically significant difference in the mean scores (p<0.05),

- pre-operatively (HYB 61.7±3.23 vs. 2TDR 50.6±3.27)
- improvement in the score (HYB 49.8±4.6 vs. 2TDR 34.7±3.95).

There was no statistical difference in the last follow-up scores at 4 years (HYB 14.14±2.6 vs. 2TDR 14.6±2.57, p=0.9).

ODI showed no statistically significant difference in the mean scores (p>0.3),

- pre-operatively (HYB 47.26±1.72 vs. 2TDR 49.32±1.63);
- 4 years (HYB 13.44±2.02 vs. 2TDR 15.88±1.92);
- improvement in the scores (HYB 32.2±0.52 vs. 2TDR 34.8±1.65)

RMDQ showed no statistical significant difference in the mean scores (p>0.3)

- pre-operatively (HYB 17.01±0.59 vs. 2TDR 16.89±0.57),
- 4 years (HYB 3.55±0.75 vs. 2TDR 4.43±0.66),
- improvement in the scores (HYB 13.32±0.93 vs. 2TDR 12.83±0.56)

Conclusion: This study shows that HYB constructs and 2 TDR are both valid options for the treatment of multi-level DDD/IDD. Similar functional improvements were seen between the groups, with no statistical difference in the outcome scores at 4 years with HYB or 2TDR groups. The clinical outcomes of both procedures are supported by the data, provided that a precision diagnosis was obtained which is matched with appropriate technology.

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Five Year Follow-up with Comparison between Fusion and TDR for Chronic LBP - Swespine Data from One Clinic

S. Berg1, H. Tropp2

1Stockholm Spine Center, Upplands Väsby, Stockholm, Sweden, 2University Hospital, Orthopedic Clinic, Linköping, Sweden

Purpose: Total disc replacement (TDR) is a relatively new method for treatment of low back pain due to degenerative disc disease. Some previous studies have not been able to show more than slightly better results for TDR than for other surgical methods at two-year follow-up while other have shown somewhat larger differences. In order to compare results between TDR and fusion in a large material after five years this register-study is performed.

Materials and methods: At Stockholm Spine Center TDR have been used for many years. All patients are followed by Swespine (Swedish Spine Register) concerning clinical outcome (back pain, leg pain, Oswestry Disability Index, SF36, global assessment). All patients in the register operated between 2001 and 2005 for low back pain with fusion or TDR were included, in total 514 patients. Patients operated with any kind of decompression were excluded, and 411 patients remained to compare, 2/3 fused and 1/3 treated with TDR.

Results: The follow-up was 67%. There were 56% female and the age at surgery was 18-85 years. “Global assessment of back pain” showed that TDR patients had better outcome than fusion patients after 5 years.36 % of TDR patients were “totally pain-free” compared to 14% in the fusion group. Improvement of VAS for back pain and ODI was larger for the TDR group. No deterioration had occurred in any group between 2 and 5 years. The patients lost to follow-up had worse results after one year concerning all outcome measurements.

Conclusion: Surgery for LBP seems to be as successful after 5 years as after 2 years. The long time results for TDR are better than for fusion. The follow-up is not random. The patients who did not answered the 5-year follow-up questionnaire were those with the worst initial results after surgery. This is a confounding factor for this type of register studies which might give false positive results for both treatment groups and for all types of surgeries.
**Introduction:** Among elderly patients with spinal stenosis and spondylolisthesis, lumbar spinal fusion is commonly performed to facilitate spinal decompression and stabilization. However, recent reports of excessive perioperative morbidity and soaring healthcare costs with fusion have led to the search for methods to improve the safety profile and to lower costs for this important surgical treatment. The purpose of this study is to quantify the perioperative outcomes, complications, and costs associated with posterior spinal fusion among Medicare enrollees with spinal stenosis and spondylolisthesis using a national Medicare claims database.

**Methods:** The 5% systematic sample of Medicare claims data (2005-2009) was used to identify and track the outcomes of patients who received any form of posterior spine fusion (PSF) for lumbar spinal stenosis (LSS) or spondylolisthesis. Surgical patients were identified by standard PSF procedural coding, while diagnoses of LSS and spondylolisthesis were identified using specific ICD-9 coding. Enrollees further required a minimum of 2 years’ follow-up, and claim history of at least 12 months prior to surgery. Patients’ length of stay, discharge status, incidence and type of complications, and treatment costs following PSF were evaluated.

**Results:** A final cohort of 1,672 PSF patients was included. LSS and spondylolisthesis were the primary diagnoses for 58.7% and 18.9% of the patients, respectively, and were the secondary diagnoses for the remaining patients. Of the 1,672 PSF patients, 50.7% had LSS only; 10.2% had spondylolisthesis only; and 39.1% had both LSS and spondylolisthesis. For the overall cohort, the average age was 71.4 +/- 7.9, and the majority (76.0% of the patients) had routine discharges, a majority of the patients (54.6%) were discharged to an outside facility (34.5%, 41.4%, and 47.9%, respectively, and were the secondary diagnoses for the remaining patients). Of the 1,672 PSF patients, 50.7% had LSS only; 10.2% had spondylolisthesis only; and 39.1% had both LSS and spondylolisthesis. For the overall cohort, the average age was 71.4 +/- 7.9, and the average length of stay was 4.6 +/- 3.2 days. While 42.2% of the patients had routine discharges, a majority of the patients (54.6%) were discharged to an outside facility (18.0%, 19.4%, and 17.2% were discharged to skilled nursing facilities, home health services, and rehabilitation facilities, respectively). At 3 months, 1 year, and 2 years post-operative, the incidence of spine reoperation was 19.9%, 24.0%, and 28.0%, respectively, while readmission for complications was 34.5%, 41.4%, and 47.9%, respectively. The overall average payment for the PSF patients was $36,230 +/- $17,020, $46,840 +/- $31,350, and $61,610 +/- $46,580 at 3 months, 1 year, and 2 years, respectively, and corresponded to an overall cost to Medicare of $60.6 million, $78.3 million, and $103.0 million for treating these patients.

**Conclusions:** Over half of the PSF-treated patients in this study had LSS alone, suggesting that factors other than spondylolisthesis play a significant role in the decision to recommend spinal fusion in this elderly population. One in 4 elderly fusion patients being treated for LSS or spondylolisthesis was reoperated on the spine within 2 years, and nearly 1 in 2 readmitted for a surgery-related complication. This data highlights several areas where improvements can be made in the effective delivery and cost of surgical care for patients with spinal stenosis and spondylolisthesis.

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**Does 360° Lumbar Spinal Fusion Improve Long-term Clinical Outcomes after Failure of Conservative Treatment in Patients with Functionally Disabling Single Level Degenerative Lumbar Disc Disease? Results of 5 Year Postoperative Follow-up of 75 Patients**

**Aim:** Five year clinical results of patients undergoing 360° lumbar fusion after failure of at least 6 months conservative care for functionally disabling single-level lumbar degenerative disc disease (DDD) are reported.

**Methods:** Post-hoc evaluation of outcomes from the ProDisc-L FDA IDE study (Zigler et al, Spine 2007) employs analysis of data from the 360° fusion group. The average patient enrolled in the study had failed 9 months of conservative care and had an ODI of greater than 60% impairment. Mean pre-operative VAS pain scores were greater than 8/10. Of 80 patients randomized to 360° fusion after their failure of nonoperative care, 75 were treated on-protocol with single-level fusions. Follow-up of this treatment group was 97% at 2 years and 75% at 5 years.

**Results:** At five years, the Fusion group maintained statistically significant improvements in ODI score compared to baseline (p < 0.0001). Mean ODI score improvements for Fusion patients were maintained from two years to five years. The majority (76.0% of Fusion patients), had ODI score improvements of ≥15% at five years, or ≥15 points at five years (64.0% of Fusion patients). Of the patients who had ODI score improvements of ≥15% at two years, 83.3% maintained...
the improvement at five years. Patients demonstrated statistically significant improvements in VAS pain scores at both two and five years (p < 0.0001). Mean percent improvements in VAS pain scores were similar at the two and five year follow-up visits. At five years, mean VAS satisfaction was 77.5 ± 26.8. At five years, the majority of patients (72.6%) maintained or improved SF-36 PCS compared to baseline. Of the patients who maintained or improved SF-36 PCS compared to baseline at two years, 83.3% also maintained or improved out to five years (Table 1).

Table 1. ODI, Pain VAS, and SF-36 PCS at Baseline, 24 Months, 60 Months

<table>
<thead>
<tr>
<th>Year</th>
<th>ODI</th>
<th>VAS (100-mm)</th>
<th>SF-36 PCS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline N=85</td>
<td>75</td>
<td>74.9 (14.7)</td>
<td>30.9 (5.6)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>71</td>
<td>43.1 (31.6)</td>
<td>38.8 (11.3)</td>
</tr>
<tr>
<td>2-Year</td>
<td>71</td>
<td>42.4% (49.0%)</td>
<td>29.8% (40.0%)</td>
</tr>
<tr>
<td>N</td>
<td>51</td>
<td>43.8% (37.1%)</td>
<td>29.9% (43.7%)</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>51</td>
<td>40.0 (32.1)</td>
<td>40.1 (13.6)</td>
</tr>
<tr>
<td>5-Year</td>
<td>51</td>
<td>47.3% (43.8%)</td>
<td>29.9% (43.7%)</td>
</tr>
<tr>
<td>N</td>
<td>51</td>
<td>44 (4.0%)</td>
<td>44 (100.0%)</td>
</tr>
</tbody>
</table>

Wilcoxon test was used to compare baseline data, t-tests used to compare 2-year and 5-year percent improvement

Neurologic success, defined as maintenance or improvement in sensory, motor, and reflex functions, was attained at five years in 89.6% of patients (43/48). Radiographic fusion rates were 97.1% and 95.6% at two and five years, respectively (Table 2).

Table 2. Radiographic outcomes at five years

<table>
<thead>
<tr>
<th>Radiographic outcome</th>
<th>Fusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>No device migration</td>
<td>45/45 (100.0%)</td>
</tr>
<tr>
<td>No device subsidence</td>
<td>45/45 (100.0%)</td>
</tr>
<tr>
<td>Disc height decrease ≤3 mm</td>
<td>41/45 (91.1%)</td>
</tr>
<tr>
<td>Fusion status</td>
<td>43/45 (95.6%)</td>
</tr>
<tr>
<td>No radioopacity</td>
<td>45/45 (100.0%)</td>
</tr>
<tr>
<td>Range of motion*</td>
<td>44/44 (100.0%)</td>
</tr>
</tbody>
</table>

*One Fusion patient was missing extension radiographs

Conclusions: This analysis shows the benefits of Fusion in appropriately selected patients. Seventy-five patients who were functionally disabled after they had failed an average of nine months of nonoperative care showed improved clinical outcomes at two years of follow-up. The five-year results of this post-hoc analysis supports 360° Fusion surgery as a predictable and lasting treatment option to improve pain and function in properly selected patients with single-level functionally disabling discogenic back pain.

309 Combined Arthroplasty and Anterior Lumbar Interbody Fusion (Hybrid Procedure) in 385 Patients with a Minimum of 2 Years Follow-up

A. Kasis, M. Scott-Young, C. Magno, D. Nielsen, E. Mitchell, N. Blanch

Introduction: The primary pain generator for axial lower back pain is the intervertebral disc. Favorable outcomes have been reported using anterior lumbar interbody fusion (ALIF) and total disc replacement (TDR). It is considered that outcomes are dependent on a precision diagnosis and strict adherence to indications and contraindications. Patients commonly present with multi-segment disc disease with different stages of degeneration at each level. A hybrid construct combines TDR and ALIF and is considered over 2-level TDR when the posterior structures contraindicate 2-level TDR. This prospective study presents the experience of a single surgeon using a hybrid construct in 385 patients. Based on the literature review conducted, it is considered that this study is the largest single surgeon series using a lumbar hybrid construct to date.

Materials and methods: Between July 1998 and December 2008, n=385 consecutive patients underwent hybrid constructs for the treatment of multi-level discogenic back pain with/without radicular pain. The prostheses used were the CHARITE® (Depuy Spine) (41.3%) and In Motion Lumbar Artificial Disc™ (40.8%) (Depuy Spine), and MAVERICK™ (17.9%) (A-Mav: Medtronic). ALIF was performed using PEEK™ cages with autograft or allograft and rhBMP-2. All patients completed self-assessment outcome questionnaires pre and postoperatively (3, 6, 12, and 24 months), including Oswestry Disability Index (ODI), Roland-Morris Disability Questionnaire (RMDQ) and Visual Analogue Score (VAS) for back and leg pain.

Results: N=385 patients were analyzed. The mean follow-up was 46.1±0.55 months (24-154). The mean age was 51.46±1.12 years. The mean duration of surgery was 77.38±1.05 minutes. The mean blood loss was 173.12±8.28 mls. The revision rate was 1.29%. Three patients (0.77%) had surgery for adjacent segment degeneration. The primary diagnosis was multi-level degenerative disc disease (DDD) in 244 (64.4%) patients, followed by one-level disc herniation and one-level DDD in 94 (24.8%) patients. The majority of the patients (n=298) had L4-5 TDR and L5-S1 ALIF, while 49 underwent L3-4 L4-5 TDR and L5-S1 ALIF. At all follow-up points, patients demonstrated significant improvement in ODI, RMDQ, VAS back and leg pain scores compared to pre-operative scores (p< 0.001). The mean improvement between pre-operative and last follow-up was 31.8 (71.4%) and 13.23 (80.9%) for ODI and RMDQ, respectively. Similarly, there was 55.5 (77.2%) and 45.3 (79%) for VAS back and VAS leg pain, respectively. There was statistically significant differences in mean outcome score improvement between the mean score at the 3 months and the scores at later follow-up for all the outcomes scores. At 2 years, 92.1% of patients rated their satisfaction as excellent/good, with 4.8% satisfactory and 3.2% poor. At 24 months, patients with pre-operative diagnosis of disc herniation, had better improvement in the VAS leg pain, compared to patients without herniation, p=0.042. When comparing the outcome of patients younger than 50 years with patients older than 50 years, the former had a statistically significant better improvement (p< 0.01) in VAS leg pain, ODI and RMDQ.

Conclusion: This study shows that hybrid constructs...
UK Experience with Total Facet Joint Replacement
J.C. Sutcliffe, H. Bhatti
1London Spine Clinic, London, United Kingdom

Introduction: Facetectomy has often been a requirement of posterior lumbar spinal decompression, but in creating instability has required fusion. While this has been recognised as an appropriate treatment modality, many of these often elderly patients will have adjacent level pathology. Therefore, the concern has been that a rigid fusion may cause adjacent level pain, leading to a requirement for further surgery. Biomechanical studies have shown that total facet replacement systems have overcome these issues and retain movement within the physiological range after total bilateral facetectomy and canal decompression. This paper highlights the triage, surgical technique issues and rehabilitation designed specifically to optimise results.

Materials and methods: 12 patients were selected for TOPS plus decompression on the basis of severe canal stenosis with facet hypertrophy and facet mediated pain, unresponsive to exhaustive conservative measures. Nine had undergone previous surgery at the same level, discectomy, laminectomy or interspinous spacer implants. 5 patients had a degree of degenerative scoliosis, with Cobb angles of less than 20° and 5 patients had a grade I spondylolisthesis. Four patients were female. Ages ranged from 37 to 86 years. The TOPS device [Implant medical, Israel] was used in all cases, being licensed in Europe for use at L3/4 and L4/5 levels.

Operative technique: The patient was positioned prone on a Montreal mattress and a midline incision was made and muscles retracted to expose the spinous processes of three levels. A laminectomy was performed in routine manner, to achieve adequate canal decompression and this was continued out laterally through both facet joints (which were grossly hypertrophied). Pedicle screws were then positioned bilaterally under fluoroscopy, into the levels above and below, using the angulation guides and the trial prosthesis was then used to determine the size required. The TOPS implant was then secured to the pedicle screws. X-ray confirmation of an appropriate placement was obtained and the wound was closed over a drain.

Results: 10 patients underwent surgery at L4/5, two at L3/4. There were no deaths, no neurological complications and no implant related complications. Average operating time was 147 minutes, average blood loss was 550mls (no patients requiring transfusion) and average hospital stay was 6.5 days. None of these patients had a CSF leak. There were no deep or superficial infections. All patients had good/excellent outcomes, with a maximum post-op ODI of 12%. 7 of the 12 who had previously been employed, returned to work.

Discussion: Maintaining normal movement in the spine is the goal of all therapies, whilst decompressing the neural elements. The TOPS device allows this, with an acceptable complication rate and good patient outcomes. In these difficult cases, with instability, kissing facets or gross facet damage, TOPS may represent an alternative to posterior fusion.
with a significantly higher percentage of surgeons not allowing return to hockey or wrestling after anterior spinal fusion (ASF). In particular, for Lenke 5C curve type, respondents allowed PSF patients quicker return to sport compared to ASF. Construct type (hooks, hybrid, pedicle screws) did not significantly affect return to sport, however patient’s with hook only constructs were never allowed to return to collision or contact sports prior to 3 months. There was only 1 reported catastrophic failure in a patient with implant pullout after snowboarding 2 weeks postoperatively.

**Discussion and conclusion:** Following corrective spine surgery for AIS, patients should be allowed to return to non-contact and contact sports within 3 to 6 months, and collision sports within 6 to 12 months post-operatively. Factors affecting decision making for return to sport include: years of practice, type of surgeon (PedOS versus SpineOS), LIV, as well as PSF versus ASF. Construct type did not affect return to sport, and the incidence of catastrophic failure after return to sport following surgery for AIS appears to be exceedingly rare.

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**Congenital Stenosis and Symptomatic Adjacent Segment Disease**

**J. Belding**, 1 J. Eubanks1, A. Rowan2, G. Moffitt2, V. Cheruvu3, J. Hohl4, A. Hilibrand5, H. Bohlin1, J. Kang4

1University Hospitals Case Medical Center, Cleveland, OH, USA, 2Case Western Reserve University School of Medicine, Cleveland, OH, USA, 3Kent State University, Kent, OH, USA, 4University of Pittsburgh Medical Center, Pittsburgh, PA, USA, 5Rothman Institute, Philadelphia, PA, USA

**Introduction:** Symptomatic adjacent segment disease after anterior cervical arthrodesis may be seen in up to 25% of patients at ten year follow-up. Some debate exists as to whether this degeneration represents the natural history of the adjacent disc or whether the increased biomechanical stresses placed by the fusion accelerate this degenerative cascade. Congenital stenosis has been established as an important risk factor in the development of myelopathy. Further, MRI studies have suggested that congenitally stenotic spines have greater pathological changes in the intervertebral discs and cord compression than spines with a wide spinal canal.

The current study hypothesized that patients with congenital stenosis would have an increased prevalence of symptomatic adjacent segment disease after anterior arthrodesis than patients with normal canal diameters.

**Methods:** A retrospective review was performed on 497 patients undergoing a one to four level anterior cervical decompression and fusion by a single surgeon. Radiographs were evaluated for bony congenital stenosis by measuring the space available for the cord (SAC) and the Pavlov Ratio (PAV), using the stenosis parameters described by Kang et al. Radiographic adjacent segment degeneration was measured according to the criteria established by Hilibrand et al. and correlated with clinically symptomatic adjacent segment disease evaluated through chart review. Clinical outcome scores were graded on the Robinson and Odom criteria. Statistical analysis was performed using student t-tests and a linear regression model comparing symptomatic adjacent segment disease among patients with and without congenital stenosis.

**Results:** Congenital stenosis was observed in 87 (17.5%) patients. There were 239 men and 255 women in the study cohort. The average length of follow-up was 46.6 months. There were 227 single level fusions (8 C3/C4, 22 C4/C5, 110 C5/C6, 47 C6/C7), 152 two level fusions (18 C3-C5, 53 C4-C6, 84 C5-C7), 84 three level fusions (23 C3-C6, 61 C4-C7), 26 four level fusions (C3-C7) and a smattering of non-contiguous, multi-level fusions. In the 87 patients with congenital stenosis, 35 had stenosis at C6 or C7. Pan-cervical stenosis (4 or more levels) was apparent in 27 patients. Of the 497 patients, 188 (37.5%) developed ASD. Neither age (p=0.78), nor gender (p=0.86), nor congenital stenosis (p=0.62) correlated with the presence of clinically symptomatic ASD. Overall, clinical results demonstrated excellent or good Robinson scores in 86.7% of patients, whereas excellent or good Odom scores were reported in 90.1% of patients.

**Conclusions:** Congenital stenosis appears in 17.5% of patients undergoing anterior cervical decompression and fusion. Despite a predominance of excellent to good surgical outcomes, symptomatic adjacent segment disease is common, occurring in 37.5% of patients. Bony congenital stenosis does not appear to be a predictor of symptomatic ASD. Adjacent segment degeneration may represent more the natural history of the degenerating disc rather than the end product of underlying biomechanics of the congenitally stenotic cervical canal or the change in forces created by surgical arthrodesis.

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**Can Different Surgical Strategies Result in Satisfactory Post-operative Sagittal Alignment?**

V. Lafage1, B. Blondel1, F. Schwab1, C. Ames2, R. Hostin3, R. Hart4, A. Akbarnia4, J. Smith4, C. Shaffrey4, K. Kebaish5, D. Burton6, S. Bess6, International Spine Study Group

1New York University Hospital for Joint Diseases, Spine Division, New York, NY, USA, 2University of California San Francisco, Neurosurgery, San Francisco, CA, USA, 3Baylor Spinal Cord Injury Research Center, Orthopedic Surgery, Plano, TX, USA, 4Oregon Health and Sciences University, Orthopedic Surgery, Portland, OR, USA, 5San Diego Center for Spinal Disorders, La Jolla, CA, USA, 6University of Virginia, Department of Neurological surgery, Charlottesville, VA, USA, 7John Hopkins Hospital, Orthopedic Surgery, Baltimore, MD, USA, 8University of Kansas Medical Center, Orthopedic Surgery, Kansas City, KS, USA, 9Rocky Mountain Hospital for Children, Orthopedic Surgery, Denver, CO, USA

**Introduction:** Adult spinal deformity (ASD) presents a wide range of deformity and clinical patterns. When non-operative care fails, surgical realignment using osteotomies is often pursued to achieve improved alignment and function. Reports have identified key radiographic spino-pelvic parameters that are associated with clinical outcomes, including Sagittal Vertical Axis (SVA< 50mm), Pelvic Tilt (PT< 25°) and Pelvic Incidence-Lumbar Lordosis (PI-LL=10°). While correction objectives have been previously described, different methods for reaching them have not been compared. This study evaluates if different strategies for realignment can lead to satisfactory post-operative radiographic sagittal alignment.

**Methods:** A multicenter (n=3 sites), retrospective
Improvement of Posterior Wedge Osteotomy Programation Using the 3D EOS Imaging System in Standing Position: Femur Angulation and Knee Flexion Are Important to Analyze. F.B.I. Technique

J. Rigal¹, S. Aunoble¹, P. Leijssen¹, M. Duarte¹, J.-C. Le Huec¹
¹University Victor Segalen Bordeaux 2, Bordeaux, France

Purpose: Using the radiograph EOS imaging system it is possible to have a global analysis of the sagittal balance with hip and knee flexion.

Study design: It is a prospective study. To determine the osteotomy angle in patients with severe lumbar kyphosis, it was decided to consider the hip flexum in the calculation. The angle of femur angulation with the vertical line was added to the angle of osteotomy.

Material and method: 25 patients have been operated for important sagittal imbalance problem. The lumbar lordosis was negative with a minus 9 degrees. The average hip flexum was 24.2 degrees. The average spino sacral angle (SSA) was 104.5° (normal is 130° +/- 7.3). The compensatory attitude with knee flexion is standing position was always reducible. A posterior wedge osteotomy using the egg shell technique was performed with pedicular based fixation from S1 to T10 or higher if needed. An additional inter-pedicular osteotomy was performed two levels above in case an additional correction was requested according to the pre-op planning. Motor and somesthesic evoked potential were used for all patients. Post op evaluation was performed using the same 3D EOS imaging system with evaluation of the same parameters.

Results: Surgeries were performed without major complications. No paraplegia, one sciatic pain L5 in two patients, one hematoma resolved spontaneously, one delayed deep infection that resolved with surgical cleaning and antibiotics for 3 months. The average osteotomy angle was 29.4 degrees (23.5° to 42°). The level of osteotomy was: L4: 16 cases, L3: 3 cases, L2: 1 case. The pre-op C7 plumb line was located 6.6 cm in the front of femoral head and was behind it in all cases at an average of 2.3 cm post operatively. The SSA increased from 104.5° to 124.3°. The pelvis tilt was dramatically increased in all patients, from 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.
Six osteoporotic and nine normal specimens were instrumented with titanium pedicle screws and the left side served as the control with perfect screw-rod alignment. On the right side, the rod was intentionally contoured with a 5 mm residual gap between ventral aspect of the rod and the inner bushing of the pedicle screw, followed by a rod reduction technique. As an alternative option to rod reduction, one of the proximal vertebra pedicle screws was removed and re-inserted through the same trajectory to simulate screw depth adjustment. The pedicle screws were pulled out “in-line” with the screw axis, with peak pull-out strength (POS) measured in Newtons (N).

**Results:** After rod reduction, pedicle screws had significantly decreased POS compared to controls (495 ± 379 N versus 954 ± 237 N), with 48% lower mean POS. Nearly half (n = 7; 46.7%) of the pedicle screws had visible pull-out during the reduction attempt, and occurred irrespective of BMD. There was no significant difference in POS between re-inserted to control screws (1013 ± 348 N versus 941 ± 316 N).

**Discussion and conclusion:** The rod reduction technique significantly decreases overall pedicle screw POS and typically results in outright failure. Therefore, the rod reduction technique should be performed with caution, and further rod contouring with use of in situ bending devices, use of multiaxial screw heads, screw depth adjustment or redirection of pedicle screw trajectory may be warranted to obtain perfect alignment of the pedicle screw-rod construct.

**Study design:** Multicenter, retrospective analysis of 183 consecutive patients undergoing lumbar osteotomy. **Objective:** To evaluate cause and impact of posterior postoperative alignment. **Summary of background data:** Sagittal malalignment in the setting of adult spinal deformity (ASD) has shown significant correlation with pain and disability. Surgical treatment often entails correction of deformity by pedicle subtraction osteotomies (PSO). Key radiographic spinopelvic objectives to reach improvement in clinical outcomes have been previously reported. While anterior alignment is a cause of poor outcomes, the impact and cause of posterior spinal alignment by PSO has not been reported. **Methods:** Inclusion criteria for patients were: pre-operative lumbar lordosis < 20°, SVA > 5 cm, PT > 25°, or thoracic kyphosis (TK) > 60°. Patients were divided into 3 groups based on post-operative SVA: neutral alignment (0< SVA< 50mm), anterior alignment (SVA>50mm) and posterior alignment (SVA< 0mm). All patients had pre and post-operative full-length sagittal spine x-rays. Differences between groups were evaluated using ANOVA and Chi-square analysis. **Results:** Groups were comparable pre-operatively for surgical status and regional alignment (LL and TK). The patients with posterior alignment were younger and had a significantly lower pelvic incidence (53˚ vs. 62˚), pre-operative PT (30 vs. 36˚), SVA (94 vs. 185mm) and cervical lordosis (16˚ vs. 25˚) than patients in the anterior alignment group. No significant differences were found in terms surgical procedure. Patients in the posterior alignment group demonstrated a significantly greater change in SVA and PT correction (p< 0.05) but with a lower gain in TK (5 vs. 12’) and reduction of cervical lordosis (4˚ vs. 22˚).

**Conclusion:** Patients with posterior alignment showed a significantly lower PI, and posterior alignment was associated with a lack of restoration of TK and a loss of cervical lordosis. Particular attention must be paid to pre-operative planning before sagittal realignment procedures. Further study will be necessary to evaluate long-term clinical outcomes of these patients.

165 Revision Surgery for Severe Kyphoscoliosis

Y. Hai1, Q. Su1, S. Lu1, J. Yang1, X. Meng1
1Chaoyang Hospital, Capital Medical University, Orthopedic Surgery, Beijing, China

Summary: 32 patients with severe kyphoscoliosis were underwent revision surgery with posterior osteotomy (SPO or VCR) at the apex, pedicular fixation and fusion. The average scoliosis and kyphosis Cobb angle was 123.2(82-156) and 87(53-129), respectively. The average correction for scoliosis and kyphosis was 52.6% and 57.4%, respectively. The Radiographic correction and clinical outcome and patient’s satisfaction were evaluated. Careful preoperative evaluation, safely performed osteotomy and rigid fixation and fusion, are the keys to achieve the successful outcome.

**Introduction:** The failure of scoliosis surgery was not rare which revision surgery was indicated when it presented with deterioration of the deformity, hardware failure, decompensation in coronal or sagittal plane, neurological deficits, etc. The revision surgery for severe kyphoscoliosis has been a challenge due to the complexity of the deformity and higher risk of the procedure. The purpose of this study was to evaluate the safety and efficacy of the revision surgery for the correction of severe kyphoscoliosis.

**Methods:** This was a retrospective review study. Between 2006 and 2009, 32 patients with severe kyphoscoliosis were underwent revision surgery. There were 7 male and 25 female with an average age of 23.8 years. The average time between the previous surgery was 11.3 (7-21) years with average 2.39 (1-7) procedures. The average scoliosis and kyphosis Cobb angle was 123.2(82-156) and 87(53-129), respectively. All patients underwent posterior osteotomy (SPO or VCR) at the apex with pedicular fixation and fusion. The average scoliosis and kyphosis Cobb angle was 123.2(82-156) and 87(53-129), respectively. The Radiographic correction and clinical outcome and patient’s satisfaction were evaluated. Careful preoperative evaluation, safely performed osteotomy and rigid fixation and fusion, are the keys to achieve the successful outcome.
Coronal Cobb Angle Correction in the Setting of Adult Spinal Deformity: A Health Related Quality of Life Assessment on Two Year Outcomes

B. Moal\(^1\), F. Schwab\(^1\), J. Smith\(^2\), K. Bridwell\(^1\), B. Blondel\(^1\), S. Glassman\(^3\), J. Demakakos\(^1\), C. Shaffrey\(^1\), V. Lafage\(^4\)

\(^1\)New York University Hospital for Joint Diseases, Spine Division. New York, NY, USA, \(^2\)University of Virginia, Department of Neurological Surgery, Charlottesville, VA, USA, \(^3\)Washington University School of Medicine, Spine Department, Saint Louis, MO, USA, \(^4\)University of Louisville, Spine Institute for Special Surgery, Louisville, KY, USA

**Introduction:** Coronal Cobb angle in the setting of adult spinal deformity (ASD) with scoliosis remains a key measure applied in the diagnosis, clinical follow up and post surgical assessment of patients. However, the necessary extent of coronal Cobb correction for favorable patient perceived outcomes remains controversial. The aim of this study was to evaluate the amount of Cobb angle correction needed to achieve incremental clinical benefit and reach Minimal clinically important difference (MCID) using SRS-30 scores.

**Methods:** This is a retrospective review of a prospectively collected database of ASD patients. Baseline and two year radiographic and SRS-30 scores of patients with thoraco-lumbar and lumbar curves greater than 50° were analyzed. Patients were divided into three groups based on postoperative Cobb angle correction: < 25°, between 25 and 35°, and >35°. Change in scores and difference with reference values were expressed in terms of MCID. Differences among groups pre-operatively, and after treatment were analyzed using t-test and one-way ANOVA.

**Results:** 60 patients meeting the inclusion criteria were analyzed. A significant improvement in all SRS domains was found between pre-op and last follow up across the study population (p< 0.05). For the entire population, the greatest offset in respect to reference values was in the pre/post operative Activity domain (Pre:-3.04 MCID; Post:-1.87 MCID). Postoperatively a correction of greater than 35 degrees coronal Cobb angle offers better scores in the Appearance, Pain and Activity domains than the two other groups, and an increased likelihood of reaching MCID in the Activity domain. A moderate correction (25° to 35°) did not bring further benefit than a correction less than 25°.

**Conclusion:** Activity score seems to be a relevant and global indicator of the difference between patients and reference. While only a substantial correction in coronal Cobb angle (< 35°) offered significant improvement in Activity domain, mild correction (< 25°) appears sufficient for a significant improvement in Pain and Appearance domains. Findings from this study add to the importance of pre-operative planning and patient counseling in terms of needs for coronal deformity correction.

**Navigation/Robotics**

265 CAMISS Is a Developmental Direction of Orthopedic Surgery

W. Tian\(^1\), X. Han\(^1\), Y.-J. Liu\(^1\), Y.-Z. Sun\(^1\)

\(^1\)Beijing Ji Shui Tan Hospital, Beijing, China

Throughout the history of orthopedic surgery, it is closely related to the progress of science and technology. The last decade has seen an evolution of minimally invasive spine surgery (MISS) with new technological developments. MISS is thought to decrease postoperative pain and allow quicker recovery by limiting soft-tissue retraction and dissection. Advances in microscopy, tissue retractors, and specialized instruments have enabled surgeons to perform procedures through small incisions. But in MISS procedures, anatomic disorientation can occur because standard landmarks are not visible. In addition, MISS is more technically demanding than open surgery because of the smaller working portal and the need for longer surgical instruments, which may increase the chance of intraoperative complications. Before the use of navigation technique, the accuracy of surgery was rely on the doctor’s experience, anatomy data and the guide of fluoroscopy. Since X-ray has been discovered by roentgen in 1895, the guide of fluoroscopy was widely used in orthopedic surgery, but it is only a two-dimensional overlapping image, which lack of significance to apprehend the three-dimensional space. On the other hand, doctor’s experience and anatomy data only represent general circumstance and regular patterns of surgery which cannot resolve individual differences. Along with the progress of science and technology, computer assisted orthopedic surgery (CAOS), a new technique which beyond the capacity of human ability has been invented and used in clinical, which is creating a new era of orthopedic surgery. Intraoperative three-dimensional navigation can provides three-dimensional information for each surgical site, which precision can reach to 0.25 mm, apparently beyond the naked eye and fluoroscopy, thus patches up the deficiency of unclear surgical exposure in MISS which can improve the accuracy of surgery and reduce complications. Consequently, computer assisted minimally invasive spine surgery (CAMISS) becomes a developmental direction of orthopedic surgery. In the recent years, navigation technique has been rapidly
Radiation Exposure to the Surgeon during Lateral Lumbar Interbody Fusion Procedures

R.L. Tatsumi

Summary: Fluoroscopy is widely used in spine surgery to assist with interbody graft and hardware placement. Studies have demonstrated radiation exposure to the surgeon for cervical and posterior lumbar applications. However, there are no studies that have evaluated radiation exposure to the surgeon during lateral lumbar spine procedures.

Introduction: A cadaveric torso was imaged with fluoroscopy to assess radiation exposure to the surgeon during lateral spine procedures. The scatter radiation to the surgeon was recorded under three different scenarios. The goals of the study were

1) identify which anatomic area the surgeon receives the most radiation exposure
2) understand ways to reduce overall radiation exposure to the surgeon.

Methods: Scatter dose measurements were obtained using radiation badges dosimeters placed on specific points on a mannequin (eye level, right and left chest, and right and left abdomen). An OEC 9800 C-arm was used to image the cadaveric torsos. Testing was performed via three different scenarios:

1) “Typical Setup,” AP and Lateral images with source close to surgeon,
2) “Pulsed Setup,” same set up as scenario 1 but in pulsed mode,
3) “Reversed Setup,” AP and Lateral images but source away from surgeon.

Each setup was tested five times with a preset number of fluoroscopic images taken. The number of fluoroscopic images was derived from actual operative cases to localize, expose, and insert a lumbar interbody cage at a single lumbar disc space.

Results: All scenarios demonstrated the highest concentration of radiation exposure occurring at the surgeon's abdominal region. The “Typical Setup” demonstrated the highest level of radiation exposure of all three scenarios (p < 0.001). There were no differences in radiation exposure between the “Pulsed Setup” and the “Reversed Setup” scenarios (p = 0.657). The “Reversed Setup” demonstrated no statistical differences when comparing the separate anatomical sites of the radiation badges (p = 0.997).

Conclusion: Radiation exposure during lateral lumbar instrumentation was concentrated at the abdominal region for the surgeon. The “Typical Setup” exposed the surgeon with the most radiation compared with the other two scenarios.

Significance: During lateral lumbar procedures, the “Typical setup” exposes the surgeon to a high amount of radiation. Radiation exposure can be significantly reduced by either using the same fluoroscopic orientation in the “Pulsed Setup” or changing the machine in the “Reversed Setup.”

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Pedicle Screw Placement in Adults Using Image-guided Navigation Is Safe and Accurate


Summary: In a consecutive series of 177 adult patients and 1511 pedicle screws, we demonstrated that pedicle screw placement using intraoperative three-dimensional (3D) image guided insertion and intraoperative CT imaging resulted in a 98.2% accuracy rate, with no major complication from screw malposition and no reoperations.

Introduction: Pedicle screws are widely used in the treatment of various spine disorders, and the accuracy of insertion has improved because of the availability of image guidance. The O-arm is an intra-operative scanner that provides real-time images for navigation, and allows intra-operative assessment of pedicle screw position. The objective of the study was to determine the accuracy of intra-operative 3D image-guided screw insertion in adult patients, looking specifically at screw revision rates and reoperation rates.

Methods: Between March 2007 and September 2010, 1511 pedicle screws were inserted in a consecutive cohort of 177 adult patients. Mean age was 59.6 years (19 to 88 years). There were 73 males and 104 females. The most common diagnoses were degenerative disc disease (62), spinal stenosis (50), degenerative spondylolisthesis (40), lytic spondylolisthesis (18) and scoliosis (16). Intraoperative 3D images were obtained with the O-arm scanner, and the images were transferred to the computerized navigation system (Stealth). Screws were then placed using real-time navigation and were then imaged. The need for screw revision (removal or redirection) based on the intraoperative scan is the primary outcome measure for this study.

Results: A total of 1511 screws were placed in 177 adult patients using the intraoperative 3D image-guided technique. A total of 28 screws needed revision based on intraoperative CT (21 redirected, 7 removed) for an accuracy rate of 98.2%. There were no major neurovascular complications from malpositioned screws and there was a 0% reoperation rate. During the study period, we used the same technique for insertion of 984 screws in pediatric patients. 35 screws were revised (3.6%) for a 96.4% accuracy rate. The accuracy of screw placement was higher in the adult population than in the pediatric population.

Conclusion: The technique of intra-operative 3D image
Percutaneous Pedicle Screw Placement Using Image-guided Navigation Is Safe and Accurate

E.R.G. Santos¹, J.N. Sembrano¹, S.C. Yson¹, A.N. Larson¹, D.W. Polly Jr.¹
¹University of Minnesota, Orthopaedic Surgery, Minneapolis, MN, USA

Summary: In a consecutive series of 33 patients, 166 pedicle screws were placed percutaneously using intraoperative 3D image guidance, resulting in 95.2% and 100% accuracy rate for K-wire placement and screw placement, respectively. Three dimensional image-guided navigation and intraoperative CT imaging resulted in 95.2% and 100% accuracy rate for K-wire placement and screw placement, respectively. No complications related to screw malposition and a 0% reoperation rate were noted.

Introduction: The introduction of image-guided navigation has led to increased accuracy of screw placement. The objective of the study was to determine the accuracy and safety of percutaneous pedicle screw insertion in the thoracic and lumbar spines using intraoperative 3D image guidance and intraoperative CT imaging.

Methods: Between April 2007 and September 2010, 166 pedicle screws were placed percutaneously using intraoperative 3D image guidance in 33 consecutive patients. Mean age was 53.5 years (13 to 87 years). There were 10 male and 23 female patients. Diagnosis included degenerative disc disease (24), lumbar stenosis (8), degenerative spondylolisthesis (4), isthmic spondylolisthesis (3), and degenerative scoliosis (2). Intraoperative 3D imaging was performed using the O-arm and the images were registered onto the computerized navigation system (Stealth). K-wires were placed using a navigated Jamshidi needle and K-wire position was then imaged. If the K-wire position was satisfactory, cannulated screws were placed. Imaging of the final screw position was then performed. The incidence of K-wire and screw revision based on intraoperative imaging was the primary outcome measure.

Results: A total of 166 pedicle screws were placed. Based on intra-operative imaging, a total of 9 (4.8%) K-wires were revised (8 redirected and 1 removed). No screws (0%) were revised, indicating a 100% screw placement accuracy rate. Reoperation rate was 0%. There were no major neurovascular complications from either malpositioned K-wires or screws.

Conclusion: We report a 95.2% K-wire placement and 100% screw placement accuracy rate using intraoperative 3D image guidance for percutaneous pedicle screw insertion.

Significance: Percutaneous pedicle screw insertion using intra-operative 3D image guidance resulted in accurate placement of screws and had no identified complications.

Computer Navigated, Anterolateral Approach to the L4-L5 Disc: Reduced Approach Related Complications

M. Mac Millan¹
¹University of Florida, Orthopaedics, Gainesville, FL, USA

Introduction: In 1997 Michael Mayer described a minimally invasive anterolateral approach to the lumbar spine. Although the approach was reliable and avoided the iliac crest, it did not gain widespread acceptance because the oblique angle made it difficult to determine the incision location and to gauge the depth of spinal penetration on fluoroscopic images. This report describes the use of computer navigation for the anterolateral approach for interbody fusion of the L4-L5 disc.

Methods: In 2010, we reported on 99 patients fused via a lateral approach of the lumbar spine under computer navigation but without neuromonitoring. In this series we found 19% of patients had transient muscular or neurologic complications. In the patients with neurologic or muscular post-operative complaints, all involved the L4-L5 level either alone or as part of a multi-level construct.

Since April of 2011 we have used computer navigation for an anterolateral interbody fusion of L4-L5. Neuromonitoring was not employed for this approach. This review compares the incidence of muscular and neurologic complications of the first eight patients utilizing the anterolateral approach to L4-5 as compared to the previous report utilizing the direct lateral approach.

Results: Seventeen patients underwent isolated interbody fusion of L4-5 through an anterolateral approach using computer navigation. Seven patients were diagnosed with degenerative spondylolisthesis, four with transitional syndrome, five with adjacent level degeneration, and one with a non-union. These seventeen patients were performed at the same institution and by same surgeon who performed the previous lateral fusion experience with computer navigation. In this group of anterolateral patients there has been no occurrences of psoas weakness, quadriceps weakness, sensory dysesthesias, or any general approach related complications. Vascular structures were visualized in two patients and retracted with an additional retraction blade. Excellent implant position was noted in all eight patients.

Conclusion: In comparing an historical patient cohort of L4-L5 interbody fusions performed trans-psoatally, with a group performed by the same surgeon at the same institution anterolaterally, there is definite, marked reduction in approach related complications. Computer navigation of the anterolateral approach to the L4-L5 disc permits safe, accurate placement of an interbody device with a significant reduction in neural and muscular complaints without the use of neuromonitoring.
Novel Description of an All Transosseous Approach to the L5-S1 Intervertebral Disc

M. Mac Millan

1University of Florida, Orthopaedics, Gainesville, FL, USA

Study design and objective: Our objective was to determine the feasibility of a transosseous technique to access the intervertebral space of the L5/S1 junction.

Background: The position of the lumbosacral junction within the pelvis makes it difficult to prepare the intradiscal space for a fusion. This has resulted in different techniques described to obtain access to the space to perform a fusion. The development of minimally invasive surgery and computer navigation have created opportunities that were not previously possible.

Methods: Three cadaveric specimens were obtained and soft tissue was removed from the specimens. Under direct visualization, a transosseous portal was created from the iliac crest through the sacral ala and entering the L5/S1 intervertebral disc space. This was performed from each iliac crest allowing us to create six transosseous portals. The integrity of the portals and the preparation of the disc space were evaluated with computer tomographic scans within the sagittal, coronal and axial planes. The length of the portals, the location of the isthmus in all planes, endplate diameters, and angles necessary to access the space were measured.

Results: A transosseous portal was successfully created in all specimens from the right and left iliac crests. The computer tomographic scans and the anatomic evaluations confirmed that the portal was bound by cortical bone until it entered the L5/S1 disc space. Upon sectioning the specimens, we determined that the sacral ala was not breached when entering the L5/S1 disc space. The narrowest point was found within the axial and sagittal planes of the sacral ala in all specimens. The average angle of the approach was 45 degrees superior within axial plane with the pelvis in a prone position and 25 degrees caudally in the coronal plane for the pelvis. The average length of the transosseous portal was 69 mm. The average angle between the L5/S1 endplates was 15 degrees.

Conclusion: A transosseous approach to the L5-S1 disc space is feasible. Further studies will be required to determine the reproducibility and utility of this pathway.

Instructional Course Symposium: Biologics Past Present and Future

Retrograde Ejaculation Following Single-level Anterior Lumbar Interbody Arthrodesis Using Stand Alone Cages and rhBMP-2 in Five Randomized Controlled Trials

J.K. Burkus1, R.F. Dryer2, J.H. Peloza3

1The Hughston Clinic, Columbus, GA, USA, 2Central Texas Spine Institute, Austin, TX, USA, 3Center for Spine Care, Dallas, TX, USA

Purpose: Our goal was to determine the incidence and assess risk factors in the postoperative development of retrograde ejaculation (RE) in men treated for degenerative lumbar disc disease at the L4-L5 or L5-S1 level with stand-alone anterior interbody implants.

Methods: Patients enrolled in 5 prospective, randomized, multi-center, FDA-approved investigational device exemption (IDE) studies were followed for a minimum of 2 years to determine the incidence and clinical outcomes of RE. There were 508 men treated for symptomatic single-level lumbar degenerative disc disease with up to grade 1 spondylolisthesis. All patients underwent anterior lumbar interbody arthrodesis with stand alone anterior implants at either L4-L5 or L5-S1. All patients were assessed preoperatively and postoperatively for retrograde ejaculation (RE) and were recorded through adverse event reporting. Two hundred seven patients were treated with an open surgical procedure using dual paired implants and recombinant human bone morphogenetic protein-2 (rhBMP-2) on an absorbable collagen sponge (ACS). The control groups (n=301) were treated with lumbar fusion cage implants and iliac crest autograft or a metal-on-metal disc arthroplasty device. Multivariate analyses of RE were performed to assess the influence of treatment (rhBMP-2), surgical approach, and treated level. Data were analyzed for each trial individually and for the data pooled from the 5 trials.

Results: RE occurred at the highest rates in the earliest clinical trial. Six out of 146 males (4.1%) developed RE postoperatively. In subsequent studies, the rates of RE ranged from 0% to 2.1%. Combining the data from all 5 trials, RE was reported in 7 (3.4%) of the 207 patients who received the rhBMP-2 treatment, compared with 5 (1.7%) in the 301 patients who received the autograft or lumbar disc treatment (p=0.242). RE cases were reported in 7 of 445 male patients (1.6%) who underwent a retroperitoneal spinal exposure; 5 RE cases were reported in 58 male patients (8.6%) who underwent a transperitoneal approach. The difference between surgical approaches was significant with a p value of 0.007. Multivariate analyses were consistent with the conclusions from Fisher’s exact tests. In the initial rhBMP-2 trial, after adjusting for effects of surgical approach and treated level, the difference in RE was not significant between the rhBMP-2 and autograft treatment groups (p = 0.177); however, the difference in RE was significant between the retroperitoneal and transperitoneal approaches (p = 0.029). The postoperative development of RE following ALIF surgery resolved spontaneously in more than half of the patients initially reporting symptoms.

Conclusions: From these 5 prospective randomized trials involving anterior lumbar interbody surgery, the use of rhBMP-2 was associated with a higher incidence of RE (3.4% vs.1.7%). This trend does not reach statistical significance. The earliest study of rhBMP-2 with threaded fusion cages had the highest rate of RE. The difference in rates of RE was statistically significant based upon the surgical transperitoneal approach. The lumbosacral level approached surgically (L4-L5 vs L5-S1) was not associated with the development of RE.
103 Do Preoperative HbA1c Levels Correlate with Postoperative Wound Infection Rates in Spine Surgery?  
G. Tepper, R. Rabbani, M. Yousefzadeh, D. Prince  
Loma Linda University Medical Center, Loma Linda, CA, USA  

Background: Diabetes mellitus affects about 20 million people in the U.S. today. This number is expected to increase. As the rate of Americans with diabetes increases, so will the rate of patients with diabetes who undergo elective spine surgery. Diabetes is a known risk factor for perioperative wound infection. Patients with poorly controlled perioperative blood glucose levels are known to have increased rates of infection. To our knowledge there have not been any previous studies that have examined HbA1c levels as an independent risk factor for infection in spine surgery.  

Hypothesis: Patients with a HbA1C greater than 7% have an increased risk of surgical site infection when undergoing elective spine surgery.  

Methods: A retrospective study was performed at our institution. Patients who had posterior spine instrumentation and fusion with diabetes from 2004-2008 were selected. All of the operations were performed by the same surgeon. Infection rates were examined in patients with HbA1c levels greater than 7 versus those with levels less than or equal to 7. Statistical analysis was performed. Age, gender, length of surgery, obesity and tobacco usage were the other risk factors assessed.  

Results: Eighteen total patients met inclusion criteria. Of these, four (8.9%) developed postoperative wound infection. The average HbA1c for all patients was 7.16% (±1.7%). 8 patients had a HbA1c of > 7% and 10 patients had a HbA1c of < 7%. Only one patient in the infection group had a HbA1c greater than 7%. The average HbA1c in the infected group was 7.75% while that in the noninfected group was 6.98%. The relative risk of infection in the HbA1c > 7% group was 0.41. After Chi square analysis, obesity and length of surgery were found to be risk factors for infection.  

Conclusion: A HbA1c level of greater than 7% was not found to be a significant risk factor for infection in patients undergoing elective orthopaedic surgery in our group of patients. Obesity and length of surgery were found to be significant risk factors for infection.  

478 Quantitative Assessment of Retrograde Ejaculation Using Semen Analysis, Comparison to a Standardized Qualitative Questionnaire, and Investigating the Impact of rhBMP-2  
M. Mikhaeil, W. Cheng  
Loma Linda University Medical Center, Loma Linda, CA, USA  

Aim: Retrograde ejaculation (RE) is a condition in which ejaculatory fluid is propelled from the seminal vesicles towards the bladder. It has long been known that anterior lumbar interbody fusion (ALIF) at the L4/L5 and L5/S1 disc levels carries with it a risk of superior hypogastric plexus damage, and as such, a potential risk of RE. To our knowledge all studies performed to date regarding this potential complication have used a nonstandardized qualitative approach and there have been no studies using quantitative analysis to determine RE. Recently, there has been increased attention paid to RE as a potential consequence of ALIF with and without the use of recombinant human bone morphogenetic protein-2 (rhBMP-2). The purposes of this study were to: 1) compare the incidence of RE as measured by a quantitative semen analysis in 360 fusion patients when BMP was used vs. patients when BMP was not used, and 2) compared the results of the quantitative semen analysis with the rate reported by patients completing a questionnaire.  

Methods: This was a prospective, blinded study. Forty-one male patients scheduled to undergo anterior/posterior interbody fusion (360° fusion) surgeries at L4-5 and/or L5-1 agreed to participate. Thirty-nine of the 41 (95.1%) patients were workers' compensation. Subjects went to a preselected cryobank for pre-operative semen and urine analysis. Subjects returned to the cryobank 3 to 6 months after surgery for repeat testing. After surgery, each patient was evaluated by the principle investigator who used the standardized questionnaire to conduct an in-depth interview to evaluate RE. The ALIF portion of the surgery was performed using femoral ring allograft: in 21 patients, rhBMP-2 was included and in the remaining 20 it was not.  

Results: Based on the quantitative semen and urine analysis, 4 of the 41 patients (9.8%) had RE. Of the patients treated with rhBMP-2, two (9.5%) were diagnosed with RE, one of which resolved spontaneously and resulted in pregnancy three years later. Of the 20 patients treated without rhBMP-2, two (10.0%) were diagnosed to have RE, one of which resolved after two years evidenced by a pregnancy. The RE rate between the two groups was not statistically significantly different (p>0.80; Fisher exact test). Patient responses to the standardized questionnaire (completed by 36 patients) resulted in 15 (41.7%) cases of RE being reported, including the four that were confirmed by quantitative analysis. Eleven patients indicated having RE based on the questionnaire; however, this was not supported by the quantitative semen and urine analysis.  

Conclusions: This study suggests that use of a standardized qualitative questionnaire, administered prospectively, tends to overestimate the incidence of RE as compared to the quantitative semen analysis. Contrary to recent studies using retrospective qualitative review, in this small group with quantitative analysis, use of rhBMP-2 was not related to an increased incidence of RE, with a rate of approximately 10% in patients receiving, and those not receiving, rhBMP-2 graft material. Further study of a larger group using pre-operative semen and urine analysis, post-operative standard questionnaire and post-operative semen analysis should be pursued to further investigate the occurrence of RE and to possibly assist in developing and validating a questionnaire for RE assessment.
Open TLIF with BMP: Dose Related Complications and Outcomes from a Large Series
D.G. Crandall, J. Patterson, E. Huish, J. Revella, D. Revela
Sonoran Spine Center, Mesa, AZ, USA, Banner Orthopaedic Residency Program, Phoenix, AZ, USA

Introduction: The use of TLIF with BMP has become a standard of care, with 50% of TLIF cases in the US using BMP. A 2011 Spine Journal editorial stated, “Adverse events associated with rhBMP-2 in PLIF or TLIF are now commonly recognized and are reported to occur in most patients, including osteolysis, endplate resorption, radiculitis, cage displacement, subsidence, infection, ectopic bone formation, and others.” And, “TLIF (with BMP) associated with poorer global outcomes.” Without any industry support, we analyzed the complications and outcomes from a very large consecutive series with long-term follow-up of patients undergoing TLIF with BMP. We propose guidelines for optimal BMP dosing for use in TLIF to achieve reliable arthrodesis with the fewest complications.

Methods: A retrospective review of prospective data from 451 consecutive adults who underwent open posterior instrumented fusion (PSF) with TLIF, PEEK cage, and rhBMP-2 at the same center using the same surgical techniques; Pre-op Diagnosis: degenerative-172, spondylolisthesis-168, scoliosis-99, kyphosis-6. Patient age averaged 60 years (range 19-91 years); 51 smokers, 183 had prior surgery for decompression/fusion. TLIF averaged 1.7 levels/patient (range 1-4 levels). Each TLIF was supported by a rectangular PEEK cage filled with autograft and the disc was backfilled with local autograft around the cage. Interbody BMP averaged 7.6 mg/disc (range 2-12mg/disc) in a total of 767 discs. Clinical outcomes were recorded pre-op, 2wks, 6wks, 3mo, 6mo, 1 and 2 years. All complications were recorded. VAS pain scores, Oswestry Disability Index (ODI), pain medication records were evaluated pre-op, 1 and 2 years. Radiographic outcomes at 2 years assessed fusion, presence of osteolysis, cage subsidence, and cage migration.

Results: At average 4 years follow-up (range 24-86 months), 99.2% of patients achieved a solid arthrodesis. Of the 9 pseudoarthrosis, 6 occurred at a level that TLIF with BMP was used and 3 occurred at a level with only a PSF. BMP related seroma and post-op radiculopathy occurred in 4 patients (all used 6-8mgBMP/disc, all resolved with decompression). Revision laminectomy was performed in 6 patients with recurrent stenosis or foraminal bony overgrowth from 3 months to 2 years post-op (all used 6-8mg BMP/disc). There was no cage migration or subsidence, and no case of radiographically notable or clinically suspected osteolysis. Other complications included adjacent level degeneration-175 (19 revised), adjacent fracture-28 (9 revised), infection-14, and late instrumentation removal-9. Significant improvement was noted in VAS (pre-op-6.2, 2yr-3.1, P<.001) and ODI (pre-50, 2yr-28, P<.001), and pain medication requirements.

Conclusions: In the largest series with the longest follow-up in the literature, TLIF with BMP appears to be a reliable procedure with excellent clinical outcomes and, contrary to the 2011 editorial, only rare BMP related complications. Instrumented posterior spinal fusion with TLIF, PEEK cage, and BMP produces fusion in 99% and significantly improved clinical outcomes in adults requiring arthrodesis. Most complications in this series occurred in deformity patients.

Osteocel Plus in Extreme Lateral Interbody Fusion: Radiographic Outcomes
A.G. Tohmeh, M. Tohmeh, W.D. Smith
Northwest Orthopaedic Specialists, Spokane, WA, USA, University Medical Center, Neurosurgery, Las Vegas, NV, USA

Introduction: The extreme lateral interbody fusion (XLIF) procedure is a minimally-disruptive alternative for anterior lumbar interbody fusion. In addition to the approach, synthetic and allograft materials have been increasingly used to eliminate donor-site pain and complications secondary to autogenous bone graft harvesting. The clinical use of allograft cellular bone graft has potential advantages over autograft by eliminating the need to harvest autogenous bone graft while mimicking autograft’s biologic function. Osteocel Plus is one such example of an allograft cellular bone matrix.

The objective of this study was to examine 12-month radiographic and clinical outcomes in patients who underwent XLIF with Osteocel Plus.

Methods: Clinical and radiographic data were collected through a prospective registry of XLIF patients from a single institution. Inclusion criteria included having been treated with XLIF with Osteocel Plus as the sole bone graft material with at least 12 months follow-up with computed tomography or fluoroscopy-guided, level-by-level, radiography assessed by a third party reviewer to determine extent of bony fusion in XLIF levels.

Of 55 eligible patients, 50 (91%) were available for follow-up (mean 10.2mo). However, only 27 (49%) met all inclusion criteria and were included in these analyses. A subset of 14 patients also had preoperative and 12-month postoperative functional outcome scores.

Mean age was 62 years, 56% had heart disease, 22% had diabetes mellitus, 11% were smokers, and 63% had undergone prior lumbar spine surgery. 47 total levels were treated in 27 patients between L1-S1. Of these, 41 were XLIF and 6 at L5-S1 were TLIF.

Results: No complications were observed. One patient underwent reoperation at an adjacent level for degeneration. A second patient has developed new symptoms, though symptom etiology and course of action is currently pending.

From preoperative to 12mo postoperative, ODI improved 42% (46.9 to 27.1), LBP improved 60% (7.8 to 3.1), leg pain improved 61.7% (6 to 2.3) and QOL (SF-36) improved 72% (37.2 to 63.9). 92% of patients at 12 months were either “very” or “somewhat” satisfied with their outcome and 88% reported being either “very” or “somewhat likely” to undergo the same procedure had their outcome been known in advance. Complete fusion was observed in 90.2% (37/41) of XLIF levels (Figure 1). Four (4) levels were assessed as incompletely fused, where ossification was present.
in the cage, but complete trabecular bridging was not observed. In these instances, 3 of 4 were in multi-level cases (one 3-level, two 2-level). No levels were assessed as indeterminately fused, or showing lucencies at endplates with or without ossification in the cage. Evidence of some degree of radiographic subsidence was observed in 10 of 47 levels (21.3%) in 7 (26%) patients, though was not clinically relevant.

**Conclusion:** The XLIF procedure in the treatment of degenerative conditions of the lumbar spine, in this series, is a safe and effective procedure. Pain, disability, and quality of life improved substantially at 12-months postoperative. Complete interbody fusion with Osteocel Plus, was shown in 90.2% of XLIF levels, with the remaining 9.8% being partially consolidated and progressing towards fusion at 12 months. There were no levels classified with an indeterminate fusion status and no levels were revised for pseudoarthrosis.

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**Neck-shoulder Crossover: How Often Do Neck and Shoulder Pathology Masquerade as the Other?**

J.N. Sembrano\(^1\), S.C. Yson\(^1\), O.C. Kanu\(^1\), E.R.G. Santos\(^1\), J.P. Braman\(^1\), A.K. Harrison\(^1\), D.W. Polly Jr.\(^1\)

\(^1\)University of Minnesota, Orthopaedic Surgery, Minneapolis, MN, USA

**Introduction:** Identification of the correct pain generator is a pre-requisite for providing effective treatment in patients with neck and/or shoulder problems. However, distinguishing between the two could be difficult. The relative frequencies of how often one is mistaken for the other have not yet been well-established. The purpose of our study is to determine the frequency of symptomatic neck pathology among patients seen at a shoulder clinic for shoulder complaints and to determine the frequency of symptomatic shoulder pathology among patients seen at a spine clinic for neck complaints.

**Methods:** Six hundred ninety-four new patients were seen at the orthopaedic shoulder clinic (n=454) and spine clinic (n=240) at an academic institution during a two-year period. One hundred nine patients had previous shoulder surgery, and 36 had previous neck surgery. The 549 patients (shoulder clinic = 348; spine clinic = 201) who had no previous surgery were reviewed for workup performed, final diagnosis, subsequent operative procedures, and incidence of referral from the shoulder to the spine clinic and vice-versa.

**Results:** Among patients seen at the shoulder clinic, 323 (92.8%) were found to indeed have shoulder pathology, 9 (2.6%) had neck and not shoulder pathology, 8 (2.3%) had both shoulder and neck pathology, and 8 (2.3%) had an unidentifiable cause of pain. Among the 17 patients who had neck pathology, only 1 (0.3%) underwent neck surgery.

Among patients seen at the spine clinic, 175 (87.1%) were found to indeed have neck pathology, 9 (4.5%) had shoulder and not neck pathology, 4 (2.0%) had both neck and shoulder pathology, and 13 (6.5%) had an unidentifiable cause of pain. Among the 13 patients who had shoulder pathology, only 1 (0.5%) underwent shoulder surgery. (See Graph).

**Conclusion:** For patients presenting to a shoulder surgeon’s clinic for shoulder pain, 5% will turn out to have neck pathology. For patients presenting to a spine surgeon’s clinic for neck pain, 6.5% will turn out to have shoulder pathology. Thus, approximately 1 in 20 patients seen at a surgeon’s clinic for either a presumed shoulder or neck problem exhibit a neck-shoulder crossover, where pathology in one may be mistaken for or co-exist with the other.
**Myelomalacia as a Predictor of Disease Severity and Surgical Outcome in Cervical Spondylotic Myelopathy**

**M. Pumberger**, D.R. Lebl, A.P. Hughes, F. Taher, F.P. Cammisa, F.P. Girardi

1Hospital for Special Surgery, Spinal Surgery, New York, NY, USA

**Introduction:** Myelomalacia is a magnetic resonance imaging (MRI) finding which may suggest spinal cord damage. However, it is not uniformly found in patients with Cervical Spondylotic Myelopathy (CSM) and its presence on MRI is of unknown prognostic significance.

**Purpose:** To investigate the relationship of myelomalacia to disease severity and surgical outcome in patients with CSM. We hypothesized that the presence of myelomalacia is not associated with more advanced myelopathy; however, it is an indicator of poor prognosis following surgical treatment.

**Methods:** We reviewed a consecutive series of CSM patients who underwent surgical intervention by three senior spine surgeons over a 10-year period (January 2000 - October 2010) at a single institution. Patient demographics, electronic medical records, and imaging studies were reviewed. Nurick Grade at presentation and MRI evidence of myelomalacia was recorded. Resolution of post-operative symptoms and Nurick grade were determined. Chi-Squared test was performed for univariate analysis and multivariate logistic regression analysis between the presence of myelomalacia and post-op improvement in Nurick Grade.

**Results:** A total of 248 patients (71 F; 177 M) presented with cervical spondylotic myelopathy during the 10-year study period. The average age was 59±13.3 years and average BMI was 28.4±5.2. Pre-operative duration of myelopathic symptoms until surgical intervention was 15.1 months (1-101 months) and the average follow-up was 15.4 (range 1-79 months). Myelomalacia was present in 53%, 34%, 11% and 2% of patients with pre-op Grade 1, 2, 3, & 4 disease, respectively (p=0.02, 0.26, 0.002, 0.329). Of patients with radiographic evidence of myelomalacia, 26% had an improvement in Nurick grade with surgery (p< 0.001). Myelomalacia had a negative association with post-operative improvement with an adjusted odds ratio (aOR) of 0.25, 0.26 and 0.01 for patients who improved to Grade 2, 1 and 0 disease (p=< 0.001, < 0.001, < 0.001) respectively.

**Conclusion:** Myelomalacia is not associated with disease severity in CSM but provides significant information on clinical recovery following decompressive surgery. The presence of myelomalacia on MRI indicates a lower likelihood of improvement with surgical intervention than in the absence of this finding.

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**Reliability of the Subaxial Cervical Spine Injury Classification System for Orthopedic Surgeons at Different Training Levels**

**A.J. Bevevino, R.A. Lehman, D.G. Kang**

1Walter Reed National Military Medical Center, Department of Orthopaedics, Bethesda, MD, USA

**Introduction:** The Subaxial Cervical Spine Injury Classification System (SLICS) was developed to address the shortcomings of other classifications which are complex, have poor reproducibility, and low prognostic value. Despite the ability of SLICS to simplify the description of cervical spine fractures and guide treatment related decisions, it has not gained widespread acceptance. The initial evaluation of a patient with cervical spine trauma is often performed by the most inexperienced orthopedic surgeon, typically an Intern or Junior level Resident, and relaying meaningful information to a Staff spine surgeon is imperative for safe efficient care and initial treatment decision making. Our study evaluates the reliability of SLICS for orthopedic surgeons at different training levels, ranging from Intern to Staff spine surgeon.

**Methods:** Ten cases of subaxial cervical spine fractures, including plain radiographs, computed tomography and magnetic resonance imaging, were reviewed and scored using SLICS by eight evaluators: Intern (n=2), Junior level orthopedic Resident (n=3), senior level orthopedic Resident (n=2), fellowship trained Staff spine surgeon (n=1). The evaluators were shown the same cases on three different occasions within a four week time period. Statistical analysis with Intraclass Correlation Coefficient (ICC) was calculated using SPSS 18.0 for Windows (SPSS Inc., Chicago, IL) to assess the inter- and intra-observer reliability of the evaluators for determining the total SLICS score, and for each component of the SLICS score (fracture morphology, neurologic status, Discoligamentous Complex (DLC) integrity). Acceptable agreement was defined a priori as an ICC of greater than 0.60.

**Results:** The intra-observer reliability for SLICS total score was acceptable, with excellent agreement at each training level and improvement in ICC with increasing training level. However, the intra-observer reliability was not acceptable for Intern and Junior level Resident evaluators with respect to evaluation of DLC integrity (r = 0.468 and r = 0.388, respectively). The intra-observer reliability for treatment recommendation based on SLICS total score (non-operative, equivocal, operative), was acceptable ranging from good to excellent agreement (r = 0.629 to 0.787), and again with improvement in ICC with increasing training level. In regard to inter-observer reliability, there was acceptable agreement for all evaluators in regards to treatment recommendation and total score, however there was not acceptable agreement for evaluation of DLC integrity (r = 0.518).

**Discussion and conclusion:** The use of SLICS demonstrated excellent intra- and inter-observer reliability among orthopedic surgeons of different training levels, ranging from Intern to Staff spine surgeon, and acceptable reliability for use in treatment recommendation. However, more experienced orthopedic surgeons, particularly senior level Resident and Staff spine surgeons had better intra-observer reliability with the use of SLICS and in evaluating DLC integrity. The SLICS proved to be reliable and accurate, suggesting that this classification is an objective way to allow Interns, Residents and Staff surgeons to effectively communicate the injury morphometry and treatment decision in cervical spine injuries.
Percutaneous TLIF with an Expandable Titanium Cage Compared to a Standard PEEK Cage: A New Transformaminal Approach to Achieve a Less Invasive Intervertebral Fusion

R. Morgenstern
Teknon Medical Center, Orthopaedic Spine Surgery, Barcelona, Spain

Background: The usual treatment of unstable DDD is highly invasive lumbar interbody fusion (TLIF, PLIF) by mini-open discectomy.

Purpose: To assess the feasibility and efficacy of vertebral fusion through a less invasive percutaneous approach with new telescopic instrumentation (Optiport™).

Study design: Ten patients were evaluated in two groups. For group A (2 patients) an expandable implant (Opticage™) was inserted into the disc with bone graft and fully expanded. For group B (8 patients) a conventional rigid PEEK cage was inserted with bone graft. The same percutaneous transfomaminal approach with the Optiport™ instrumentation was employed to deliver the implants in both groups. These ten patients were evaluated as part of a preliminary clinical study (total of 60 patients). Oswestry Disability Index (ODI) and Visual Analog Scales (VAS) were performed at 3 weeks, 6 and 12 months post-op with CT-scan control.

Methods: Inclusion criteria: DDD with discogenic pain and/or spondylolisthesis up to grade II with or without radicular pain. The posterolateral approach was performed with specially designed telescopics instruments (Optiport™) through a minimal skin incision (12mm) under fluoroscopic guidance. In all cases a percutaneous minimall foraminoplasty was performed to widen the foramen and allow the transfomaminal access. After careful endplate preparation, the expandable Opticage™ implant (group A) or the inexpandable PEEK cage (group B) was delivered in to the disc under fluoroscopic control. Posterior traspedicular percutaneous screws were applied in all cases to achieve posterior stabilization. Student’s paired T-test was applied to assess differences in both groups.

Results: Ten patients were evaluated. Mean age was 55.2 ± 17.4 years. Four patients presented DDD at L3-L4 and/or L4-L5 level and six patients presented spondylolisthesis at L4-L5 or L5-S1 level. The average follow-up was of 10.1 ± 7.2 months. The mean pre-op VAS back scores of (6.3± 1.2) dropped to (1.8 ± 2.6) post-op. Pre-op leg scores of (6.9± 0.5) dropped to (1.3 ± 2.3) post-op. Pre-op ODI scores of (33.3± 6.7) dropped to (11 ± 2.3) post-op. The patients showed a significant (p < 0.05) reduction in VAS back and leg pain. The outcome according to McNab scoring was excellent for both patients in group A, while for group B we obtained 6 excellent, 1 good, 1 fair and no poor results. Average recovery time for all patients was of 1-2 days post-op and no rigid brace was required.

COMPLICATIONS: Three patients in group B experienced mild to moderate postoperative radicular pain (transient disesthesia) that resolved after 4 weeks with oral corticosteroids treatment. One patient in group B experienced moderate leg weakness but recovered fully after two weeks.

Conclusions: The results show significant (p < 0.05) reduction in pain at all time points evaluated for both groups. This preliminary data suggests that a TLIF done with a percutaneous transfomaminal approach using the Optiport™ instruments seems promising for treating degenerative disc disease with or without spondylolisthesis up to grade II in a less-invasive manner than classic mini-open TLIF. The expandable titanium cage (Opticage™) seems to deliver similar results to the classic PEEK cage. Nevertheless, additional cases should be performed to confirm the outcome in a larger patient series.

The Effect of Prophylactic Local Spinal Steroid Delivery in a Spinal Cord Injury Model

M. Quirno1, A. Yoo1, J.M. Cuellar2, K. Campbell3, C. Hoelscher4, P. Ricart-Hoffiz1, T. Andres1, T. Kirsch1, T. Errico1
1N.Y.U-Hospital for Joint Diseases, Orthopaedic Surgery, New York, NY, USA

Introduction: Spinal cord injury during high-risk spinal deformity surgery still occurs despite best efforts. Current neurophysiological monitoring can only report an injury after it happens and some injuries fail to be captured. This catastrophic complication is usually irreversible. Our purpose was to evaluate prophylactic injection of the local epidural space with methylprednisolone prior to mechanical spinal cord injury to determine if this could mitigate the long-term consequences of spinal cord injury.

Methods: In rats a standardized model of incomplete spinal cord injury (SCI) was utilized by introducing a small arterial fogarty catheter through a T10 laminotomy and compressing the cord by balloon inflation. There were three study groups: the treatment group that received prophylactic local epidural injection of methylprednisolone (MP) prior to SCI (“SCI + MP”; N = 13), a control group that received pre-operative normal saline and SCI (“SCI + Saline”; N = 12) and an additional control group that underwent local epidural injection of methylprednisolone without SCI (“MP only”; N = 7). Rats were tested weekly by two independent, blinded evaluators for 8 weeks utilizing the Basso-Beattie-Bresnahan (BBB) behavioral scoring system. At the end of the study animals were sacrificed and perfused with 4% paraformaldehyde and spinal cords were processed for histological analysis using Luxol Fast Blue.

Results: The MP only injection control group without SCI recovered from surgery rapidly without signs of significant cord pathology. Both the SCI + MP and SCI + saline groups displayed significant motor impairment induced by the balloon catheter expansion. The BBB score of the animals in the SCI + MP group recovered faster and to a greater extent than the SCI + saline group, particularly over the first 4 weeks (See Figure 1). There was a statistically significant difference (p < 0.01; ANOVA with Games-Howell post-hoc multiple comparisons test) between the MP only and the SCI + MP and SCI + saline groups at all time points. There was a statistically significant difference between the SCI + saline and SCI + MP groups at weeks 1-4.
Conclusion: The spinal cord injury induced by this model resulted in severe, long-term motor impairment. Although no animals recovered completely, rats treated with prophylactic local spinal epidural methylprednisolone recovered faster and to a significantly greater extent compared to those treated with saline only. Prophylactic treatment of high-risk spinal deformity surgery patients with a high concentration of intrathecal or epidural methylprednisolone may have potential to mitigate spinal cord injury severity. This possibility deserves further investigation in animals and human subjects.

Methods: We analyzed the interim results of 99 patients (41m, 58f), who were treated with single-level (2xC3/4, 5xC4/5, 49xC5/6, 43xC6/7) CTDR (activ C™) at 11 European sites. 82 of them received a STANDARD and 17 a FLAT implant version. One major difference between both types is the sagittal position of the COR, which is more anterior in FLAT components. Examinations were pre-operatively, 6weeks, 6months, 1year and 2years postoperatively. Computerized radiographic measures and statistical analysis were performed independently.

Results: Mean NDI changed from 40,5 preoperatively to 22,4 at 6weeks, 19,6 at 6months, 18,8 at 1year and 19,1 at 2year follow-up, mean VAS for neck pain severity from 50,3 to 21,6, 20,9, 23,4 and 23,4 and for arm pain severity from 51,1 to 17,6, 16,0, 17,0 and 19,0. 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 VAS for neck and arm pain severity preoperatively (p=0,010/p=0,029).

For STANDARD components the mean preoperative segmental angle increased from -2,4º lordosis to -5,7º after 6weeks and remained at -5,7 after 6months, 5,6 after 1year and -5,7º after 2years and for FLAT components from -1,0º lordosis to -6,3º after 6weeks and remained at -6,5 after 6months, 6,6 after 1year and -6,2º after 2years. (no significant differences by implant version). However, correction of disc angle achieved (preop vs. 2years) shows the tendency to be differed between STANDARD and FLAT implants (3,3º vs. 5,2º lordotic correction, p=0,062).

Correlation analyses showed a medium effect (Pearson Rho -0,353, 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 10,2º preoperatively, 7,7º after 6weeks, 7,8º after 6months and 6,2 after 2years. For FLAT components these measures were 9,4º, 8,1º, 8,2º and 7,4º. The results showed a good maintenance of ROM in the FLAT group, and a statistically significant decrease of ROM in the STANDARD group (preoperative vs. 6week p< 0,001 and 6months vs. 2years p< 0,001). No significant differences between both groups were detected during the follow-up period and no statistically significant correlation between CORi and ROM after 2years.

Lateral device placement was considered to be ideal for all cases (98/99, 1x indeterminate). No device subsidence (>3mm), migration (>3mm) or expulsion occurred (98/99, 1x indeterminate) and no signs of osteolysis were recorded (98/99, 1x indeterminate).

Conclusions: Our results demonstrate a relationship between 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. A proper sagittal profile might be essential for good rotational movement in longterm, future analysis should investigate the development of segmental motion. Clinical practice has to consider COR positioning for specific CTDR devices accordingly.

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...
Metanalysis of Heterotopic Ossification (HO) Following Cervical Artificial Disc Replacement (CADR)

K.A. Pettine

1The Spine Institute, Loveland, CO, USA

Purpose: Attempt to ascertain the incidence of HO following CADR and whether this incidence is influenced by implant type, class of data, or length of follow-up.

Methods: Forty-seven articles and abstracts were reviewed for data on HO following CADR. This information was then stratified based on type of data (class I to III), severity of HO grade 0 to 4 (McaFee classification), length of follow-up and CADR type.

Results: Class I data from FDA IDE studies indicates the incidence of grade-4 HO in ProDisc-C to be 4% at 24 month and 8% at 48-month follow-up, 4% of any HO in Kineflex-C at 24 months, Bryan not reported. PCM had 4.4% incidence of grade-3 or 4 HO at 24 month follow-up. Prestige had zero anterior HO at 2 and 5 year follow-up. A review of all available class II data indicates ProDisc-C at four-year follow-up grade-0 - 12%, 1 - 13%, 2 - 12%, 3 - 45%, 4 - 18%; Mobi-C disc at two-year follow-up grade-0 - 25%, 1 - 9%, 2 - 33%, 3 - 3%, 4 - 6%; M6 at two-year follow-up an HO incidence of 48%; Bryan disc at one-year follow-up 17.8% of patients had some type of HO and 6.7 had grade-3 or 4. One class III paper reported a comparison of three CADR with an HO incidence of Bryan disc 21%, Mobi-C 52.5% and ProDisc-C 71.4%. One class II paper reported on the efficacy of NSAIDs to prevent HO; 64% with HO took no NSAIDs while 60% without HO took NSAIDs. Grade-3 and 4 HO in all the FDA IDE studies decreased range of motion but did not appear to impact clinical success.

Conclusions: Implant type, length of follow-up and class of data appear to influence the reported incidence of HO following CADR. Class I FDA IDE data indicates an overall HO incidence of: ProDisc-C - 8%, Kineflex-C - 4%, Prestige - zero, Bryan - no data, PCM grade-3 or 4 - 4.4%. Class II data reports a much higher incidence of HO with ProDisc-C at 71-88%, M6 - 48%, Mobi-C - 52-75%, Bryan 18-21%. The discrepancy in data between class I, 2 and 3 will be discussed. The incidence of HO appears implant type dependent and the length of follow-up increases the incidence. There is little or no data to indicate HO can be decreased by drugs or surgical technique. Adding an anterior phalange appears to prevent HO.

Biomechanical Investigation of a Cervical Dynamical Stabilization Device in Comparison to Fusion and TDR

D. Daentzer1, C. Hurschler2, M. Schwarze2, A. Packheiser1, S. Tak1, B. Richter2, B. Welke2

1Hannover Medical School, Department of Orthopaedic Surgery, Hannover, Germany, 2Hannover Medical School, Laboratory for Biomechanics and Biomaterials, Hannover, Germany

Introduction: In most degenerative disc diseases of the cervical spine the spinal fusion still represents the standard treatment. However, long term clinical studies have shown evidence of an increased incidence of pathologies in the adjacent levels [1,2,3]. In addition, an increased mobility and increased intradiscal pressure (IDP) in the adjacent segments after a cervical fusion were observed in biomechanical studies [4,5,6]. As an alternative to spinal fusion, motion-preserving intervertebral disc prostheses have been developed which permit some retained mobility in the affected level. Aim of the presented study is the biomechanical comparison between the cervical fusion, total disc replacement and dynamic stabilization with a new
Materials/methods: Six ovine multi-segmental specimens (C2-5) were tested under pure moment loading by means of a sensor-guided serial robot (± 2 Nm) while loaded with a follower load of 120 N. The tested motion consisted of flexion/extension, lateral bending and axial rotation. Initially, the physiological intact state of the specimens was investigated, and subsequently with a dynamic implant (DCI™, Paradigm Spine) placed at the C3/4 level, a disc prosthesis (activ C®, Aesculap), and finally with a simulated fusion performed using a cage (CeSpace®, Aesculap) and a plate (CASPAR®, Aesculap). The analysis was performed according to the “Hybrid Test Method” suggested by Panjabi [7]. The parameters total range of motion, inter-segmental range of motion (iROM), neutral zone, and intradiscal pressure (IDP) were compared. For the statistics a Wilcoxon signed-rank test for related samples was used.

Results: In flexion/extension, the treated segment was dynamically stabilized by the DCI™ with some remaining residual mobility (iROM_C3/4 -58%). In adjacent levels the kinematic significantly changed in C2/3 (iROM_C2/3 +117%) and in C4/5 without significant changes (iROM_C4/5 +7%). With the prosthesis, the physiological range of motion was almost preserved in the three levels with no significant change in the iROM. After fusion, iROM_C3/4 was decreased significantly by around -96%. In C2/3, the increase in the iROM was significant with +133% and also in C4/5 with +28%.

In lateral bending, the treated segment was stabilized significantly by the DCI™ (iROM_C3/4 -71%) without significant changes in the kinematics of the adjacent levels. The prostheses preserved the physiological motion in the three tested segments as well. After fusion, the iROM in C3/4 was significantly reduced (-88%) with a significant increase in C4/5 (+39%).

Discussion: Based on these experimental findings, we conclude that from biomechanical perspective the DCI™ implant could indeed provide an alternative to fusion and total disc replacement in the cervical spine with an intermediate position. In particular, the facet joint osteoarthritis and kyphotic deformity, as a contraindication to the arthroplasty, could be a clinical application of the dynamic DCI™. Indeed, initial clinical studies [8] have shown good results, but these are still to be verified in long-term studies.

Literature:

Purpose: Interspinous plating systems have been introduced as alternatives for achieving minimally disruptive posterior fixation, especially when used in conjunction with interbody fusion devices. While most of these systems are comprised of plates with fixed spikes, a novel interspinous plating system (ISP) (PrimaLOK™ SP) has been developed with multiple polyaxial features to better accommodate natural anatomic variations and achieve optimal implant placement and fixation of the spine. Objectives: 1. Evaluate the effect of the polyaxial ISP device on the three-dimensional motion response of the instrumented segment when used both as a stand-alone and as a posterior adjunct to an Anterior Lumbar Interbody Fusion (ALIF) spacer. 2. Compare the stability offered by the ISP device to unilateral and bilateral pedicle screws (PS) when used as a posterior adjunct to ALIF spacer.

Methods: Seven fresh-frozen human lumbar spines (L1-sacrum; age:44.1±4.9 years) were used. Specimens were mounted in a custom spine simulator that allowed continuous cycling between specified maximum moment endpoints in flexion and extension (FE), lateral bending (LB), and axial rotation (AR). The vertebral motion was measured using an optoelectronic motion system. The specimens' range of motion (ROM) was tested under the following sequential steps:

1. Intact;
2. L4-L5 Interspinous Plating System (ISP);
3. ALIF+ L4-L5 ISP;
4. ALIF+ Unilateral Pedicle Screws & Rod (PS) (ISP removed);
5. ALIF+ Bilateral PS (ISP removed).

Each specimen was tested in flexion (8Nm) and extension (6Nm) without preload (0N) and with 400N preload, and in LB (±6Nm) and AR (±5Nm) without preload. Implant sizes were selected such that segmental lordosis at the implanted levels was maintained close to intact values. Range of motion values were analyzed using repeated measures ANOVA with Bonferroni correction for three comparisons. The level of significance was set at p< 0.05.

Results: ISP significantly reduced FE ROM when compared to intact (p<0.01). FE ROM of the ISP-instrumented segment was 2.1±0.6 degrees under ON preload and 1.7±0.4 degrees under 400N preload. When ISP was used as an adjunct to ALIF, the resulting FE-ROM was comparable to ALIF with bilateral PS (p=0.33) and ALIF LB-ROM was comparable to ALIF+ unilateral PS-fxation (p=0.19), but larger than ALIF+ bilateral PS (p=0.06). ISP+ ALIF AR ROM was equivalent to ALIF+ unilateral or bilateral PS.

Conclusions: As a posterior fixation device, the ISP offers excellent motion restriction in FE. The axis of rotation of an intact lumbar spine segment in FE is located 2-4 mm posterior to the midline of the disc space;
hence, anchoring to the spinous process is effective in limiting the FE ROM. When augmenting an ALIF cage the ISP is as effective in limiting the FE ROM as bilateral PS fixation. However, since the device sits close to the mid-sagittal plane of the segment, it is not as effective in restricting motions in LB and AR. When used as an adjunct to an interbody fusion construct, the use of polyaxial spinous process fixation offers an effective and less invasive option when compared to the traditional pedicle screw fixation.

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Accuracy of a New Functional X-ray Analysis Method for the Spine
F. Heuer1, M. Schulze2, F.T. Trautwein2, M.J. Raschke2, T. Vordemvenne2
1ACES GmbH, Medical Devices, Filderstadt, Germany, 2University of Muenster, Department of Trauma and Reconstructive Surgery, Muenster, Germany

Introduction: Identifying instability of a spinal segment accounts for one of the important aims of the functional x-ray analysis. Instability of a segment is indicated by an increase in rotation (RoM) and/or translation and in turn changes the physiological center of rotation (CoR). The CoR location reflects the biomechanical situation of the segment and is an important parameter to identify and quantify pathologic situations. In today’s practice, determining the CoR from functional x-rays is neglected, due to missing appropriate methods. Therefore, the analysis is mostly limited to the manual measurement of vertebral body translation towards anterior/posterior direction. In this study, a method will be presented, which is capable of evaluating x-rays automatically. It employs a grayscale correlation algorithm that registers vertebral bodies and subsequently computes RoM and CoR. The aim of this study was to validate the method based on in vitro measurements.

Methods: The investigation was carried out on n=6 spinal specimens (L3-4) from calves. The specimens were affixed in a robot (KR125, Kuka, Augsburg). Subsequently, CoR were predefined at specimens using a cross laser level. The CoR was pinpointed using an x-ray marker. A reference x-ray was taken at the zero position and the marker was removed. Specimens were exposed to flexion/extension movements about the predefined CoR with 0.1°, 0.5°, 1°, 2°, 3° and up to 9°. Lateral x-rays were taken at the end positions by means of a mobile x-ray source (PX-15HF, Raytech Diagnostics, Canada) and digital memory foils (ADCC-MD-plate, Agfa). The x-ray source was placed in a distance of 75 cm away from the specimens. The x-ray beam was aligned to target the center of the intervertebral disc. Movements were additionally recorded using an optical motion tracking system (Optotrak Certus, NDI, Radolfzell). X-ray images and motion tracking data were evaluated for RoM/CoR and subsequently compared.

Results: Moving the specimens to a RoM=0.1° resulted in recordings of 0.10°±0.16° with the motion tracking system and 0.04°±0.13° using the x-ray analysis. Both correlated with 0.998 (p<.001). There were no statistical differences detected between both methods. In determining the CoR, the FXA locations using the x-ray analysis method yielded largest deviations from the CoR preset with a bias>40 mm for RoM=0.1°. With a RoM=1°, CoR position error showed a median bias of 6.04 mm (min: 0.84 mm, max: 12.54 mm). The maximum accuracy for the CoR location was found for a RoM≥1°.

Discussion: The aim of the study was to produce intersegmental positions and movements that were uniquely defined in RoM and CoR. For this reason, we employed a robot unit due to its capability of moving objects about a predefined CoR with a high reproducibility. The study showed that the employed algorithms deliver highly accurate results. The validation was maintained by two distinct methods (robot and motion tracking system). Utilizing the automatic functional x-ray analysis method, poly-segmental RoM, CoR evaluation and implant migration assessments can be conducted in daily practice. This can foster the quality of patient diagnostics and increase the scientific value of clinical studies.

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Preventing Hardware Failure in Pedicle Subtraction Osteotomy Constructs: Pilot Biomechanical Analyses of Rod Configurations
Z.S. Jager1, W.K. Cheng1, A.E. Voss1, D.K. Palmer1, S. Inciooglu1
1Loma Linda University, Orthopaedic Surgery, Loma Linda, CA, USA, 2Arizona College of Osteopathic Medicine, Glendale, AZ, USA

Purpose of the Study: Pedicle subtraction osteotomy (PSO) is an effective way to treat flat back syndrome or positive sagittal imbalance. Pseudarthrosis with hardware failure is a known complication. The purpose of the present study was to compare fatigue resistance and stiffness among various configurations simulating unilateral PSO constructs.

Methods: Test rods measuring 5.5 mm in diameter were cut to 165 mm in length. A French Bender was then used to add a 50-degree bend to each rod to approximate PSO lordosis. Pedicle screws placed into ultra high molecular weight polyethylene blocks were used to hold the rods, simulating a corpectomy model. Each polyethylene-rod construct was secured into a materials testing machine. Each construct was loaded under 300 N compression simulating sagittal bending motion and cycled 15 times at 0.1Hz. Titanium alloy single rod, double rod, bridging cross link, and bridging rod constructs were tested for comparison (Figure 1) in simulated patient flexion (N=5) and extension (N=1). Load-displacement data was collected and average stiffness for each construct was calculated using the last 5 cycles. Stiffness was defined as the secant modulus of each cycle. Normalization and single factor analysis of variance was performed to compare construct stiffness in simulated patient flexion.
Figure 1: Configurations simulating unilateral pedicle subtraction osteotomy rod constructs. Biomechanical testing simulates flexion of the patient. Patient extension was simulated by switching the top and bottom blocks and rotating the rod 180-degrees. A) single rod; B) double rod; C) bridging cross link; and D) bridging rod.

Results: No statistically significant differences were observed between constructs for stiffness when simulating patient flexion. Stiffness in simulated patient extension, however, was observed to be only about 15% that in flexion. Preliminary construct data for stiffness in simulated patient extension increased in the order of: single rod, bridging cross link, bridging rod, and double rod.

Conclusions: The dramatically lower construct stiffness in simulated patient extension compared to flexion suggests rods are failing when the patient extends the spine. Preliminary data from this study has shown that the double rod configuration has the highest stiffness and potentially should be used during the index surgery in patients undergoing PSO to decrease chances of failure.

Discussion: It is confirmed from this study, the Stabilimax dynamic rod rotates about a pedicle screw with a spherical seat during flexion extension bending under pure moment loading of the lumbar spine. The ROM about the L5 pedicle screw in the two level constructs rotated significantly less than either single or hybrid constructs. Devices designed to serve as an adjunct to fusion have traditionally relied on arthrodesis to off-load the implant over time, as the fusion mass gains structural integrity. However, motion preservation devices are expected to function in conjunction with the remaining tissue within the FSU for extended periods. Therefore, understanding how these devices perform is the first step in predicting a successful clinically relevant kinematic response.
Biomechanical Stability of Stand-alone Interbody Spacers with Integrated Screws for Multi-level Cervical Arthrodesis

R.A. Lehman1, A.E. Dmitriev1, M. Cardoso2, H. Paik1, R. Gaume1, D.G. Kang2, A.J. Bevevino1
1Walter Reed National Military Medical Center, Orthopaedic Surgery, Bethesda, MD, USA, 2Walter Reed National Military Medical Center, Neurosurgery, Bethesda, MD, USA

Introduction: Postoperative complications after anterior cervical fusions have been attributed to anterior cervical plate profiles 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. The objective of this study is to evaluate the biomechanical stability of multi-level cervical reconstruction using the stand-alone interbody spacer with integrated screws.

Methods: Thirteen human cadaveric cervical spines (C2-T1) were non-destructively tested under axial rotation, flexion-extension, and lateral bending 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.

Results: No significant difference in ROM was noted between the ACP and SAS for single-level fixation. For multi-segment reconstructions (two and three levels) the ACP proved superior to SAS and intact condition, with significantly lower ROM in all planes. 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 with no significant difference between the ACP and SAS constructs.

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 caution in the setting of multi-level cervical fusion, unless supplemented with posterior fixation.

Biomechanical Evaluation of Nucleus Augmentation with an Injectable in situ Cured Hydrogel

D.J. Cook1, A. Hanlon1, D.M. Whiting2, R.C. Cheng1,2
1Allegheny General Hospital, Neurosurgery, Pittsburgh, PA, USA, 2Drexel University, Neurosurgery, Pittsburgh, PA, USA

Introduction: Nucleus replacement devices have been of interest due to the potential for these devices to replace or augment the characteristics of clinically diagnosed pathologic intervertebral discs. In order to gauge the efficacy of hydrogel augmented nucleus pulposus relying on 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 element removal in order to quantify and compare the anterior column kinematic contributions with and without nucleus augmentation. In addition to range of motion (ROM), the maximum slope of the hysteresis loop (displacement vs. load) going into each direction of loading was measured for each treatment condition.

Materials and methods: Sixteen fresh frozen human lumbar cadaveric specimens were processed with the intent of sparing the osteoligamentous structures. After radiographic screening for severe degeneration, 25 FSU were qualified for the study and carefully separated from their respective lumbar segments prior to mechanical testing. Each FSU was subjected to a flexibility protocol consisting of ±5.0Nm flexion extension and lateral bending. Each FSU was tested in the Intact condition, after removal of the posterior elements (Disc) and following nucleus augmentation (Augmented). Hysteresis plots of angular displacement vs. applied load were generated for the third cycle of testing for each FSU in each treatment and mode of loading. The top and bottom of each loop were fitted separately with cubic splines using robust regression. The slope along the hysteresis loop was calculated continuously by differentiating the fitted splines. A repeated-measures analysis of variance (ANOVA) was used to detect differences among treatment groups with a Bonferroni post hoc test to specify pair wise differences.

Results: Flexion extension ROM increased significantly for the Disc condition with respect to Intact (p< 0.001). No other significant changes were detected based on ROM. The maximum slope of hysteresis going into flexion, extension, left lateral bending and right lateral bending was significantly reduced for the Disc condition with respect to both Intact and the Augmented treatment condition (p< 0.043).

Discussion: The slope of the hysteresis loop for continuously loaded specimens indicates the maximum laxity throughout the range of movement. This is conceptually similar to the measurement of neutral zone derived from discrete, quasi-static spine testing, which has no direct equivalent in continuously driven testing. The results presented indicate that nucleus augmentation with an injectable hydrogel significantly stiffens the lumbar intervertebral disc near the neutral portion of its range in flexion extension and lateral bending but does not significantly reduce range of motion in either mode of loading. Further, these results indicate that ROM, while appropriate for the comparison of fixation devices, may not be sufficient for the characterization of implants intended to restore normal motion to the pathologic spine.

Effects of Arterial N-acetylcysteine (NAC) on the Expression of Protein Chaperones PDI, ERP57, Heat Shock Protein 40, 60, 70, 90 kd, the Qualitative Presence of Intracellular Apoptosis Markers, and Lipid Peroxidation in Postischemic Reperfusion in Rat Spinal Cord

M.E. Berbeo1, A.M. Rodriguez2, Grupo de Neurociencias HUSI PUJ
1Hospital Universitario San Ignacio - Pontificia Universidad Javeriana, Neurociencias - Neurocirugia, Bogota, Colombia, 2Universidad El Bosque, Fac Medicina, Bogota, Colombia

Purpose: To assess the effects of administering arterial N-acetylcysteine (NAC) on the expression of protein chaperones PDI, ERP57, heat shock protein 40, 60, 70,
90 kd, the qualitative presence of intracellular apoptosis markers, and lipid peroxidation, in postischemic reperfusion in rat spinal cord.

**Methods**: In this study Wistar male rats were used. 48 animals were included in four groups. Group 1: control animals without surgery, without treatment with NAC. Group 2: Animals with surgical intervention (ischemia) without treatment after spinal cord ischemia. Group 3: Animals with surgical intervention (ischemia) and reperfusion post ischemia with NAC. Group 4: Animals with surgical intervention (ischemia) and reperfusion post ischemia with saline solution. From each group of animals 6 animals were used for intracardiac perfusion and histological cuts of nervous tissue, the other 6 animals were sacrificed by overdose of anesthetic, its spinal cord removed and immediately frozen in liquid nitrogen. From these tissue proteins of interest were determined by ELISA and western blot. Ischemia time was 45 minutes. The dose of NAC was 150 mg / kg. The spinal cords of the animals in the experimental groups 3 and 4, after 45 min of ischemia were perfused with NAC (group 3) or saline (group 4), and then pulled the clip to restore blood flow (at 45 min after the start of ischemia). Within 24 hours of surgery, animals were induced cardiac arrest under anesthesia with sodium thiopental (100mg/kg) and transcardiac perfusion was performed with 200 ml of PBS (0.05mol / l) followed by 200 ml of paraformaldehyde 4%. Spinal cord was removed and the tissue was posts fixed in parafomaldehyde overnight at 4 ° C and embedded in paraffin for microtome cuts and perform immunocytochemistry and immunofluorescence.

**Results**: We identified heat shock proteins that are modified significantly during ischemia and during reperfusion postischemic. Likewise, was established the modification of tissue levels of malonyl dialdehyde as a marker of lipid peroxidation which was significantly different with and without the administration of NAC during postischemic reperfusion.

**Conclusions**: Microsurgical technique was standardized for transient ischemia of the spinal cord in rats by occlusion of the infrarenal abdominal aorta. Also, was standardized the microsurgical technique for post ischemic reperfusion medicated and unmedicated of spinal cord in rats after occlusion of the infrarenal abdominal aorta. The results of this work show that NAC reduces the harmful effects of free radicals in post ischemic reperfusion of spinal cord nerve tissue. In all analysis the results favor the hypothesis that NAC has protective effect in reperfusion after ischemia of nerve tissue.

**Keywords**: Free radical, scavengers, reperfusion injury, n-acetylcysteine, spinal cord.

**Methods**: Eleven human spines (C2-C7) were studied in a 7-Axis testing system with a hybrid protocol (OBRL, Univ. of Utah, Salt Lake City, UT). Intact was tested in flexion/extension to 1.5Nm. C4-C5 was implanted utilizing an implant placement fixture at neutral, 2mm anterior, and 2mm posterior positions. C-TDR testing order was randomized. Applied moments, forces (AMTI, Watertown, MA), and rotations at C2 and C7 (Omron, Schaumburg, IL), and 3D vertebral movements (Optotrak, NDI, Waterloo, Ontario, CAN) were collected. Implant level force - displacement curves were analyzed by blinded individuals. Statistical analysis included paired-ANOVA with paired Student-t post hoc test. Statistical significant p< 0.05.

**Results section**: Table 1 shows the mean and SD of the Flexion/Extension (Nzs) (Nm/deg). After the TDR implantation the tri-lobe NZS was reduced by an average of 12% while the ball-in-trough NZS was reduced by 61% over the intact specimen (p< 0.05). Additionally, when observing individual test specimen, the tri-lobe did not exhibit any negative slopes while the ball-in-trough did. Table 2 show the mean and standard deviation of the Neutral Zone Range of Motion(deg). After the TDR implantation the tri-lobe NZROM was increased by an average of 9.8% while the ball-in-trough was increased by 35.6% over the intact specimen (p< 0.05).

**Discussion**: Many spinal kinematics studies focus on the passive supporting elements of the spine instead of the intervertebral disc by testing to the viscoelastic limits of the ligamentous/capsular structures. The neutral zone is an important region for proper spinal kinematic motion and stability. The results of this study show that while implantation of a C-TDR can destabilize the spinal column, a well designed and properly placed device can limit destabilization of the motion segment. This study highlights the importance of comparing performance of the reconstructed disc relative to the “correct motion” of the normal intact within the neutral zone.

Introduction: Extra-discal dynamic stabilization products have traditionally been assessed in single loading modes in accordance with current ASTM and ISO standards. However, the in vivo biomechanical behavior of these systems may subject them to more complex motion patterns. The objective of this study was to evaluate durability performance and wear characteristics of a novel pedicle based PEEK/silicone posterior neutral stabilization (PNS) system in a more physiologically relevant scenario.

Methods: A device-specific multi-mode testing scenario was designed in silico using LifeMOD™ simulation software in a two-step procedure. First, the PNS rod was applied bilaterally to the destabilized L4-L5 lumbar motion segment of a cadaverically-validated lumbar spine model. Pure moments of ±6 Nm, ±5 Nm and ±4 Nm in flexion/extension lateral bending, and axial rotation, respectively, were applied to the lumbar model with and without a 450 N follower load to determine physiologically relevant ranges of motion and rod forces for each condition. In the second step, the resulting 4-axis test profile (figure 1) was applied to an experimentally-validated computational model of a bilateral test construct, which confirmed that it would induce the intended physiological loading conditions. In vitro testing was performed on four bilateral PNS rod constructs subjected to the computationally-derived multi-axial test profile for 10 million cycles (Mc) at 2 Hz using an MTS Bionix® Spine Wear Simulator (MTS, Eden Prairie, MN). One additional construct was used as a load soak control. All constructs were submerged in 25% Alpha Calf™ Fraction solution during the test, which was analyzed for particle characterization at the conclusion of testing. Wear was also measured gravimetrically for two constructs.

Result: Computational stress predictions indicated that the multi-mode test protocol induced higher stresses in the PNS rods than for any of the single-mode test conditions. All in vitro test constructs completed 10 Mc without functional failure. Particle analysis of the serum showed the presence of silicone, PEEK and titanium wear debris. Weight loss in the rods of two constructs after 10 Mc was 8.22 mg and 13.73 mg (0.5 mg and 0.8 mg of wear debris when adjusted to match rabbit’s weight), which is well under the dosages used (3 mg silicone and 4 mg PEEK) in the reported rabbit studies with no evidence of an acute neural or systemic histopathologic response.1,2

Discussion: The proposed test method is a viable addition to the traditional test protocols for extra-discal dynamic stabilization products and would align with the current ASTM and ISO test methods for intra-discal spinal motion preserving implants.

References:
2) Cunningham et al. (2007) The Spine Journal 7 (5, 1), 2-3S.

C. Chaput1, A.M. Muzumdar2, D. Gloystein2, V. Zerris1, P. Tortolani1, M. Rahm4, M. Moldavsky3, S. Chinthakunta2, S. Khali1
1Scott and White Hospital, Temple, TX, USA, 2Globus Medical Inc., Research, Audubon, PA, USA, 3Darnall Army Hospital, Fort Hood, TX, USA, 4Union Memorial Hospital, Baltimore, MD, USA

Introduction: Facet fractures involving complete separation of the lateral mass from the cervical vertebra and lamina are at high risk of displacement. These fractures are surgically stabilized using single level anterior fixation and/or two level posterior fixation. Another option for single level fixation is to utilize a spacer with integrated plate/screws (COALITION®, Globus Medical, Audubon, PA) in addition to an anterior cervical plate for additional stability. The current study compares the biomechanics of the novel fixation technique to the more traditional posterior and anterior fixation techniques in a cervical spine model with a simulated facet fracture.

Methods: Seven cadaveric cervical spines (C2-C7) were tested by applying pure moments of ±1.5Nm. Range of motion (ROM) at C5-C6 was obtained in flexion-extension, lateral bending, and axial rotation modes. Constructs tested included: 1) intact; 2) injured (transsection of right C5 pedicle/ lamina with complete posterior ligamentous injury); 3) posterior screws and rod at C4-C6 with cross connector (Pi); 4) interbody spacer and anterior cervical plate at C5-C6 (S+ACP); and 5) spacer with integrated plate and anterior cervical plate at C5-C6 (SA) [Figure 1]. ANOVA and Tukey’s post hoc test were used for analysis (p< 0.05).

Results: Injured ROM was higher than intact in all loading modes. All constructs significantly reduced ROM compared to the injured condition. The Pi construct significantly reduced ROM compared to intact (p< 0.05) in all modes, while S+ACP significantly reduced ROM in lateral bending (p< 0.05) only. The novel construct (SA) significantly reduced ROM compared to intact in both flexion-extension and lateral bending. However, there were no significant differences between the three fixation constructs [Figure 2].

Discussion: The proposed test method is a viable addition to the traditional test protocols for extra-discal dynamic stabilization products and would align with the current ASTM and ISO test methods for intra-discal spinal motion preserving implants.

References:
2) Cunningham et al. (2007) The Spine Journal 7 (5, 1), 2-3S.
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Comparative Study on Biomechanical Behavior of Two Different Cervical Total Disc Replacement Designs in Terms of Concavity and Constraints: ProDisc-C® vs. Prestige LP®

K.M. Park1, S.H. Woo1, D.H. Lim2, K.Y. Lee2, S.J. Lee1
1Inje University, Biomedical Engineering, Gimhae, Korea, Republic of, 2Sejong University, Mechanical Engineering, Seoul, Korea, Republic of

Study purpose: Recently, many cervical total disc replacement (TDR) devices have been introduced in a variety of designs in an attempt to recreate motion behavior of the normal cervical spine thereby to limit the progression of adjacent degeneration. As kinematics and load distribution of the postoperative spine largely depend on the concavity and constraints of the articulating surfaces, biomechanical viability of design features need to be compared and elucidated. The purposes of this study were to evaluate and compare the range of motion (ROM) and location of instant center of rotation (COR), and load sharing characteristics of two major products with different design concepts in cervical TDR - Prodisc-C® and Prestige LP®.

Methods: A 3-D finite element (FE) model of intact cervical spine (C3-6) was made from CT scans of a normal person and validated. Based on this model, postoperative FE models simulating TDR implantation at the C4-5 disc space were made for Prodisc-C®, (Synthes Spine, Paoli, PA) and Prestige LP® (Medtronic Sofamor Danek, Memphis, TN), respectively. These two TDR devices feature different design concepts that affect kinematics: Rotations and some translations were allowed at the articulating surface of Prestige LP® as the ‘concave down’ articulating surface is less constrained whereas only rotations were allowed with Prodisc-C® that features ball & socket articulating surface in ‘concave up’ orientation. Each implant size was made identical with height(6mm), depth(14mm), and width(17mm) and articulating surfaces were recreated based on 3-D scanning data. Friction coefficient of 0.07 was assumed at the articulating surfaces and complete bony on the bone-implant interface via ‘tie’ contact condition. Hybrid protocol (intact: 1Nm) with a compressive follower load of 73.6N were applied at the superior endplate of the C3 vertebral body. The inferior endplate of C6 vertebral body was constrained in all directions.

Results: At the index level, Prestige LP® showed 15% less motion than ProDisc-C® in extension and about the same in flexion. Differences in ROM were negligible at the adjacent level. Here, the COR of Prestige LP® was located more postero-inferiorly than that of ProDisc-C® by about 1-mm during extension at the index level. Facet load was less with Prestige LP® by about 10% at the index level but 14% more at the adjacent level.

Discussion and conclusion: The results of this study indicated that the biomechanical behavior of the postoperative cervical spine can be indeed influenced by the design features such as concavity orientation and extent of constraint of the articulating surfaces. Particularly, ROM and COR location as well as the facet loads at the index level and adjacent levels were more sensitive during extension. It would be interesting to note that resulting differences in facet load at the index and adjacent levels between the two designs will manifest to different clinical results in terms of postoperative facet degeneration.

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New Radiculopathy after TLIF with BMP: Large Series Incidence, Natural History, and Comparison to Laminectomy

D. Crandall1, E. Huish1, J. Patterson2, J. Revella1, D. Revella1, R. McLemore2
1Sonoran Spine Center, Mesa, AZ, USA, 2Banner Orthopaedic Residency Program, Phoenix, AZ, USA

Purpose: “Off label” use of rhBMP-2 in transforal lumbar interbody fusion (TLIF) has been complicated by new radiculopathy, with laboratory evidence of irritation of neural tissue. The clinical implication, incidence, and natural history of new BMP-related radiculopathy is unknown. This is the first study to analyze timing of leg pain resolution after TLIF using interbody BMP compared to laminectomy alone.

Methods: This is a retrospective review of prospectively collected clinical and radiographic outcomes on 412 consecutive adults age 60 years(19-91 years) undergoing open laminectomy at one center. Additional arthrodesis (TLIF Group) was performed in 343 who required laminectomy 2.6 levels (range1-6), posterior instrumented fusion 4.3 levels (range 2-17) and TLIF 1.7 levels (range1-4). Diagnoses included degenerative-146, spondylolisthesis-117, deformity-80. Laminectomy only was done in 69 patients (Lami group) at 3.0 levels (range1-5). Excluded: simple disc herniations, anterior-posterior fusion. Leg pain presence and distribution (buttock only, thigh, past knee) was analyzed Pre-op/6wek/3/month/6/month/1/year/2/year. Pain scores (VAS) were compared with the sign test. Oswestry(DI) differences tested for normalcy using Anderson Darling, compared using paired t-tests. Outcomes evaluated with chi square.

Results: Follow-up averaged 65 months (range 33-114 months). Lami group VAS improved from 5.7 pre-op to 2.8(p=0.026) at 6week, 3.5 at 3months (p=0.042) and remained stable. ODI improved from 49 pre-op to 25 (p< 0.001) at 6week, 32 at 3 months (p=0.049) and remained stable. For TLIF group, VAS improved from 6.2 pre-op to 3.9 (6 weeks), 3.5 (3months), 3.1(6months), 2.9 (1year), 3.1 (2year); ODI improved from 49 pre-op to 32 (6weeks), 34(3months), 28(6months), 26(1year), 28(2year)< p= 0.001. Leg pain past the knee in 271 TLIF group was still present in 62 at 6 weeks(23%), 45 at 3 months (16%), 41 at 6months (15%), and remained stable. Lami group leg pain past the knee was still present in 7 at 6 weeks(15%), 8 at 3months (17%), 9 at 6 months(19%). Both groups achieved similar relief of radicular pain long-term (p=0.152). Both groups had similar levels of revision surgery, with slightly more in the TLIF group: 131(38%) vs. 15(32%). Transient increase in buttock or thigh pain at 6 weeks was seen in revision laminectomy (26%), revision TLIF(12%), and primary TLIF(1%), each returning to baseline by 3 months.

Conclusions: Comparing laminectomy vs. TLIF with BMP in patients with leg pain, TLIF had a small transient increase in leg pain at 6 weeks, with both groups similar at 3 months. Revision surgery was associated with more residual leg pain short and long-term, without difference between groups. Post-op buttock/thigh pain showed transient increase in both groups. Lami group clinical outcomes were stable after 6-12 weeks, with TLIF group stabilizing after 6 months.
Clinical Cervical Therapies

353 Five to Seven-year Results of the ProDisc-C Total Disc Replacement Multi-center Randomized Controlled Clinical Trial

J. Zigler, M. Janssen, R. Delamarter, D. Murrey, J. Spivak

Texas Back Institute, Dallas, TX, USA, Center for Spinal Disorders, Denver, CO, USA, Cedars Sinai Spine Center, Los Angeles, CA, USA, OrthoCarolina Spine Center, Charlotte, NC, USA, N.Y.U-Hospital for Joint Diseases, New York, NY, USA

Purpose: Cervical total disc replacement (TDR) is intended to treat symptomatic cervical disc disease (SCDD), as an alternative to cervical fusion. TDR maintains motion at the vertebral segment, while allowing for decompression and relief of radicular symptoms. The study was conducted to compare the long-term safety and effectiveness results of cervical TDR, ProDisc-C (Synthes Spine Company, L.P., West Chester, PA), to anterior cervical disectomy and fusion (ACDF) surgery for the treatment of single-level SCDD between C3 and C7.

Methods: A prospective, randomized, controlled clinical trial was performed. Patients were enrolled and treated in accordance with the US Food and Drug Administration (FDA) IDE-approved protocol. Up to 7 year follow up data is presented. The study was conducted at 13 sites. A noninferiority design with a 1:1 randomization was used. Outcome measures included Visual analog scale (VAS) pain and intensity (neck and arm), VAS satisfaction, Neck Disability Index (NDI), neurological exam, device success, adverse event occurrence, and Short Form-36 (SF-36).

Results: Two hundred nine patients were randomized and treated (106 fusion (ACDF); 103 ProDisc-C (PDC-R)). An additional 136 non-randomized continued access (CA) patients received single-level ProDisc-C implants and followed the same protocol as the randomized study.

Demographics were similar among the three patient groups (PDC-R: 42.1 years, 44.7% males; CA: 43.5 years, 42.6% males; and ACDF: 43.5 years, 46.2% males). For all groups, the most commonly treated level was C5-C6 (PDC-R: 56.3%, CA: 60.3%; ACDF: 57.5%). Mean follow-up times were 76.9 months for 78 ACDF patients; 62.6 months for 55 CA patients; and 75.6 months for 83 ACDF patients. A total of 38 ACDF and 42 PDC-R patients had follow-up out to 7 years. For all clinical outcomes at the patient’s last visit, there was significant improvement compared to baseline values with no significant differences between the treatment groups. NDI was significantly improved from baseline (p < 0.0001) with PDC-R: 20.5 (61.5% mean improvement); CA: 21.5 (55.9% mean improvement); and ACDF: 22.4 (54.8% mean improvement). VAS satisfaction scores (0 = no satisfaction; 100 = completely satisfied) were similar out to 7 years with PDC-R 83.3; CA 84.3; and ACDF 80.2. Range of Motion at the index level at the last visit averaged 0.6° for ACDF, 8.6° for PDC-R, and 9.2° for CA.

Secondary surgery rates for the index and adjacent level were statistically significantly lower through 7-year follow-up (Fisher’s Exact Test p < 0.05) for ProDisc-C patients (5.0%, 12/239) compared to ACDF patients (16.0%, 17/106). There was no significant difference in other adverse events.

Conclusions: Outcome data for patients up to 7 years postoperative from the ProDisc-C clinical trial (including ACDF, and randomized and continued access PDC patient populations) show that total disc replacement is a safe and effective treatment for single-level cervical degenerative disc disease, and is at least as effective as ACDF in the treatment of single-level symptomatic cervical degenerative disc disease. Additionally, total disc replacement appears to require a lower incidence of secondary surgery at the index or adjacent levels, and maintains a more physiological range of motion.

405 SECURE®-C Cervical Artificial Disc: Outcomes from a Prospective, Randomized IDE Study at 24 Months and Beyond


Pennsylvania Spine Institute, Harrisburg, PA, USA, Charleston Brain and Spine, Charleston, SC, USA, Peachtree Neurosurgery, Atlanta, GA, USA, West Augusta Spine Specialists, Augusta, GA, USA, Greater Chesapeake Orthopaedic Associates, Baltimore, MD, USA, Globus Medical, Inc., Audubon, PA, USA

Purpose: A pivotal Investigational Device Exemption (IDE) study was conducted to evaluate the safety and effectiveness of the SECURE®-C Cervical Artificial Disc. Results from the 380 subjects who were treated in the study are presented, including follow-up beyond two years.

Methods: The prospective, randomized IDE study was conducted at 18 sites across the U.S. The purpose of the study was to compare results from patients treated with the investigational SECURE®-C device (Globus Medical, Audubon, PA) to those receiving the control. Enrolled patients were randomized 1:1 to either the SECURE®-C disc or the control anterior cervical disectomy and fusion (ACDF), except the first five treated at each site who received the disc. Per the approved IDE protocol, overall success requires the following: 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). An alternate FDA definition of overall success requires improvement in NDI by 15 points, maintenance or improvement in neurologic status, absence of device-related events, and no intraoperative change in treatment. Secondary outcome measurements include Visual Analog Scale (VAS) neck and arm pain, SF-36 Health Status survey, and patient satisfaction. Outcome measures were collected pre-operatively and at 6 weeks, 3, 6, 12 and 24 months and annually thereafter. Several patients have now reached 5 year follow-up.

Results: Efficacy data is presented for 151 patients randomized to SECURE®-C and 140 patients randomized to control ACDF. Demographics were similar between the two randomized groups. At 24 months post-op, 89.2% of SECURE®-C patients demonstrated improvement in NDI by at least 15 points from pre-op vs. 84.5% of control patients. Ninety six percent
(96.0%) of SECURE®-C and 94.9% of ACDF patients were neurosurgical successes. Two percent (2.1%) of SECURE®-C patients required a removal, revision or reoperation at the index level as compared to 7.5% for the control group. Device-related adverse events (including reoperations) were reported in 2.8% of patients treated with SECURE®-C vs. 8.4% of ACDF patients. Two percent (2.0%) of SECURE®-C patients experienced an intraoperative change in treatment versus none in the control (this was not permitted in the study protocol). VAS neck and arm pain scores improved in both groups at 24 months as compared to baseline. At 24 months post-op, patient satisfaction was 95.7% for the SECURE®-C group and 85.2% for ACDF patients. Overall success rates were 83.8% for the SECURE®-C group and 73.2% for the control group, using the FDA-defined criteria. Superiority of the SECURE®-C group to the control was established for overall success, with a posterior probability of 98.1% for the FDA-defined criteria. Beyond 24 months, one SECURE®-C patient required secondary surgery at the index level (at 31 months) as compared to four ACDF patients who underwent device removal (from 34 to 51 months). Outcomes remain stable for SECURE®-C patients at later visits.

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 ACDF, with promising long term results.

30 Comparison of Clinical and Radiological Changes between Total Disc Replacement and Anterior Cervical Fusion in Single Level Degenerative Cervical Disc Diseases: More than 5-year Follow-up K.-S. Ryu1, M.-H. Shin1, C.-K. Park1

1Seoul St. Mary’s Hospital, The Catholic University, Seoul, Korea, Republic of

Objective: The purpose of this retrospective study is to compare minimum 5 years clinical and radiological outcomes between cervical total disc replacement (C-TDR) using Prodisc-C and anterior cervical interbody fusion (ACIF) for the treatment of single-level degenerative cervical disc disease.

Methods: Eighteen patients of C-TDR and 14 patients of ACIF were enrolled in the present study. All 32 patients underwent C-TDR or ACIF during the same period of time between June 2005 and June 2006. The clinical and radiographic outcomes were obtained preoperatively and at 1 month and minimum 5 years after surgery. The clinical outcome was assessed using visual analog pain scale (VAS) and neck disability Index (NDI). Segmental angle and range of motion (ROM) in the index and adjacent segments were measured. Global (C2-C7) angle and ROM were also investigated. The UCLA grading scale was used to evaluate the prevalence of adjacent segment degeneration on plain radiography.

Results: Mean follow-up of C-DTR was 63 months, and ACIF was 61 months. In both groups, mean preoperative VAS and NDI scores were considerably decreased at postoperative 1 month, and these improvements were maintained until last follow-up. In the C-TDR group, segmental ROM at index segment was changed from 11.4±4.9°(preoperative) to 8.9±3.8° (postoperative 1 month) and 11.5±4.5° (last follow-up). Preoperative global cervical ROM (41.3±15.9°) significantly decreased at the postoperative 1 month (32.6±11.0°) (P=0.001), however, the last follow-up value showed the similar one with the preoperative (40.1±17.0°) (P=0.06). Upper (12.1±6.1°) and lower (10.3±4.7°) adjacent segment ROM showed a significant decrease at postoperative 1 month (8.9±4.1°, 7.7±4.3°, respectively) (P<0.05), and it was also returned to the preoperative values at the last follow-up (11.9±5.8°, 10.2±4.6°, respectively) (P<0.05). In the ACIF group, preoperative global cervical ROM (45.1±11.8°) was significantly decreased at the postoperative 1 month (40.4±11.9°, P=0.005), and it was maintained at the last follow-up (40.0±16.1°). Preoperative upper (11.7±4.9°) and lower (13.5±4.2°) adjacent segment ROM exhibited a significant increase at postoperative 1 month (14.4±4.5°, 14.9±4.9°, respectively) (P<0.05), and it was maintained at the last follow-up (12.7±4.9°, 14.4±4.3°, respectively) (P<0.05). In the C-TDR group, the mean preoperative UCLA score of degeneration grade (1.4±0.5) was significantly increased at last follow up (1.8±1.0, P=0.002). In the ACDF group, the mean preoperative UCLA score (1.4±0.5) was significantly increased at the last follow-up (2.4±0.9, P=0.000). With comparison between two groups, the mean UCLA score was significantly higher in the ACIF group than in the TDR group (P=0.006).

Conclusions: The present study demonstrates that the C-TDR and ACIF groups are comparable to each other in postoperative clinical improvement of the patients with single level degenerative cervical disc diseases in more than 5-year follow-up. On the other hand, in the comparative study between preoperative and postoperative radiological examinations, the C-TDR group appears to present more favorable results to the adjacent segments, and the incidence of adjacent segment degeneration is significantly higher in the ACIF than in the C-TDR group.

410 Treatment of Cervical Myeloradiculopathy with the PCM Total Disc Arthroplasty Compared to ACDF in a Prospective Randomized Clinical Trial C.D. Chaput1, F.M. Phillips2, A. Cappuccino3, F.H. Geisler4, J.G. DeVine5, K. Gilder6, K.M. Howell7, P.C. McAfee8

1Scott and White Hospital, Orthopaedic Surgery, Temple, TX, USA, 2Midwest Orthopedics at Rush University, Chicago, IL, USA, 3Buffalo Spine Surgery, Buffalo, NY, USA, 4Chicago Back Institute, Chicago, IL, USA, 5Dwight D. Eisenhower Army Medical Center, Fort Gordon, GA, USA, 6NuVasive, Inc., Biometries, San Diego, CA, USA, 7NuVasive, Inc., Clinical Resources, San Diego, CA, USA, 8St. Joseph’s Hospital, Baltimore, MD, USA

Introduction: Cervical arthroplasty in patients with symptomatic myelopathy remains controversial. It is unknown if motion preservation techniques can effectively treat myelopathic symptoms and prevent disease progression. The present evaluation was performed to compare the clinical results of cervical total disc replacement to anterior cervical discectomy and fusion in the treatment of myeloradiculopathy.

Methods: Post hoc analyses were performed of the prospective, randomized, multicenter, IRB-approved IDE clinical trial evaluating longitudinal outcomes over 2 years comparatively between arthroplasty (PCM)
Purpose: Cervical total disc replacement (TDR) is intended to address pain and preserve motion between vertebral bodies in patients with symptomatic cervical disc disease (SCDD). One of the hopes of TDR is that it would result in fewer secondary surgeries for index level revision and adjacent level disease than anterior cervical discectomy and fusion surgery (ACDF). Previously, the two-year and five-year follow-up results from the investigational device exemption (IDE) clinical trial of the ProDisc-C (Synthes USA Products, LLC, West Chester, PA) cervical TDR were reported. With continued follow-up of this patient population, and the addition of continued access patients (PDC-CA), the longer-term results three patient cohorts can now be evaluated to determine the need for secondary surgical procedures.

Methods: A prospective, randomized, multicenter Food and Drug Administration (FDA) regulated IDE clinical trial was conducted at 13 sites, utilizing a 1:1 randomization ratio. The first IDE surgery was performed in August 2003 and 345 patients were treated. Patient cohorts include 106 patients randomized to ACDF (Fusion Randomized), 103 patients randomized to ProDisc-C (PDC-R), and 136 non-randomized patients receiving single-level ProDisc-C under a continued access (PDC-CA) program with FDA approval (same inclusion/exclusion criteria and follow-up as the randomized patients). Patients were evaluated pre-operatively, and post-operatively at 6 weeks, 3, 6, 12, 18, 24, 36, 48, 60, 72, and 84 months. Patient self-assessments were Neck Disability Index (NDI), Visual Analog Scales (VAS) for pain and satisfaction, and SF-36. Physical and neurologic exam, and radiographic evaluations were completed. Secondary surgical procedures were specifically tracked, levels, and type of surgery recorded.

Results: Demographics were similar among the three groups (ACDF: 43.5 years, 53.8% females, BMI 27.4; PDC-R: 42.1 years. 55.3% females, BMI 26.3; PDC-CA: 43.5 years, 57.4 females, BMI 26.7). The most commonly treated level was C5-6 (ACDF: 57.5%; PDC-R 56.3%; PDC-CA 60.3%). Ninety percent of randomized patients had 7 year follow-up. PDC-CA patients had a mean follow-up of 5.2 years. Secondary surgical procedures were identified in 16.0% of 106 ACDF patients, and in 5.0% of 239 ProDisc-C patients (PDC-R: 5.8%; PDC-CA: 4.4%), a statistically significant difference. In the ACDF population, 17 total patients required 26 secondary surgeries. Eight patients required index level revision, and 11 patients had adjacent level surgery. Among PDC-R patients, there were 6 secondary procedures required. In the PDC-CA population, 6 patients required secondary surgery.

Conclusions: Secondary surgical procedures at both index and adjacent levels were significantly reduced in both the randomized and continued access ADR treated patient populations (randomized and continued access) compared to the randomized fusion treated patients. Reoperation was 3 times more common in the fusion patients. These findings, with longer follow-up in the 209 patients in the randomized cohorts and the addition of 136 non-randomized CA patients, support earlier reports at two and five years demonstrating fewer secondary surgeries in the arthroplasty patients.
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Five-year Clinical and Radiological Follow-up of the Heterotopic Ossification after Bryan Cervical Disc Arthroplasty

Z. Feifei1, S. Yu2
1Peking University 3rd Hospital, Orthopaedics, Beijing, China

Objective: To evaluate the long-term clinical and radiological outcome of the heterotopic ossification after Bryan cervical disc arthroplasty.

Methods: A total of 28 patients (single-level 26 cases and bi-level replacement 2 cases, in total of 30 segments) underwent Bryan cervical disc (Medtronic Sofamor Danek Inc, Memphis, TN) replacement from December, 2003 to November, 2005 were reviewed retrospectively. All cases were followed up for more than 5 years (range, 57-72 months; average, 60.3 months). Occurrence of HO was investigated with the McAfee classification on the follow-up cervical dynamic X-ray. We also measured cervical range of motion (ROM) to identify HO’s biomechanical effects. For the clinical effects, JOA score, VAS for neck pain, VAS for arm pain and NDI were evaluated to CSM patients and CSR patients in correlation with the occurrence of HO.

Results: In 30 treated segments, a total of 12 HOs were detectable. The occurrence rate of HO was 40% and the classification of HO by McAfee’s criteria distributed as follows: grade II 1 case, grade III 3 cases, grade IV 8 cases. Compared with initial occurrence, six in twelve (50%) HOs developed during follow-up with an average of 1.7 McAfee grade. Mean NDI, VAS for neck pain and VAS for arm pain for 8 CSR patients were reduced from 29.3±8.6, 4.6±0.9, and 6.1±0.6 preoperatively to 5.5±3.9, 1.3±1.3, and 0.4±0.7 postoperatively(P<0.05). JOA score for 20 CSM patients were increased from 13.2±2.2 preoperatively to 15.9±1.1 postoperatively(P<0.05). However, patients with or without HO did not show any statistical significance in those clinical outcome assessments(P>0.05). General segmental ROM was reserved from 6.9°±3.1° preoperatively to 7.2°±3.8° postoperatively, but patients with HO(4.6°±3.6°) was much lower than who without HO(9.0°±2.8°) (P<0.05).

Conclusion: The overall incidence of HO after cervical artificial disc replacement was relatively high. The occurrence of HO did not affect the clinical symptoms, but may reduce the segmental ROM.

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Comparison of Re-operations in Cervical Total Disc Replacement vs. Anterior Cervical Fusion: Results with Mean 48 Month Follow-up

S.L. Blumenthal1, R. Guyer1, D.D. Ohnmeiss2, J. Zigler1
1Texas Back Institute, Plano, TX, USA, 2Texas Back Institute Research Foundation, Plano, TX, USA

Aim: Anterior cervical fusion has (ACF) been the primary treatment of neck pain for many years. However, the possibility of pseudoarthrosis has always been a risk as well as accelerated deterioration of the adjacent segment, either of which may result in subsequent reoperation. It was hoped that the development of a total disc replacement (TDR) would avoid or reduce these problems. The purpose of this study was to compare the re-operation rates in cervical TDR patients vs. ACF.

Methods: A total of 135 patients enrolled in one of 6 prospective, randomized FDA IDE trials were included in the study: 84 TDR patients and 51 ACF patients. Adverse event reports and surgery logs were reviewed to identify re-operations. Only patients with minimum 24 month follow-up data were included. The mean follow-up was 49.7 months with a maximum of 88 months. Selection criteria in the 6 trials were very similar and there were no significant differences between the groups based on demographic or baseline assessment scores or in follow-up duration.

Results: The re-operation rate in the TDR group was significantly less than in the ACF group (6.0% vs. 17.6%; p<0.05; Table 1). Among the 5 reoperations in the TDR group, 1 was a decompression at the index level (1.2%), 1 was a decompression at the index and adjacent segment (1.2%), 2 were at an adjacent segment (2.4%), and one patient underwent implantation of a spinal cord stimulator for pain control (1.2%). In the ACF group, 4 patients underwent reoperation for pseudoarthrosis (7.8%) and 5 (9.8%) at an adjacent segment. The length of time between the index surgery and re-operation was significantly greater in the TDR group (Table 1).

Using re-operation as the survival endpoint, the results of a Kaplan-Meier survival analysis found that the TDR group had a significantly longer survival period than ACF (p<0.05; see figure).

Conclusion: This study found the re-operation rate was significantly less in the TDR group compared to ACF and that the survival time to reoperation was greater in the TDR group. There were reoperations in both groups for adjacent segment changes; however, these were less frequent and occurred later with TDR than with ACF. These results support that TDR is associated with a reduced reoperation rate compared to ACF.
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Quantifying Biomechanical Alterations of Cervical Disc Degeneration: An In Vivo Spinal Stiffness Assessment Methodology
C.J. Colloca¹, R. Gunzburg², M. Szpalski³, B.J. Freeman⁴, M. Afifi⁵, R.J. Moore⁶
¹Arizona State University, Department of Kinesiology, Chandler, AZ, USA, ²Eeuweestkliniek Hospital, Antwerp, Belgium, ³Hôpitaux Iris Sud/IRIS South Teaching Hospitals, Department of Orthopaedics, Brussels, Belgium, ⁴University of Adelaide, Department of Spinal Surgery, Adelaide, SA, Australia, ⁵University of Calgary, Faculty of Kinesiology, Calgary, AB, Canada, ⁶Adelaide Centre for Spinal Research, Adelaide, SA, Australia

Introduction: In vitro and in vivo biomechanical studies have examined spine kinematics during posteroanterior loading but few (if any) studies have quantified loading-induced spinal motion responses in the degenerated cervical spine. The objective of this prospective in vivo experimental animal study was to determine the effects of disc degeneration on dorsoventral (DV) cervical spine kinematic responses.

Methods: Adolescent merino wethers (n=15, mean 47 kg) were mechanically tested in vivo using a validated computer controlled force application apparatus designed to quantify PA stiffness. Four months prior, Seven sheep randomly underwent a survival surgical procedure to induce anular injury via scalpel wound that resulted in chronic disc degeneration of the C4-C5 intervertebral disc. Eight age and weight-matched animals served as controls having cervical spine exposure surgery only and prior the TDR insertion. The wire was introduced posteriorly through a single puncture hole in the endplates, segmental lordosis at the implanted level, and overall sagittal alignment of the cervical spine. The purpose of this study was to investigate the effect of PLL resection on the kinematics of cervical motion segments after implantation of a disc prosthesis.

Methods: Nine human cervical spines were tested in flexion-extension (FE), lateral bending (LB) and axial rotation (AR) to maximum moments of ±1.5 Nm. Response in FE was measured under 150N compressive follower preload. Segmental ROM was measured using optoelectronic instrumentation. After testing the intact specimen a TDR was implanted at C6-C7 through a wide anterior discectomy window with the prosthesis midline posterior to the midline of the disc and while leaving the uncinate processes and PLL intact. Finally, the PLL was cut while keeping the disc prosthesis in place. This was accomplished by placement of a 0.36 mm stainless steal wire looped around PLL after performing discectomy and prior the TDR insertion. The wire was introduced posteriorly through a single puncture hole in the ligamentum flavum. The flexibility tests were repeated for each step. ROM and stiffness in the high flexibility zone around the neutral posture were analyzed using repeated measures ANOVA.

Results: With the PLL intact, the FE-ROM was significantly decreased after insertion of TDR compared to intact (12.6±3.2 to 9.5±2.7 degrees) (p< .05). PLL Resection returned the FE-ROM closer to intact magnitude 10.8±2.7 degrees (p>0.05). PLL resection did not affect the ROM in LB or AR (p>0.05) Segmental flexion stiffness significantly increased after TDR with intact PLL (0.09±0.05 to 0.17±0.08 Nm/deg) (p< .05) while after PLL resection the segmental flexion stiffness (0.13±0.07 Nm/deg) was closer to the intact level (p>0.05).

Conclusions: In vivo dorsoventral vertebral motions of the cervical spine are are significantly reduced in animals with degenerated cervical spine discs. These biomechanical findings may be useful in understanding the biomechanical consequences of cervical intervertebral disc pathology.

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Effect of PLL Resection on TDR Kinematics: To Cut or Not To Cut
A.G. Patwardhan¹, I.I. Voronov¹, P.P. Tsitsopoulos¹, T. Potuf³, S. Hannon², J. Zelenakova², G. Carandang², F.M. Phillips³, M.R. Zindrick¹, A.J. Ghanayem¹, R.M. Havey¹
¹Loyola University Chicago, Orthopaedic Surgery and Rehabilitation, Maywood, IL, USA, ²Edward Hines Jr. VA Hospital, Hines, IL, USA, ³Rush University Medical Center, Chicago, IL, USA

Purpose: The need for resection of the PLL during artificial disc replacement surgery has been debated by many. Some advocate partial or complete resection of the PLL to achieve a more parallel disc space distraction for the insertion of the prosthesis, while others advocate its preservation for biomechanical stability of the implanted segment if its entire removal is not required for neural decompression. The presence of the PLL will influence the ‘shell angle’ (angle between the prosthesis endplates), segmental lordosis at the implanted level, and overall sagittal alignment of the cervical spine. The purpose of this study was to investigate the effect of PLL resection on the kinematics of cervical motion segments after implantation of a disc prosthesis.

Methods: Nine human cervical spines were tested in flexion-extension (FE) , lateral bending (LB) and axial rotation (AR) to maximum moments of ±1.5 Nm. Response in FE was measured under 150N compressive follower preload. Segmental ROM was measured using optoelectronic instrumentation. After testing the intact specimen a TDR was implanted at C6-C7 through a wide anterior discectomy window with the prosthesis midline posterior to the midline of the disc and while leaving the uncinate processes and PLL intact. Finally, the PLL was cut while keeping the disc prosthesis in place. This was accomplished by placement of a 0.36 mm stainless steal wire looped around PLL after performing discectomy and prior the TDR insertion. The wire was introduced posteriorly through a single puncture hole in the ligamentum flavum. The flexibility tests were repeated for each step. ROM and stiffness in the high flexibility zone around the neutral posture were analyzed using repeated measures ANOVA.

Results: With the PLL intact, the FE-ROM was significantly decreased after insertion of TDR compared to intact (12.6±3.2 to 9.5±2.7 degrees) (p< .05). PLL Resection returned the FE-ROM closer to intact magnitude 10.8±2.7 degrees (p>0.05). PLL resection did not affect the ROM in LB or AR (p>0.05) Segmental flexion stiffness significantly increased after TDR with intact PLL (0.09±0.05 to 0.17±0.08 Nm/deg) (p< .05) while after PLL resection the segmental flexion stiffness (0.13±0.07 Nm/deg) was closer to the intact level (p>0.05).

Conclusions: PLL resection results in the significant
Facet Engagement in the Intact Cervical Spine

R. Havey¹, J. Goodslitt², T. Potluri², S. Hannon¹, B. McIntosh³, F. Phillips⁴, M. Zindrick¹, P. Tsitsopoulos¹, L. Voronov¹, A. Patwardhan¹

¹Loyola University Chicago, Orthopaedic Surgery and Rehabilitation, Maywood, IL, USA, ²Edward Hines Jr. VA Hospital, Hines, IL, USA, ³Loyola University Chicago, Maywood, IL, USA, ⁴Rush University Medical Center, Chicago, IL, USA

Purpose: The goal of this study was to assess the facet engagement in intact cervical spine specimens undergoing motions in flexion-extension (FE), lateral bending (LB), and axial rotation (AR) using a specimen-specific CT model, which did not require assumptions regarding host anatomy or tissue properties.

Methods: Nine cadaveric spines (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 (0.63mm) axial CT scans. A digital link was made between the radiopaque markers in the CT reconstruction and the 3-D motion measurement system using a registration technique. Three-dimensional motion of each vertebra was tracked optoelectronically as the specimen was subjected to moments in FE, LB and AR. The 3-D vertebral motion data was used to drive the CT anatomical model. As a result, motion of any anatomical landmark could be assessed in response to loads applied during flexibility testing.

From the kinematic data, facet overlap area was calculated throughout the ROM in FE, LB and AR. Overlap calculations were performed in the plane of the superior facet surface of the inferior vertebrae of each joint (Figure 1). The facet plane was determined by performing a least squares fit on the facet perimeter. In this abstract we present results for FE and AR.

Results: In AR the overlap area on the contralateral facet decreased relative to neutral posture where as the ipsilateral facet area did not change (Table 1). In FE the total facet overlap area was similar for both C5-C6 and C6-C7 (p>0.05). At both levels flexion motion significantly reduced facet overlap area relative to the neutral posture (p<0.05). Extension motion had a smaller effect on facet overlap area compared to flexion at both segmental levels. Accuracy of this model to determine the 3-D motion of any anatomical landmark was 0.14 ±0.05 mm.

Conclusion: 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. This model will be useful for the evaluation of facet joints before and after interventions such as decompression, arthrodesis or arthroplasty. This is the first report of normative facet overlap area. This facet engagement area will be sensitive to any changes in motion segment kinematics caused by degenerative changes and surgical interventions such as arthroplasty and presence of adjacent fusion.
and pedicle at the isthmus, and from the borders of the SAF to the boundaries of the pedicle. We calculated the morphologic relationship of the ventral lamina and center of the pedicle (COP), to the SAF.

**Results:** 229 pedicles were measured (1 excluded due to SAF fracture). The VL was clearly identifiable in all specimens at all levels forming the roof of the spinal canal, and confluent with the medial pedicle wall (MPW). The mean distance from SAF midline to MPW was 1.34±1.25 mm medial. The MPW was lateral to SAF midline in 34 (14.85%) pedicles, with a mean distance of only 0.52±0.51 mm lateral. The mean distance from SAF midline to COP was 2.22±1.49 mm lateral. The COP was medial to SAF midline in only 9 (3.39%) pedicles. The mean distance from the SAF superior border to the COP was 13.15±2.47 mm.

**Discussion and conclusion:** The ventral lamina is a valid and anatomically reproducible structure, consistently located medial to the SAF midline (85%). We also found the COP consistently lateral to the SAF midline (97%). Based on these morphologic findings the optimal starting point for thoracic pedicle screws, termed the “Superior Facet Rule”, should be 2-3 mm lateral to the SAF midline, allowing screw placement in the center of the pedicle and avoiding penetration into the spinal canal.

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**In vitro Lumbar TDA Wear Rate Susceptibility Depends on Phasing of Motions and Device Design**

**P.J. Hyde**<sup>1</sup>, **J. Fisher**<sup>2</sup>, **R.M. Hall**<sup>3</sup>

<sup>1</sup>University of Leeds, Institute of Medical and Biological Engineering, Leeds, United Kingdom

**Introduction:** Common lumbar total disc arthroplasty (TDA) devices rely heavily on existing total joint arthroplasty technology and as such are a potential generator of bio-reactive wear particles. In hip and knee arthroplasty, periprosthetic wear-induced osteolysis has been widely reported. However, in the spine the potential wear-debris related risks have not been given sufficient credence. This osteolytic possibility is of great concern for the lumbar spine, both due to the difficulty in revision and also because TDA patients tend to be younger than hip/knee arthroplasty patients and consequently may be a generator of wear particles for a longer period in vivo. The amount of cross shear motion at bearing surfaces has been linked to higher wear rates in metal-UHMWPE bearings. The sensitivity of wear in TDA devices due to the cross shear effects of phasing of input motions has not been adequately investigated.

**Aim:** The aim of this experiment was to study two typical metal-UHMWPE TDA devices utilising similar materials, but of differing mechanical design, in a custom designed spine simulator using two separate input cycle waveforms and assess the wear behaviour in terms of both gravimetric magnitude and osteolytic potential.

**Method:** Prodisc and Charité TDA devices were tested. Firstly, a standard ISO 18192-1 cycle was used as a baseline on both devices. This was followed by a reduced cross shear cycle created by phase shifting the lateral bend input to be in-phase with the flexion-extension input. Every million cycles (MC) the gravimetric wear was recorded.

**Results:** For the standard ISO cycle the wear rates for the Prodisc and Charité were 16.1±1.4 mg/MC and 11.5±1.7 mg/MC respectively. For the reduced cross shear cycle the wear rates were 6.0±1.3 mg/MC and 7.3±1.5 mg/MC respectively (Figure 1).

![Figure 1](image)

**Discussion:** The difference between the ISO cycle wear rates for Prodisc and Charité tests was significant (p<0.01). Conversely, the reduced cross shear tests were not significantly different (p=0.37). This anomaly can be explained by the differing TDA designs. The Charité device has a mobile core which was observed to allow rotation in the transverse plane of the device during the ISO cycle, thereby reducing its cross shear susceptibility.

**Conclusion:** The phasing of the input motions has a large effect of the wear rate of metal-UHMWPE TDAs. The Charité device exhibited less wear during the higher cross shear ISO test. Osteolytic potential will be reported separately by research colleagues.

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**The Effect of Changing the Length in Levels of a Posterior Instrumentation Construct on Induced Lumbosacral Screw Strains and ROM**

**G. Fleischer**, **J. Malcolm**, **A. Freeman**, **L. Ferrara**

<sup>1</sup>Spine and Brain Center of New England, Nashua, NH, USA, <sup>2</sup>Pinnacle Orthopaedics, Marietta, GA, USA, <sup>3</sup>Excellen Center for Bone and Joint Research and Education, Minneapolis, MN, USA, <sup>4</sup>OrthoKinetic Technologies, LLC, Southport, NC, USA

**Introduction:** Previous biomechanical experiments have shown the screw strains at S1 to be affected by long posterior instrumented fusion constructs. To the authors’ knowledge, no significant investigation of the effects of changing the length of the same posterior fusion construct on L4, L5 and S1 screw strains has been published. This study endeavors to understand the shifting strain and ROM at L4, L5, and S1 levels of a posterior instrumented construct as the length of the construct changes.

**Methods:** The range of motion (ROM) at each level and bending moments on the L4, L5, and S1 pedicle screws of six L2-S1 cadaveric spines was assessed using a
pure-moment flexibility testing protocol (±7.5 Nm) in flexion and extension. The ROM was measured using an optical tracking system, and the strains were measured with strain gauge instrumented pedicle screws. Specimens were tested with a posterior fusion from L2-S1 and then a transsacral rod was implanted and the posterior fusion was progressively shortened to L5-S1 by cutting the rods in situ. The L5-S1 segment was tested with and without a transsacral axial rod.

Results: As the fusion construct sequentially decreased in length from L2-S1 to L5-S1 the ROM at L5-S1 experienced slight increases in flexion-extension from 0.98° to 1.02° to 1.08° to 1.41°, respectively. Without transsacral anterior axial fixation, there was a significant increase in lumbosacral ROM . L4 ROM remained relatively constant for all construct lengths that extended above L4. S1 screw bending moments remained relatively constant regardless of the length of the construct, but they more than doubled without the axial rod. L5 screw bending moments were relatively constant when the construct extended to L4 or above. There was a significant increase in L5 strain in L5-S1 short constructs, which more than doubled with the removal of the axial rod. L4 bending moments trended upward as the length of the construct decreased.

Discussion: This study evaluated changes bending moments and construct ROM resulting from different posterior fusion lengths with and without single-level transsacral axial rod fixation. The pedicle screw bending moments followed a logical trend in that the inferior- and superior-most screws experienced the highest moments and screws contained within the fusion had smaller, uniform moments. Intermediate pedicle screws within a long fusion are protected from bending by the screws above and below, which span the intermediate screws and limit the amount of motion that can occur. Similarly, lumbosacral strain and ROM in long and short fusion constructs were mitigated by the addition of transsacral axial rod.

59 In vivo Forces on Pedicle Screws during Posterior Correction Procedures for Adolescent Idiopathic Scoliosis
M. Ito1, Y. Abe2, K. Fujisaki3, S. Tadano2, K. Abumi2, H. Sudo3, Y. Kotani1, K. Nagahama1, A. Iwata2
1Hokkaido University Graduate School of Medicine, Department of Advanced Medicine for Spine and Spinal Cord Disorders, Sapporo, Japan, 2Hokkaido University Graduate School of Medicine, Sapporo, Japan, 3Hokkaido University Graduate School of Engineering, Sapporo, Japan

Summary: Pedicle screw (PS) instrumentation has become popular for scoliosis correction due to its biomechanical superiority. There is, however, a lack of information about how much forces are exerted on each PS during correction procedures. This study evaluated in-vivo mechanical forces on PSs, such as pulling-out and pushing-in, during posterior correction procedures by using 3D-CT images to monitor shape changes of titanium rods and a finite element analysis.

Introduction: Though PSs are widely used for scoliosis correction, mechanical forces on PSs during deformity correction are not understood precisely. This study evaluated in-vivo mechanical forces exerted on PSs during scoliosis correction procedures and to find out an optimal setting of PSs.

Methods: 6-mm diameter titanium rods with known mechanical properties and simultaneous double rod rotation technique with two pre-bent rods were used for scoliosis correction. Shape changes of rods measured by rod-tracing and postoperative 3D-CT images of each patient were analyzed by a CAD software to create finite element models. Elastic linear plastic material model in ANSYS 11.0 was used for calculations. Ten patients with Lenke type1 adolescent idiopathic scoliosis (14 years old and 66 degrees of Cobb angle on the average) were enrolled to estimate the forces on PSs in vivo. We also conducted further calculation with this model to simulate different conditions with decreased number of PSs.

Results: Though the convex side rods did not show contour changes, the concave side rod showed averaged 50% loss of contour after correction. For PSs at both ends of the concave side rods, averaged 206N was exerted on each PS to push-in. At the middle of the curve, averaged 143N was on the PSs to pull-out on the concave side. The maximum pushing-in force was observed at the most caudal screw and the maximum pull-out force was at the apex of the curve. The forces on PSs were getting higher as the increase in curve magnitudes. As reducing the number of PSs, forces on PSs increased proportionally and exceeded 500N of pullout force at the apex of rigid curves.

Conclusion: Pullout forces on Ps around the apex on the concave side were the highest and smaller number of PSs may increase risks of screw pullout when intending to create thoracic kyphosis with rod rotation techniques. Better understanding of curve rigidity and biomechanical characteristics of implant settings are indispensable for effective and safe scoliosis correction.

Significance: In-vivo forces on PSs were calculated by measuring contour changes of rods and using a finite element analysis.
Effects of Vertebral Endplate Fracture on Kinematics and Indirect Spine Decompression in XLIF Fusion Con structs

A.E. Castellvi1, G.T. Alexander2, A. Nayak3, A. Cabezas3, B.G. Santoni4, R. Murtagh5, G. Marulanda6, J. Billys1
1Florida Orthopaedic Institute, Orthopaedic Spine Surgery, Tampa, FL, USA, 2University of South Florida, Orthopaedics and Sports Medicine, Tampa, FL, USA, 3Foundation for Orthopaedic Research and Education, Hugh Spiegel Orthopaedic Research Laboratory, Tampa, FL, USA, 4Moffitt Cancer Center, University Diagnostic Center, Tampa, FL, USA, 5University of South Florida, Department of Orthopaedics and Sports Medicine, Tampa, FL, USA

Introduction: Extreme lateral interbody fusion (XLIF) is a minimally invasive procedure available for patients with lumbar spinal stenosis (LSS) with promising early results. However, little data exists regarding the effects of intra/post-operative complications, notably endplate fracture and interbody cage subsidence, and the subsequent effect on indirect decompression and stability of the affected level. The purpose of this study is to report on the effects of five endplate fractures documented radiographically as part of larger study in human cadaveric lumbar spines.

Materials and methods: Eighteen human cadaveric spines (L1-S1) were instrumented at the L3-L4 and L4-L5 levels using XLIF cages and either anterior-lateral plate (ALP, n=18 levels) or bilateral pedicle screw-rod (PSR, n=18 levels) fixation. Post-instrumentation radiographs indicated superior or inferior vertebral endplate fracture at five (n=5) levels. All eighteen specimens underwent pre- and post-instrumentation: (1) computed tomography (CT) scanning and (2) kinematic range of motion (ROM) analysis that consisted of pure-flexion-extension (FE), left/right lateral bending (LB) and left/right axial rotation (AR). ROM reductions at both index levels as well as XLIF cage translation during loading was recorded with a motion analysis system. Change in disc height and foraminal and canal areas were measured on pre- and post-instrumentation CT scans to quantify the effects of XLIF cages on radiographic indices of indirect decompression. The effect of vertebral endplate fracture subsequent to XLIF cage implantation on ROM reduction, cage translation during cyclic loading and disc height, lateral recess and canal areas were compared to the non-fractured levels.

Results: PSR group: ROM (FE/LB/AR) at L3-L4 was reduced from 8.3°/12.8°/7.8° for the intact case to 5.7°/5.0°/6.3° after inferior endplate fracture at that level, corresponding to a 32.3%/61.1%/19.5% reduction in ROM relative to the intact condition. Comparatively, average reductions in ROM in the non-fractured levels were 48.2%/53.8%/56.9% relative to the intact condition. Concomitant increases in XLIF cage translation at the fractured levels from 0.2 mm to 3.2 mm were noted. Disc height and lateral recess areas were not increased to the same degree as the non-fractured levels.

Conclusion: Results of this in vitro cadaveric study indicate that endplate fracture during XLIF surgery may place the patient at increased risk for complications without mitigating the neurologic pain associated with spinal stenosis. If an endplate fracture is noticed intra-operatively with lateral plate fixation, revision with posterior pedicle screw rod may confer stability. However, study findings indicate that indirect decompression may not be afforded subsequent to endplate fracture and open laminotomy may be necessary to alleviate spinal stenosis.

Cytokine Profiling in an Animal Model of Non-compressive Intervertebral Disc Herniation Using Epidural Lavage

J.M. Cuellar1, P.M. Borges2, Y.G. Cuellar3, G.J. Scuderi2, D.C. Yeomans4
1N.Y.U-Hospital for Joint Diseases, Orthopaedic Surgery, New York, NY, USA, 2Stanford University School of Medicine, E.N.T., Palo Alto, CA, USA, 3Stanford University School of Medicine, Orthopaedic Surgery, Palo Alto, CA, USA, 4Stanford University School of Medicine, Anesthesia, Palo Alto, CA, USA

Introduction: Although strong evidence for an inflammatory component exists, the biochemical processes underlying pain following spinal intervertebral disc herniation remain unknown. It has recently been observed that inflammatory cytokines are elevated in the epidural space of patients with leg pain from nerve root irritation following disc herniation. We designed a rat model to study the biochemical alterations in the epidural space in the presence of herniated nucleus pulposus.

Methods: 48 adult rats were used. Under isoflurane anesthesia the left dorsal surface of the L5 dorsal root ganglion (DRG) was exposed by left hemi-facetectomy. Epidural lavage was performed with 50ul of sterile phosphate-buffered saline to the L5 DRG. The sample was stored at -80C until analysis. This procedure was performed at baseline (T=0) immediately after DRG exposure and 3, 6 or 24 hours after placement of autologous nucleus pulposus (NP; N=15) freshly harvested from a tail disc, saline (N=15), or NP + an interferon-gamma inhibitor (anti-IFNg; N = 18) directly onto the L5 DRG epidurally. The lavasates were analyzed using a BioRad Bioplex immunofluorescent assay to simultaneously quantify interleukin (IL-)1 alpha (IL-1a), IL-1beta, IL-2, IL-4, IL-6, IL-10, tumor necrosis factor-alpha (TNFa), IFNg and granulocyte macrophage colony stimulating factor (GM-CSF). In addition, autologous NP was analyzed for these cytokines by placing the NP into sterile saline and measuring the relative cytokine concentration. Comparisons were performed for group and time for each cytokine using ANOVA with Bonferroni post-hoc multiple comparisons corrections.

Results: All cytokines initially measured at low baseline levels (0-100pg/ml). Compared to saline, NP application to the L5 DRG without mechanical compression caused
a statistically significant elevation in IL-6 that peaked at T=3h and was prevented by anti-IFNg. NP application similarly resulted in a significant elevation of TNF-a that peaked at T=24h and was prevented by anti-IFNg. The NP-induced elevation of TNF-a was 4-fold greater than the level of TNF-a measured in autologous NP. The concentration of IFNg was also significantly elevated after NP application at T=3h and T=24h. The concentration of IL-1α was similar after saline and NP but was significantly elevated at T=24h in the anti-IFNg group. The concentrations of IL-1β and IL-10 were significantly elevated over time, peaking at T=6h and remaining elevated at T=24h in all groups without a between-groups difference, presumably in response to surgery alone. The level of IL-4 peaked at T=3h in the NP group and was statistically different than the saline and NP + anti-IFNg groups but the time effect was not significant. There was no significant change over time and no group difference for the concentration of GM-CSF. The mean concentration of cytokines measured in normal autologous nucleus pulposus was 0 for all measured cytokines except TNF-a, which was 60+/-24pg/ml.

Conclusions: In this rat model of acute noncompressive disc herniation, nucleus pulposus caused the rapid elevation of epidural cytokines IL-6, TNF-a and IFNg; all prevented by simultaneous IFNg blockade. IL-1β and IL-10 were both significantly elevated by surgery alone and their response was not prevented by IFNg blockade. This model may prove useful in the study of the biochemical processes by which NP induces inflammation-induced nerve root irritation and radiculopathic pain.

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Calcium Sulphate Degradation and Osteoblast Proliferation Regulated by Basalt Fibers
X. Chen1, Z-P. Luo2
1Soochow University Orthopaedic Institute, Suzhou, China

Purpose: Calcium sulphate (CS) has been proved to be biocompatible as bone scaffold. However, CS has been criticized for its rapid resorption before the bone tissue has the time to grow into the defect. In this study, we proposed basalt fibers (BF) as a potential biomaterial to prevent CS from rapid degradation. As a first step toward its clinical application, we examined whether basalt fibers could slow down the degradation rate of CS, and regulate osteoblast proliferation and function.

Methods: 3wt% basalt fibers (diameter of 8µm, length of 2mm) were dispersed uniformly with calcium sulphate, mixed with distilled water to form a paste. CS/BF porous scaffolds (15mm in diameter, 4 mm in height) were fabricated by particle-leaching method. Sodium chloride particles of 300µm in diameters were used as porogens. Surface morphology of the scaffolds was examined by SEM, and the porosity was measured by liquid displacement method. The scaffolds degraded in simulated body fluid for 6 weeks, respectively. After the set time, the scaffolds were dried until constant weight, and the final weight was measured. The scaffolds with different degradation periods were sterilized by 60Co irradiation. MC3T3 cells were then seeded onto the samples with a density of 4×104 cells/sample in osteogenic α-MEM medium. After culturing for 7 days, the proliferation and function of MC3T3 cells were assessed quantitatively using MTT assay and ALP activity, respectively, and compared with culture plate control.

Results: Initially, the porosity of CS/BF scaffolds was 80% with pore diameters of 300µm. Two weeks later, the degradation rate of CS/BF (2.38 ± 0.20%) was slower than that of CS (2.88 ± 0.30%) due to the presence of BF. CS/BF degraded relatively slowly during the first two weeks, and then accelerated afterwards (7.83 ± 1.10% at 3w; 14.50 ± 1.12% at 4w; 16.20 ± 0.96% at 5w; and 18.27 ± 1.35% at 6w). The proliferation of cells on the scaffolds varied as the degradation period changed. Cell numbers decreased after 2 week degradation (OD value=0.510 ± 0.017 at 0w; OD value=0.395 ± 0.016 at 2w), increased significantly at 4w (OD value=0.580 ± 0.017), and then decreased at 6w (OD value=0.526 ± 0.021). ALP activities results were consistent with those obtained by the MTT assay.

Conclusion: The resorption of CS is faster than formation of new bone in vivo, which is inadequate to the reconstruction of bone defect. In this study, we found the presence of basalt fibers not only slowed CS degradation rate but regulated osteoblast proliferation. Recent research showed that osteoblasts were sensitive to the substrate, the new bone formation is closely related to surrounding environment and degradation of bone substitute. But the interaction of osteoblasts and degradation process of the scaffold is still poorly understood. Results of the present study indicated that the proliferation and ALP activity of osteoblasts could be regulated directly by the structure of the scaffolds and addition of BF at different degradation period. Therefore, we proposed the cellular growth rate could be controlled to better match with the degradation rate of bone substitute. The scaffolds after 4 week degradation represented the optimal structure for osteoblast growth.

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Bone Marrow Aspirate and Biomaterials for Osteoregeneration: Improvement of Stem Cell Concentration by Density Gradient Centrifugation and Pre-cultivation in vitro
C. Eder1, E. Falkner2, J. Meissner1, P. Becker1, A. Tuschel1, M. Ögon1
1Orthopädisches Spital Wien - Speising, Wien, Austria,
2University of Vienna, Vienna, Austria

Introduction: The limited supply of autografts for spinal fusion has prompted extensive research on bone graft substitutes. Various biomaterials have been applied either stand alone or impregnated with blood or bone marrow aspirate to promote spinal fusion. Bone marrow aspirate harvested from the iliac crest is known to contain osteoprogenitor cells, which are supposed to differentiate into osteoblasts and form new bone at the desired fusion site. According to literature, only 0.001% - 0.01% of bone marrow aspirate cells are in fact osteoprogenitor cells (Science 1999;248:143).
Aim of the presented study is to analyze the potential of native bone marrow aspirate in combination with 3 different biomaterials and try to improve results by cell concentration and pre-cultivation.

Materials & methods: Surplus material remaining after cage and intervertebral space preparation for routine spinal fusion surgery was assessed from 5 patients. Bone marrow aspirate was analyzed native as well as after concentration of stem cells by density gradient centrifugation and the potential of the stem cells to differentiate into the osteogenic, chondrogenic and adipogenic lineage was investigated. Three different biomaterials (demineralised bone matrix - DBX, ChronOS® and HealOS®) were impregnated with bone marrow aspirate according to specifications of the supplier and analyzed immediately after seeding and after a 2 weeks pre-culture period.

Results: Most of the cells in native bone marrow aspirate were identified as erythrocytes while only a small fraction was identified as nucleated stem cells. Density gradient centrifugation resulted in a homogenous fraction of stem cells with an average cell yield of 6.5x10⁶ mononuclear cells per ml. Concentrated cells from all patients could be differentiated into the osteoblastic, chondrogenic and adipogenic lineage according to the mesenchymal stem cell definition.

After biomaterial impregnation with native bone marrow aspirate, average stem cell density was 1.13 cells/mm² (ChronOS®, 0.92 cells/mm² (HealOS®) and 0.008 cells/mm² (DBX)). Pre-cultivation of the constructs in vitro did not significantly alter stem cell densities in ChronOS® and HealOS®, but significantly increased cell density to 8.7 cells/mm² if combined with DBX (p<0.0001).

After 2 weeks, some tissue islands formed by the mesenchymal stem cells were visible in all biomaterials tested. The tissue consisted of a heterogenous cell population resembling bone marrow rather than bone and did not exhibit typical osteogenic markers.

Conclusion: Impregnation of biomaterials with native bone marrow aspirate can only deliver very small amounts of osteoprogenitor cells to the implantation site. Density gradient centrifugation represents a rapid and effective method to purify stem cells from bone marrow aspirate and allow the transplantation of higher cell densities. If applied in combination with demineralized bone matrix, a pre-culture period of stem cells together with the biomaterial significantly improves cell seeding density and tissue formation. Irregular tissue formation was visible in all biomaterials tested, but the further addition of osteogenic differentiation factors might be required to enforce the differentiation into trabecular bone tissue.

Aims: Low back pain is a leading healthy problem in the USA that is associated with the nucleus pulposus (NP). To date, approaches for replacement of diseased NP have been confined to purely mechanical devices. A biological NP replacement implant is desirable. Here, we report a novel nanofibrous (NF) scaffold from a biodegradable polymer to regenerate NP tissue.

Methods: The NF scaffolds were prepared using a phase separation process recently developed in our lab. Rabbit MSCs were seeded in the NF scaffold and were cultured under hypoxia in vitro for 3 weeks. Expression of nucleus pulposus-related genes was analyzed using real-time PCR. The nucleus pulposus-specific marker (hypoxia-inducible factor (HIF)-1α) was detected by immunofluorescent staining. Then the constructs were applied to the caudal spine of athymic rats for up to 12 weeks. The regenerative effect was evaluated by x-ray and histology. For all experiments, values were reported as mean ± SD. To test the significance of observed differences between the study groups, an unpaired Student’s t-test was applied. A value of p<0.05 was considered to be statistically significant.

Results: NF scaffold could support rabbit MSCs differentiation towards a nucleus pulposus-like phenotype in vitro, as evidenced by upregulated expression of a few important nucleus pulposus-associated genes (Fig. 1), abundant deposition of extracellular matrix (glycosaminoglycan (GAG) and type II collagen) (data not shown), and the continuous expression of the nucleus pulposus-specific marker (HIF-1α) (Fig. 1).

When implanted into the rat caudal spine, tissue-engineered NP implant from nanofibrous scaffolds maintained disc space height (Fig. 2) and produced abundant extracellular matrix (data not shown).
Conclusions: The nanofibrous scaffold could work mimic physiological environment in nucleus pulposus and thus to enhance TGF-β1 induced MSCs differentiation towards nucleus pulposus phenotype. The tissue-engineered nucleus pulposus can be implanted into the caudal spine, remain in place, maintain the disc height, and survive and produce functional extracellular matrix similar to the native nucleus pulposus tissue.

90 Vertebroplasty Increases Strain in Adjacent Intervertebral Discs and Vertebrae in Osteopenic Spines
S. Nagaraja1, H.K. Awada1, S. Gupta1, M.L. Dreher1
1US Food and Drug Administration, Office of Science and Engineering Laboratories, Silver Spring, MD, USA

Background: New vertebral fractures occur in approximately 25% of patients following vertebroplasty (Lin et al. 2004), and vertebrae adjacent to cemented levels have a 3 times greater fracture risk than those further away (Kim et al. 2004). Compression fractures are of particular concern in elderly women due to accelerated osteopenia after menopause. Although vertebroplasty may stabilize the fracture and reduce pain, it may negatively impact spine biomechanics, reducing the overall safety of this procedure. Therefore, the objective of this research study was to quantify the effects of vertebroplasty on deformation and damage in adjacent intervertebral discs and vertebrae.

Methods: Five level motion segments (T11-L3) from female cadaveric spines (age range: 51-98 years) were dissected and the ends potted to enable mechanical testing. A wedge fracture was created in the L1 vertebral body (VB) according to previously published methods (Kettler et al. 2006). Micro-CT (51.4 µm voxel size) and DEXA scans were used to assign specimens into either control or vertebroplasty groups (n=10/group) such that BMD, bone volume fraction, trabecular thickness, mineralization, and age were statistically similar between groups (p>0.5). For the vertebroplasty group, 5 ml of PMMA bone cement was injected into the fractured VB using a transpedicular approach under fluoroscopic guidance. Cyclic axial compression was performed on all spine segments for 115,000 cycles with loading from 685-1370 N (~1-2X average body weight for 70-80 year old females) and intermittent fluid spray to maintain hydration. Micro-CT scans of all specimens were performed after cyclic loading. From these images, a custom algorithm was written to quantify strain in adjacent IVDs and VBs based on height change from pre and post testing scans. IVD strain was calculated spatially (anterior, anterior-middle, middle-posterior, and posterior).

Results: Cyclic compressive strain in the vertebroplasty group was significantly higher than the control group (Figure 1, p<0.001). This increased compressive strain in the vertebroplasty group manifested locally as approximately 13% higher in the anterior and 9% in anterior-middle regions of the upper adjacent IVD (T12-L1) when compared to controls (Figure 2). In addition, the upper vertebral body (T12) compressed on average over 4 times more in the vertebroplasty group than the control group; however, this difference was not significant. No significant differences were also observed in the lower IVD or vertebrae.

Conclusions: This study demonstrated that vertebroplasty negatively impacts spine biomechanics resulting in increased compression in the upper adjacent IVD and vertebral body. This finding, in combination with previous vertebroplasty studies, is useful clinically when determining the risk-benefit ratio of vertebroplasty in elderly females.

468 Which Factors Prognosticate Spinal Instability Following Lumbar laminectomy? A Human Cadaver Study
A. Bisschop1, B.J. van Royen1, M.G. Mullender1, C.P.L. Paul1, A.J. van der Veen1, T.U. Jiya1, I. Kingma3, J.H. van Dieën3
1VU University Medical Center, Orthopedic Surgery, Amsterdam, Netherlands, 2VU University Medical Center, Physics and Medical Technology, Amsterdam, Netherlands, 3VU University Amsterdam, Faculty of Human Movement Sciences, Amsterdam, Netherlands

Introduction: Lumbar laminectomy has been shown to have a substantial effect on shear strength and stiffness of treated spinal segments. Reduction of spinal strength causes instability in motion segments and can
lead to degenerative changes post-operatively (i.e., spondylolisthesis and fracturing). Therefore, the aim of the current study is to determine the relationship between a variety of pre-operatively available parameters of human lumbar spines and the in vitro measured shear strength and stiffness of the spinal segments before and after laminectomy. Accurate prediction of biomechanical properties using lumbar spinal characteristics may prove valuable in assessment of residual shear strength and stiffness after laminectomy and thereby aid surgical decision-making. We hypothesize this can be achieved using standard imaging techniques.

Methods: Ten human cadaveric lumbar spines were obtained (mean age 72.1 years, range 53-89 years). The lumbar spines were imaged with radiographs and MRI. Lumbar segments were classified using validated degeneration scores. In addition, segmental geometry, facet joint angles (both MRI), and bone characteristics (DXA) were analyzed. Laminectomy was performed either on L2 or L4, equally divided within the group of ten spines. Spinal motion segments were dissected (L2-L3 and L4-L5) and tested in shear, while simultaneously loaded with 1600N axial compression. Shear stiffness (SS), yield force (YF) and shear force to failure (SFF) were measured from load-displacement curves. Relations between independent (imaging parameters) and dependent variables (YF, SS and SFF) were determined using a correlation model. Backward linear regression techniques were used for final statistical analysis.

Results: Lumbar laminectomy had a substantial effect on SS, YF and SFF (respectively: 23.9, 41.1, and 44.2%). YF after laminectomy depended on disc geometry (length: p=0.039; surface: p=0.037 and volume: p=0.032), while SFF depended only on length (p=0.016). YF of untreated segments was strongly affected by pedicle geometry (p=0.003). SS depended on facet joint orientation (p=0.022). Bone characteristics determined both treated and untreated segments. In untreated segments SFF depended on bone mineral content (BMC) (p=0.002) and bone mineral density (BMD) (p=0.013). YF (p=0.041) and SFF (p=0.005) of treated segments depended only on BMC. Disc and other parameters of degeneration (Pfirrmann: p=0.045; Lane: p=0.017; Pathria: p=0.044 and Griffith: p=0.026) only affected SS after laminectomy. SS, YF and SFF could be predicted with reasonable accuracy (r² respectively: 0.53, 0.81 and 0.77) and without laminectomy (r² respectively: 0.500, 0.83 and 0.83). Bone geometry and characteristics are the most important factors in the model predicting biomechanics of the untreated segment, whereas parameters of disc geometry and degeneration are important for predicting biomechanics after treatment.

Conclusion: Bone characteristics were important for strength parameters of both treated and untreated segments. In treated segments YF and SFF were best predicted by intervertebral disc geometry. Intervertebral disc and facet joint degeneration were important predicting parameters for SS. Shear behavior of untreated segments depended primarily on pedicle geometry (YF) and facet joint orientation (SS). DXA outcomes, disc geometry and degenerative parameters are indicative for biomechanical shear properties of lumbar spinal segments. Thus, post-operative instability is most likely to occur in small spinal segments with low BMD and mild IVD degeneration scores. We conclude that assessment of these parameters is of added value to surgical decision-making.

351 Impact of Different Interspinous Implant Designs on Kinematics & Load Bearing of the FSU. An in-vitro Flexibility Study

M. Pfeiffer, C. Schilling, T. Grupp, W. Blömer

Introduction: Dynamic Interspinous Stabilization experienced a fast boost over the last decade and became more popular than the pedicle-based dynamic systems. In consequence this new surgical treatment option was used in a broad range of indications and different patient populations, each of these specific and individual situations requiring a specific and differentiated biomechanical solution. Hence this new technique had to face a significant amount of failures and revisions, which led to an extensive and critical discussion about dynamic interspinous devices over the last two years and to flattening and decrease of implanted units. The objective of the present study was to compare 3 marketed interspinous implants and a new device with the unique ability to determine intra-operatively the height of the implant, and therefore adjusting the interspinous space and height to the individual anatomy and biomechanical situation of the patient. This opens up new features as to adapting the angulation, alignment and intra-discal pressure of index and adjacent levels to the individual requirements of the patients anatomy and pathology.

Material & methods: 12 lumbar functional spinal units (FSU) from six human specimen (FSUs from L2/3 + L4/5, mean age of 65.3, range 54-74) were used to carry out an in-vitro flexibility tests. 3 marketed and 1 new interspinous implant were tested and compared to the native (NAT) and decompressed (DEF) situation of the FSU. The marketed devices were DIAM (DIA), Coflex (COF), Wallis (WAL), the new one Inter-activ (IA). “Native” evaluation (as a base line) was followed by decompression. Succession of different devices was randomized for each specimen. Evaluation was conducted on a spinal simulator according to Crawford et al.1, applying pure moments for flexion/extension, lateral bending and axial rotation (+/-7.5Nm) with and without axial preload with defined velocity. Range of motion (ROM), neutral zone (NZ) and the instantaneous centers of rotation (COR), were calculated based on the velocity pole method using a 3D ultrasonic motion analysis system, measuring 6 degrees of freedom2,3. Simultaneously the intradiscal pressure (IDP) was measured using a pressure transducer (Samba
Results & discussion: The strongest difference between the impact of each interspinous device on the inter-segmental rotation and stabilization was detected in flexion/extension, whereas impact on lateral bending and axial rotation did not show significant differences between different systems and native/decompressed status.

Conclusion: Major impact of dynamic interspinous devices is in sagittal plane. Especially effect on intradiscal pressure compared to native and decompressed situation is significant and suggests an visible impact on the clinical application of these devices regarding index and adjacent disc loading.

The effect of the devices on these biomechanical dimensions depends on the different designs of implants and has to be evaluated further more in clinical tests.

MIS: Hope or Hype

224 Can Minimally Invasive Surgical Strategies for Deformity Correction Avoid the Need for Routine Osteotomies in Moderate to Severe Adult Scoliosis?

N. Anand1, B. Khandehroo1, S. Kahwaty1, E.M. Baron1
1Cedars-Sinai Medical Center, Spine Center, Los Angeles, CA, USA

Introduction: Spinal osteotomy is a well-known surgical option to accomplish realignment of severe rigid scoliosis. However this correction is associated with considerable morbidity and blood loss. Minimally Invasive Surgery (MIS) has previously been shown to achieve comparable deformity correction in both sagittal and coronal plane but lower morbidity and complications in mild cases of thoracolumbar scoliosis. This study assesses MIS techniques' efficacy in more severe scoliosis without performing any osteotomies.

Methods: This is a retrospective study of 33 consecutive patients with significant thoracolumbar scoliosis (COBB angles greater than 30°), who underwent MIS correction. Deformities included Idiopathic Scoliosis (19), Degenerative Scoliosis (13), and Iatrogenic Scoliosis (1). All underwent deformity correction and fusion using all or a combination of 3 MIS techniques: Segmental Multilevel Percutaneous Pedicle Screw Fixation (Posterior Instrumentation) (33), Lateral Transpsoas Discectomy (DLIF) (27), AxialLIF (14). None of our patients underwent any kind of osteotomies for deformity correction.

Results: 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 56 yrs (range: 15-81). Mean Follow-up was 22 months (range 4-52). Patients with one-stage same day surgery had a mean blood loss of 592 ml and a mean surgical time of 257 min for Posterior Instrumentation and/or AxialLIF. Mean hospital stay was 8.7 days (range 3-26). Clinical and functional outcomes are charted in figure1. The mean pre-op COBB angle was 41.7° (range: 30.3°-74.7°), which was corrected to 17.03° (range: 4°-46.16°). The mean pre-op coronal balance was 33.09mm (range: 5.46-142.9), which was corrected to 15.25 mm (range: 0-48.84). The mean pre-op sagittal Balance was 26.37mm, which was corrected to 2.34mm. The mean pre-op lumbar AVT was 41.46mm (range: 15.66-88.44), which...
was corrected to 17.58mm (range: 0-44.71). Total of 8 patients had adverse events requiring intervention: 3 patients with L5-S1 Psuedoarthrosis, 1 with stenosis and radiculopathy, 1 with delayed onset adjacent osteomyelitis, 1 with sacral wound dehiscence, 1 with proximal screw prominence, 1 with idiopathic cerebellar hemorrhage, and 1 with retrocapsular renal hematoma.

Conclusions: In this study, patients with significant thoracolumbar scoliosis undergoing Minimally Invasive Surgical correction had outstanding cosmetic and radiological improvement in both sagittal and coronal plane, and a considerably lower morbidity and complication rate at both early and long term follow up. Therefore MIS may obviate the need for routine osteotomies which are associated with significant morbidity such as major blood loss, dural tear, acute and delayed neurological deficits, epidural and wound hematoma.
Discussion and conclusion: Our meta-analysis revealed that MIS TLIF performed with interbody bone grafting alone has similar fusion rates to MIS or open TLIF performed with additional posterolateral bone grafting.

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Guyer Lumbar Interbody Fusion (GLIF) Procedure: Safety and Efficacy Multi-center Results in a Commercial Setting

A. Araghi, D.O., 1 M.P. Lorio, 1 C. Lauryssen, 2 H.D. Brown 2
1The Core Institute, Phoenix, AZ, USA, 2Neuro-Spine Solutions, P.C., Bristol, TN, USA, 3Olympia Medical Center, Beverly Hills, CA, USA

Introduction: The GLIF procedure is a lateral lumbar interbody fusion intended to treat degenerative disc disease, coronal and/or sagittal plane deformities. This technique allows lateral lumbar interbody fusion to be performed with the patient in the prone position rather than the lateral decubitus position. This allows the intra-peritoneal structures to gravitate away from the spine. GLIF avoids the need for lateral positioning and subsequent repositioning for posterior procedures. This is a multicenter retrospective review of the results of the Beta site release of this novel technique and is intended to report its safety and efficacy.

Methods: Data were analyzed retrospectively from Beta clinical sites. The patients were treated with the GLIF procedure, as well as other concomitant procedures as clinically indicated. In the GLIF procedure patients were positioned prone. Hence, the surgeon had the ability of implanting pedicle screws, distracting the disc space, or correcting sagittal or coronal plane deformities prior to advancing with the GLIF cage across the disc space without the need for repositioning. The GLIF technique initiates with a targeting apparatus to localize the optimum skin incision position for a curvilinear approach to the lateral aspect of the disc. The dorsolateral aspect of the spine is navigated via a retroperitoneal approach through serial dilators placed and guided by the same targeting apparatus. The psoas is then separated with the assistance of neuro monitoring and a curved port is placed on the lateral aspect of the disc and fixated with bone pin(s) and tangs. Expansion of the concave side of the curved port will now allow direct visualization of the disc space. The disc is prepared with a series of shavers, curettes, and rasps. The cage is placed after trialing. The final position of the cage is identical to other lateral interbody fusion techniques.

Results: A total of 40 cases and 47 levels were performed. 35 single levels, 3 double levels and 2 triple levels. There were no GLIF related complications, except one case of quad weakness and pain present at one month f/u. Non GLIF related complications were: one post op pneumonia, one incidental durotomy, and one self-limited posterior wound drainage. Average time to discharge was 3.6 days. 24 out of the 40 cases included multilevel posterior decompressions or fusions and or removal of hardware from adjacent levels.

Summary: The GLIF technique is a lateral lumbar interbody fusion which offers the unique advantage of performing an interbody fusion with the patient in the prone position, eliminating “flip.”

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MIS Lumbar Fusion in an Ambulatory Surgery Center (ASC): Safety, Treatment Outcomes, and Comparison with Inpatient Lumbar Fusion

W.D. Smith 1, G. Christian 2
1University Medical Center, Neurosurgery, Las Vegas, NV, USA, 2Western Regional Center for Brain and Spine Surgery, Research, Las Vegas, NV, USA

Introduction: Ambulatory surgery centers (ASC) are regularly utilized for procedures with low risk profiles, short ORT, and minimal needs for extended postoperative observation. Recent advancements in minimally disruptive approaches for lumbar interbody fusion have shown, with minimal approach morbidity, that early postoperative discharge is safe and reproducible in select patients. The object of this work was to examine early safety and treatment outcomes following a mini-open lateral approach for lumbar fusion performed at an ASC and compare those results to similar inpatient procedures.

Methods: 54 consecutive patients were treated at an ASC with extreme lateral interbody fusion (XLIF). Retrospective chart review was performed to collect treatment (ORT, EBL, & LOS), complication, hospitalization, or ER visits data. Patients completed a post-discharge survey to assess general condition and pain. Mean age was 50.6 years, 31% were female, BMI was 28.3, 41% were smoked, and 39% had previous surgery. 80 total levels were treated from L1-S1, with L1-5 treated with XLIF and L5-S1 treated with AxialIF (7 cases, 9%) or MIS TLIF (9 cases, 11%). One-, two- and three-level procedures were performed in 57%, 37%, and 6% of cases, respectively. The most common fixation method was anterolateral plating (37%).

Results: Mean ORT, EBL, and LOS were 86 mins (range 28-150), 71cc (range 20-400), and 5:46 (range 2:35-20:15). No intraoperative complications were observed. Two (3.7%) hospitalizations occurred: One transfer for urinary retention, which resolved in-hospital, A second was discharged admitted for uncontrolled pain following a three-level fusion. Two (3.7%) ER visits occurred, one for testicular pain, and the other for a fever on post-op day 2 which resolved without infection. Side effects of the approach included hip flexor weakness in three (5.6%) patients, anterior thigh discomfort in 10 (18.5%) patients. No perioperative reoperations occurred. 91% of patients completed the postoperative questionnaire an average of 4 days postoperative. Describing their current condition, 92% rated themselves as excellent (14.3%) or good (77.6%) and fair or poor in 8% (6.1% fair, 2% poor) of patients. Pain was none or slight in 67% of cases (8.3% none, 58.3% slight) while 25% reported moderate and 6.3% severe pain. Between one-level and two- and three-level cases, elevated ER visits and hospitalizations were observed in the two- and three-level (3.2% vs. 4.3%; 0% vs. 8.7%, respectively). Excellent or Good general postoperative condition were similar (93% vs. 91%).
and pain was less for one-level patients compared to two- and three-level cases (None/Slight: 73% vs. 59%). A concurrent series of 61 one-level XLIFs and 48 one-level ALIFs performed inpatient showed postoperative rehospitalizations in 2.7% and 6.8% of cases, compared to 0% for the ASC one-level XLIFs.

Conclusions: Highly selected patients (by health and indication) can safely be treated in ASCs with XLIF or other MIS approaches without increased hospitalizations or ER visits compared to those treated as inpatients. One-level procedures appear to be slightly more favorable than two- or three-level cases in an ASC. With ASCs receiving 65% to 70% of inpatient coding, due to ASC modifiers, this has the potential to both substantially decrease payer costs in highly select patients and procedures, while providing patients with a safe surgery and ability to spend the early postoperative period recovering at home.

466 Percutaneous Fixation of Thoracolumbar Fractures: 2-year Follow-up

M. Sharma1, F. Siddiqui1, J. White2, S. Safdari1
1Spine Care Center, Manassas, VA, USA, 2Inova Fairfax Hospital, Fairfax, VA, USA

Introduction: 2 year retrospective follow-up of percutaneous fixation of thoracolumbar fractures was evaluated by 3 spinal surgeons. Percutaneous fixation allows for rapid mobilization in the multi-trauma patient, with less morbidity then traditional open procedures.

Methods: 21 patients with thoracolumbar fractures over a 2 year period were retrospectively followed. All surgeries were performed by the 3 MD authors. The parameters involved to retrospectively analyze were:
1. Or time
2. Ebl
3. Length of Stay.
4. Pre-op VAS scores compared with VAS score at 1 month and 2 years.
5. # of levels fused.

Results: Our results showed:
1. mean OR time 93 minutes,
2. Ebl at 57cc,
3. length of stay 1.6 days.
4. VAS at 2 year follow-up was 1.5/10,
5. Mean levels fused 3.9
6. There was no reoperation for pseudoarthrosis & no infections in the 2 year follow-up.

Conclusions: 21 patients with thoracolumbar fractures were treated with a two year follow-up time period by 3 spinal surgeons, using percutaneous pedicle screw fixation with posterolateral fusion. At 2 years follow-up, the VAS score was 1.5/10 & there was no re-operation in the study group for pseudoarthrosis. Percutaneous pedicle screw fixation is a viable & less invasive option in the treatment of thoracolumbar fractures.

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477 Interim Results from a US IDE Trial Evaluating the OsseoFix Implant for Treatment of Vertebral Compression Fractures

M.P. Lorio1, D. Beall2, R. Eastlack3, A. Maharr4,5
1Neuro-Spine Solutions, P.C., Bristol, TN, USA, 2Clinical Radiology of Oklahoma, Oklahoma City, OK, USA, 3Scrpps Clinic, La Jolla, CA, USA, 4Department of Orthopedic Surgery, University of California - San Diego, San Diego, CA, USA, 5Biomechanical and Clinical Research, Alphatec Spine, Carlsbad, CA, USA

Vertebral compression fractures (VCF) are a burgeoning problem for the aging spine. Previous kyphoplasty treatments have been shown effective for pain relief but have also reported endplate fractures and cement leakage. An expandable titanium mesh device has been designed to provide surgeon directed control in the reduction of the VCF and to facilitate cement delivery (OsseoFix®, Alphatec Spine, Carlsbad, CA). The implant was designed to improve symptomatic patients suffering from VCF between T6-L5 by providing internal structural fixation prior to cement delivery (unlike a balloon type device). This minimally invasive (one or two level) procedure takes about 30 minutes per vertebra. We present the early combined clinical data from three sites treating patients presenting with one or two VCFs that were treated with the implant and PMMA. These data are the initial experience/results from the prospective, multi-centered clinical study that follows patients for one year. Pain (VAS) and function scores (ODI) were collected starting pre-operatively with follow-up visits at four weeks, three months, six months and one year. Data were pooled from three surgical sites involved in the ongoing study. All available data are presented with 13/15 patients at six month and 8/15 at twelve month end point analysis. Fifteen patients (11 females, 73.3% and 4 males, 26.7%) with an average age of 80.5±6.0 years were treated for one level (14/15 or 93.3%) or two level (1/15 or 6.7%) VCF. At 12 months, improvement of VAS exceeded more than 55mm on average, demonstrating a dramatic and sustained relief in pain. At 6 months, improvement of ODI exceeded more than 50% change on average, demonstrating a dramatic and sustained improvement in function. A one-way ANOVA with a Tukey’s post hoc test found a statistically significant improvement in pain (VAS p< 0.0001) and function (ODI p< 0.0001) at 4 weeks compared to pre-op which was maintained with no statistical difference between 4 week and subsequent time points.

Although these results are promising--we are not implying a definitive difference rather simply presenting a limited analysis for a small incomplete cohort. There were no device related complications that required intervention, nor were there observed endplate fractures. There was one instance of an asymptomatic cement leakage. Preliminary analysis shows OsseoFix augmentation for VCF between T6-L5 decreased pain and improved function. The one or two level minimally invasive surgical procedure is a new option for the aging population that most often suffer from VCF. The surgical technique allows the surgeon to place and expand the device where desired as opposed to other pneumatic systems that do not allow for surgeon directed control. Further study and completion of the full enrollment is necessary prior to definitive confirmation of success.

[Figure 1: Changes in VAS and ODI scores over time]
Minimally Invasive Treatment of Thoracolumbar Spine Fractures
T. Julien

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 performed 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.
patients revealed the inferior type, which we attributed to the fractured bony fragments invading into the spinal foraminal space. Therefore, acute aggravated leg pain after osteoporotic VCFs counted as true radiculopathic leg pain, rather than referred pain. Even if the acute, aggravated leg pain after osteoporotic VCFs was accompanied with spinal stenosis or other spinal diseases, performing a vertebral augmentation procedure first is preferred.

TDR Evidence-Based Medicine

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ProDisc<sup>®</sup>-L Total Disc Replacement Over Time: 4-10 Year Follow-up

R. Bertagnoli<sup>1</sup>

<sup>1</sup>ProSpine, Straubing Bogen, Germany

Introduction: Lumbar total disc replacement (TDR) is an alternative to spinal fusion surgery for the treatment of degenerative disc disease (DDD) between L2-S1. It is intended to address discogenic pain and has the potential benefit of preserving functional motion in vertebral bodies; TDR may thus reduce long-term subsequent degeneration at adjacent disc levels, although continuing study results are needed to quantify this statement. The purpose of this study was to evaluate the 4 - 10 year clinical results of the ProDisc<sup>®</sup>-L (Synthes GmbH) TDR.

Methods: From 2000-2017, a prospective, controlled, consecutive case series of 789 patients (total number of implants 1130) was conducted. Patients were assessed pre-operatively and post-operatively at 3, 6, 12 and yearly thereafter. Evaluations included Oswestry Disability Index (ODI), Visual Analog Scales (VAS) for pain and satisfaction, and SF-36 patient self-assessments, physical and neurological exams, and radiographic evaluation.

Results: 51.4% were men (average age 48.3 yrs.) and 48.6% women (average age 49 yrs.). Out of the 789 patients, 537 underwent single-level; 170 two-level; 76 three-level; 5 four-level; and 1 five-level surgery. The most frequently treated single-level was L5-S1. In multi-level cases two levels were most common (with L4-S1 being the most frequent as in three levels the L3-S1. The baseline mean ODI score of 48.6 ± 15.4 improved significantly at 3 months (31.0 ± 19.4) and maintained this improvement at all follow-up time points (29.3% - 33.4%). At 3 months, the average VAS pain intensity score showed significant improvement from baseline (7.5 ± 3.8) and maintained similar improvement out to 10 years (3 months: 3.6 ± 2.4); then range 3.6 - 4.3). SF-36 scores indicated improvement in the physical component at 12 months and remained similar at all subsequent follow-up points (baseline: 31.5 ± 6.4; 12 months 36.4 ± 9.5); the mental component stayed consistent at all time points (baseline: 26.4 ± 9.2; 12 months 28.9 ± 8.9) and the total (baseline: 69.6 ± 14.6; 12 months 79.9 ± 15.8).

Conclusions: This longer term investigation shows clinical outcomes of the ProDisc<sup>®</sup>-L TDR are maintained and provide significant improvement for patients with single and multilevel treatment and remains within the same range with this larger group of patients compared to data of last year. These results support earlier reports that ProDisc<sup>®</sup>-L is a safe and effective surgical treatment of discogenic pain in patients who meet the study criteria.

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Late Subsidence after Cervical Disc Arthroplasty at One to Four Levels

M.F. Gornet<sup>1</sup> B.A. Taylor<sup>1</sup> J.H. Peloza<sup>2</sup> F. Schranck<sup>1</sup>

<sup>1</sup>The Orthopedic Center of St. Louis, Spine Research Center, St. Louis, MO, USA, <sup>2</sup>Center for Spine Care, Dallas, TX, USA

Introduction: Single-level cervical disc arthroplasty (CDA) is an FDA-approved alternative to anterior cervical discectomy and fusion (ACDF) for patients whose cervical radiculopathy and/or myelopathy is unresponsive to conservative therapy. Since historical re-operation rates in the literature are 5-10% two years after single-level ACDF, complication rates after CDA are still a subject of much interest in the literature. With CDA device subsidence/migration typically defined as 3mm or more in published FDA trials to date, the incidence of this complication may be underreported. This study examines late subsidence in a large consecutive series of CDA patients.

Methods: Between April 2003 and September 2011, 355 patients with similar preoperative diagnoses including cervical degenerative disease were treated by two fellowship-trained spine surgeons with CDA at 551 total levels (248 Prestige-ST, 43 Prestige-LP, 260 ProDisc-C) using a standard anterior approach. Patient demographics, intraoperative measures, baseline and postoperative clinical outcomes, secondary surgical procedures, and radiographic complications including device subsidence or migration evident on plain films were collected and reviewed.

Results: Patients (200 male/155 female) with average age of 45.8 years were treated at one (189), two (137), three (28) or four (1) levels, including 12 prior ACDF patients undergoing CDA at one or more levels. Median time since index CDA surgery was 29.1 months. Mean operative time was 90.2 minutes (mean 62.1 minutes per level). Mean improvements vs. baseline in NDI, neck and arm pain were all clinically significant (p< 0.001) at standard follow up intervals. Excluding 2 postoperative trauma cases, 12 patients (3.4%) underwent a second surgery, a median 325 days (range 104-918) after their index CDA or hybrid procedure. Nine devices (8/260 ProDisc-C, 3.1%; 1/248 Prestige-ST, 0.4%) showed progressive subsidence radiographically beginning 3 or more months after surgery. Two ProDisc-C were revised: one superior to a Prestige-ST (FIG 1: 3 weeks (left) and 5 months (right) after index surgery), revised to anterior fusion. All 3 patients undergoing CDA at one or more levels. Median time since index CDA surgery was 29.1 months. Mean operative time was 90.2 minutes (mean 62.1 minutes per level). Mean improvements vs. baseline in NDI, neck and arm pain were all clinically significant (p< 0.001) at standard follow up intervals.
Conclusion: CDA was shown to be safe and effective in three large FDA prospective RCTs, and multilevel studies are in progress. In this large case series, reported rates of secondary surgery after CDA were equivalent to or better than published rates for ACDF or CDA. Late angular subsidence is a potential concern particularly in keeled devices, where toggling may lead to increasing pain and disability and potential revision. Further study is warranted to quantify the incidence and clinical relevance of late subsidence after cervical disc arthroplasty.

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A Prospective, Randomized Clinical Investigation of the Porous Coated Motion (PCM) Artificial Cervical Disc: Radiographic Outcomes
FH Geisler1, JG DeVine2, CD Chaput3, FM Phillips4, A Cappuccino5, KGilder6, K Howell7, PC McAfee2
1Chicago Back Institute, Chicago, IL, USA, 2Dwight D. Eisenhower Army Medical Center, Fort Gordon, GA, USA, 3Scott and White Hospital, Orthopaedic Surgery, Temple, TX, USA, 4Midwest Orthopedics at Rush University, Chicago, IL, USA, 5Buffalo Spine Surgery, Buffalo, NY, USA, 6NuVasive, Inc., Biometrics, San Diego, CA, USA, 7NuVasive, Inc., Clinical Resources, San Diego, CA, USA, 8St. Joseph’s Hospital, Baltimore, MD, USA

Introduction: The PCM prosthesis is a new non-constrained cervical disc arthroplasty device that recently completed a large FDA IDE clinical trial in the USA. As the goal of cervical disc arthroplasty is motion preservation, cervical arthroplasty devices must demonstrate maintenance of motion in addition to the decompressive effects of increased disc height.

Methods: A prospective, randomized, multicenter, IRB-approved US FDA IDE clinical trial evaluated longitudinal outcomes over 2 years comparatively between arthroplasty and anterior cervical disectomy and fusion (ACDF) with allograft and plate. Patients 18-65 years of age with degenerative disc disease at one level between C3 and T1 with neurologic symptoms unresponsive to conservative care were included. Prior adjacent-level fusions were allowed. The per protocol patient sample at 2 years included 395 patients (211 PCM, 184 ACDF control).

An independent radiographic analysis (Medical Metrics, Inc.) was performed for each group to evaluate disc height, range of motion (ROM), heterotopic ossification (HO), and lucency at the operative level at each timepoint. The protocol defined patients moving ≥3 degrees without evidence of bridging trabecular bone as having “clinically meaningful” motion. Radiolucency was evaluated at each endplate interface (e.g., superior and inferior, relative to the prosthesis or graft) and lucency >50% of the length of the prosthesis or graft was considered to be significant. Heterotopic ossification was graded according to the method of McAfee, et al. (JSDT 2003), a five-point scale: Class 0=no HO, Class I=bone fusion that does not influence ROM, Class II=possible affects ROM, Class III=blocks ROM, and Class IV=bony ankylosis.

Results: At 24 months, 96.7% (176/182) of the PCM group and 85% (119/140) of the ACDF group had normal disc height (defined as at least 80% of the height of the adjacent level). Disc height of ≥80% of the postoperative value was retained in 90.4% (160/177) of the PCM group and 83% (112/135) of the ACDF group. Despite anterior cervical plating, a higher percentage of patients in the PCM group had normal disc heights and maintained their postoperative disc height over the 24 month period (chi-square p=0.0002).

Average range of motion of the operative level was relatively maintained in the PCM group, at 7.9 degrees preoperatively, 5.1 degrees at 3 months, 5.5 degrees at 6 months, 5.8 degrees at 12 months, and 5.7 degrees at 24 months. In the ACDF group, ROM was 7.8 degrees preoperatively, 1.5 degrees at 3 months, 1.2 degrees at 6 months, 0.9 degrees at 12 months, and 0.8 degrees at 24 months.

At 24 months, 92.3% (168/182) of the PCM and 100% (152/152) of the ACDF superior interfaces showed no significant lucencies, while at the inferior interface, no significant lucencies were observed in either group.

In the PCM group at 24 months, heterotopic ossification was Class 0 in 62.1%, Class 1 in 15.9%, Class 2 in 17.6%, Class 3 in 3.3%, and Class 4 in 1.1%.

Conclusion: This randomized, prospective FDA IDE study found the PCM device achieves and maintains a clinically relevant disc height and motion, with negligible radiographic issues such as lucency and inadvertent fusion.

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Clinical Outcomes for a Viscoelastic Total Disc Replacement Compared to Other Total Disc Replacements in the SWISSspine Registry
B Rischke1, V Kammermeier2, M Runkel, K B Zimmers3, J M Kuras1
1Center of Orthopaedic and Spine Surgery, Spine-Center-Rischke, Zurich, Switzerland, 2Konstanz Hospital, Konstanz, Germany, 3AxioMed Spine Corporation, Garfield Heights, OH, USA

Purpose: To compare the outcomes for patients treated with a viscoelastic total disc replacement (VTDR) to those treated with other total disc replacements (TDR) in the SWISSspine Registry.

Introduction: The SWISSspine Registry is the first mandatory registry of Swiss orthopaedics. Its goal is to generate evidence for use in decision making by the Swiss Federal Office of Health regarding reimbursement for technologies and treatments by the basic health insurance of Switzerland. Since 2009, a VTDR has been included in the registry. To benchmark the initial data from a viscoelastic technology, clinical outcome data was evaluated and compared to that for the other TDR technologies in the registry.

Methods: Prospective, multi-center data from two surgeons for VTDR patients has been collected preoperatively and at 3 to 6 months, 1 year and 2 years postoperatively. The outcome data assessed were EQ-5D health status index and VAS low back and leg pain scores. This data was compared to data in the SWISSspine Registry for all other TDRs. A Wilcoxon Rank sum test was used for comparisons of continuous variables between the VTDR and pooled data for all other TDRs in the database. Proportions were compared using a chi-square test.
Results: The VTDR population included 28 patients (11 males, 17 females) with an average age of 50 (range 26-68). The SWISSspine TDR population included 777 patients (451 males, 326 females) with an average age of 42 (range 19-65). The prevalence of single-level and two-level cases was 36%/64% for VTDR and 85%/15% for TDR. EQ-5D health status indices and VAS low back and leg pain scores improved significantly more (p < 0.05) for the VTDR patients compared to the other TDR patients in the registry. Health status scores improved from 0.269 preoperatively to 1.000 at two years for VTDR patients and from 0.348 preoperatively to 0.793 at two years for other TDRs (Figure 1). VAS low back scores improved from 76.3mm to 5.0mm for the VTDR group and from 69.1mm to 27.6mm for the TDR group from pre-op to two years follow up (Figure 2). VAS leg pain scores improved from 69.2mm preoperatively to 0.0mm at two years follow up for the VTDR group and from 53.6mm preoperatively to 20.9mm at two years for the TDR group.

Conclusions: In this early benchmarking evaluation, clinical outcomes improved significantly more for VTDR patients than for the pooled group of other TDR patients in the SWISSspine Registry.

![Figure 2: Mean VAS Low Back Pain Scores](image)

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The Change of Cervical Motion with Progression of Heterotopic Ossification in Cervical Artificial Disc Replacement
S. Yi\(^1\), H. Lee\(^2\), N. You\(^1\), J. Oh\(^1\), T.Y. Kim\(^1\), G. Choi\(^1\), K.N. Kim\(^1\), D.H. Yoon\(^1\)
\(^1\)Spine and Spinal Cord Institute, Yonsei University, College of Medicine, Neurosurgery, Seoul, Korea, Republic of
\(^2\)Hospital for Special Surgery, New York, NY, USA

Purpose: Heterotopic ossification (HO) is the major cause limiting the range of motion after cervical artificial disc replacement, but the correlation of heterotopic ossification grade transition and cervical motion has not been elucidated yet. The purpose of this study was to investigate the alteration of the range of motion (ROM) of the cervical spine in the treated segment after cervical artificial disc replacement and to examine the relationship between heterotopic ossification (HO) transition and alteration of cervical range of motion.

Materials and methods: Sixty-seven patients, mean age 43.8 ± 9.8 years (from 14 to 66 years, male:female=46:21), underwent cervical artificial disc replacement using the Bryan disc, Mobi-C and ProDisc-C artificial disc, were enrolled in this study. Radiologic follow-up was performed at the regular two time point postoperatively. The existence of heterotopic ossification (HO) and the severity were investigated and graded according to the McAfee classifications by plain radiography. The investigation of heterotopic ossification was already made in the mid-term observational study at the 1st follow up time point after operation. Cervical lateral radiographs and computed tomography obtained after the last observation were used to identify the change in the heterotopic ossification. The overall cervical motion measured by C2–7 cobb’s angle, functional spine unit (FSU) motion and shell angles at each time point were measured and then correlated with the change of heterotopic ossification (HO).

Result: The mean follow up period was 36.9 ± 12.2 months (range 23-77). The overall incidence of HO after cervical artificial disc replacement was 46.3% (31 of 67 patients). The paired comparison between the alteration of HO grade and range of motion of each patient does not revealed any statistically significant difference. But investigation after collecting all patients showed statistically significant difference of motion by severity of heterotopic ossification. At the first follow up, the mean shell range of motion (ROM) on each grade of HO were as follow; 11.8° ± 4.7° on HO grade 0, 13.8° ± 5.3° on HO grade 1, 10.3° ± 4.2° on HO grade 2, 7.7° ± 3.0° on HO grade 3 and 0.7° on HO grade 4 (p=0.012). At the last follow up, the mean shell range of motion (ROM) on each grade of HO were as follow; 13.4° ± 4.5° on HO grade 0, 12.7° ± 5.4° on HO grade 1, 11.5° ± 3.8° on HO grade 2, 9.8° ± 4.8° on HO grade 3 and 3.3° ± 6.6° on HO grade 4 (p=0.024).

Conclusion: This study proved that the segmental range of motion decreases in proportion to progression of HO after cervical artificial disc replacement. And the HO formation could be recognized as one of the major causes to limit the motion by this study.

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Lumbar Total Disc Replacement: Clinical and Radiographic Outcome Comparison between One and Two levels with Average of 60 Months Follow-up
K. Zhang\(^1\), F. Mo\(^2\), C. Abjomson\(^2\), F. Girardi\(^2\), J. Yue\(^1\), F. Cammissa\(^2\)
\(^1\)Yale New Haven Hospital, New Haven, CT, USA, \(^2\)Hospital for Special Surgery, New York, NY, USA

Study design: Prospective study of clinical and radiographic outcomes comparing one and two levels lumbar total disc replacements.

Objective: To evaluate clinical difference between one
and two levels total disc replacement at an average 5 years follow-up.  

Summary of backgrounds: Lumbar total disc replacement (TDR) has been pursued in the last decades. There are variety of class I to class IV studies have demonstrated their safety and efficacy. Following FDA approval of lumbar disc replacement, lumbar TDR have been widely utilized in US clinical practice. With regards to long term follow-up data, there are few studies to compare one and two levels total disc replacement.  

Methods: The patients participated in the prospective randomized Food and Drug Administration (FDA) investigation device exemption (IDE) clinical trial for lumbar Prodisc-L versus circumferential fusion study. A cohort of Forty-two patients had one or two levels lumbar disc replacements surgery at single institution. Pre- and postoperative disc height and range of motion (ROM) at surgical level and adjacent level were measured. Pre- and post-op Oswestry Disability Index (ODI), SF-36 and Visual Analog Scale (VAS) associated with post-op satisfaction rate were collected as well. The cephalad adjacent levels were evaluated for degeneration. Student t test were performed to determine if there is any difference between one and two levels lumbar TDR groups.  

Results: Results from these patients with an average follow-up of 60 months (range, 40 to 79 months) were included in this study. The average post-op ROM between one vs. two levels are 7.9mm and 8.2mm (P=0.837), the disc height are 15.3mm and 15.7mm (P=0.585); ODI are 31.2 and 45.4 (P=0.127); SF-36 physical are 43.4 and 38.5 (P=0.302); SF-36 mental are 48.8 and 48.1 (p=0.867); VAS are 39.3 and 52.6 (P=0.246). The patient satisfaction rate are 76.8 and 49.7 (P< 0.015). The incidence of adjacent level degeneration at one level is 2 out of 32 (6.25%) and none of two level group patients.  

Conclusion: At average 60 months follow-up, there is clinical outcome different between one and two level(s) TDA treatment, especially, with patient’s satisfaction. However, the radiographic outcomes are not different between one and two level TDR treatment. Multi-center clinical results may need to verify these results.  

Instructional Course Symposium: Difficult Spinal Presentations: Rheumatoid Arthritis and Infection  

8 Posterolateral Endoscopic Debridement and Irrigation for Postoperative Spinal Infections in the Thoraco-lumbar Spine  

K. Nagahama1, M. Ito2, N. Hojo2, K. Abumi2, Y. Kotani2, H. Sudo2, M. Takahata2, A. Iwata2, A. Minami2  

1Hokkaido University, Orthopaedics, Hokkaido, Japan  

Background: One of the most concerned complications after spinal surgery is postoperative spinal infection (PSI). It has been reported that posterolateral endoscopic debridement and irrigation (PLEDI) brought immediate pain reduction, early subsidence of spinal infection. Clinical results of PLEDI for PSI were analyzed.

Purpose: To report clinical results of PLEDI for PSI and to evaluate the effect of PLEDI in treatment of intractable PSI in the thoracic or lumbar spine.  

Methods: Five patients (male; 4, female; 1, averaged age 60) with PSI in the thoracic or lumbar spine who had undergone spinal surgeries in previous institutes were enrolled. Course of treatment in previous institutes, the methods of the salvage surgery, pain response using visual analog scale, and inflammation parameters were investigate.  

Results: Original diagnoses were lumbar disk herniation in 2, lumbar canal stenosis in 2, ossification of the ligamentum flavum in thoracic spine in 1. Follow-up period after the PSI was 33.4 months in the average. Most patients had serious comorbid medical problems, such as diabetes in 2, gastric cancer in 1, and virus hepatitis in 1.Surgical methods conducted by previous physicians were hemiutoxy of lumbar disk in 2, medial facetectomy in 2, and posterolateral fusion with pedicle screw system in 1. After diagnosis of PSI, antibiotic therapies were administered for all patients, and averaged duration of chemotherapy was 160 days. Four out of the five patients with PSI underwent surgical interventions by previous physicians (including two patients who underwent twice operation). These intensive treatments failed to subsidence of PSI, and averaged interval from the primary operation to the salvage surgery was 196 days. In the salvage surgeries, PLEDI alone underwent in three patients, and PLEDI with posteriorly open -debridement underwent in two patients with spreading of infection to vertebral posterior elements and back muscles. PLEDI were performed into single intervertebral disk in four patients, but treatment into adjacent two disks needed in a patient. Average operation time was 73 minutes in PLEDI alone procedure, 133 minutes in PLEDI with open -debridement procedure. Intraoperative blood loss was minimal in all PLEDI alone procedures, 440ml in the average in PLEDI with open-debridement. In all patients, bacteriological diagnoses were successful by cultural studies of the specimens in PLEDI; MRSA in 3, and Pseudomonas cepacia, Bacillus cereus in each one. Averaged duration of the antibiotic therapy was 157 days after the salvage surgery. Averaged VAS for low back pain was 84, 68, and 20 before the salvage surgery, postoperative 1 week, and six weeks respectively. Averaged CRP was 14.6 and 1.7 before the salvage surgery, postoperative 2 weeks, and six week respectively. Preoperative 1.1"of averaged local spinal kyphosis progressed 9.4° at the final follow-up. In postoperative imaging studies, epidural abscess and abscess in the iliopsoas muscle disappeared.  

Conclusion: PLEDI for PSI was effective for immediate pain reduction, subsidence of infection spreading anterior vertebral portion, and bacteriological diagnosis. In PSI, however, elongated duration of antibiotic therapy often caused appearance of drug resistant strains and advanced erosion of spinal construct. The most importance in treatment of PSI was early diagnosis and proper treatment.
Aim was the evaluation of infection rate and outcome of the percutaneous minimally invasive mono- and bi-segmental dorsal stabilization versus the open dorsal stabilization. Indications have been the FBSS, osteochondrosis and spondylolisthesis I° - II° by Meyerding combined with spinal stenosis.

Methods: Retrospective, monocenter study on a consecutive number of patients from 1/2006 - 6/2011. In 284 patients dorsal open stabilizations with decompression and in 199 patients percutaneous minimal invasive stabilization with the Expedium LIS system mono- or bi-segmental with has been done. Follow up: 38 (22-60) months. Two groups one with deep and one with superficial infection with bacterial spectrum were determined. All deep infections have been treated with wide debridement, jet lavage, drainage, parenteral antibiotics over 7 to 10 days with antibiogramm. The superficial infections have been treated after revision 3 days with parenteral then with oral antibiotics by antibiogramm.

Results: 01/2006 - 06/2011 156 open mono- and 128 bi-segmental dorsal stabilisations. 2.46% deep and 1.76% superficial infections have been evaluated. 114 mono- and 85 bi-segmental percutaneus, minimainvasive dorsal stabilizations without any infections have been done. In open dorsal stabilisations 2006 there have been 4.08% deep, 3.06% superficial infections, 2007 2.06% deep, 1.03% superficial, 2008 1.12% deep and 1.12% superficial infections. In 1 case of resection and positive Staph. aureus infection with a 2nd revision with debridement, jet lavage, irrigation-suction-system and long-term antibiotics was necessary. 1.29% screw loosening cause of infection in the open stabilized group was seen. Bacterial deep infections in two cases showed Staph. aureus, in 3 cases MRSE, in 1 case E. coli and in 1 case MRSA. Superficial infections showed in 3 cases Staph. aureus, in 1 case E. coli and in 1 case MRSE.

Conclusions: The muscualr trauma by the paravertebral Wiltse approach and the postoperative scar of the muscle is much lower. The multifidus muscle keeps completely intact and the longitudinal muscle is less destroyed by paravertebral splitting. Rate of complication in case of screw displacement, neurological complications, pseudoarthrosis, and failure of the instrumentation is similar. The shorter time of operation, the less invasive trauma for the muscle and the less volume of blood loss in minimal invasive percutaneus dorsal stabilization reduce the risk of infection significant and also the rate of screw loosening is reduced significant.

Keywords: Rate of infection, dorsal open stabilization, percutaneus minimal invasive stabilization, Expedium LIS.
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Anterior Cervical Fusion with Stand-alone Polyetheretherketone (PEEK) Cages: 82 Cases and 182 Levels Clinical Experience Focusing on Subsidence

1 Taichung Veterans General Hospital, Department of Neurosurgery, Taichung, Taiwan, Republic of China, 2 National Defense Medical Center, School of Public Health, Taipei, Taiwan, Republic of China, 3 Taichung Veterans General Hospital, Department of Radiology, Taichung, Taiwan, Republic of China, 4 China Medical University Hospital, Department of Orthopaedic Surgery, Taichung, Taiwan, Republic of China

Background context: Cervical spinal injury, spondylotic myelopathy and radiculopathy are common diseases in modern countries. Anterior interbody fusion is the treatment of choice to restore the physiological disc height and provide segmental stability and solid arthrodesis after adequate decompression. Plate and screw fixation are thought to be more stable during ACDF but a stand-alone cage is beneficial for lower risk of implantation loosening and swallowing discomfort. However, subsidence may occur in the interbody fusion process with a stand-alone cage. This report reviews patients who underwent the same type polyetheretherketone (PEEK) cage in interbody fusion surgery. The subsidence rate, possible mechanism and treatment are discussed.

Purpose: To determine the possible risk factors causing interbody cage subsidence and how to prevent it.

Study design: A retrospective analysis of image findings and clinical results.

Patient sample: 82 patients were included.

Methods: We retrospectively reviewed 82 patients with cervical trauma or cervical spondylisis who received anterior cervical interbody fusion operations with the same type of PEEK cage from September, 2005 to June, 2009 by a single experienced spinal surgeon. The treatment levels were from C2-C7. All patients received preoperative magnetic resonance image (MRI) and preoperative and postoperative plain radiography studies. The incidence of subsidence and fusion were calculated. Several parameters were measured by two radiologists. The factors influencing subsidence, fusion and clinical presentation were analyzed.

Outcome measures: Preoperative radiography analysis and clinical outcome.

Results: One hundred eighty-two levels of cervical PEEK cages were used. There were 39 levels (21.4%) in 31 patients (37.8%) found with radiological subsidence. After statistical analysis, significant differences were found in two factors:
1) operations with more than two levels;
2) relative post-operative disc height change using larger cage size.

There were no significant differences in age and gender. No neurological deterioration or significant recurrent neck pain were found in patients with cage radiological subsidence.

Conclusions: Although subsidence may occur in anterior cervical fusion surgery with stand-alone PEEK cages, we can choose adequate cage sizes according to the preoperative cervical disc height and alignment. Plate and screw system fixation may be necessary for patients having disease with more than two levels. However, neurological deterioration may not occur if adequate decompression is achieved.

Keywords: Anterior cervical fusion, stand-alone, PEEK cage, subsidence

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Anterior Cervical Discectomy and Fusion versus Cervical Disc Arthroplasty: Cost Analysis of Peri-operative and Operating Room Related Costs

D.T. Warren1, T.M. Andres2, P.A. Ricart Hoffiz1, C.M. Hoelscher1, J.A. Bendo1, J.A. Goldstein1
1 NYU Hospital for Joint Diseases, New York, NY, USA, 2 Westchester Medical Center, Valhalla, NY, USA

Purpose: Patients with cervical disc herniation and radiculopathy from single-level disease have traditionally been treated with Anterior Cervical Discectomy and Fusion (ACDF) with excellent results. Cervical Disc Arthroplasty (CDA) has been shown to result in similar clinical outcomes. Evidence of lower revision surgery rates and reduced adjacent segment degeneration is promising. The purpose of this study is to compare the direct care cost and relative charges and payments received in ACDF versus CDA for single level cervical disc disease. These will be reported as operating room and peri-operative related costs. We aim to structure to future research in relative cost effectiveness of alternative surgical options.

Methods: The medical and financial records of 28 cervical spine patients undergoing either ACDF (n=15) or CDA (n=13) at our institution between 2008 and 2010 were reviewed. All patients were treated for single-level cervical disc disease. Data collected included the total hospital cost, charge, and payment received for each patient’s procedure, as well as an itemized breakdown of each service and product that was used during the patient’s treatment. Statistical comparisons of all costs, charges and payments were then performed.

Summary of results: Of the demographic information collected, the patients of ACDF and CDA were only significantly different in mean age, with ACDF patients being older (P = 0.02). Of hospital cost, charge, payment received, and total cost, the two procedures were only significantly different in the cost of the surgeon (P < 0.01). The total cost was $19,811 for ACDF and $18,440 for CDA. When hospital costs are broken down into operating room related costs (ORRC), ACDF is significantly more costly for anesthesia, neuromonitoring, and time in the operating room, while the two procedures were not significantly different in OR materials and supplies, recovery room or x-ray costs. Total ORRC was $11,783 for ACDF and $11,847 for CDA. When
peroperative related costs (PORC) were examined, ACDF was more costly in the room charge (P < 0.00); this was the only significant difference between the two procedures. Total PORC were $4,451 and $4,017 for ACDF and CDA, respectively.

**Conclusions:** Our results suggest similar hospital costs, charges, and payments received for both treatments. Though the total ORRC and PORC for the two procedures are similar, the allocations of these costs vary. Overall, the direct care costs to the hospital and patient for ACDF and CDA are comparable and therefore may not be a decisive factor when a surgeon is considering how best to treat a patient with single-level cervical disc disease.

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**Comparative Clinico-Radiological Study of Interlaminar Decompression in Lumbar Canal Stenosis with and without Coflex™ Interspinous Spacer; Prospective Observational Study**

**N. Kumar**, Y.H. Ng, B.W.L. Tan

1National University Health System, Orthopaedic Surgery, Singapore, Singapore

**Purpose:** To determine whether additional implantation of Coflex™ following decompression provides better clinical outcomes compared to decompression alone. To study whether clinical outcomes were related to any of the radiological parameters studied.

**Materials and methods:** A prospective observational study comparing outcomes of patients undergoing decompressive surgery for symptomatic lumbar canal stenosis & back pain with or without additional implantation of Coflex™ interspinous spacer (ISP). 46 patients were treated for 1 or 2-level symptomatic lumbar canal stenosis & back pain. Patients opting for Coflex™ implantation formed the Coflex™ group (22 patients) while those opting for decompression alone formed the Control group (24 patients). Pre- and postoperative disability and pain scores were measured using the Oswestry Disability index (ODI), the Visual Analogue Scale (VAS) for back and leg pain, and Short Form-36 (SF-36). Pre- and postoperative radiological parameters (disc heights, intervertebral foraminal heights, sagittal angles) of the operated segment were assessed. Patients underwent postoperative assessments at 3, 6, 12 and 24 months and were followed up for at least 2 years.

**Results:** Coflex™ patients experienced statistically greater improvements (p < 0.0005) in all 3 clinical outcome indicators (ODI, VAS for back and leg pain, SF-36) at 6 months, 1 year and 2 years. The radiological parameters also showed significantly greater improvement (p < 0.0005) in the Coflex™ group but we were unable to establish any correlation with clinical outcomes.

**Conclusions:** The Coflex™ device provides an effective additional treatment in decompressive surgery for lumbar canal stenosis and associated back pain, with better clinical outcomes sustained at 2 years.

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**L5-S1 Isthmic Spondylolisthesis Stabilized with AxiaLIF and Percutaneous Posterior Fixation: A Novel Technique**

R. Nasca, T. Raley, W. Tobler, P. Gerszten

1Trans-1, Wilmington, NC, USA, 2Georgetown University Medical Center/ Virginia Hospital Center, Orthopaedics, Arlington, VA, USA, 3Mayfield Clinic, Neurosurgery, Cincinnati, OH, USA, 4University of Pittsburgh Medical Center, Pittsburgh, PA, USA

**Object:** Spondylolisthesis is seen in approximately 6% of the adult population. Ninety percent of isthmic spondylolisthesis occurs at the L5-S1 level. The traditional surgical approach for this disorder has been to remove the posterior arch of L5 and decompress the L5 nerve roots if the patient presents with radicular complaints. An arthrodesis of L5 to S1 is then performed to prevent further slippage. This study reports a new minimally invasive technique for the treatment of grade 1 and 2 isthmic spondylolisthesis at the L5-S1 level in which the interbody fusion is accomplished through a muscle-sparing pre-sacral axial approach using an AxiaLIF rod (Trans1, Wilmington, NC) supplemented with percutaneous posterior instrumentation.

**Methods:** Twenty-six consecutive patients with symptomatic L5-S1 level isthmic spondylolisthesis (grade 1 or grade 2) successfully underwent this combined procedure. Patients were prospectively evaluated using self-reported outcomes instruments that included Visual Analogue Scale for Pain (VAS), Oswestry Disability Index (ODI), and Odom’s Outcome Criteria.

**Results:** An overall 69% improvement in the VAS pain scores were documented for the study cohort following surgery with a minimum follow up of at least 2 years (median greater than 3 years). All patients achieved a solid radiographic fusion. Using Odom’s Outcome Criteria, long term outcome was rated as excellent in 16 patients, 5 good, 3 fair, and 2 poor. The mean blood loss was 64 cc, and the mean hospital stay was one day (range 1 to 2 days). A reduction in one or more grade of the spondylolisthesis was achieved in 13 of the patients. No complications resulted from the procedures. Two patients subsequently required an open micro-foraminotomy after the index surgery for persistent radicular complaints due to nerve root compression.

**Conclusions:** The minimally invasive pre-sacral axial interbody fusion and posterior instrumentation technique was determined to be a safe and reliable method for the treatment of grade 1 and 2 isthmic spondylolisthesis. The procedure was associated with minimal morbidity while avoiding the risks associated with traditional open decompression and interbody fusion techniques.
Lessons Learned on Cervical Total Disc Replacement after 8 Years Follow-up

L. Marchi1, 2, L. Oliveira1, R. Amaral1, C. Castro1, T. Coutinho1, E. Coutinho1, L. Pimenta1, 3
1 Instituto de Patologia da Coluna, São Paulo, Brazil, 2 Unifesp, DDI, São Paulo, Brazil, 3 University of California San Diego, Neurosurgery, San Diego, CA, USA

Purpose: 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.

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 joint 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 developed HO, preoperative radiographs showed incipient osteophytes that progressed during the follow up period resulting in bone formation. Painful adjacent level disease occurred in 5.7% of patients, lower than the 20.3% described by Hilibrand et al for ACDF (2.9% a year).

Conclusion: Our experience in cervical TDR has revealed valuable clinical and radiological data when compared to ACDF. The motion preservation allowed a better biomechanical restoration of the spine, unloading the facets and preserving the adjacent discs. The good clinical results also corroborate with the superiority of cervical TDR in comparison to ACDF results described on the literature.

Accuracy of Abstracts for Original Randomized Controlled Clinical Trials of the Lumbar Spine in Spine Journals

J.A. Lehmen1, R.M. Deering2, A.K. Simpson2, C.S. Carrier2, C.M. Bono2
1 Harvard Medical School, Brigham & Women’s Hospital, Department of Orthopaedic Surgery, Boston, MA, USA
2 Harvard Medical School, Brigham & Women’s Hospital, Department of Orthopaedics, Boston, MA, USA

Background: Randomized controlled trials (RCTs) represent the gold standard data source in scientific literature upon which evidence-based treatment decisions are made. Inconsistencies between an abstract and full paper can mislead readers’ interpretation of the findings and conclusions. Findings and conclusions of abstracts of RCTs are often quoted and cited without reference to the manuscript itself. In other fields of medicine, studies have shown discrepancies between the abstracts and full manuscripts of RCTs.

Objective: It was the current study’s purpose to perform a similar comparison of abstracts and full manuscripts of RCTs published in the recent spinal literature.

Methods: A literature search restricted to Spine, The Spine Journal, and Journal of Spinal Disorders and Techniques of RCTs published in the ten year period from 2001-2010 was performed. All articles that were described as randomized trials concerning lumbar spinal surgery were selected. These articles were analyzed in detail using a standardized 21-item questionnaire to collect specific data points regarding inconsistencies or bias in the abstract compared to the full text article. Among other features, abstracts were considered deficient if they contained data that were either inconsistent with or not found in the full manuscript, or if they failed to include important findings from the full manuscript. Four reviewers reported on the 40 articles that met the inclusion criteria. Each article and its abstract were reviewed by 2 reviewers. In the event of conflicts in analysis, resolution was achieved through discussion between the reviewers.

Results: At least one inconsistency was found in 75% of studies. Despite that the word “randomized” appeared in the title in 75% and in the abstract in 92.5% of the articles, the method of randomization was not described in 37.5% of manuscripts. In those articles in which the randomization method was reported, it was considered unacceptable in 28%. One article (2.5%) failed to report the number of patients in the abstract, while 17.95% of abstracts only reported the number of patients enrolled. The number of analyzed patients was reported in the abstract in 25.64% and both analyzed and enrolled in 56.41%. The primary outcome of the study was clearly stated in only 22.5% of abstracts and 47.5% of manuscripts. Pertinent negatives were not reported in 40% of the abstracts, while pertinent positives were reported in 90% of abstracts. Relevant statistically significant results were reported in only 60% of abstracts. One article presented data in the abstract which was not present in the manuscript. Two articles presented data differently than in the manuscript, and the implied meaning was different in the abstract versus the manuscript in 15% of the articles.

Conclusions: These data demonstrate that the abstract is discrepant with the full manuscript in a surprisingly
Introduction: Engaging in recreational activities is not only important for quality of life and pleasure, but also can contribute to overall health. Pain may interfere with a patient’s ability or interest to participate in such activities. In reviewing our clinic’s data from patients undergoing anterior cervical spine surgery for pain related to degenerative conditions, it was noted that among the 10 scales of the Neck Disability Index (NDI), the mean pre-operative score was greatest on the scale asking about ability to participate in recreational activities. A literature search found very little information available on recreational limitations associated with cervical degenerative conditions. The purpose of this study was to analyze the impact of cervical symptoms on recreational activities and changes following surgery.

Methods: Data for this study were collected from patients undergoing either anterior cervical fusion (ACF) or total disc replacement (TDR) for the treatment of neck and/or arm pain related to cervical radiculopathy and/or painful disc degeneration. Responses to NDI recreation scale were analyzed to determine the extent of recreational activity limitations before surgery and compare that to the post-operative activity level. The study included 100 patients with pre-operative and 12-month post-operative follow-up data.

Results: Pre-operatively, only 2.0% of patients indicated that they could engage in all of their recreational activities and did so with some pain. Post-operatively, this figure improved significantly post-operatively (p<0.01; see figure) with 78% of patients indicating that they could participate in all of their recreational activities (47% indicating they could do so with no pain). On the six-item scale, 22% of patients improved one level and 71% improved at least 2 levels. Five percent of patients remained at the same level of recreational activity and 2% had reduced levels of recreational activity after surgery.

Discussion: Pain related to cervical symptoms greatly limited patients’ ability to participate in recreational activities with 48% of patients reporting they could engage in no or “hardly any” recreational activities prior to surgery. This great of a limitation may be underappreciated and there is little information available in the literature. Post-operatively, significant improvement was demonstrated with 58% of patients recreating with little or no pain and no limitations. Regaining the ability to engage in recreational activity may improve the patient’s overall quality of life.
by 22.0% ± 37.5%. Both C2-C7 SVA and CGH-C7 SVA negatively correlated with PCS (r=-0.43, p<0.001 and r=-0.36, p=0.005, respectively). C2-C7 SVA positively correlated with NDI scores (r=0.20, p=0.036).

On average, C1-C2 lordosis constituted 76.0% ± 15.8% of total cervical lordosis (defined as the sum of C1-C2 and C2-C7 lordosis). C2-C7 SVA positively correlated with C1-C2 lordosis (r=0.33, p=0.0003).

For significant correlations between C2-C7 SVA and NDI scores, regression models predicted a threshold C2-C7 SVA value of approximately 40 mm, beyond which correlations were most significant.

**Conclusions:** Positive cervical sagittal malalignment, measured by C2-C7 SVA, negatively affects HRQOL scores following multi-level cervical fusion at intermediate follow-up. Correlations between measures of cervical SVA and C1-C2 lordosis suggest that these parameters are linked as patients attempt to optimize craniocervical alignment. C1-C2 alignment may be the terminal link between the cranium and the cervical spine to regulate the angle of gaze. The high positive correlation (r=0.88, p<0.0001) between C2-C7 SVA and CGH-C7 SVA indicates that the C2 segment plays a critical role in determining the location of the head center of gravity. This is the first study to examine the impact that regional SVA in the cervical spine has upon HRQOL following multi-level cervical fusion. Our findings demonstrate that, similar to the thoracolumbar spine, the severity of disability increases with positive sagittal malalignment following surgical reconstruction.

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**The Clinic Outcome and the Status of Adjacent Segment Degeneration Five Years after Bryan Disc Replacement**

Y. Sun1, Y. Zhao1, F. Zhou1, F. Zhang1, S. Pan1, Z. Liu1

1Peking University Third Hospital, Orthopaedic Surgery, Beijing, China

**Objective:** To study the long-term outcomes of cervical arthroplasty with Bryan disc prosthesis and the status of adjacent segment degeneration.

**Methods:** Clinical and radiographic evaluation including dynamic X-ray and MRI scan at baseline and at final follow-up were performed.

**Results:**

1. Since Dec. 2003 first case of cervical arthroplasty with Bryan disc prosthesis performed in our institute, 70 patients have achieved five years period after the surgery. 57 patients gained follow-up. The mean follow-up period was 60 months (57-69 months). There were 14 cases of radiculopathy, 38 cases of myelopathy and 5 cases of radiculopathy complicated with myelopathy. There were 47 cases of single-level, 9 cases of two-level and 1 case of three-level arthroplasty. The levels of surgery included C3/4 (5 cases), C4/5 (10 cases), C5/6 (45 cases) and C6/7 (8 cases).

2. Clinical outcome: The mJOA score in 38 cases of myelopathy and 5 cases of radiculopathy complicated with myelopathy were improved from 13.4±1.9 up to 16.1±1.1. The recovery ratio was 75.0%. The radiculopathy was almost fully recovered in 14 cases of radiculopathy and 5 cases of radiculopathy complicated with myelopathy. The VAS of arm pain was improved from 3.3±1.9 to 0.9±1.2 (P<0.05). The VAS of neck pain was improved from 3.0±1.5 to 1.6±1.4 (P<0.05). NDI score was improved from 14.8±8.6 to 5.7±4.2 in 19 cases with radiculopathy (P<0.05). According to Odom’s criteria, 21 patients have achieved excellent result and 27 of good, 7 of fair, 2 of poor result.

3. On X-ray assessment: 28 cases obtained pre-OP and post-OP radiograph. The range of motion (ROM) at operated level was 6.9°±3.0° at baseline and 7.2°±3.7° at final follow-up (P<0.05). The heterotopic ossification around the prosthesis was observed in 12 of 30 segments (12/30, 40%) according to McAfee classification. There was one segment of grade II, eight segments of grade III and three segments of grade IV. All segments with grade IV have lost motion (ROM<2°) at final follow up (3/30, 10%).

4. On MRI assessment: 25 patients gained MRI follow-up. According to Miyazaki classification, 7 of 50 adjacent segments (14.0%) had disc degeneration deteriorating one more grade with 3 upper and 4 lower segments. The invasion ratio of disc protrusion to the spinal canal was increased from 17.9% to 19.1% (P<0.05) at upper segment and from 81.4% to 95.1% (P<0.05) at lower segment. 17 cases had series MRI (pre-OP, 2-3 years and 5 years). There were only two discs which invasion ratio of disc protrusion increased more than 5% during 5 years period. The majority disc protrusion increased only 1.1-1.3% during 5 years period and increased 0.3-0.5% every year.

**Conclusions:** Cervical arthroplasty with Bryan disc prosthesis provided a favorable outcome in our study. The range of motion (ROM) was well preserved at final follow-up. There was no evidence of accelerated adjacent segment degeneration.

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**Analysis of the Effects of Cervical Arthroplasty Compared to Anterior Cervical Discectomy and Fusion on Adjacent Level Disease**

J. Marzluff1, J.M. Highsmith1, J. Myers2, K. Baker2

1Charleston Brain and Spine, Charleston, SC, USA, 2Globus Medical, Inc., Audubon, PA, USA

**Purpose:** Adjacent segment disease is an important factor in the progression of symptomatic cervical disc disease. Loss of motion at the index level following anterior stabilization has been theorized to promote degeneration at adjacent levels. Range of motion and reoperation rates at neighboring levels were compared between a cervical arthroplasty device (SECURE®-C) and anterior cervical discectomy and fusion (ACDF). Results are presented from study patients who have reached at least 24 months post-operative.

**Methods:** A prospective, randomized pivotal IDE study of the SECURE®-C device (Globus Medical, Audubon, PA) was conducted at eighteen sites in the US. Enrolled patients were randomized 1:1 to either the investigational SECURE®-C disc or the control ACDF, with the first five non-randomized patients at each site receiving the disc. Range of motion above and below the index level
Reconstruction and Deformity: Oral Posters

215 Impact of Magnitude and Percentage Global Sagittal Plane Correction on Health Related Quality of Life at 2 Years Follow up
V. Lafage1, B. Blondel1, F. Schwab1, B. Ungar1, J. Smith2, K. Bridwell3, S. Glassman4, C. Shaffrey2, B. Moal2, J.-P. Farcy1
1New York University Hospital for Joint Diseases, Spine Division, New York, NY, USA, 2University of Virginia, Department of Neurological Surgery, Charlottesville, VA, USA, 3Washington University School of Medicine, Spine Department, Saint Louis, MO, USA, 4University of Louisville, Spine Institute for Special Surgery, Louisville, KY, USA

Background: Sagittal plane malalignment has been established as the main radiographic driver of disability in adult spinal deformity (ASD).

Objective: This study aims to evaluate the amount of sagittal correction needed for a patient to perceive improvement (Minimal Clinically Important Difference, MCID) in health related quality of life (HRQOL) scores.

Methods: This was a multicenter, retrospective analysis of prospectively consecutive enrolled ASD patients. Inclusion criterion was a sagittal vertical axis (SVA group) >80mm. Demographic, radiographic, and HRQOL pre-operative and 2 year post-surgery data were collected. Surgical treatment was categorized based on SVA correction: < 60mm, 60mm-120mm, and >120 mm. Changes in parameters was analyzed using paired t-test, one-way ANOVA, and chi-square test.

Results: 69 patients (pre-op SVA=140 mm) were analyzed; each sub-group revealed significant HRQOL improvements following surgery. Compared with the < 60mm correction group, the likelihood of reaching MCID was significantly improved for the >120mm group (ODI) but not for the 60mm-120mm group. A significantly greater likelihood of reaching MCID thresholds was observed for corrections above 66% of SVA.

Conclusions: Best HRQOL outcomes for ASD patients with severe sagittal plane deformity were obtained with a correction >120mm for SVA and at least 66% of correction. While lesser amounts of SVA correction yielded clinical improvement, the rate of MCID threshold improvement was not significantly different for mild or modest corrections. These results underline the need for substantial Sagittal plane deformity correction if high rates of HRQOL benefit are sought for patients suffering from marked sagittal plane deformity.

211 Adjacent Level Total Disc Replacement Supplemented by Spinal Osteotomy as a Treatment for Failed Fusion Surgery
U.R. Hahnle1, I.R. Weinberg2
1Netcare Linksfield Hospital, Orthopaedic Surgery, Johannesburg, South Africa, 2Netcare Linksfield Hospital, Neurosurgery, Johannesburg, South Africa

Purpose of study: The optimal surgical treatment for younger patients with a failed fusion remains controversial. Successful outcome after total disc replacement (TDR) for adjacent segment disease (ASD) has been reported, but failure may occur in cases with significant sagittal imbalance due to flat back deformity within the fusion mass. We present a consecutive patient series of highly selected failed fusion patients that we treated with a combination of dorsal-ventral-dorsal spinal osteotomy (DVD OT) and total disc replacement at the cranial adjacent segment.

Methods: Out of a single center prospective TDR registry, 12 patients with failed lumbar fusion and ASD had been treated with combined DVD OT through the existing fusion mass and TDR at the cranial adjacent motion segment and have been followed for over 2 years. The clinical outcome was assessed by VAS, ODI as well as subjective patient satisfaction. Changes in radiographic spinal balance parameters were studied.

Results: The mean age at index surgery was 44.3 years (35-59); nine patients were females; mean follow-up was 41.3 ± 11.7 months. Operative time: 321 ± 153 min; operative blood loss: 731 ± 552 mls. Operative complications: one spinal leak and one transient unilateral hip flexor weakness. Radiological changes: the
sagittal balance decreased from 4.9 cm ± 4.3 to 0.7 cm ± 2.2 (p ≤ 0.01), pelvic tilt (p ≤ 0.05) and junctional lumbar lordosis (p ≤ 0.01) decreased significantly. There was a significant increase in sacral slope (p ≤ 0.05), lumbar lordosis (p ≤ 0.005), segmental lumbar lordosis (p ≤ 0.005) and in thoracic kyphosis (p ≤ 0.01). Clinically the ODI improved from 48.8 ± 13.6 to 16.7 ± 13.4; VAS improved from 8.2 ± 0.9 to 2.72 ± 1.79. All patients would undergo the same operation again. Two patients, with inadequate balance restoration at index surgery, underwent further revision surgery 28 and 52 months after index procedure.

Conclusion: This is the first report on a highly selected group of failed fusion patients who were treated with a combination of spinal realignment osteotomy and TDR at the cranial junction. Intermediate term outcomes are good, but meticulous balance restoration is essential. We consider this treatment regimen as a viable alternative in younger failed fusion patients with marked sagittal imbalance.

508 Anterior MIS Rod Instrumentation with XLIF
Deformity: Techniques and Outcomes
P. McAfee1, L. Chotikul2, E. Shucosky2
1St Josephs Hospital, Spine and Scoliosis Surgery, Baltimore, MD, USA, 2St Josephs Hospital, Spine and Scoliosis Center, Towson, MD, USA

Study design: 36 consecutive cases underwent XLIF for deformity with anterior rod instrumentation in same stage instead of second stage posterior supplemental MIS pedicle instrumentation.

Objective: Report on the outcomes of anterior instrumentation performed thru the lateral approach. We wished to determine the feasibility of a posted screw and offset rod for anterior fixation compared to a one level plate. This system allows variability in screw position and preservation of a neurovascular bridge of psoas muscle (and contents) along the construct.

Summary of background: Little published literature is available that discusses the advantages of a lateral approach with anterior instrumentation for deformity compared to MIS two stage posterior pedicle screw instrumentation.

Methods: Thirty-six patients of average age 52.3 years (range 18 to 68 years old) presented mainly with degenerative scoliosis were treated with XLIF, mean of 3.7 levels (range from 3 to 6) of anterior instrumentation. The mean length of surgery was 110 minutes (range 60 to 152 minutes) and had mean EBL 180 (range 50 to 600cc). At follow-up, CTs and flexion/extension radiographs were reviewed to assess fusion. Patients with osteoporosis (Z score worse than - 1 standard deviation) were selected out of this procedure.

Results: The length of stay compared favorably to traditional open posterior lumbar deformity surgery 3.1 days (range of hospitalization 3 to 8 days). At mean follow-up of 27.7 months, 32/36 (88.8%) of patients showed evidence of solid arthrodesis and no subsidence on CT and flexion/extension radiographs. The remaining 4/36 patients have not completed final follow-up but are demonstrating further consolidation of fusion status without demonstrating loss of correction or requiring supplemental posterior instrumentation.

Conclusions: Our preliminary experience with single stage long anterior instrumentation and XLIF supports the findings from our retrospective study that the clinical outcomes, coronal/sagittal alignment improve postoperatively after a XLIF procedure and are maintained at intermediate-term follow-up. Traditional posterior pedicle screw approaches and decompression are reserved strictly for patients with spinal stenosis and MRI evidence of soft tissue causing spinal compression such as cases with synovial cysts. The main indication for supplemental posterior MIS pedicle instrumentation was osteopenia.

413 When Do Lumbar TDR Patients Achieve Maximum Medical Improvement?
R. Garcia1, J.Y. Yue1, M. Taylor1
1Orthopedic Care Center, Aventura, FL, USA, 2Yale University School of Medicine, New Haven, CT, USA, 3Orthopedic Care Center, Aventura, FL, USA

Introduction: There is strong scientific evidence that lumbar TDR in well selected patients results in significant improvement in pain and function. A major theoretical advantage of TDR over lumbar fusion is quicker recovery and return to near or normal function. Therefore, a common clinically significant question is regarding the length of time of recovery from lumbar TDR or time to maximum medical improvement. Another related question is whether implant design affect the clinical outcome or the speed of recovery following surgery.

Purpose: The purpose of this study is to document the length of time following lumbar TDR at which most of the benefit from the intervention has been achieved and after which no significant worsening or improvement is expected. A secondary purpose of this study was to determine if implant design affects clinical outcome or the speed of recovery post-operatively.

Methods: 97 patients were included in this study. All data was collected prospectively. Patients undergoing single level lumbar TDR as part of an FDA IDE trial from 2 study sites were included in this study. No patients were excluded. Patients were randomly assigned to 1 of 3 implant designs; unconstrained, semi-constrained, constrained. Pre-operative ODI and VAS was compared to results at 6 weeks, 3 months, 6 months, and 12 months post-operatively.

Results: ODI Unconstrained Semi-Constrained Constrained Baseline 53.8 59.3 64.8 6 Weeks 36.7 31.5 34.8 3 Months 27.5 23.9 40.8 6 Months 29.4 23.0 34.4 12 Months 30.0 19.0 32.0 24 Months 33.7 16.5 23.3 36 Months 45.2 18.8 22.0 Back VAS Unconstrained Semi-Constrained Constrained Baseline 71.6 80.8 84.0 6 Weeks 36.7 20.8 38.2 3 Months 27.5 21.1 47.7 6 Months 29.4 23.6 42.4
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Combined Assessment of Pelvic Tilt, Pelvic Incidence/Lumbar Lordosis Mismatch and Sagittal Vertical Axis Predicts Disability in Adult Spinal Deformity: A Prospective Analysis
V. Lafage1, B. Blondel1, S. Bess2, C. Shaffrey3, J. Smith2, O. Boachie-Adjei2, B. Akbarnia2, C. Ames3, B. Moal1, R. Hart1, J. Demakakos1, F. Schwab1, International Spine Study Group 1New York University Hospital for Joint Diseases, Spine Division, New York, NY, USA, 2Rocky Mountain Hospital for Children, Orthopedic Surgery, Denver, CO, USA, 3University of Virginia, Department of Neurosurgical Surgery, Charlottesville, VA, USA, 4Hospital for Special Surgery, Orthopedic Surgery, New-York, NY, USA, 5San Diego Center for Spinal Disorders, La Jolla, CA, USA, 6University of California San Francisco, Neurosurgery, San Francisco, CA, USA, 7Oregon Health and Sciences University, Orthopedic Surgery, Portland, OR, USA

Study design: Prospective multi-center study evaluating operative (OP) vs. nonoperative (NON) treatment for adult spinal deformity (ASD).

Objective: Evaluate correlations between spino-pelvic parameters and health related quality of life (HRQOL) scores in ASD patients.

Summary of background data: Sagittal spinal malalignment (SSM) is commonly defined by an increased sagittal vertical axis (SVA), however SVA alone may underestimate the severity of SSM. Spino-pelvic parameters provide a more complete assessment of SSM. Little data has correlated spino-pelvic parameters with disability.

Methods: Demographic, radiographic, and HRQOL data were obtained for all patients enrolled in a multicenter consecutive database. Inclusion criteria were: age >18 years and radiographic diagnosis of ASD. Radiographic evaluation was conducted on the frontal and lateral planes and HRQOL questionnaires (ODI, SRS-22 and SF-12) were available. Radiographic parameters demonstrating highest correlation with HRQOL values were evaluated to determine thresholds predictive of ODI>40.

Results: 492 consecutive ASD patients (mean age 51.9 years) were enrolled. Patients treated OP (n=178) were older (55 vs. 50.1 years, p<0.05), had greater SVA (5.5 vs. 1.7cm, p<0.05), greater pelvic tilt (PT; 22° vs. 11°, p<0.05) and greater pelvic incidence/ lumbar lordosis mismatch (PI-LL; 12.2 vs. 4.3; p< 0.05) than NON (n=314). OP demonstrated greater disability on all HRQOL measures compared to NON (ODI =41.4 vs. 23.9, p< 0.05; SRS total=2.9 vs. 3.5, p< 0.05).

Conclusions: SSM is a disabling condition. Prospective analysis of consecutively enrolled ASD patients demonstrated that PT and PI-LL combined with SVA can predict patient disability and provide a guide for patient assessment. Threshold values for severe disability included: PT≥22°, SVA ≥47mm, and PI-LL≥11°.
alignment. These changes are not correlated with coronal plane correction of the deformity. In contrast to all-screws constructs, hybrids constructs appear to permit TK restoration and favorable postural adaptation. Further studies will include pelvic parameters and clinical scores in order to evaluate the impact of the noted reciprocal changes.

509 Minimally Invasive Treatment of Adult Scoliosis with XLIF: Radiographic Outcomes and Predictors from a Prospective Multicenter Study
F.M. Phillips1, A. Tohmen2, W.B. Rodgers3
1Rush University Medical Center, Chicago, IL, USA, 2Northwest Orthopaedic Specialists, Spokane, WA, USA, 3Spine Midwest, Jefferson City, MO, USA

Background: The use of the XLIF approach as a stand-alone procedure has the advantage of avoiding a secondary posterior surgery in this typically elderly, frail population. Little data exists to support the degree of deformity correction achievable with XLIF with or without posterior fixation. The purpose of this report is to examine the radiographic correction of adult degenerative scoliosis treated with a lateral interbody fusion. The study specifically aims to identify supplemental fixation-dependent difference in deformity reduction.

Methods: 107 patients were treated for adult scoliosis with XLIF. Radiographs and clinical outcomes were collected preoperatively and at 0.5, 3, 6, 12, and 24 months. This report details the change in measures from pre- to post-op and maintenance of correction at 12 months. Measures include lumbar lordosis (L1-S1), coronal Cobb, subsidence and migration.

Results: This analysis includes 101 patients (74% female) treated with XLIF at 309 levels (T11-L5). The average patient age was 68 years (45–87). Patients were treated with 6 or fewer XLIF levels (average: 3.1/patient). Supplemental internal fixation at the surgeon’s discretion included (by patient) bilateral pedicle screws (50%), unilateral pedicle screws (26%), anterolateral plating (7%); 17% of patients were stand-alone. All unilateral pedicle screws were placed percutaneously. Bilateral pedicle screws were placed percutaneously (44%) as well as with an open technique (56%). Initial Cobb correction was greatest in XLIF patients with bilateral pedicle fixation and least in patients with no supplemental fixation (13°, 42% correction vs. 2°, 10% correction). Preoperative to postoperative Cobb correction was achieved in all fixation scenarios, but not in patients without supplemental fixation (p=0.242).

In patients treated with bilateral pedicle screws, Cobb measures were maintained from post-op to 12 months (p=0.458). In patients treated with unilateral pedicle screws Cobb correction was not maintained from post-op to 12 months (post:14°, 12 mo:17°, p=0.047). In patients treated with bilateral pedicle screw fixation, those with open placement resulted in greater coronal correction than those performed percutaneously (16°, 49% vs. 9°, 34%, p=0.024). Treatment with open or percutaneous bilateral pedicle screws, resulted in maintenance of Cobb correction at 12 months (p>0.05).

50 patients were hypolordotic (defined as L1-S1 lordosis >-40°) at baseline. In hypolordotic patients, lordosis improved from an average of -28° to -39° after XLIF (p< 0.001), and an average of -35° at 12 months. Loss in correction at 12 months was significant (p=0.004). Sub-groups were too small to determine if correction/maintenance of correction were dependent on supplemental fixation. Subsidence at 12 months was influenced by choice of supplemental fixation (p=0.012), with the greatest incidence in stand-alone segments (56%) and the lowest in patients with bilateral fixation (30%). There was one observation of implant migration that did not require revision.

Conclusion: XLIF has been popularized as a useful adjunct in the treatment of adult scoliosis with a lower complication than traditional surgical reconstruction. The current study supports that supplemental posterior fixation; specifically bilateral fixation optimized coronal plane deformity correction and reduced subsidence after XLIF.

330 Spinopelvic Alignment Following Long Lumbar Fusions with and without Iliac Fixation for Degenerative Lumbar Scoliosis
S.-A. Park1, D.-G. Chang1, K.-Y. Ha1
1Seoul Sanit Mary’s Hospital The Catholic University of Korea College of Medicine, Spine Center, Seoul, Korea, Republic of

Purpose: The iliac fixation increases the rigidity of the lumbosacral fixation and reduces the pseudarthrosis rate at L5-S1 following long lumbar fusion. However, the effects on the spinopelvic alignment have not been investigated yet. This study was to evaluate changes of the spinopelvic alingment following long lumbar fusions with and without iliac fixation for degenerative lumbar scoliosis (DLS).

Methods: DLS patients who underwent long fusions to S1, with and without iliac fixation, were retrospectively selected for groups of iliac fixation (ILF, n=27) and non-iliac fixation (Non-ILF, n=23), respectively. Whole-spine radiographs were taken with the patients in standing preoperatively and 3-month, 12-month and 24-month postoperatively. The pelvic incidence (PI), sacral slope (SS), pelvic tilt (PT), lumbar lordosis (LL), T9 offset (T9O) and thoracic kyphosis (THK) were measured on a sagittal X-Ray at each time-point. Changes of each dependent variable were compared at consecutive time-points in each group.

Results: The PI (52.5±13°) and the SS (23.0±13.3°) of the ILF significantly increased to 55.0±12.4° (P=0.012) and 27.3±12.5° (P=0.021), respectively, at 3-month but did not change during measurements taken at later times. The PT did not change postoperatively in any of the two groups. The LL of both groups and the T9O of the ILF significantly increased at 3-month but did not change at the later times. In contrast, the THK of the ILF significantly increased 3- and 6-month post-operatively.

Conclusion: A long lumbar fusion increased the LL of both groups, as well as the PI, SS, T9O and THK of the ILF group, but did not change the PT of any of the
Extreme Lateral Interbody Fusion (XLIF): Clinical Results from One Center


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

Aim: Traditionally, access to spine has been performed through open approaches. Access to the spine through minimally invasive surgical (MIS) approaches has become popular over the last decade. One such MIS approach is the extreme lateral interbody fusion (XLIF) technique, where the anterior spinal column is approached through the lateral retroperitoneal space with trans-psoas muscle exposure. Potential advantages to this approach include avoidance of the great vessels and peritoneal viscera. The purpose of this study was to determine the outcome of XLIF in a large series of patients from a single center.

Methods: A total of 102 patients who had anterior column fusion with the XLIF technique at a multisite clinic were identified. Only patients with minimum one-year follow-up were included. Data collected retrospectively from chart review included: demographics, surgical details, complications, reoperations, and outcome assessments including visual analog scales (VAS) assessing back and leg pain and the Oswestry Disability Index (ODI). An outcome assessment questionnaire was mailed to patients who had not recently been evaluated in the clinic. The majority of cases involved the use of a PEEK fusion cage and BMP or other biological bone graft material. The XLIF was performed in the thoracic spine in 12.7% of patients, primarily for the treatment of spinal deformity or thoracic herniated disc.

Results: The mean patient age was 55.0 years and the mean body mass index (BMI) was 29.9. The mean scores on the various outcome measures improved significantly (see table). Approximately 17% of patients had lower extremity numbness, pain, or described other sensation changes after surgery that were not present pre-operatively.

<table>
<thead>
<tr>
<th>VAS back pain</th>
<th>Post-op</th>
<th>Significance</th>
<th>% improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6.7</td>
<td>4.1</td>
<td>p&lt;0.05</td>
</tr>
<tr>
<td>VAS leg pain</td>
<td>4.5</td>
<td>2.9</td>
<td>p&lt;0.05</td>
</tr>
<tr>
<td>ODI</td>
<td>44.6</td>
<td>28.4</td>
<td>p&lt;0.05</td>
</tr>
</tbody>
</table>

Discussion: There was improvement in back pain, leg pain, and ODI scores in patients undergoing XLIF, although some patients did note new lower extremity symptoms post-operatively that have been reported by others as well. This is thought to be related to the approach required to access the anterior column through the psoas. However, the approach does avoid the potential for vascular injury encountered with traditional anterior spinal fusion and may reduce the risk of dural tears or direct injury to the posterior neural elements that can occur with posterior interbody fusion approaches. XLIF may provide a viable alternative to other approaches to the anterior spinal column, particularly for the thoracic and upper lumbar spine, but surgeons and patients should be aware of the risk of post-operative lower extremity symptoms that can occur.

Basic Science and Biomechanics: Oral Posters

Reliability of Thoracolumbar Injury Classification System for Orthopedic Surgeons at Different Training Levels

A.J. Bevevino1, D.G. Kang1, R.A. Lehman1

1Walter Reed National Military Medical Center, Department of Orthopaedics, Bethesda, MD, USA

Introduction: Despite increased use of the Thoracolumbar Injury Classification and Severity Score (TLICS), due to its simplicity and ability to guide treatment related decisions, it has not gained universal acceptance. The initial evaluation of a patient with thoracolumbar spine trauma is often performed by the most inexperienced orthopedic surgeon, typically an Intern or junior level Resident, and relaying meaningful information to a Staff spine surgeon is imperative for safe efficient care and initial treatment decision making. Our study set out to examine the reliability of TLICS for orthopedic surgeons at different training levels, ranging from Intern to Staff spine surgeon.

Methods: Eight cases of thoracolumbar spine fractures, including plain radiographs, computed tomography and magnetic resonance imaging, were reviewed and scored using TLICS by eight evaluators: Intern (n=2), junior level orthopedic Resident (n=3), senior level orthopedic Resident (n=2), fellowship trained Staff spine surgeon (n=1). Each participant evaluated the same cases on three different occasions within a four week time period. Statistical analysis with Intraclass Correlation Coefficient
HNP classified into three types (protruded, extruded, sequestered) using T1-weighted sagittal images. The sequestered disc classified by the extent of migration (to proximal 1/3, middle 1/3, distal 1/3 of vertebral body height, Fig 3,4). The Visual Analog Scale (VAS) and Oswestry Disability Index (ODI) were used to evaluate clinical outcomes.

Results: Significant resorption of HNP was shown at the follow-up MRI. The mean initial mass was 1300.7±792.6㎜² and the mean follow-up mass was 826.9±536.0㎜². The mean mass change was 473.8±309.9㎜². In type 1 HNP (intact PLL), the morphologic change shows slight decrease or no changes (14/16). In type 2 or type 3 HNP (ruptured PLL), herniated disc markedly decreased or disappeared (13/18) (Table 1). There was statistically significant difference (Fisher’s Exact test, p=0.001).

Distally migrated sequestered HNP material were more resorbed than proximally migrated HNP (proximal 1/3, 60% resorption; middle 1/3, 75% resorption; distal 1/3, 86% resorption). However, clinical symptom alleviation was not correlated with HNP displacement and amount of resorption (p=0.323, p=0.603 respectively) (Table 2).

Radiating pain and back pain subsided during the follow-up period. Interestingly, back pain redeveloped around 2 year follow-up and then subsided afterward (Fig 7).

Conclusion: Transligamentous extension of herniated disc materials through the ruptured PLL was important to its reduction in size. Disappearance of HNP was seen frequently in much more migration happened. Clinical outcome of conservative treatment to HNP was good. However, clinical outcome did not depend on the HNP migration and amount of resorption.

128 Novel Anterior versus Combined Anterior-posterior Instrumentation Technique for a Simulated Bilateral Cervical Facet Dislocation: An in-vitro Human Cadaver Study

W. Beutler1, W. Peppelman1, M. Gudipally2, M. Adu-Lartey4, J. Brooks3, P. Niknam5, S. Khalil6
1PA Spine Institute, Harrisburg, PA, USA, 2Globus Medical, Inc., Audubon, PA, USA

Introduction: Bilateral facet dislocations (BFD) can be highly unstable and involve complete disruption of the posterior column ligament complex. Surgical treatment includes posterior wiring/plate fixation, anterior cervical discectomy with plating, as well as combined anterior and posterior instrumentation. The present study was aimed at comparing a novel anterior fixation technique to a combined anterior and posterior instrumentation technique.

Methods: Seven fresh human cervical cadaveric spines (C3–C6) were tested on a custom built spine simulator under pure moment of ± 1.5 Nm in flexion-extension (FE), lateral bending (LB), and axial rotation (AR). The BFD injury was simulated by disrupting the entire posterior column ligament complex (supraspinous ligament, interspinous ligament, ligamentum flavum, and facet capsule). The novel anterior interbody device Coalition® [Globus Medical, Audubon, PA] is an...
integrated plate-spacer (COA) with two screws. The traditional anterior instrumentation used was Colonial® [Globus Medical] anterior interbody fusion spacer (C) and Providence® [Globus Medical] anterior cervical plate (ACP) and posterior instrumentation (PI) was lateral mass screws with rod (Figure 1). All the spines were sequentially tested for three cycles in the following order: 1) Intact 2) BFD Injury 3) COA + ACP 4) C + ACP + PI.

Results (Figure 2): The simulated BFD injury considerably increased ROM compared to the intact condition, but did not show any statistical significance. The novel anterior technique of augmenting Coalition® with an anterior plate significantly reduced ROM by 79.8% in FE, by 83.4% in LB, and by 67.4% in AR compared to intact and by 97.0% in FE, by 102.8% in LB, and by 91.7% in AR compared to BFD injury. The traditional combined anterior-posterior instrumentation significantly reduced ROM by 89.1% in FE, by 92.1% in LB, and by 82.5% in AR compared to intact and by 106.3% in FE, by 111.4% in LB, and by 106.8% in AR compared to BFD injury. Statistically no significant difference was observed between the two techniques.

Conclusion: The current study showed that the COALITON integrated plate-spacer with an anterior plate provided as much stability as a combined anterior-posterior construct. The major advantage of this anterior approach may be that the decompression, reduction, interbody grafting, and instrumental stabilization can all be performed using the same operative incision. However, the clinical benefits should be confirmed with clinical studies.

Introduction: The optimal surgical approach for multi-level cervical spondylotic myelopathy (CSM) remains controversial. Multilevel ACDF and corpectomy (ACCF) are commonly employed treatment techniques to achieve cervical decompression. However, they are associated with complications such as pseudoarthrosis, graft or plate dislodgment and loss of lordotic alignment. This has led to the use of hybrid constructs combining ACCF and ACDF. The current study evaluated the biomechanics of an ACDF and a hybrid ACCF-ACDF in a 3-level CSM cervical model. The hypothesis was that the hybrid technique may provide adequate biomechanical rigidity compared to multilevel ACDF.

Methods: Seven calf cervical spines (C2-C6) were tested by applying pure moments of ±1.5Nm. Range of motion (ROM) at C2-C5 was obtained in flexion-extension, lateral bending, and axial rotation modes. Constructs tested included: 1) intact; 2) 3-level ACDF (3D); 3) 1-level ACCF +1-level ACDF using a spacer and anterior cervical plate (1C1D_{S+ACP}) and; 4) 1-level ACCF + 1-level ACDF using integrated spacer and plate (1C1D_{ISP}) [Figure 1]. ANOVA and Tukey’s post hoc test was used for statistical analysis (p< 0.05).

Results: All constructs significantly reduced ROM compared to intact in all loading modes (p< 0.05). ROM in flexion-extension was reduced by 65% in all constructs compared to intact. In lateral bending and axial rotation, there were higher percentage changes between constructs. Three-level ACDF was biomechanically most stable among the constructs (p>0.05). The two hybrid constructs were comparable in all loading modes (p>0.05). However, in terms of percentage differences, the 1C1D_{S+ACP} construct provided increased stability compared to the 1C1D_{ISP} construct [Figure 2].
Conclusion: Biomechanical data suggests that three-level ACDF was the most stable construct in terms of ROM differences. Hybrid constructs were statistically similar to the multi-level ACDF construct. Patients exhibiting severely narrowed disc spaces could benefit from a hybrid construct combining corpectomy and ACDF as a viable surgical option for treatment of multi-level CSM.

131 The Use of Self-mating PEEK for Cervical Disc Arthroplasty
T. Brown¹, Q.-B. Bao³
¹Pioneer Surgical, Marquette, MI, USA

Purpose: Past tribological investigations of materials used in joint arthroplasty devices have shown that their wear behavior can be critically influenced by the load and kinematic parameters, test frequency, lubricant and device design. The hypothesis for this study was that the simulated wear behavior of a hydroxyapatite (HA) coated, self-mating PEEK cervical disc arthroplasty device (CDA) would be dependent on these same parameters.

Methods: Five groups of N = 6 CDA devices were evaluated under suggested ASTM and ISO load and motion profiles. This evaluation utilized different testing frequencies, protein content of simulator fluid, and the potential for third body wear from the HA coating (Table 1). The average wear rates were determined using linear regression analysis. Significant differences between wear rates were determined via the Wald test (p < 0.05).

Results: The results of this study support our hypothesis that the simulated wear behavior of this self-mating PEEK CDA is dependent upon the tribological environment, where decreasing the cyclic loading frequency resulted in approximately a doubling of the amount of wear when slowed from 2 Hz to 1 Hz. While a 3-fold decrease in the amount of protein in the simulator fluid increased the wear by approximately 10% (Gr 3 vs. 2b), the elimination of protein from the simulator fluid resulted in nearly a 3-fold increase in the wear rate (Gr 1a vs. Gr 4), demonstrating the protective effect of protein in the simulator fluids. All implants for each group maintained full functionality throughout each test duration. Visual and light microscopy revealed no evidence of gross deformation, delamination or fatigue cracks in the implants after testing. Closer examination under light microscopy revealed an abrasive wear mechanism occurring, with scratches and highly polished surfaces for all groups. The use of an HA coating did not appear to adversely affect the wear rate. There were no notable differences in the images suggesting that third body wear was occurring (Gr 5). The significant difference in the wear rates (Gr 4 vs. 5) is likely attributable to the gradual dissolution of the coating. Overall, the experimental wear rates found in this investigation are consistent with other tribological investigations of CDA devices that are used clinically.

[Table 1. Wear Testing Summary]

<table>
<thead>
<tr>
<th>Group</th>
<th>Load and motion profile</th>
<th>Test Frequency</th>
<th>Test Medium</th>
<th>Test Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a - Uncocated</td>
<td>ASTM</td>
<td>2 Hz</td>
<td>20 g/lt, serum</td>
<td>0-10 million cycles</td>
</tr>
<tr>
<td>1b - Uncocated</td>
<td>ISO</td>
<td>2 Hz</td>
<td>20 g/lt, serum</td>
<td>0-10 million cycles</td>
</tr>
<tr>
<td>2a - Uncocated</td>
<td>ASTM</td>
<td>1 Hz</td>
<td>20 g/lt, serum</td>
<td>0-4 million cycles</td>
</tr>
<tr>
<td>2b - Uncocated</td>
<td>ISO</td>
<td>1 Hz</td>
<td>20 g/lt, serum</td>
<td>0-4 million cycles</td>
</tr>
<tr>
<td>3 - Uncocated</td>
<td>ISO</td>
<td>1 Hz</td>
<td>5 g/lt, serum (80%)</td>
<td>0-3 million cycles</td>
</tr>
<tr>
<td>4 - Coating removed</td>
<td>ISO</td>
<td>2 Hz</td>
<td>saline</td>
<td>0-10 million cycles</td>
</tr>
<tr>
<td>5 - Coated</td>
<td>ISO</td>
<td>2 Hz</td>
<td>saline</td>
<td>0-10 million cycles</td>
</tr>
</tbody>
</table>

[Figure 1. Wear rate comparison (mean ± SD).]

Conclusions: The results of the testing performed in the current investigation demonstrates that a single set of parameters cannot fully predict the performance of a CDA device, similar to previously published data on the wear behavior of other joint arthroplasty devices. This emphasizes the importance of matching simulator results with ongoing retrieval analysis to determine which set(s) of criteria are most relevant for clinical prediction of wear performance.

172 A Comparison of Intra-Capsular Facet (IF) and Peri-Facet (PF) Injections in Patients with Low Back Pain (LBP)
D. Wardlaw¹, A. Nandakumar¹, J. Beastall¹, A. Kumar¹, F. Smith¹
¹Woodend Hospital, NHS Grampian Hospital, Aberdeen, United Kingdom

Introduction: Facet joint steroid injections have been used for treatment of LBP with varied reports of pain relief. Peri-facet steroid injections have also been clinically successfully performed for many years.

Methods: A Blinded Randomised Controlled Trial was carried out to compare IF and PF injections for LBP.

Questions? (866) 423-9440 (U.S.) +1(630) 995-9994 (Int’l)
Patients randomised into IF and PF groups. Bilateral L4/5 and L5/S1 levels injected. 40mg of Depo-Medrone with Lignocaine (total 1ml) in IF group. 80mg of Depo-Medrone with 1ml of 0.5% Chirocaine (total 3ml) in PF group. Pain visual analogue score (VAS) and analgesic chart - completed till six months. At the time of injection during IF injections the medication is confined to the facet joints. In the PF group of patients the contrast is seen to extend widely around the facet joints into the surrounding myofascial tissues. Statistical analysis was done using using paired t-tests.

Results: Eighty eight patients in total, fourteen withdrew, sixty nine patients' feedback was available. Sixty-three patients (91%) had significant pain relief at one week following injection 86% (IF) and 94% (PF) group. Duration of pain relief was a mean of 12.4 weeks, range 0 - 32 weeks, 13 weeks (IF), range 0 - 16 months and 12 weeks (PF) range 0 to 24 months. Five patients have had complete long term relief at the last review time point, two of 16 months (1 PF and 1 IF), one of 22 months (PF) and two of 24 months (both PF). Mean pain Visual Analogue Score (VAS) score before injection was 7 (range 2 to 10) and after injection was 3 (range 0 to 9) and was the same for both groups (IF-4, PF-4; P= 0.001). Change in VAS was calculated from pre-injection score to the score one week following injection and throughout the period of pain relief. The number of analgesic / anti-inflammatory tablets that the patients used before and after injection was noted. The mean analgesic use before injection was 4.2 for all patients, [4.2 (IF) and 4.1(PF) groups] and after injection was 1.7 [1.1(IF) and 1.9 (PF) group]. Mean change in analgesic use before & after injection was 2 tablets. (IF-2.9, PF-2.3). Radiation dose area product (DAP) for IF injections-603 and PF- 45 mGy.cm². 45 (51%) came for repeat injections, 19 & 26 in IF & PF groups.

Conclusions: 1. Majority had pain relief (91%), with no statistically significant difference between 2 groups in change in pain severity, duration of pain relief or change in analgesic intake.
2. Significant change in VAS after injection in both groups (from 7 to 3) with pain relief for a mean duration of 12.4 weeks.
3. PF injections are technically easier - 9 patients randomised to IF group had PF injections (facet joint osteophytes).
4. Radiation doses much higher for IF injections even in expert hands (P=0.007). It took double the time to perform IF injections compared to PF (30 and 15 minutes).
5. Perifacet injections bring about equal pain relief to facet injections suggesting a musculo-fascial source of pain rather that the facet joints alone.

Can the Intradiscal Inflammation after Annulus Puncture Be Prevented by Polylactic Acid Patch Repairment? An Animal Model Study

X. Liu¹, H. Liu²

¹Sichuan University, Chengdu, China, ²West China Hospital, Sichuan University, Department of Orthopaedics, Chengdu, China

Objective: The current study was designed to construct a kind of polyactic acid (PLA) The reparative effect of injured annulus fibrosus and preventative effect of intradiscal inflammation was evaluated, so that a possible solution for intradiscal inflammation and secondary degeneration after disc injection could be provided.

Methods: PLA patch was constructed with solution casting and solvent moulding / foaming technique. Thirty six new zealand white rabbits were used as experimental animals. Annulus penetration animal model was established with 25G, 22G and 18G sized needles, and the injured site was repaired with the previously mentioned PLA patch sticked by Shunkang Medical Adhesive. Meanwhile, sham operation group and Shunkang medical adhesive solo reparative group were setup as controls. The successfulness of animal modeling was tested pathologically. Sample from the target intervertebral discs of the previously mentioned animals were collected, and then underwent histologic staining and microscopy and ELISA examination to determine the relationship between the severity of annulus penetration injury and the level of intradiscal inflammation, as well as the preventative effect of PLA patch against intradiscal inflammation after annulus puncture and the secondary degeneration thereafter.

Results: HE stained picture showed that the cells in the disc tissue from the annulus punctured groups with various sized needles were significantly fewer in amount, and distributed separately and disorderly, with a great many vacuoles. The extra-cellular matrix was broken down in texture, distorted and disorder in arrangement. Such phenomenon was most apparent in the 18G needle punctured group. The cell density of disc tissue from reparative group with PLA patch adhered by Shunkang medical adhesive was close to that of sham operated group. The tissue morphology and arrangement was close to normal. No obvious broken or dead cell, or vacuole was observed. The histological manifestation of tissue from disc repaired simply with medical adhesive was basically similar to that of annulus punctured groups, but less serious than that of the 18G needle punctured group, with slightly larger cell amount, and more abundant and better arranged extra-cellular matrix. Masson stained pictures showed similar results. The results of immunohistochemical test and ELISA indicated that significant expression of important humoral immunity related factors including IL-1β, TNF-α and iNOs, as well as important inflammatory cell surface markers including CD4, CD6 and CD20 was present 1 week after annulus puncture. And the intensity of such expression elevated with the increase of the size of the puncture needle. After repair of the annulus pinhole left by 18G needle puncture with PLA patch, the expression level of the previously mentioned factors was significantly lower than that of the 25G needle punctured group, though still not completely normal.

Conclusions: Repairing the annulus puncture injury by adhering the PLA patch to the injured annulus fibrosus with Shunkang medical adhesive could effectively suppress the intradiscal inflammation in the early stage, which meant that this patch repairing method could hopefully prevent secondary disc degeneration after annulus puncture injury and might provide a possible way to safely induce the therapeutic agents into the disc.
Rotational Instability of the Lumbar Spine Following Laminectomy: Is there a Role for Bone Mineral Density and Disc Degeneration?  
1VU University Medical Center, Orthopedic Surgery, Amsterdam, Netherlands; 2VU University Amsterdam, Faculty of Human Movement Sciences, Amsterdam, Netherlands; 3VU University Medical Center, Physics and Medical Technology, Amsterdam, Netherlands

Introduction: Symptomatic degenerative lumbar stenosis is common in the elderly. Affected nerves can be decompressed by laminectomy. However, laminectomy disrupts the integrity of the pars interarticularis and the posterior longitudinal ligament, which is essential in limiting axial rotation of the spine. The lumbar spine is subjected to axial rotation during daily activities and occurrence of spinal injury due to rotational forces is common. In some patients lumbar laminectomy may therefore reduce spinal strength and increase the risks of injury and degenerative changes. The aim of this study is to assess whether laminectomy influences rotational stability of a lumbar motion segment and to what extent bone mineral density (BMD) of the vertebrae and intervertebral disc (IVD) degeneration affects this relationship.

Methods: Ten cadaveric mature human lumbar spines (L2-L5) were obtained (mean age 75.5 years, range 59-88 years). DXA scans were performed on all spines to assess BMD, with BMD values below median (< 0.76gr/cm²) defined as “low BMD”. MRI scans were obtained to assess intervertebral disc degeneration (using the Pfirrmann score). IVDs were subsequently subdivided into mild (score 2-3) and severe (4-5) degeneration groups. Laminectomy was performed either on L2 or L4, equally divided within the group of 10 spines. Motion segments L2-L3 and L4-L5 were isolated and mounted in a mechanical testing machine. The segments were then subjected to a rotation moment until failure, while simultaneously being loaded axially (1600N). Torsion moment to failure (TMF) and torsion stiffness (TS-1: 20-40% of TMF; TS-2: 60-80% of TMF) were determined from the load displacement curves. Univariate analyses of variance (ANOVA) was performed to compare outcome parameters between tested groups.

Results: Both laminectomy (p=0.032) and low BMD (p< 0.001) resulted in a reduced TMF. No significant interaction between BMD and laminectomy was found (p=0.131). Neither BMD, nor its interaction with laminectomy affected TS-1 or TS-2. In contrast, severe disc degeneration was associated with increased TS-1 (p< 0.001), but not with TS-2 (p=0.561). For both TS-1 and TS-2 an interaction with laminectomy was found (TS-1: p=0.023 and TS-2: p=0.040). Laminectomy independently affected TS-1 (p=0.009) as well. IVD degeneration on its own did not affect TMF (p=0.190), but there was an interaction effect of disc degeneration and laminectomy on TMF (p< 0.01).

Conclusion: In mature human lumbar spines rotational strength depends strongly on BMD. Laminectomy reduces rotational strength, but its effect is smaller than the effect of a low BMD. Rotational stiffness, on the other hand, depends significantly on the severity of intervertebral disc degeneration. Severe IVD degeneration is associated with increased rotational stiffness and is likely to hamper rotational motion. This effect on torsion stiffness is, however, reduced by laminectomy. In conclusion, residual rotational strength and stiffness of the lumbar spine are strongly dependent on BMD and severity of IVD degeneration. Hence, assessment of BMD (with DXA) and disc degeneration (MRI) may give additional information about spinal biomechanics, which may aid surgical decision-making.
Metanalysis of Class I Results of Anterior Cervical Decompression and Fusion with Allograft and Plating
K.A. Pettine1, L. Eiserman2
1The Spine Institute, Loveland, CO, USA, 2Eisertech, Sandiego, CA, USA

Purpose: What are the clinical results of anterior cervical disectomy 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.

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), Kinflex-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 averaged 9.8% (table one illustrates individual study results). Clinical success rates at two year follow up averaged 68% (table two illustrates individual study results).

Table One
Reoperation Rates at Two Year Follow Up

<table>
<thead>
<tr>
<th>Device</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prestige</td>
<td>19.9%</td>
</tr>
<tr>
<td>ProDisc-C</td>
<td>08.5%</td>
</tr>
<tr>
<td>Bryan</td>
<td>04.1%</td>
</tr>
<tr>
<td>PCM</td>
<td>06.6%</td>
</tr>
<tr>
<td>Kinflex-C</td>
<td>13.5%</td>
</tr>
<tr>
<td>Secure-C</td>
<td>06.25%</td>
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</tbody>
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Table Two
Clinical Success at Two Year Follow Up

<table>
<thead>
<tr>
<th>Device</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prestige</td>
<td>72.6%</td>
</tr>
<tr>
<td>ProDisc-C</td>
<td>68.8%</td>
</tr>
<tr>
<td>Bryan</td>
<td>72.7%</td>
</tr>
<tr>
<td>PCM</td>
<td>69.9%</td>
</tr>
<tr>
<td>Kinflex-C</td>
<td>61.7%</td>
</tr>
<tr>
<td>Secure-C</td>
<td>71.7%</td>
</tr>
</tbody>
</table>

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.
VAS was high in both groups: 82.8 PCM and 81.4 control (p=0.0071). At 2 years the ROM at the index level averaged 5.7 degrees (range 0-17.2) for the PCM group and 0.8 degrees (range 0-6.3) for the controls.

**Conclusion:** This randomized, prospective FDA IDE study found that treatment of symptomatic single-level cervical spondylosis with the PCM device achieves clinical outcomes that are equivalent to ACDF. Additionally, patients receiving the PCM device had a statistically lower rate of both major complications and prolonged dysphagia along with greater patient satisfaction scores.

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SECURE®-C Cervical Artificial Disc Two Year Clinical Outcomes: Randomized vs. Non-randomized Patients

**Purpose:** A statistical comparison of patient outcomes in the SECURE®-C clinical trial for the randomized and non-randomized investigational SECURE®-C groups.

**Methods:** The SECURE®-C device (Globus Medical, Audubon, PA) is the subject of a randomized, prospective Investigational Device Exemption (IDE) pivotal study conducted at multiple centers across the U.S. Enrolled patients were randomized 1:1 to receive the SECURE®-C disc or the control anterior cervical discectomy and fusion (ACDF). The first five patients treated at each site were non-randomized patients who received the SECURE®-C disc. Indications include symptomatic cervical disc disease (SCDD) in one vertebral level (C3-C7) defined by neck and/or arm pain, herniated nucleus pulposus, radiculopathy or myelopathy, and other conditions as specified in the study protocol. All patients were to have completed at least 6 weeks of conservative therapy, have a Neck Disability Index (NDI) of at least 30 (as a percentage of the 50 point total) and were between 18 and 60 years of age. Outcome measures and radiographic evaluations were collected preoperatively and at 6 weeks, 3 months, 6 months, 1 year and 2 years postoperatively. Outcome measurements include NDI, Visual Analog Scale (VAS) neck and arm pain, SF-36 Health Status Survey, and patient satisfaction. Safety data included the frequency of adverse events (AEs), maintenance or improvement in neurologic status, and the incidence of secondary surgery. Adverse event data were collected preoperatively and at 6 weeks, 3 months, 6 months, 1 year and 2 years postoperatively. Outcome measurements include NDI, Visual Analog Scale (VAS) neck and arm pain, SF-36 Health Status Survey, and patient satisfaction. Safety data included the nature and frequency of adverse events (AEs), maintenance or improvement in neurologic status, and the incidence of secondary surgery. An adverse event is any clinically adverse sign or symptom that occurs or worsens during the study, regardless of cause or severity. Data from 151 randomized SECURE®-C patients and 89 non-randomized SECURE®-C patients are compared.

**Results:** Ninety one percent (91.4%) of the randomized SECURE®-C patients demonstrated a greater than 15 point improvement in NDI at 24 months, as compared to 85.9% of non-randomized patients. Average NDI for randomized patients at 24 months was 13.2 ±17.79 as compared to 14.1 ±17.99 for non-randomized patients. Both groups also demonstrated improvement in VAS neck and arm pain at 24 months. The average VAS neck pain for randomized patients at 24 months was 14.3 ±22.46 as compared to 17.1 ±25.94 for non-randomized patients. Average VAS left arm pain for randomized patients was 9.0 ±20.67 as compared to 8.9 ±20.27 for non-randomized patients at 24 months. Average VAS right arm pain for randomized patients was 6.6 ±17.52 as compared to 4.6 ±12.65 for non-randomized patients at 24 months. Protocol-defined overall success at 24 months was 90.1% for randomized patients and 84.8% for non-randomized patients. Seventy two percent (72.2%) of randomized patients reported having an adverse event of any kind, compared to 67.4% of non-randomized patients. Device-related events were reported for 2.6% of randomized SECURE®-C patients compared to 2.2% of non-randomized patients. Secondary surgery at the index level was required for 2 non-randomized patients and 3 randomized patients. There were no statistical differences between groups for any of the outcome measures, with all Bayesian Credible Intervals (BCIs) including zero.

**Conclusion:** There were no differences in safety or efficacy outcomes between the randomized and non-randomized groups. These data suggest that there is no significant learning curve associated with the SECURE®-C Cervical Artificial Disc.
were determined and the significance levels were computed based on the paired t-test. Thirty patients (11 female; 19 male) were enrolled at 3 sites with a mean age of 45 years (females: 44; males: 46). Twelve patients were treated at 1 level and 18 at 2 levels for a total of 48 implanted discs (C4-C5: 7; C5-C6: 27; C6-C7: 14). The NDI has decreased significantly (p < 0.001) from 67.8% at baseline to 20.8% at 24 months. At 24 months, neck, right and left arm pain VAS decreased significantly from baseline (p < 0.001) (7.7, 6.0 and 6.3 at baseline versus 2.3, 2.0 and 1.4 at 24 months, respectively). There was a small postoperative decrease in Global and Index Level ROM, but each has been adequately maintained over time. Disc height increased and remained stable through 24 months (baseline: 3.8 mm, 6 wks: 5.9, 3 months: 5.9, 6 months: 5.7, 12 months: 5.8, 24 months: 6.0). At the most recent follow-up, 2 patients had less than a 15% percentage point decrease in NDI score and 1 patient had a slight neurological deficit with a one point decrease in sensation at 24 months compared to baseline. Device position has been maintained for all patients with no evidence of device migration or expulsion. One surgery-related adverse event (AE) was observed to remove partial wound drain. Through 24 months, there have been no additional surgical procedures at the index or adjacent cervical levels. The overall 24-month clinical success rate, defined as, improvement in neurological function, improvement in NDI by 15%-point, no serious AE, no removals or revisions to device, is 90.0%. The M6-C Artificial Cervical Disc demonstrates satisfactory clinical and radiographic outcomes at 24 months. Further assessment of this cohort and the performance of a US IDE pivotal study will be completed to confirm these initial results.

### 75 Factors Determining the Long-term Clinical Success Rate after Anterior Cervical Discectomy and Fusion for One and Two-level Radiculo-myelopathy

**P.D. Nutley**, A. Jawahar, E.J. Kerr, D.A. Gavanaugh, M. Boltes, D. Coric

1Spine Institute of Louisiana, Orthopedic Surgery, Shreveport, LA, USA. 2Spine Institute of Louisiana, Neurosurgery, Shreveport, LA, USA. 3Carolina NeuroSurgery & Spine Associates, Neurosurgery, Charlotte, NC, USA

**Introduction:** Anterior cervical discectomy and fusion is a reasonable surgical option in the management of symptomatic cervical disc degeneration non-responsive to conservative treatment. Although previously published studies have established the longer term safety and efficacy of the procedure, specific factors predictive of a better success rate remain controversial. One possible reason for this is the lack of uniform definition of success and paucity of literature with long term (> 5 years) follow-up. We analyzed the long term clinical outcomes in 88 consecutive patients who underwent ACDF for one and two-level intractable cervical radiculo-myelopathy as a "control" arm of four different prospective randomized clinical trials.

**Material and methods:** Since 2003, three separate centers (7 surgeons) enrolled 271 patients in prospective multi-center RCT’s for surgical management of one and two-level symptomatic cervical disc degeneration. Patients were screened with strict inclusion/exclusion criteria and were randomized (2:1) to receive either total disc replacement or ACDF surgery. A total of 96 patients were thus randomized to receive ACDF as the "control" group and 88 have been followed according to the protocols. Clinical follow-up data included VAS pain score (0-100 mm); Neck Disability Index (0-100 points) and a detailed neurological examination. The data time-points were 3 months, 6 months, 12 months and then annually until the final follow-up (range 48-100 months).

**Results:** Mean age was 46 years with marginal female predominance (56,43). 35% were smokers (>1PPD); 16% had osteopenia and 27% had pre-existing lumbar spine degenerative disease. At baseline, mean VAS and NDI were 79 and 60 respectively and 27% had neurological deficits. At the median follow-up of 52 months mean VAS and NDI were 27 and 90% had no neurological deficit (p = 0.0002). 69% patients satisfied the requirements for clinical success, defined by >20 points reduction in VAS and NDI, absence of neurological deterioration and no subsequent surgical intervention. 12.5% developed symptomatic adjacent segment disease and 4.5% demonstrated radiological pseudarthrosis. NDI was a better predictor of clinical success as opposed to the VAS scores. Long term (>5years) success was better maintained in patients >45 years (p = 0.03). Non smokers show a significantly higher success rate within the first 5 years while smokers showed slower success (0.004). Nevertheless, the final success rates for both cohorts were similar. During the first 5 years, success rate in patients with two-level surgery was significantly higher (p = 0.003) but the final success rates were comparable for single and two-level surgeries.

**Conclusion:** ACDF can provide clinical benefit even 5 years after surgery especially in patients older than 45, smokers and single level disease. The previously reported lower success rates in these patient cohorts can possibly be attributable to shorter follow-up time and/or inconsistent clinical criteria for success. The more recent studies reporting better success rates for total disc replacement surgeries than ACDF have not reported longer term follow-up (>5 years) and will have to stand the test of time before a true comparison of clinical benefits from the two procedures can be made.

**Lumbar Therapies: Oral Posters**

### 267 Outpatient Minimally Invasive Lumbar Fusion

**K.A. Pettine**

1The Spine Institute, Loveland, CO, USA

**Purpose:** MIS techniques are currently associated with a steep learning curve. This abstract describes a consecutive series of lumbar fusions performed with a standard midline incision familiar to all spine surgeons. The advantage of this technique is incorporating surgical skills familiar to all spine surgeons as an outpatient MIS procedure. The surgical technique involves a 3-5cm midline incision with a standard exposure to the facet.
Low-grade Degenerative Spondylolisthesis Treated by Stand-alone Lateral Interbody Fusion

L. Marchi1,2, L. Oliveira1, R. Amaral1, C. Castro1, E. Coutinho1, T. Coutinho1, L. Pimenta1,3

1Instituto de Patologia da Coluna, São Paulo, Brazil, 2Unifesp, DDI, São Paulo, Brazil, 3University of California San Diego, Neurosurgery, San Diego, CA, USA

Purpose: Satisfactory radiological outcomes for the treatment of degenerative spondylolisthesis have been reported with posterior approaches, but these techniques still bring risks, muscle damage and postoperative morbidity. The optimal surgical treatment for lumbar spondylolisthesis remains unclear. The purpose of this paper was to investigate the stand-alone lateral interbody fusion as a minimally invasive for the treatment of low-grade degenerative spondylolisthesis.

Methods: The series consists of 90 cases involving 47 males and 43 females. The average age of the patient was 56 (range 26 to 81) with an average BMI of 29. There were 46 cases performed with only a posterolateral fusion at one level and 44 two level fusions. There were 7 cases performed with a TLIF procedure at one or two levels.

Results: The average pre-operative VAS for one level Coflex-F was 21 (p<0.001) and ODI was 34 (p<0.01). The average operative time for a one-level procedure was 42 minutes and a two-level procedure averaged 73 minutes. Adding a TLIF increased the operative times an average of 17 minutes per level. All TLIF fusions were performed utilizing locally harvested autogenous graft, BMP and an expandable PEEK implant. The average blood loss for a one-level procedure was 23cc and a two-level procedure was 38cc. The average fluoroscopy time was three seconds for location identification prior to skin incision and post operative implant x-rays. The average stay in the convalescent center was 17 hours. Two cases required more than a 23-hour recovery. One of these was a patient with a pseudomeningocele requiring bed rest for a dural tear repair. The second patient involved an 81-year-old female. There were no perioperative complications or re-operations. There were four re-operations which will be discussed.

Conclusions: This consecutive series of 90 patients indicates performing a one- or two-level lumbar fusion through a minimal midline incision using the interlaminar Coflex-F implant can be successfully performed as an outpatient procedure. There are several advantages to this MIS technique. All spine surgeons are familiar with a midline approach performed under direct vision. This procedure incorporates the standard current techniques through a small MIS dissection. This technique can be performed outpatient and is not associated with a learning curve.

Clinical Outcome of Two-level Total Disc Replacement in 84 Patients with Minimum 5 Years Follow-up

M. Scott Young1, A. Kasis1, C. Magno1, D. Nielsen1, E. Mitchell1, N. Blanch1

1Gold Coast Spine, Gold Coast, QLD, Australia

Introduction: The majority of spine patients present with discogenic low back pain, originating from either degenerative disc disease (DDD) or internal disc disruption (IDD). Successful treatment of this patient population relies on obtaining precision diagnosis and careful patient selection, as well as matching the pathology with reliable technology. Total disc replacement (TDR), as an alternative to spinal fusion in the treatment of DDD or IDD, has been studied and reported for several decades in long-term follow-up.
Pedicle Based Posterior Dynamic Stabilization System (DSS®)
R. Bertagnoli

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 spondylothesis. 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 with degenerative disc disease at one or more levels including grade 1 spondylothesis. 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 (tapping 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 87 patients is to investigate the safety and efficacy the DSS® system used in motion and hybrid constructs. Fusion only patients (n=18) are not evaluated. Employed parameters were VAS and ODI. Patients are assessed pre and postoperatively 3, 6, 12, 24 and 36 month.

Results: The mean age of 49 males was 53 yrs. (29 - 75) and of the 38 females 55 yrs. (33 - 83). Patients received single or multi level surgeries between Th09 and S1. In a total of 44 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 (76,5 %). There are 6 two level, 2 three and 1 five level cases.

43 Patients received hybrid multilevel implantations including combinations with TDR. The most frequent two level construct (n=15) was L3-L5 (60%) followed by L4-S1 and in three level constructs (n=15) L2-L5 (40%) equals L3/S1 (40%). In four level cases (n=10) L2-S1 predominates (80%); there are 2 five level and each 1 7 and 8 level cases. VAS, ODI values decreased significantly at 3 month postoperative and were maintained throughout the follow up.

VAS scores decreased from a mean score of 6.4 ± 1.8 baseline to 4.1 ± 2.1 at 3 months; 4.9 ± 2.6 at 6 months; 4.8 ± 2.2 at 1 yr.; 4.7 ± 3.1 at 2 yrs.; 5.7 ± 3.0 at 3 yrs. ODI scores (in %) were reduced from 52.2 ± 17.5 baseline to 43.6 ± 15 at 3 months, 44.8 ± 14.8 at 6 months; 42.4 ± 17.2 at 1 yr; 43.2 ± 15.3 at 2 yrs and 46.5 ± 21.6 at 3 yrs. 4 year data not representative yet due to small sample.

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. The combination of the system with TDR offers new possibilities to stabilize these prostheses if necessary. These results of the patient sample are further completed by long term observation.
ROM results are consistent with current clinical practice for posterior placement; however the most posterior placement did limit extension. Anterior-posterior position of L4 endplate (opening or closing the facet capsule) relative to L5 plays a significant role in the motion available at the segment. Understanding the influence of TDR placement on range of motion and facet loading can improve functional outcomes of this procedure.

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Review of Adjacent Segment Degeneration in Patients who Have Had Laminectomy versus Laminectomy and Fusion

Y.-P. Lee1, P. Farjoodi2, R. T. Allen1, S. Garfin1
1UCSD Medical Center, San Diego, CA, USA

Introduction: Adjacent segment degeneration refers to the degeneration of an intervertebral disc above or below vertebrae previously fused together. In the normal spine, the intervertebral discs act as shock absorbers. The concern is that after a spinal fusion is performed, the disc above or below a fused level will have to absorb more stress, and may have accelerated wear and tear because of the increased forces placed on those discs. Surgeons may choose to perform a laminectomy to avoid the potential complication of adjacent segment degeneration. The purpose of this study is to compare patients who have had a laminectomy to those who had a laminectomy and fusion to determine if adjacent segment degeneration occurs in laminectomy patients, and if so at what rate relative to patients who had a fusion.

Methods: A retrospective chart review of all patient who had a laminectomy or laminectomy and fusion was performed. Patients were limited to a one or two level laminectomy or one or two level laminectomy and fusion. The fusions were performed by posterolateral instrumentation with iliac crest bone graft or transforaminal lumbar interbody fusion with BMP-2. The indications for fusion were due to spondylolisthesis. The levels were limited specifically to the L3 to L5 vertebrae. All patients were followed for at least 3 years.

Results: There were 26 patients in the laminectomy group. The mean age of the patients was 57.5 (±13.4) years of age. There were 18 males and 8 females. After 3 years of follow up, 2 patients in this group required surgery for adjacent segment degeneration. In the laminectomy and fusion group, there were 30 patients. The mean age of the patients was 66.2 (±9.6) years of age. There were 12 males and 18 females. There were 13 patients fused by transforaminal lumbar interbody fusion and 17 patients fused by posterolateral fusion. After 3 years of follow up, 2 patients required surgery for adjacent segment degeneration. Both of these patients had decompression and posterolateral fusion.

Using Student’s t-test, there was no significant difference in the rate of reoperation for adjacent segment degeneration for patients who had a laminectomy versus those who had a laminectomy and fusion (P=0.58).

Conclusions: The results of this study show that laminectomy patients are also at risk of developing adjacent segment degeneration. This may be due to
natural history. However, this may also be due to loss of stabilization as a result of the removal of the midline structures. The loss of stabilization from the spinous processes and inter-spinous and supraspinous ligaments may result in increased force transmitted to the adjacent segment. Based upon this finding, it would be worthwhile to consider a prospective study comparing laminectomy versus laminotomy and foraminotomy to determine the rate of adjacent segment degeneration. If so, an argument can be made for procedures that preserve the midline structures or for dynamic stabilization.

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24 Month Functional Outcomes from a US IDE Trial Evaluating a Lumbar Posterior Dynamic Stabilization (PDS) System with Inter Pedicel Travel (IPT)

N. Anand, T. Castellvi, K. Yonemura, S. Kitchel, B.C. Cheng, B. Robie

1 Cedars Sinai Medical Center, Los Angeles, CA, USA, 2 Florida Orthopaedic Institute, Tampa, FL, USA, 3 Washougal Neurological Surgery, Bountiful, UT, USA, 4 Orthopedic Spine Associates, Eugene, OR, USA, 5 Drexel University, Neurosurgery, Pittsburgh, PA, USA, 6 Robie Device Group, North Andover, MA, USA

Introduction: Pedicle screw based PDS systems are intended to offer stability and are used in conjunction with decompression to treat patients with degenerative lumbar stenosis. These devices offer patients a potential alternative to traditional decompression and fusion. This study reports 24 month clinical outcomes from an IDE trial for one-level symptomatic stenosis patients treated with the a PDS system that featured greater than one mm of IPT.

Methods: Patients with leg/back pain due to degenerative spinal stenosis were enrolled in a prospective, randomized clinical trial. Decompressive surgery was performed at a single level. The operative levels included L3 to S1. Patients were evaluated preoperatively and at six weeks, 3, 6, 12, 18 and 24 months postoperatively. Primary outcomes were ZCQ-SS (Symptom Severity), ZCQ-PF (Physical Function), VAS-R (Right Leg Pain), VAS-L (Left Leg Pain). Secondary outcomes included the ODI. Statistical evaluation compared preoperative outcomes to postoperative outcomes, using a paired t Test. Device failures and reoperations are also reported.

Results: 60 consecutive cases (35 females, 25 males) with mean age of 59.4 years were enrolled at 19 sites. Surgery was most often performed at the L4-L5 level. There was a highly significant improvement in all outcome measures in comparison to pre-op (p<0.001). There were six patients who had fractured grit-blasted screws and grit-blasting was found to be the root cause as it diminished the fatigue life of the titanium alloy screws. There was one reoperation for a potential disassembly which was found to be intact.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Pre-Op (mean ± sd)</th>
<th>Last Fw (mean ± sd)</th>
<th>p Value</th>
</tr>
</thead>
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<tr>
<td>ZCQ-SS</td>
<td>3.08 ± 0.64</td>
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<td>p&lt;0.001</td>
</tr>
<tr>
<td>ZCQ-PF</td>
<td>2.51 ± 0.55</td>
<td>1.64 ± 0.65</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td>VAS-L (symptomatic side)</td>
<td>75 ± 21</td>
<td>15 ± 29</td>
<td>p&lt;0.001</td>
</tr>
<tr>
<td>ODI</td>
<td>48.3 ± 13.8</td>
<td>13.1 ± 13.5</td>
<td>p&lt;0.001</td>
</tr>
</tbody>
</table>

[Table 1. Results]

Discussion: The data shows a significant improvement in patient based outcomes at 24 months following decompression and placement of a PDS device designed with greater than one mm of IPT. The screw failures identified in this trial forced a stop to the trial before significant numbers of control patients could be enrolled, thus preventing a comparison to an accepted control. The positive results found in this patient cohort support the underlying PDS technology. Further study of PDS systems is warranted with comparisons to a control population to prove the benefit of the technology.

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Retrospective Analysis of L5-S1 Axial Lumbar Interbody Fusion (AxiaLIF™), a Comparison with and without Use of Bone Morphogenetic Protein (rhBMP-2)

R. Nasca, W. Tobler, T. Raley, P. Gerszten

1 Trans-1, Wilmington, NC, USA, 2 Mayfield Clinic, Neurosurgery, Cincinnati, OH, USA, 3 Georgetown University Medical Center/Virginia Hospital Center, Orthopaedics, Arlington, VA, USA, 4 University of Pittsburgh Medical Center, Pittsburgh, PA, USA

Purpose: In this comparative analysis, the authors assess fusion rates and clinical outcomes of patients who underwent a presacral axial lumbar interbody fusion (AxiaLIF™) (TranS1, Wilmington, NC) at L5-S1 with posterior instrumentation, with or without rhBMP-2.

Study design: Retrospective case-matched chart review. A matched cohort of 99 patients underwent fusion performed by two surgeons at two institutions (2005-2007): specifically, 45 patients at The Christ Hospital received rhBMP-2 and 54 patients at the University of Pittsburgh had no rhBMP-2.

Methods: Data were collected prospectively. Demographic data, including sex and age, were matched. Pre- and postoperative Visual Analogue Scale (VAS) scores were recorded as were physiologic data on fusion rates, blood loss, and length of stay. Preoperative and postoperative Oswestry Disability Index (ODI) scores were obtained for patients treated with rhBMP-2. Odom’s outcome criteria were obtained at 2-year follow up for patients without rhBMP-2.

Results: During the 2-year follow-up period, patients noted reduction in back pain and improved functional outcome measures. Mean pre- and postoperative VAS scores improved 59% from 72.9 to 30.1 with rhBMP-2 and 72% from 81.3 to 22.6 without rhBMP-2. In rhBMP-2-treated patients, mean ODI scores were 54.4% preoperatively and 23.7% postoperatively, a 56.4% improvement at 2 years; 80% reported excellent to good outcome measures. Mean pre- and postoperative VAS scores improved 59% from 72.9 to 30.1 with rhBMP-2 and 72% from 81.3 to 22.6 without rhBMP-2. In rhBMP-2-treated patients, mean ODI scores were 54.4% preoperatively and 23.7% postoperatively, a 56.4% improvement at 2 years; 80% reported excellent to good outcome measures. Mean pre- and postoperative VAS scores improved 59% from 72.9 to 30.1 with rhBMP-2 and 72% from 81.3 to 22.6 without rhBMP-2. In rhBMP-2-treated patients, mean ODI scores were 54.4% preoperatively and 23.7% postoperatively, a 56.4% improvement at 2 years; 80% reported excellent to good outcome measures.

Conclusions: In our case-matched series, clinical outcomes were similar for patients who underwent an AxiaLIF L5-S1 interbody fusion with or without rhBMP-2.
### Dynamic Interspinous Spacer Implants vs. Discectomy for Treatment of Lumbar Degenerative Disease: A 18-month Follow-up Study

C.-H. Kao, S.A. Brau, R.B. Delamarter
1Department of Surgery, Chi Mei Medical Center, Yung Kang City, Taiwan, Republic of China, 2Center for General Education, Southern Taiwan University of Technology, Tainan, Taiwan, Republic of China

Object: Spinal discectomy (simple, cheap and effective resolve the uncomfortable) was common consider for stable lumbar degenerative disorders, but long-term follow up patient have some problems (loss the disc stability and increase the risk of secondary surgery) over the years. Most patients did not consider accessing the arthropathy surgery at the cost-effect factor. Interspinous process implants becoming more common an alternative for lumbar degenerative disease. This report of our experience updates the surgical results of using the Dynamic interspinous spacer implants.

Methods: 99 Patients with degenerative disease were indicated for the simple one-level operation from June 2007 to February 2010. The patients received surgery with discectomy or combined with the DIAM™ system. The patients involved due to disc hernia, foraminal stenosis, and excluded infection, spondylolisthesis, and fracture. We compared the surgical results (followed up 1.5 to 4 years) of the pre- and post-JOA index, pain score (VAS), ODI, the blood loss, post-operative analgesic usage, and the rate of second-surgery.

Results: 49 patients (F/M=14/35, ave. age 46.46 years, 20~79 years) operated by discectomy with the DIAM™ system, and 50 patients (F/M=15/35, ave. age 42.79 years, 22~77 years) operated with discectomy. The mean postoperative follow-up period was 2.72 years (19 to 57 months). On the group surgery with DIAM™ system, the average post-operative analgesic usage (31.73 to 24.27 days) and operation times (2.06 to 1.35 hours) were significantly increased than the group surgery with discectomy. The improved lumbar-JOA (26.1 to 29), VAS (3.6 to 1.3) and blood loss (121.88 to 90 ml) were no significantly between two groups. The DIAM™ system was no morbidity related to device, and 2 patients operated by discectomy associated with second-surgery.

Conclusions: In this study, the patients treated with the DIAM interspinous spacer did not show any morbidity or complications, were significantly better than the group surgery with discectomy (4%). Early-term results (up to 1.5 years) are encouraging with no implant loosening or fracture of spinal process. A longer follow-up period of 5 to 10 years in this device is necessary to investigate the post-operative complications. At present, the DIAM interspinous spacer has the advantage of no complications, and patients will have another choose surgical way.

### Anterior Lumbar Surgical Revisions with Anti-adhesion Barrier in Place

S.A. Brau, R.B. Delamarter
1Spine Access Surgery Associates, Los Angeles, CA, USA, 2Cedars Sinai Spine Center of Excellence, Los Angeles, CA, USA

Purpose: To present findings encountered during three revisions in which an anti-adhesion barrier was implanted during index anterior lumbar surgery.

Method: A 34 y/o male had 3 level arthroplasty (L3-S1) 16 months prior. BMI was 31.6. On 8 June 2010 the patient underwent removal of the L5-S1 prosthesis and fusion. BMI at revision was 37.3. Revision was performed via right-sided retro-peritoneal approach. A 36 y/o female had an L4-5 arthroplasty 20 months prior. On 12 October 2010 she had removal of the prosthesis and fusion. BMI was 22.5. Revision was via left antero-lateral retro-peritoneal (ARPA) approach. A 55 y/o male, BMI 26, had an L3-4 ALIF on 23 July 2009 3 yrs and 5 mo after initial L4 to S1 ALIF.

Findings: In the L5-S1 revision, entering the retroperitoneal space on the right side presented no significant problem. The right iliac vessels and ureter were easily identified. Upon reaching the promontory loose adhesions were found overlaying the disc space. Easy mobilization of the adhesions lead to the barrier, which was then incised and easily separated from the underlying tissues by blunt dissection. In fact, the barrier material was completely removed leaving behind a clear plane providing excellent re-exposure of the L5-S1 disc space. The approach took about 25 minutes with no significant blood loss. The prosthesis was removed and replaced with a stand-alone interbody cage. The case took one hour with no significant blood loss.

In the L4-5 revision the ARPA approach led to the psoas and there dissection became difficult leading to the disc space. Upon reaching the disc space, the barrier was found and removed for easy exposure of that disc space. Exposure took 30 minutes. The prosthesis was removed and fusion performed. The case took 70 minutes.

In the L3-4 revision via ARPA approach, the barrier was found at the level of the mid body of L4 and lifted away to easily establish good exposure at L3-4 without stretching the iliac vessels. The exposure took 20 minutes and the entire case took under 1 hr.

Conclusions: Lately the use of anti-adhesion barriers has been advocated to make revision of anterior lumbar surgery less challenging. Three devices are approved in the U.S. When comparing these revisions with cases where a barrier was not placed, the barrier was effective in facilitating return to a previously instrumented or adjacent disc spaces. The adhesions to the barrier itself were flimsy and easy to separate with blunt dissection. After identifying the barrier it was easily separated from surrounding tissues, including the iliac vessels, also with blunt dissection and relative ease. This created a clear area, which was the same size as the barrier itself (5 x 6 cm) and which provided sufficient exposure for re-instrumentation.

Revisions of a previously instrumented or adjacent disc spaces continue to present significant challenges to the spinal access surgeon. These cases illustrate the benefit obtained from the use of an anti-adhesion barrier and may be indicative of their value.
Lumbar Therapies

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Degenerative Lumbar Disease Surgery Outcomes in Elderly Patients
D. Pérez Prieto, M. Ramirez, C. Lozano, G. Saló, M. Anton, L. Andreu
1Hospital del Mar, Orthopaedic Surgery, Barcelona, Spain,
2Hospital del Mar, Barcelona, Spain

Background: There is limited data for quality of life outcomes in older patients who underwent surgery for degenerative lumbar disease. Recent studies seem to suggest that there are no differences in clinical outcomes between older and younger patients.

Purpose: To evaluate the differences in disability, quality of life and satisfaction between patients under 65 (group 1) and patients who were 65 years or older (group 2) treated for degenerative lumbar disease.

Design: Retrospective review of prospectively collected outcomes of patients who underwent surgery for degenerative lumbar disease.

Methods: We studied 263 patients, mean age of 54.0 years old (22-86/y/o). Of them, 131 patients were women (49.8%). 189 (71.87%) were under 65 years old and 74 (28.13%) were 65 years old or older. We evaluated the questionnaires mentioned above before surgery and at 2 years time. Differences between both groups were analyzed using parametric Mann-Whitney U test in quantitative variables and Ji square or Fisher’s exact for categorical data. Association between two quantitative variables was measured using Rho Spearman correlation.

Results: We observed an improvement from baseline in all quality of life measures in the two age groups. The statistics studies did not show relevant differences in other epidemiological factors between both groups of age (p>0.05). In group 1 patients median improvement of ODI was found in ODI versus 12.00 in group 2. Median improvement of SF36 PCS in group 1 was 6.95 while 12.00 improvement was reported in group 2. The SF36 MCS improved 4.48 points in group 1 and 4.96 points in group 2. In terms of treatment satisfaction, 66.9% of younger patients were pleased or very pleased whereas this could be found in 59.7% of elderly. In the ≥65y/o group there was a significant better outcome (32.89%) in the Emotional Role of SF36 points versus 11.33 in group 2 (p< 0.001). There were no other significant differences in the rest of the outcomes (p>0.05).

Conclusions: Since this study shows there are no differences in quality of life improvement outcomes between older and younger than 65 y/o patients, we can conclude that age should not be a contraindication for surgery in aged patients with degenerative lumbar disease, taking quality of life as a reason.

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Adjacent Level Degeneration after Lumbar Total Disk Replacement with Average of 60 Months Post Op
K. Zhang, F. Mo, M. Pumberger, C. Abjomson, G. Girardi, J. Yue, F. Cammisa
1Yale New Haven Hospital, New Haven, CT, USA, 2Hospital for Special Surgery, New York, NY, USA

Objective: To quantify the long term risks of adjacent segment degeneration in patients who have undergone lumbar disk replacement.

Summary of background data: Motion preservation of the lumbar spine through lumbar disk replacement ideally maintains physiological range of motion. We hypothesize, that lumbar disc replacement decreases the risk of adjacent level disease, compared to instrumented fusion of the lumbar spine. However, there is controversy regarding the rate of adjacent level change after lumbar disc replacement and paucity of long term follow-up. A retrospective study was preformed to investigate whether adjacent level disease is influenced by motion preservation techniques.

Methods: Forty-two patients who underwent lumbar total disc replacement from October 2001 to July 2003 met the inclusion criteria. We collected patient demographics, surgical level, pre and post op range of motion, implant characteristics, patient outcomes and rates of adjacent level changes. Radiographs were analyzed to look for adjacent level degeneration preoperatively and at the time of last patient visit. Disk height was measured and compared along with vertebral body endplate changes as a marker of adjacent level degeneration. Preoperative and postoperative patient VAS and ODI data and intraoperative surgical variables were analyzed to explore the potential association with outcomes.

Results: All patients received Prodisc-L implants. There were 18 male and 24 female patients. Average patient age was 40.2 years. Thirty-two patients underwent 1 level disk replacement, one had L3-4, four had L4-5, and twenty had L5-S1. All of the two level procedures were L4-S1. The average follow-up was 60 months (range 28-93), VAS decreased 39% (69.3 to 42.5) and ODI decreased 43% (60.7 to 34.6). Two patients (4.7%) were found to have adjacent level degeneration above the level of lumbar disk replacement (L5-S1); nevertheless, their ODI declined from 46 to 25 and VAS declined from 53.8 to 48.2. Range of motion, level of surgery, pre operative disk height, implant size and lordosis were not found to be associated with adjacent level degeneration.

Conclusions: The rate of adjacent level change of lumbar disk replacement was 4.7% at an average of 60 months post op. There appears to be no correlation between pre and post operative ROM or implant characteristics with arthritic failure of the adjacent segment.
Closing the Barn Door: Can an Endoprosthesis Prevent Reherniation and Loss of Disc Height?

M. Vilendecic1, D. Ledic2, G. Grahovac1, D. Vukas2
1University Hospital Dubrava, Zagreb, Croatia, 2University Hospital, Rijeka, Croatia

Introduction: Closing an anular defect with a mechanical barrier may reduce the incidence of re-herniations and maintain disc height by retaining nuclear material. The purpose of this single-arm, prospective, multi-center study was to evaluate the safety and performance of an anular closure device (ACD). Comparison to a single-arm, prospective, multi-center study of similar discectomy patients allowed evaluation.

Methods: 30 primary discectomy patients were treated with the ACD at two Croatian sites. Inclusion criteria included 6 weeks of conservative treatment, ODI and VAS leg scores ≥ 40/100, and radiographic confirmation of herniation. Follow-up visits included VAS, ODI, x-rays at 6 wks, 3, 6, 12, and 24 months, and MRIs and CT at 12, 24 months. The ACD consisted of a woven-polyester mesh intended to close an anular defect secured to the adjacent vertebral body by a titanium bone anchor. 46 control cohort patients were used in the evaluation as they directly matched the Barricaid cohort by site, surgeons, and inclusion/exclusion criteria.

Results: In the ACD cohort, 29 (97%) patients have completed 24 months follow-up with one patient lost to follow-up. There have been no serious adverse events that were associated with the device by the 24 month timepoint. Symptomatic reherniation rate at 24 months was 0% in the ACD group versus 6.5% in the control group. 24 months clinical outcomes of ACD versus Control: VAS back 10.5 vs. 20.9, p=0.1257; VAS leg scores 8.9 vs. 18.3, p=0.0100; and ODI scores 11.6 vs. 20.9, p=0.0687 (Wilcoxon Rank-sum). Defining clinical significance as a reduction of ≥20 points in VAS or ≥15 points in ODI, 97% of implanted patients exhibited clinically significant reductions in VAS leg (vs. 96% control) and 100% in ODI (vs. 87% control, p=0.0800 1-Sided Fisher’s Exact). 97% of ACD patients demonstrated a clinically significant reduction in VAS back (vs. 70% control, p=0.016 1-Sided Fisher’s Exact). At 24 months, the ACD group maintained an average of 88.5% of their preop disc height, (vs. 85.1% for the control group p=0.2092 unpaired t-test).

Discussion: Implantation of an ACD has demonstrated preliminary safety and effectiveness in these patients, with no implantation complications and no serious adverse events related to the device by the 24 month timepoint. Although this is an early analysis of a limited number of patients, to date the device is preventing reherniation and exhibiting excellent clinical outcomes; further investigation is warranted.

166 Selective Decompression and Inter-laminar Dynamic Stabilization for the Treatment of Degenerative Lumbar Stenosis: Clinical Application and Complications

Y. Hai1, S. Lu1, L. Zang2
1Chaoyang Hospital, Capital Medical University, Orthopedic Surgery, Beijing, China

Background: The decompressive laminectomy with fusion with or without instrumentation was mainstay of surgical management for lumbar stenosis. However, fusion poses various problems especially adjacent segment disease. To overcome shortcomings associated with fusion, concept of dynamic stabilization was introduced and a number of devices have been developed.

Objectives: To evaluate the efficacy of the treatment of degenerative lumbar stenosis utilizing Coflex inter-laminar dynamic stabilization, a retrospective study was conducted and the indication and complications of this technique were discussed.

Methods: In a period of two years which was between September 2007 and August 2009, 78 consecutive patients with degenerative lumbar stenosis were treated with posterior selective decompression and inter-laminar dynamic stabilization utilizing Coflex. There were 31 male and 47 female with an average age of 54.8 years old (38-81). All patients were with radiculopathy or neurological claudication with or without low back pain pre-operatively and were confirmed diagnosis of degenerative lumbar stenosis by imaging study (CT and MRI). VAS and Oswestry score, ROM, complications and patients’ satisfaction were evaluated pre and post operatively.

Results: All patients underwent the procedures safely. There were 76 patients with one level Coflex implantation and 2 patients with two levels. The average surgery time was 78 mins (60-110). The average blood loss was 210ml (180-350). There were no major complications (nervle injury, etc.) occurred intro-operatively. The patients were evaluated for follow up of clinical and radiographic outcome at 1, 3, 6, 12 and 24 months post-operatively. All patients were followed up for at least 24 months. The average VAS score and Oswestry Disability Index were improved 90.1% and 87.4 %. The disc space height and ROM of the index level was well maintained. The complications were occurred in 11 patients (12.8%). The device related complications (7.8%) included two cases of fractures of spinous process, three cases of migration of the implant and one case of instability of index segment. No revision procedure was performed due to mild symptom with those six patients. Other complications included one dural tear, one delayed discitis, one delayed deep infection and two superficial infections. Two patients underwent revision surgery for the infection and discitis. At the latest follow up, 86% of patients were satisfied with their results.

Conclusion: Satisfactory clinical and radiographic outcome could be achieved in patients with degenerative lumbar stenosis treated by decompression and Coflex implantation. To avoid complications, attentions must be paid of careful selection of the patient, implantation of the device at proper size, and adequate decompression. From our experience, inter-laminar dynamic stabilization with Coflex is an effective therapy for the treatment of single or double levels degenerative lumbar stenosis.
Does Two Level 360° Lumbar Spinal Fusion Improve Long-term Clinical Outcomes after Failure of Conservative Treatment in Patients with Functionally Disabling Two Level Degenerative Lumbar Disc Disease? Results of 5 Year Follow-up in 62 Randomized Postoperative Patients

**Introduction:** The authors report five-year results of outcomes and radiographic findings in patients enrolled in a prospective multicenter study in which they were randomized to circumferential fusion for two-level lumbar degenerative disc disease (DDD).

**Methods:** Patients with symptomatic two-level DDD who failed at least 6 months of conservative therapy were treated with 360° circumferential fusion. Inclusion criteria were: DDD at two contiguous vertebral levels between L3-S1, failed conservative treatment for a minimum of six months, back and/or leg pain, and a minimum ODI score of ≥ 40% impairment. The average patient had pain VAS > 7/10, ODI of 64.8%, and was symptomatic for more than 12 months. A total of 72 were treated with fusion. Four patients were lost to follow-up, and six had secondary surgeries and are excluded from analysis. The 62 patients followed for 5 years with complete data are reported in this post-hoc analysis.

**Results:** At five years, Fusion patients maintained statistically significant improvements in ODI score compared to baseline (p < 0.0001). Mean preoperative ODI scores averaged 63%. Sixty-four percent had ≥15% improvement in ODI score at two years, and 54.9% had ≥15-point improvement in ODI scores. Patients demonstrated statistically significant improvements in VAS pain scores at both two years and five years compared to baseline (p < 0.0001). VAS satisfaction scores were 67.3±31.5 at two years and 77.5±26.8 at five years. At two years, 70.0% of patients experienced maintenance or improvement in SF-36 PCS. At five years, 72.6% maintained or improved SF-36 PCS compared to baseline. Of patients who maintained or improved SF-36 PCS compared to baseline at two years, 83.3% maintained or improved at five years. Neurologic success was defined as maintenance or improvement to all neurologic criteria: sensory, motor, reflexes, and straight leg raise test. At two years, the Fusion group demonstrated success in 81.4% (57/70 patients). Compared to two years, the percentage of patients achieving overall neurologic success at five years increased (43/48 patients, 89.6%). Five radiographic outcome components, determined by independent radiologists, refer to qualitative evaluations of device migration, device subsidence, disc height maintenance, fusion status, and radiolucency. High success scores were attained. Radiographic fusion rates were 97.1% and 95.6% with available films at two and five years, respectively. All patients had < 3 mm translation and < 5° of flexion/extension motion on five-year radiographs.

**Conclusions:** This post-hoc analysis shows the benefits of Fusion in appropriately selected patients. Highly disabled patients were treated successfully with spinal fusion, measured by various outcome measures. Their improvements following surgery remained stable. This study supports that, in an appropriately selected patient, spinal surgery is a good treatment option for improving multiple parameters for life quality.

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**Clinical Outcome of Stand-alone Anterior Lumbar Interbody Fusion**

**Aim:** The use of anterior lumbar interbody fusion (ALIF) without supplemental posterior fixation has been debated. Over the course of several years, many new options for interbody fusion implant designs and material as well as graft materials have evolved. The purpose of this study is to examine patient outcomes following stand-alone ALIF.

**Methods:** A review of the surgery logs at a single spine specialty center identified 98 patients who had undergone stand-alone ALIF. Only patients with minimum 12 month follow-up were included in this study. Patients were excluded if any posterior instrumentation was used, the procedure was part of an ALIF/total disc replacement hybrid procedure, or if the ALIF was performed following a previous posterior fusion. The primary diagnosis was symptomatic disc degeneration. Some patients also had Grade I spondylolisthesis or disc space narrowing and/or instability following a previous laminectomy/discectomy procedure. If the patient had not been recently seen in the clinic for follow-up, a questionnaire was mailed to them including a visual analog scale (VAS) to assess back and leg pain, an Oswestry Disability Index, and asking patients if they had undergone subsequent surgery (in the event the surgery was performed at another facility). Clinical data were collected from patient charts, including general demographics: gender, age, body mass index, operative level(s), estimated blood loss, access surgeon, previous surgery, graft material used, implant type, complications, reoperations, and the pre-operative Oswestry and VAS scores. The majority of cases involved the use of a PEEK fusion cage and BMP or other biological based graft materials.

**Results:** The patients’ ages ranged from 23 to 79 years with a mean of 45.9. The mean body mass index was 27.5. Single-level ALIF was performed in 94.8% of cases, with the majority being at L5-S1 (66.7%). The mean blood loss was 79.8 ml. Complications including two cases of intra-operative vascular injury (neither with serious sequel) and 3 superficial wound infections. There were two re-operations: one was a posterior lumbar fusion to treat a failed ALIF, and one patient received a spinal cord stimulator for pain management. There were significant improvements in the Oswestry and VAS pain scales (p < 0.05; see table).

<table>
<thead>
<tr>
<th></th>
<th>Pre-op</th>
<th>Post-op</th>
<th>Significance</th>
<th>% improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oswestry</td>
<td>48.4</td>
<td>21.4</td>
<td>p&lt;0.01</td>
<td>55.1%</td>
</tr>
<tr>
<td>VAS back pain</td>
<td>6.1</td>
<td>3.1</td>
<td>p&lt;0.05</td>
<td>49.2%</td>
</tr>
<tr>
<td>VAS leg pain</td>
<td>5.0</td>
<td>2.6</td>
<td>p&lt;0.05</td>
<td>48.0%</td>
</tr>
</tbody>
</table>

**Conclusions:** The results of this study found a significant improvement in Oswestry as well as back and leg pain scores following stand-alone ALIF. The need for re-operation was low. These findings suggest that stand-alone ALIF can produce good outcomes and may be a viable alternative to the use of supplemental posterior fixation in the absence of pathology requiring a posterior approach to address.
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The Incidence of Intercalary Pseudoarthrosis in Second Generation Anterior Lumbar Interbody Devices: A Prospective Study
J.J. Yue1, J. Du1, R. Arunakul1
1Yale University School of Medicine, Orthopaedic Surgery, New Haven, CT, USA

Background content: Anterior interbody lumbar fusion (ALIF) is a commonly used procedure for treating lumbar bone disease processes. In the past, this procedure has been performed using cortical ring allografts or cylindrical cages coupled with supplemental posterior fixation. Recently, stand alone devices ALIF devices without posterior supplemental fixation have gained popularity in the treatment of lumbar segmental pathology.

Purpose: To assess the efficacy of stand alone ALIF devices in the treatment of lumbar disc degeneration associated with lumbar spondylosis.

Study design/setting: Patients were evaluated from a single site/single surgeon using the LDR ROI-A or Synthes Synfix devices with autograft cancellous bone for single or double level symptomatic lumbar spondylosis from L2 to S1.

Patient sample: A total of 31 patients were evaluated. 24 single level patients and 7 double level patients were included in this evaluation. A total of 38 devices were used including 23 ROI-A and 15 Synfix devices.

Outcome measures: Patients were evaluated employing the Oswestry Disability Index (ODI), Visual Analog Scales (VAS) at pre-op, 6 months and 1 year post-op. Pre-op xray, CT, and MRI was performed. Post-op xrays and CT (1yr only) scans were performed.

Methods: Primary inclusion criteria was discogenic pain with or without radicular pain confirmed by clinical evaluation, radiographic imaging, and CT/discography. Back pain persisted for at least 1 year with unsatisfactory results from conservative care. All patients underwent either a right or left sided paramedian anterior retroperitoneal approach. An ALIF device packed with autologous bone graft was placed without supplemental posterior or non-implant related anterior fixation. Student's paired T-test was performed to assess.

Results: Average age of all patients was 46.5 years old. Mean follow-up was 19.2 months. Overall complete radiographic fusion occurred in 84% of all levels treated. In 16% of cases, an intercalary pseudoarthrosis (ICPS) occurred in which complete bridging of the proximal and distal sides of the fusion mass did not unite. In all cases, bony bridging was accomplished at the distal and proximal endplate interfaces. 87% of patients note improvement in their outcome related scores (VAS back p<0.0001, VAS legs p=0.3), and ODI p<0.002). In those patients with intercalary.

COMPLICATIONS: One LDR cage experienced a single sided fin fracture. Two intercalary pseudoarthroses were symptomatic and required supplemental posterior fixation (one 1 level LDR and one 2 level Synfix).

Conclusions: Intercalary pseudoarthroses occurred in 16% (6 levels) of all stand alone index levels. Two of these patients required posterior fusion. One patient required posterior fixation for device related fixation failure. Overall, clinical success in 87% of patients with good to excellent clinical outcomes. In 2/3 of patients the presence of ICPS was asymptomatic both clinically and radiographically at an average follow-up of 19 months.

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Contralateral Motor Deficit Following Extreme Lateral Interbody Fusion
F. Taher1, D.R. Lebl1, A.P. Hughes1, M. Pumberger1, R.R. Huang1, A.A. Sama1, F.P. Cammisa1, F.P. Girardi1
1Hospital for Special Surgery, Spine Service, New York, NY, USA

Purpose: To report on the rare finding of motor deficit contralateral to the approach site in patients who underwent extreme lateral interbody fusion (XLIF) and to discuss the clinical course and possible reasons for this complication. To define an incidence of contralateral neurological deficits following an XLIF approach.

Summary of background data: There is a growing body of literature about sensorimotor deficits ipsilateral to a transpsoatic surgical approach. However, there is a paucity of data on motor deficits contralateral to an XLIF approach. To date, there has only been one prior report of two patients with contralateral motor deficits following XLIF.

Methods: The electronic medical records and radiographic imaging studies of 240 patients, mean age at surgery 61.5 years, 98 male and 142 female, who underwent XLIF at our institution between 2006 and 2009 were retrospectively reviewed for reports on motor deficits which occurred contralateral to the surgical approach. We discuss possible reasons for this rare complication with consideration to unique patient anatomy and surgical technique.

Results: Of the patients reviewed, 2.1% (5/240) presented with a postoperative motor deficit contralateral to the site of surgical approach, the most severe of which presented as a 1/5 weakness of the quadriceps muscle. An average of three levels (range 2-4) were fused in the five patients who developed a contralateral motor deficit and in three of the five patients an anterior decompression and interbody fusion (ALIF) was performed in addition to the XLIF. At the one year time point, two patients presented with complete resolution of their muscle weakness, one patient still suffered from mild weakness and one patient had decreased range of motion in the affected joint. One remaining patient was lost to follow-up two weeks postoperatively.

Figure 1 shows a representative image for an exuberant inflammatory response to bone morphogenic protein (BMP) contralateral to the transpsoatic approach in a patient who underwent XLIF at our institution and subsequently developed a motor deficit.

[Figure 1]
Conclusion: This data is the largest report of contralateral motor deficits in patients who underwent XLIF by a transpsoatic approach. We define an incidence for this rare complication, which can play an important role in surgical consideration and preoperative patient counseling regarding risk for this complication. Possible underlying mechanisms include entrapment of the contralateral nerve root through translational correction of spondylolisthesis, front-to-back misalignment of the cage resulting in an oblique cage, as well as a direct neurapraxia during release of the contralateral annulus. Axial traction on the nerve root from restoration of the anterior column by means of cage implantation, as well as an abundant inflammatory response to BMP are other possible etiologies of contralateral motor deficit after XLIF. Peroneal nerve compression through lateral positioning during surgery, as well as damage to the nerve root caused by retraction for concomitant anterior procedures (ALIF) are additional mechanisms that deserve consideration.

515 Prevalence and Influence of Depression and Anxiety among Chronic Low Back Pain Patients Undergoing Surgery for Lumbar Degenerative Conditions: Initial Findings from the SAD-Back Project (Screening for Anxiety and Depression in Back Pain Patients)  
M. Hanna1, T. Errico2  
1Mercury Spine Healthcare Consulting, Middletown, CT, USA, 2New York University Hospital for Joint Diseases, New York, NY, USA

Background: Surgery is often highly successful in relieving low back pain attributed to lumbar degenerative conditions. Nonetheless, about 15-45% of patients do not show meaningful clinical improvement. These unsuccessful cases can generate bad publicity for spine surgery and make it difficult to secure insurance coverage for surgical treatment of lumbar degeneration. It is widely thought that many of these patients do not improve because of psychiatric co-morbidity or other psychosocial health factors.  

Purpose: The purpose of the SAD-Back project is to explore whether specific subtypes of depression and/ or anxiety can predict which back-pain patients will not benefit from surgery. This abstract reports the initial pilot study findings on the preoperative prevalence and influence of depression and anxiety from the first study site.  

Methods: The study is designed to be a prospective multicenter patient registry. Adult patients with degenerative conditions at 1-2 levels scheduled for first-time lumbar surgery were eligible. Baseline data includes: sociodemographics, medical history, back pain (VAS), disability (ODI), depression - Center for Epidemiological Studies Depression scale (CES-D), and anxiety - General Anxiety Disorder screener (GAD-7).  

Results: By Aug 2011, the study had enrolled 68 patients, equally men and women, with a median (range) age of 52 (27-85). Relevant social and medical factors are summarized in the table. The distribution and correlation of baseline scores for back pain, disability, depression, and anxiety are visualized in the figure. There were 21 of 66 patients (32%) suffering from subclinical depression (CES=16-26), while another 10 of 66 (15%) were diagnosable as depressed (CES=27+). There were 13 of 67 patients (19%) experiencing mild anxiety (GAD=8-14), and another 6 of 67 (9%) suffering severe anxiety (GAD=15+). Interestingly, among the 27 patients who screened positive for depression and/or anxiety and had complete medication data available, only 6 (22%) were taking any kind of psychiatric medication. In multivariate linear regression, pain (VAS) and anxiety (GAD-7) were not significantly dependent on any other tested variables. Disability (ODI) was predicted strongly by being depressed (p< 0.001), older (p=0.024), disk herniation (p=0.004), stenosis (p=0.077), and problem drinking (p=0.002), but inversely (and paradoxically) by having two-level spinal diagnoses (p< 0.001) and being overweight/obese (p=0.010). Depression was predicted by disability (p=0.067), use of opiate pain medication (p=0.017), and being overweight/obese (p=0.019).  

Conclusions: Depression and anxiety are common among patients seeking surgery for degenerative lumbar spinal conditions. These co-morbidities seem to seldom be receiving psychiatric treatment. Most importantly, although back pain appears to affect all types of patients equivalently, the severity of a patient’s disability (ODI) appears to be strongly dependent upon other psychosocial health issues including depression, age, and drinking problems. This might suggest that even if surgery successfully treats the lumbar source of pain, patients with these other psychosocial health problems will remain disabled.
Introduction: The objective of our study is to determine if measured arterial blood pressure and estimated blood loss (EBL) are correlated, in lumbar surgery. Our study was a retrospective and observational study. Hypotensive anesthesia is requested by many spine surgeons during lumbar surgery to minimize blood loss and improve visualization of the surgical field. This request is based on the belief that blood pressure is correlated to blood loss. However, there are conflicting findings in the literature about what affects blood loss the most in lumbar surgery. Some of these findings include venous pressure and surgery time. These examples of conflicting findings suggest that there are probably more variables involved in determining what affects blood loss. Our study aims to add to the body of evidence that currently exists in determining the variables that affect blood loss in lumbar surgery.

Methods: Upon obtaining IRB approval, we conducted a retrospective chart review of 120 patients who had undergone lumbar surgery at one institution by one spine surgeon within the last 5 years. We obtained their anesthesiology records to retrieve their blood pressure and EBL data. Blood pressure was obtained as 4 variables for each patient during the case, namely, maximum systolic pressure, minimum systolic pressure, average systolic pressure, and average mean arterial pressure. We used linear regression analyses to find statistically significant correlations in our data.

Results: The estimated blood loss ranged from 100 ml to 3700 ml within our dataset consisting of 120 patients. Initially, no statistically significant correlations were found between EBL and any of our 4 blood pressure variables were found. However, when we narrowed our dataset to contain only patients with an EBL above 1000 ml, we found a statistically significant strong correlation between EBL and average mean arterial pressure and average systolic pressure (p-values=0.025, 0.035, respectively).

Discussion: Our data suggests that there is no correlation between blood loss and blood pressure when the blood loss is low. We, however, found correlations between blood loss and blood pressure when the blood loss was over 1000 ml. To further clarify, the two blood pressure variables that showed statistically significant correlations were average systolic pressure and average mean arterial pressure. Maximum and minimum systolic pressure did not yield statistically significant correlations. This might be because surgery is a continuous event and transient fluctuations in blood pressure do not have a significant effect on blood loss. To the surgeon, blood pressure is not of great concern in lumbar surgery when the blood loss is minimal, but when the blood loss is high the surgeon is much more concerned about blood pressure. As our data suggests that blood loss is positively correlated to blood pressure in larger or longer cases, i.e. high blood loss cases, it is important to consider using controlled hypotensive anesthesia to reduce blood pressure so that blood loss is minimized. As a limitation, we recognize that our dataset was small and we believe that larger studies could help in further elucidating this observation.

359 A Peri-operative Cost and Charge Analysis Comparing Single-level Minimally Invasive and Open Transforaminal Lumbar Interbody Fusion

K. Singh1, F.M. Phillips2, M.A. Pelton1, G. Andersson3, D. Isayeva2

1Rush University Medical Center, Orthopaedic Surgery, Chicago, IL, USA, 2Rush University Medical Center, Chicago, IL, USA

Study design: A financial analysis of cost, charge and payment data.

Background data: Emerging literature suggests superior clinical outcomes of MIS (Minimally Invasive Surgery) TLIFs (Transforaminal Lumbar Interbody Fusion) compared to open fusions. Few studies to date have analyzed the cost and payment differences between the two techniques.

Objective: To determine the differences in hospitalization costs and payments for patients treated with primary single-level minimally invasive (MIS) versus open transfational lumbar interbody fusion (TLIF). The impact of clinical outcomes and their contribution to financial differences was explored as well.

Methods: 66 consecutive patients undergoing a single-level TLIF (open/MIS) were analyzed. Thirty-three patients in each cohort (MIS/Open) were matched based on race, sex, age, smoking status, medical co-morbidities (Charleston disability index), payor and diagnosis. Every patient in the study had a diagnosis of either degenerative disc disease or spondylolisthesis and stenosis. Statistical analysis was conducted using SPSS Statistics version 16.0.

Outcomes measures: Hospital costs (direct and indirect) as well as charges and payments were recorded. Operative time (minutes), length of stay (LOS, days), estimated blood loss (EBL), anesthesia time (minutes) were measured (Table 2).

Results: Average surgical time was shorter for the MIS than the Open TLIF group (113.5 vs186 minutes; p=0.001). Length of stay was also reduced for the MIS versus the Open group (2.0 days vs 2.9 days; p < 0.001). Average anesthesia time and EBL was also lower in the MIS group (p<0.001). Financial analysis demonstrated lower total hospital costs in the MIS versus the Open group ($27,321 v. $33,312 respectively; p < 0.001) (Table 1). Direct hospital costs (blood, imaging, implant, lab, pharmacy, PT/OT/Speech, room and board) were also lower in the MIS cohort ($19,224 v. $23,550, p < 0.001). Implant costs were similar (p=0.812) in both groups with these accounting for about two-thirds of the hospital direct costs in the MIS cohort ($13,714) and half of these costs ($13,778) in the open group. Hospital payments were $9,093 higher for open TLIF patients compared to the MIS group ($47,182 v. $38,090 respectively) (p=0.132).

Conclusions: MIS TLIF technique demonstrated...
significant reductions of operative time, LOS, anesthesia time, and EBL compared to the open technique. This reduction in peri-operative parameters translated into lower total hospital costs. Implant costs was the largest single cost driver for either procedure. Although hospital reimbursements are higher in the open group, shorter surgical times and length of stay days with the MIS technique provide opportunities for hospitals to reduce utilization of resources and to increase surgical case volume.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Patient Demographics</th>
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<tbody>
<tr>
<td>Race</td>
<td>MIS (n=33) N (%), Mean ± SD</td>
</tr>
<tr>
<td>White</td>
<td>23 (69.7%) 20 (60.0%)</td>
</tr>
<tr>
<td>Black/African-American</td>
<td>4 (12.1%) 7 (20.0%)</td>
</tr>
<tr>
<td>Hispanic/Latino</td>
<td>4 (12.1%) 6 (17.1%)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (3.0%) 1 (3.0%)</td>
</tr>
<tr>
<td>Gender</td>
<td>Male</td>
</tr>
<tr>
<td>Age at admission (years)</td>
<td>MIS</td>
</tr>
<tr>
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<tr>
<td>SRS</td>
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<table>
<thead>
<tr>
<th>Table 2</th>
<th>Comparison of Clinical Outcomes</th>
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</thead>
<tbody>
<tr>
<td>Length of Stay</td>
<td>MIS (n=33) N (%), Mean ± SD</td>
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<tr>
<td>Surgical Time (min)</td>
<td>2.0 ± 0.8</td>
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<tr>
<td>Anesthesia Time (min)</td>
<td>179.9 ± 35.7</td>
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<tr>
<td>Estimated Blood Loss (ml)</td>
<td>127.2 ± 54.3</td>
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<thead>
<tr>
<th>Table 3</th>
<th>Comparison of Hospital Costs</th>
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</thead>
<tbody>
<tr>
<td>Hospital Direct Costs</td>
<td>MIS (n=33) N (%), Mean ± SD</td>
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<tr>
<td>Medical</td>
<td>180.91 ± 55.04</td>
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<tr>
<td>Direct Cost (Implant)</td>
<td>96.9 ± 47.04</td>
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<tr>
<td>Direct Cost (Surgeon)</td>
<td>11.66 ± 1.85</td>
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<tr>
<td>Total Cost</td>
<td>213.7 ± 63.7</td>
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**Introduction:** Previous studies have shown AxiaLIF to be a safe minimally invasive L5-S1 interbody fusion with significant reduction in blood loss, operative times, and morbidity and complication rate as compared to more invasive open surgeries such as ALIF, PLIF or TLIF. Moreover, iliac bolt fixation is a well-known surgical procedure to reduce lumbar sacral strain at the base of a long segment spinal fusion. In this study we assess if AxiaLIF can prevent the need for iliac screw fixation, which has a significant complication rate.

**Methods:** This is a retrospective study of 45 consecutive patients who underwent AxiaLIF lumbar sacral fusion at the base of a long construct (3 or more levels) in correction of thoracolumbar deformity. Deformities included Idiopathic Scoliosis (10), Degenerative Scoliosis (30), and Iatrogenic Scoliosis (5). All patients underwent a combination of 3 MIS techniques: Posterior instrumentation (44), DLIF (43) and AxiaLIF (45). None of our patients underwent iliac screw fixation. Fusion was augmented with local bone, RhBMP2 and Grafton Putty both in the interbody space and the facets posteriorly. Radiographs, Visual Analog Score (VAS), treatment Intensity Scores (TIS), SF-36, Oswestry Disability Index (ODI) were assessed preoperatively and at each postoperative visit.

**Results:** Mean follow up was 27 months (range 2-50 months) with greater than a year in 40 patients. Mean age was 66.5 years (range 22-81 years). Mean operated levels were 5.4 levels (range 3-11 levels). Clinical and functional outcomes are charted in figure 1. Solid arthrodesis at L5-S1 was confirmed in 32 patients on follow up X-rays and CT Scan. 7 patients had adverse events requiring intervention: 3 Patients developed an L5-S1 pseudoarthrosis. Two as a result of late onset infection after 18 months post surgery. Both were revised with removal of the implant, ALIF and iliac screw fixation. The third patient had sacral pedicle screw loosening revised with new S1 pedicle screws and bilateral iliac screws. All 3 have fused after revision surgery. 2 other patients developed post-up radiculopathy, 1 with heterotopic ossification and other one with stenosis and both underwent revision microdecompression at one year post-up. There were two patients with superficial wound dehiscence. There have been no bowel injuries, sacral fractures, sacral screw fractures or neural injuries.

**Conclusion:** Our data shows AxiaLIF provides safe minimally invasive access to the L5-S1 disc space and is an excellent method for fusion and stabilization of the lumbar sacral spine at the base of a long segment construct when it is indicated. This approach biomechanically improves the strength of the construct and it may obviate the need for iliac screw fixation. Therefore it lowers morbidity and prevents complications associated with iliac screw fixation including sciatic notch injury, sacral fracture, hardware prominence and iliac screw back out.

**Figure 1. Clinical and Functional outcomes**

220 Can Transsacral AxiaLIF Fixation at the Bottom of a Long Construct Avoid the Need for Iliac Bolt? N. Anand, B. Khandehroo, S. Kahwaty, E.M. Baron

'Cedars-Sinai Medical Center, Spine Center, Los Angeles, CA, USA

**Introduction:** AxiaLIF to be a safe minimally invasive L5-S1 interbody fusion with significant reduction in blood loss, operative times, and morbidity and complication rate as compared to more invasive open surgeries such as ALIF, PLIF or TLIF. Moreover, iliac bolt fixation is a well-known surgical procedure to reduce lumbar sacral strain at the base of a long segment spinal fusion. In this study we assess AxiaLIF can prevent the need for iliac screw fixation, which has a significant complication rate.

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**Figure 1. Clinical and Functional outcomes**
**An Ipsilateral Bi-portal Arthroscopic Trans-iliac Approach to L5-S1 Disc and Foramen - A Cadaver Study**

**S.G. Osman**

1. American Spine Center, Surgery, Frederick, MD, USA

**Background:** Multiple MIS procedures have been added to the armamentarium of surgical approaches of the lumbar spine including X-LIF, MIS TLIF, AxiaLIF, laparoscopic, and endoscopic approaches. The downside of the posterior endoscopic approach is violation of the spinal canal. The X-LIF cannot access the L5-S1 because of the intervening iliac bone. AxiaLIF, in addition to possible injury to the bowel, cannot tackle intra-canal pathology, and laparoscopic approach risks injuries to the major vessels, the bowel and pre-sacral plexus. The arthroscopic micro-discectomy approach can access the L5-S1 disc and foramen in most cases, however, in a deep-seated L5-S1, a supra-iliac crest approach may not access the disc in its axial plane and may lean on the exiting L5 nerve root causing injury.

**Objectives:** To determine the feasibility of a trans-iliac approach to L5-S1 disc and foramen, and to evaluate the safety of this approach by studying the anatomical relationship to the trans-iliac access cannula.

**Materials and methods:** 5 fresh cadavers were used for the study. Pre-operative axial CT scan was taken, in the plane of the disc equator to determine the portal site and angle of instrumentation. Under fluoroscopic guidance, a guide wire is driven through the iliac crest through the iliac bone window into the posterolateral corner of the disc. A core-drill was used to excise a cylinder of iliac bone from around the guide wire after insertion of access cannula. 18-gauge spinal needle was inserted through the iliac bone window into the posterolateral disc. The rest of instrumentation was carried out as described by Kambin et al. Another cannula was inserted supra-iliac to triangulate with the trans-iliac in the foramen and biportal arthroscopic procedure is performed. Distances from vital structures were measured and the integrity of the skeletal structures was investigated.

**Results:** The access cannula passed through the Gluteus Maximus and Medius in 4 cadavers and only through Glut. Maximus in 1. Distances from the trans-cannula to:

(a) PSIS = 4.16 cm;
(b) iliac crest = 2.24 cm;
(c) lumbo-sacral trunk = 1.93 cm;
(d) superior gluteal nerve = 4.8 cm.

The volume of iliac bone dowel was 3.93 cc. There were no injuries to the facet joints, sacro-iliac joints or ilio-lumbar ligaments.

**Conclusion:** Access to the L5-S1 disc and foramen is possible through trans-iliac approach. Vital structures were at safe distances from the path of the access channel, and no injury to the skeleton other than the trans-iliac window, was recorded.

**Keywords:** Arthroscope, bi-portal, ipsilateral, supra-iliac, trans-iliac.

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**The Tissue Retraction Index: A New Tool to Compare the Relative Invasiveness of Different Minimally Invasive and Open Posterior Approached Spinal Procedures**

**G.J. Regev**, K. Salame, O. Keynan, Z. Lidar

1. Tel Aviv Sourasky Medical Center, Spine Unit, Department of Neurosurgery, Tel-Aviv, Israel, 2. Tel Aviv Sourasky Medical Center, Spine Unit, Department of Orthopaedic Surgery, Tel-Aviv, Israel

**Background:** Minimally invasive spine (MIS) surgery techniques strive to minimize the damage to the paraspinal soft tissues. Previous studies used only the length of the surgical incision in order to quantify the invasiveness of certain MIS procedures. However, this method does not take into account the volume of muscle tissue that is dissected and retracted from the spine in order to achieve sufficient exposure. To date, no technique has been reported to measure the volume of the surgical exposure and to quantify the invasiveness of a surgery.

**Study objectives:** To measure the volumetric surgical exposures of different MIS and open posterior approached spinal procedures and to develop a method to compare the relative invasiveness of these procedures.

**Methods:** The length and volume of the surgical exposure were obtained from 50 patients who underwent either open or MIS, posterior approached surgery. The volume of exposure was obtained by measuring the amount of water needed to completely fill the surgical wound once the surgical retractors were deployed and opened. The tissue retraction index (TRI) was then calculated by dividing the volume of exposure by the length of the incision.

**Results:** The surgical volume of exposure ranged from 7cc for a single level MIS discectomy to 470cc for a L2-5 open fusion. The TRI for MIS procedures ranged from 5 to 9.7 and were significantly smaller then the TRI for open procedures (8.5-24.6). The relative invasiveness of a single level MIS discectomy was 70% of that of an open discectomy and 40% of that of laminectomy. The relative invasiveness of MIS TLIF was 30% of that of an open TLIF ranging from 20% to 40% depending on the technique used for the contralateral instrumentation.

**Conclusions:** Direct volumetric measurement of the surgical exposure is easily and reliably obtained by measuring the amount of water needed to fill the exposed cavity. The TRI enables to normalize the volume of soft tissue retraction per 1cm of skin incision. Using this index the relative invasiveness of different spinal procedures can be compared.
New minimally invasive surgical (MIS) techniques for treating spinal disorders have improved patient outcomes and opened new avenues of research. One technique was the development of the lateral transpsoas approach to the lumbar spine. While the cage may be left as a stand alone implant, patients often need further posterior surgery resulting in staged procedures or surgical delay to “flip” the room. A new technique, the Guyer lateral interbody fusion (GLIF) technique allows for lateral transpsoas approach with the patient in the prone position eliminating the need for a “flip” or a staged procedure. This study presents a single center, single surgeon experience on the learning curve associated with the GLIF technique.

Patients were selected based on their eligibility to receive a typical lateral approach. A total of 27 patients were treated at 31 levels using the GLIF technique. The technique utilizes a curved portal that is placed in the posterolateral aspect of the patient’s lumbar spine while in the prone position (Figure 1). Neuromonitoring is first accomplished via multiple curved cannulas to ensure safe docking of the final portal. Direct visualization is then possible and the typical discectomy can be performed. Total surgical time, time specifically for the GLIF portion as time per level and EBL were captured in the operative notes.

![Figure 1](image1.png)

Figure 1: Docked curved portal via posterio-lateral transpsoas approach.

While surgical time varied over time due to the required posterior surgical intervention, the GLIF portion of the surgery showed a rapid decrease in surgical time (Figure 2). This learning curve appears to approach just over one hour by 10th level. The operated levels were as follows: L1-L2 (2 levels), L2-L3 (7 levels), L3-L4 (20 levels), L4-L5 (2 levels). EBL for GLIF procedure was estimated to be below 100cc per level.

![Figure 2](image2.png)

Figure 2: Learning curve of GLIF technique demonstrates rapid decrease in time with experience.

The learning curve for the GLIF surgery appears reasonable as the first few levels demonstrate a rapid decrease in time for that portion of the case. This learning curve does not appear onerous for adoption of this technique, especially when considering the time savings of not needing the room “flip” or the costs of a staged procedure with the patient remaining admitted to the surgery center. While patient outcomes will be reported separately, only one patient exhibited a complication (ipsilateral GLIF related persistent neuralgia post-op). Theoretically, with the GLIF portion of the case working from the posterolateral position, surgeons could simultaneously be placing posterior instrumentation and this will be evaluated in subsequent studies.

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Non-fusion, Fracture Vertebral Augmented, Percutaneous Short Segment Transpedicular Screwing after Postural Reduction and Percutaneous Implant Removal in Neurologically Intact Unstable Thoracolumbar Burst Fractures

H.S. Kim1, S.J. Jeong1, H.J. Ahan2, K.H. Jeon1, W.J. Choi1, K.T. Kim1, C.I. Ju2, S.W. Kim1, S.M. Lee2, H. Shin2

1Hurisarang Spine Hospital, Neurosurgery, Daejeon, Korea, Republic of, 2College of Medicine, Chosun University, Neurosurgery, Gwangju, Korea, Republic of

Purpose: It will be inevitable for fusion surgery of the thoracolumbar burst fracture to induce the motion limitation. However, non-operative treatment also will be induce the kyphotic deformity. The aim of this study was to evaluate the non-fusion percutaneous screwing and implant removal for methods of preservation of motion segment and reducing the kyphotic deformity.

Material & methods: The present study retrospectively evaluates the results of surgical outcome. Between May 2007 and Jan 2011, 44 patients underwent percutaneous short segment screwing including fracture level itself due to unstable thoracolumbar burst fractures. Among those patients, 16 patients who underwent percutaneous short segment screwing and implant removal using the same route for unstable burst fractures greater than 50% loss of vertebral height were enrolled in this study. The surgical procedure included postural reduction for 2 days, fractured vertebrae augmented by polymethylmetacrylate (PMMA) (with osteoporosis) or non-PMMA materials (without osteoporosis). Based on the osteoporosis of the fracture vertebrae, patients were assigned to the following two groups:

(1) Group A (n=8): Non-osteoporotic fracture vertebrae underwent Non-PMMA fracture vertebral augmentation.
(2) Group B (n=8): Osteoporotic fracture vertebrae underwent PMMA fracture vertebral augmentation.

The vertebral augmentation procedure was performed for fracture level itself in group A: with non-PMMA augmentation materials, in group B: with PMMA. Percutaneous screw fixation was performed using a percutaneous screwing system (Apollon System, Solco Medical, South Korea).
All patients obtained solid fusion of the fracture vertebrae by CT images after 6 months later from percutaneous screwing. The following outcome measures were compared between the two groups: loss of vertebral height, kyphotic angle, motion range in flexion-extension were measure radiologically at times of preoperative, after percutaneous screwing and last follow-up after implant removal.

**Results:** In the corresponding order of Group A, B, mean follow-up period to implant removal was 7.25 months and 6.63 months, mean follow-up period after implant removal was 12.63 months and 10.75 months. Mean age was 40.25 years and 64.75 years. In the corresponding order of preoperative, after percutaneous screwing and final follow-up after implant removal, loss of vertebral height in group A was 58.12%, 15.25% and 17.37%, in group B was 65.62%, 12.87% and 15.12%. Kyphotic angle of fracture vertebrae in group A was 24.88 degree, 7.50 degree and 8.63 degree, in group B was 25.63 degree, 7.25 degree and 8.88 degree. Motion range (flexion / extension) in group A was 3.13 degree (19.00 degree / 15.88 degree), 0.75 degree (6.25 degree / 6.00 degree) and 6.38 degree (11.3 degree / 4.88 degree), in group B was 7.13 degree (18.38 degree / 11.25 degree), 1.13 degree (5.88 degree / 4.75 degree) and 7.25 degree (11.13 degree / 3.88 degree).

![Imaging of the transpedicular screwing and removal](image.png)

**Conclusion:** Using the postural reduction and fracture vertebral augmentation, non-fusion percutaneous screwing was effective methods of kyphotic deformity correction for the unstable burst fracture in spite of grater than 50% loss of vertebral height and preserving the motion segment. Therefore, we have restored the motion segment effectively using the implant removal after obtained the solid fusion of fracture vertebrae.

**Introduction:** Thoraco-Lumbar corpectomy is indicated for fractures, primary or secondary tumors, and bacterial osteomyelitis that compromise the neural canal or cause severe deformity or pain. The anterior thoraco- lumbar spine can be exposed through a variety techniques including posterolateral, anterolateral and anterior approaches. The selection of a surgical technique is determined by the level involved, the disease entity, and surgeon knowledge. However, traditional anterior approaches to the thoracic and thoracolumbar spine require open thoracotomies or thoracoabdominal approaches that are associated with significant morbidity and extended post-operative pain and hospitalization. Given the morbidity of open procedures and the learning curve of endoscopic approaches, XLIF lumbar approach has gained popularity to treat different degenerative spine diseases.

**Methods:** To determine the feasibility of a thoracic and/or lumbar corpectomy, a minimal-access transthoracic surgical technique were performed using principles of the XLIF lumbar approach. Data will be collected pre-operative and from O.R. Adverse events and surgical related complications will also be recorded.

**Results:** 17 patients with different diseases that included trauma and tumors between T5 to L4 were enrolled. A modified transthoracic XLIF direct lateral approach was performed through a 6 cm incision using the expandable retractor Maxcess II (Nuvasive, San Diego, CA), no rib resection was required in thoracic spine; and direct surgeon visualization using surgical microscope was used assisted by fluoroscopy. Anterior reconstruction was performed using an expandable titanium cages with anterior instrumentation or percutaneous posterior minimal invasive pedicle screws supplementation. 47.05% of the patients underwent only anterior procedure. With surgical experience mean operative times were reduced for cases later in the series. Of the 17 patients included in this study, not conversion to an open procedure was required. All patients recovered uneventfully. Patients experienced minimal pot-operative pain and were discharged 3 days after surgical procedure in 14 cases. There were no postoperative neurologic deficits. No revision procedure was performed.

**Conclusions:** Current study demonstrates that minimally invasive transthoracic and lumbar corpectomy using a direct lateral XLIF modified approach safely and successfully allows decompression and stabilization, decreased morbidity over traditional anterior or posterior approaches. This technique could be a therapeutic alternative for spinal surgeons.
MAST (Minimal Access Spinal Technology) vs Open Surgery: A Micro-costing Analysis of Spinal Fusion Procedure

Methods: The analysis was conducted in two Italian hospitals in which the learning curve could be considered completed and through interviews with medical staff the patient flow was mapped and the resource consumption during hospitalization was valorized. The following unit costs were analyzed: staff time, diagnostic tests, drugs/consumables, operating room and general expenses. Costs were compared between pathways (open vs. MAST) and for each phase (pre-hospitalization, hospitalization, surgery, post-surgery and follow-up).

Results: In both hospitals MAST was associated with less overall resource use mainly due to a shorter post-operative LoS (2 vs 4 days), less blood loss and less demanding wound care. Total hospitalization costs were €6,970-8,310 for MAST and €8,021-8,760 for OS. If the pre-hospitalization and follow-up phases resulted in similar resources consumption, significant differences emerge in surgery and post-surgery episodes (which accounts for 14% of the total costs in MAST and 24% in OS).

Conclusions: The study confirms that less invasive provides significant economic benefits of a less invasive procedure. Despite higher initial investment (instrumentation, learning curve), MAST has demonstrated to be an effective and cost-saving alternative to OS.

Minimally Invasive Anterior Lumbar Interbody Fusion with Stand-alone Cage in Treatment of Degenerative Lumbar Spinal Disease: Comparative Study with Minimally Invasive Transforaminal Lumbar Interbody Fusion

Objective: This prospective study was performed to compare the clinical and radiological results of anterior lumbar interbody fusion (ALIF) using two different stand-alone cages and minimally invasive transformaminal lumbar interbody fusion (mini-TLIF) in the treatment of degenerative lumbar spinal disease.

Method: Between April 2007 and July 2010, 27 patients underwent single level stand-alone ALIF using SynFix-LR® (Synthes Bettlach, Switzerland) and 30 patients underwent single level mini-TLIF in our hospital. The mean follow up periods were 15.2 and 16.5 months. Inclusion criteria for patients were degenerative disc disease with foraminal stenosis, low grade degenerative disease with foraminal stenosis, low grade degenerative lumbar interbody fusion (ALIF) using two different stand-alone cages and minimally invasive transformaminal lumbar interbody fusion (mini-TLIF) in the treatment of degenerative lumbar spinal disease.

Results: The MI-LIF patients, 335 were treated for ASD. Clinical and radiographic measures were prospectively collected and evaluated.

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

Keywords: MI-LIF, adjacent segment degeneration, spinal fusion, minimally invasive
spondylolisthesis. We performed clinical and radiologic evaluation postoperatively. Clinical outcomes were graded using the visual analogue scale (VAS) scores and Oswestry disability index (ODI). Radiologic outcomes were evaluated on plain and dynamic radiographs. Segmental kyphotic angle, whole lumbar kyphotic angle, disc height, foraminal height and width were used as parameters to evaluate radiographic change in the 2 treatment groups.

**Result:** The mean VAS scores for back and leg pain decreased from 5.9 and 5.85 to 1.9 and 1.85 in ALIF group (P=0.000, P=0.000) and from 6.1 and 7.4 to 2.3 and 1.6 in the mini-TLIF group. (P=0.000, P=0.000) The mean ODI score improved from 45.8 to 17.9 in ALIF group (P=0.000) and from 54.3 to 27.6 in the TLIF group (P=0.000). In both groups, the VAS scores for back and leg and ODI score significantly improved postoperatively. There was no significant difference between groups in terms of changes in VAS score for back and ODI score. (Statistical significance test was done by Mann-Whitney U-test) (P=0.654, P=0.667). However, VAS score for leg pain improvement after surgery was significantly higher in mini-TLIF group (P=0.026). In ALIF group, all radiologic parameters were improved significantly after surgery. In mini-TLIF group, changes in the disc height, foraminal width and foraminal height were significant. (P=0.001, P=0.000, P=0.002). The amount of change between preoperative and postoperative disc height, segmental kyphotic angle, foraminal width and height were significantly greater in ALIF group. (P=0.000, P=0.000, P=0.015, P=0.001) There was no surgical complication in ALIF group. One patient in mini-TLIF group suffered from postoperative infection.

**Conclusion:** Our study has some limitation of relatively small number of patients and short follow up period. However, single level stand-alone ALIF showed good clinical and radiologic results comparable to minimally invasive TLIF. ALIF using stand-alone cage can be a good surgical option in the treatment of symptomatic degenerative lumbar spinal disease.

**Introduction:** Surgical correction of Adult spinal deformity is traditionally done through an open posterior approach. This is associated with considerable blood loss and a significant complication rate. Minimally Invasive Pedicle Screw instrumentation and fusion represents a newer method for correction of spinal deformity. This study assesses the efficacy of these MIS techniques in Adult Scoliosis.

**Methods:** This is a retrospective study of 94 consecutive patients with Adult Scoliosis (Cobb > 15 degree) who underwent MIS Correction and fusion. Deformities included Degenerative scoliosis (65), Idiopathic scoliosis (22), and iatrogenic scoliosis (7). All underwent deformity correction and fusion using segmental multilevel percutaneous pedicle screw fixation (94). Other MIS techniques were also used such as DLIF (79) and AxiaLIF (45). 52 of the patients were staged with DLIF done first followed by the posterior instrumentation including AxiaLIF done later. 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 63 yrs (range 21-81). Mean Follow-up was 27mths (range 3-56) with greater than 2 yrs FU in 51 and greater than 3 yrs FU in 30 patients. Patients with one-stage same day surgery (42) had a mean blood loss of 575 ml and a mean surgical time of 312 min. Patients with two-stage surgery (52) had a mean blood loss of 284ml and surgical time of 178 min for lateral discectomy and interbody fusion with 344ml and 238min respectively for posterior instrumentation and fusion including AxiaLIF. Mean hospital stay was 7.8 days (range 3-26). Figure 1 charts the clinical and functional outcomes. The mean Pre-op Cobb angle was 30.4° (range: 15°-74.6°), which corrected to 11.5° (range: 1.7°-35.2°). The pre-op Coronal balance was 30.4mm (range: 5.16-142.9), which corrected to 15mm (range: 0 to 38.8). The mean pre-op Sagittal balance was 25mm (range: -59 to 160) and corrected to 6.26mm (range: -119 to 124.40). The pre-op lumbar AVT was 32.4mm (range 6.7-90.3), which corrected to 12.7mm (range 2.3-30.5). Lumbar Lordosis was also maintained at final follow-up. There were 15 adverse events in 12 patients: 3 patients developed L5-S1 Pseudoarthrosis, 2 with malpositioned screws, 4 with persistent stenosis, 1 with hardware prominence, 1 with osteomyelitis, 1 with idiopathic cerebellar hemorrhage, 1 with retrocapsular renal hematoma, and 2 with sacral wound dehiscence.

**Conclusions:** Minimally Invasive Multilevel Percutaneous Pedicle Screw Instrumentation and Fusion represents a newer method for correction of adult spinal deformity with achieving long-term outcomes comparable to those obtained with open methodologies. Our results show that MIS deformity correction is associated with a lower pseudarthrosis rate, significantly improved functional outcomes, excellent clinical and radiological improvement, with considerably lower complication rates at early and at long term follow-up.

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**Minimally Invasive Pedicle Screw Instrumentation and Fusion for Adult Scoliosis - Functional and Radiological Outcomes**

* N. Anand, B. Khandehroo, S. Kahwaty, E.M. Baron

1Cedars-Sinai Medical Center, Spine Center, Los Angeles, CA, USA

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MIS in the Treatment of Idiopathic Scoliosis. A Comparison Study
C. Wimmer, T. Pfandlsteiner, K. Seidel
Schön Klinik Vogtareuth, Clinic for Spine and Deformity, Vogtareuth, Germany

The aim of the retrospective comparison study was to examine the advantages and disadvantages of MIS in comparison to open procedures. In the literature there exists no prospective study about this new technique.

The indication for surgery was idiopathic thoracic and thoracolumbar scoliosis in both groups. In group I 29 patients (24 female/5 male) were operated from 2/2008 to 12/2009 with the new instrumentation. All patients were instrumented with this new minimal invasive technique. The mean age at operation was 18.3 years (range from 16 to 28).

In group II 31 patients (26 female/5 male) were operated from 1/2008 to 12/2009 with the open approach. All patients were instrumented with open instrumentation from the same company. The mean age at operation was 17.3 years (range from 14 to 21).

For the clinical examination VAS and patients satisfaction score were used. The mean Cobb angle was in both groups before surgery was 65.5 degrees (range from 45 to 80).

The mean follow up was 18 months (range from 6 months to 26 months). The mean time of operation in group I was 178 minutes (145 to 210); blood loss was in mean 155 ml (100 to 300), time of radiation in mean 82 sec. (65 to 139).

The mean time of operation in group II was 235 minutes (145 to 270); blood loss was in mean 655 ml (300 to 950), time of radiation in mean 12 sec. (5 to 39). There was a significant difference in blood loss and time of surgery (p<0.05).

In both groups there was no difference in correction and cosmetic result. Correction of the curve was in mean 75% (55 to 85%). The fusion rate was 95%. Patient satisfaction score showed in 81% excellent, and in 19% improved results. The cosmetic result showed before surgery 9/10 and after surgery 1.5/10 there was a significant difference with a p value of p<0.005.

In group I, there was none infection, none neurological complication. In three cases the pedicle screw was outside of the pedicle without clinical evidence. In three cases radiolucent lines were seen, without clinical consequence.

In group II, there was one superficial infection, none neurological difference. In two cases the pedicle screw was lateral.

The first results have shown that the treatment of deformities is possible with excellent results, less blood loss as in open procedures. The technique is difficult, but possible for advanced MIS user. Disadvantage is the longer time of radiation.

Complication Associated with Lateral Lumbar Interbody Fusion Surgery. A Prospective Report on 173 Patients. Up to 4 Years Follow up
H. Nicola, M. Da Silva
Hospital San Juan de Dios, Caracas, Venezuela, Clinica Sanatrix, Caracas, Venezuela

Background context: The Lateral Lumbar Interbody Fusion (LLIF) offers a less invasive and therefore more tolerable surgical option for these patients. LLIF allows for minimally invasive placement of a large anterior graft, facilitating disk height and alignment restoration. In addition this technique has the potential to decrease patient recovery time, length of hospital stay, and overall occurrence of surgical complication.

Purpose: To evaluate complications of the LLIF procedure

Study design/setting: Prospective clinical study.

Patient sample: 173 patients with degenerative disease of the lumbar spine were treated with the LIF procedure between 2007 and 2010.

Methods: 173 patients underwent LLIF for the treatment of symptomatic degenerative disease. All Patients were prospectively reviewed including operative reports and postoperative medical and radiographic records to determine what complications were encountered.

Results: A total of 173 patients underwent LLIF surgery. Complications occurred in total 39 (22.54%) (26 Female/13 Male) Mean age was 54.2 of the 173. This complications included superficial infection 3 (1.73%), P4seudarthrosis 8 (4.62%), subsidence 25 (14.45%), psuedoarthrosis and subsidence 4 (2.31%), hematoma 2 (1.15%), Lumbar Plexus Neuropraxia 4 (2.31%), Weakness of the Psoas Muscle 39 (22.54%), Paresthesia of the lateral aspect of thigh 22 (12.71%),Inguinal and inner aspect of thigh Dysistesia 16 (9.24%), vascular injury 1 (0.5%).

Conclusions: The complication rate associated with LLIF in the present study was relatively low (22.54%) and was lower than previously published complication rate for Transforaminal lumbar interbody fusion (33.6%) and Anterior lumbar interbody fusion (38.3%). The most common complications were weakness of the Psoas Muscle 39 (%) subsidence of the graft 25 (%). It is important for surgeons to be aware of the potential for these complications. Many of these complications can likely be avoided with proper patient selection and preoperative planning. Preoperative MRI and detailed patient physical evaluation and history, and the use of EMG intraoperative can help to prevent complication with LLIF surgery.

A Comparative Study On Cage Subsidence Following Standalone Lateral Interbody Fusion
L. Marchi, L. Oliveira, R. Amaral, C. Castro, T. Coutinho, E. Coutinho, E. Pimenta
1Instituto de Patologia da Coluna, São Paulo, Brazil, 2Unifesp, DDI, São Paulo, Brazil, 3University of California San Diego, Neurosurgery, San Diego, CA, USA
 Purpose: Previous studies on lateral lumbar interbody fusion revealed that indirect decompression of the neural structures with standard cages is feasible. But there is an important cage subsidence occurrence, which may limit ability for decompression. The influence of the cage width on indexes of surgical goals and complications is yet unknown and it is the main goal of this work.

Methods: Retrospective analysis on prospective clinical studies. Seventy-four patients (57.2 ± 14.8 y/o; BMI 24.9 ± 2.5). Standing lateral radiographs were performed preoperatively, postoperatively at 1 and 6 weeks, 3 and 12 months. Clinical outcomes were assessed by ODI and VAS up to 24 months. Standalone short-segment lateral lumbar interbody fusion was investigated. The fused segments were: 3 at L1L2, 7 at L2L3, 22 at L3L4, 66 at L4L5. Forty-six patients (56.7 ± 24.7 y/o; BMI 24.7 ± 3.1), 61 lumbar levels, were treated with standard cages (18mm) and twenty-one patients (57.2 ± 24.5 y/o; BMI 25.0 ± 2.3), 37 lumbar levels, were treated with wide cages (22mm). Radiological measurements were done regarding segmental lumbar lordosis and subsidence occurrence. Subsidence grading followed a method that estimates the percentage of the cage is inside the vertebral body: 0-24% of subsidence - grade I; 25-49% - grade II; 50-74% - grade III; 75-100% - grade IV. All patients completed 12-month follow-up evaluations.

Results: VAS and ODI scores improved equally in both groups. Although all patients had gain in segmental lumbar lordosis, wide group gain were higher than for standard group (7% for standard and 17% for wide - p= 0.0004). Difference in subsidence was evident at 6w, 3mos, and 12mos (p=0.01). At 12mos: grade I/II - 70% in standard group and 81% in wide group; grade III/IV - 30% in standard group and 14% in wide group. Subsidence was early detected on 6-week and didn’t significantly progressed. Moreover, subsidence was seen to occur predominantly (68% of the cases) in the inferior endplate of the assessed intervertebral disc.

Conclusions: Wider cages have a significant impact on avoiding cage subsidence occurrence in standalone lateral interbody fusion. Better alignment correction of the lumbar spine is also achieved with this kind of implant. Moreover, cage subsidence must be carefully evaluated at early follow-up.

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Tapping Insertional Torque Allows Prediction for Better Pedicle Screw Fixation and Optimal Screw Size Selection
M.D. Helgeson1, R.A. Lehman1, A.E. Dmitriev2, D.G. Kang1, A.J. Belevivo1, S.J. Luhmann1
1Walter Reed National Military Medical Center, Orthopaedic Surgery, Bethesda, MD, USA, 2Washington University School of Medicine, Orthopaedic Surgery, St. Louis, MO, USA

Introduction: Several studies have evaluated pedicle screw insertional torque(IT) and its direct correlation with pullout strength, however there is limited clinical application with pedicle screw IT as it is measured during screw placement and rarely causes the spine surgeon to change screw size. However no study has evaluated tapping IT, which precedes pedicle screw placement, and would allow for intraoperative feedback. We set out to investigate tapping insertional torque and its ability to predict pedicle screw pullout strength and optimal screw size.
Methods: Five specimens (n=10 pedicles) were used to perform a pilot study, as there were no previously established values for optimal tapping IT. Each pedicle during the pilot study was measured using a digital caliper, the optimal tap size was then selected as the tap diameter 1 mm smaller than the pedicle diameter. Each pilot specimen pedicle was tapped using the optimal tap size, and all tapping IT values exceeded 2.5in-lb. The threshold tapping IT value for optimal pedicle screw and tap size was determined to be 2.5in-lbs, and a comparison tapping IT value of 1.5in-lbs was selected. Next, 15 test specimens (n=30 pedicles) were measured with digital calipers, probed, tapped, and instrumented using a paired comparison between the two threshold tapping IT values (Group 1: 1.5in-lbs; Group 2: 2.5in-lbs), randomly assigned to the left or right pedicle on each specimen. Each pedicle was sequentially tapped to increasing size (3.75 mm, 4.00mm, 4.50mm, 5.50mm) until the threshold value was reached based on the assigned group. Pedicle screw size was determined by adding 1 mm to the tap size which crossed the threshold torque value. Torque measurements were recorded with each revolution during tap and pedicle screw insertion. Biomechanical testing was then performed with pedicle screw pullout "in-line" with the screw axis at a rate of 0.25 mm/sec. Peak pull-out strength (POS) was measured in Newtons (N).

Results: The peak tapping IT was significantly increased (50%) in Group 2 (3.23±0.65in-lbs) compared to Group 1 (2.15±0.56in-lbs) (p=0.0005). The peak screw IT was also significantly increased (19%) in Group 2 (8.99±2.27in-lbs) compared to Group 1 (7.52±2.96in-lbs) (p=0.02). The pedicle screw pullout strength was also significantly increased (23%) in Group 2 (877.9±235.2N) compared to Group 1 (712.3±223.1N) (p=0.017). The mean pedicle screw diameter was significantly increased in Group 2 (5.70±1.05mm) compared to Group 1 (5.00±0.80mm) (p=0.0002). There was also an increased rate of optimal pedicle screw size selection in Group 2 with 9 of 15 (60%) pedicle screws compared to Group 1 with 4 of 15 (26.7%) pedicle screws within 1mm of the measured pedicle width. There was a moderate correlation for tapping IT with both screw IT (r=0.54) and pedicle screw POS (r=0.55).

Discussion and conclusion: We found tapping IT directly correlates with pedicle screw IT, pedicle screw pullout strength, and optimal pedicle screw size. We recommend sequentially increasing tap size until a tapping insertional torque threshold of 2.5in-lb is reached, which will maximize fixation strength and obtain optimal pedicle ‘fit and fill’ with the largest screw possible. Tapping insertional torque may be a reliable method to intra-operatively judge pedicle screw fixation strength.

298 Effects of Magnesium Ion on Proliferation and Differentiation of Human Bone Marrow Stromal Cells D.-H. Lee1, K.-S. Lee1, J.-H. Kim1, M.-R. Choi1, J.-S. Chang1 1Asan Medical Center, Univ. of Ulsan, College of Medicine, Dept. of Orthopaedic Surgery, Seoul, Korea, Republic of

Introduction: Recently, magnesium (Mg) has been proposed as a bone implant biomaterial due to their biodegradability and good mechanical properties. Mg deficiency is known as a risk factor for osteoporosis, but the detail of effects of Mg on bone metabolism remains unclear. Although divalent cations such as calcium (Ca) and strontium (Sr) are now being used as an effective treatment of osteoporosis and their effects on bone-forming cells have been fully elucidated, the effects of Mg on osteoblasts have not been elaborate. Recent studies indicate that the calcium-sensing receptor (CaR) and Wnt/β-catenin signaling are important for promoting osteoblast differentiation and bone formation, which are involved in the beneficial effects of strontium. Therefore, we investigated the effects of Mg ions on proliferation and osteoblastic differentiation of human bone marrow stromal cells (hBMSC) and whether the CaR and Wnt/β-catenin signaling is involved in this mechanism or not.

Methods: We isolated BMSC from human bone marrow aspirated from femur medullary canal during hip joint arthroplasty with informed consent. To evaluate the effects of Mg ions on osteoblastic differentiation of hBMSC, we examined the difference among the groups with Mg chloride, Ca chloride, Sr chloride and control by measuring the hBMSC proliferation, alkaline phosphatase (ALP) activity. Proliferation was evaluated by WST method with a cell-counting kit and ALP activity was determined using p-nitrophenyl phosphate as the substrate. Then we analyzed mRNA expression of osteogenic-related genes, including ALP and osteocalcin (OCN), and CaR, using RT-PCR. Next, we examined the effects of CaR inhibitor, calhex231, on that of hBMSC to determine whether CaR may impact on Mg-induced proliferation of hBMSC. Finally, to confirm the effects of Mg on Wnt signaling, we analyzed the protein expression of β-catenin by Western Blot analysis. β-catenin, the pivotal protein in the Wnt signaling, was also observed by immunofluorescence analysis for nuclear translocation.

Results: hBMSC proliferation during 48th, 72h was significantly increased in Mg (p<0.5 and p<0.01), Ca (p<0.1 and p<0.01), and Sr (p<0.5 and p<0.1) groups comparing with the control group. Treatment of hBMSC with Mg for 14 days also enhanced ALP activities similar to Sr-treated cells (p<0.01). In addition, both ALP and OCN mRNA levels were tended to be increased by Mg treatment. Mg also increased the mRNA expression of CaR. Interestingly, 24h pre-treatments of the cells with calhex231, a CaR inhibitor, significantly and almost totally antagonized Mg-induced proliferation of hBMSC (p<0.01). Moreover, Western Blot analysis showed that Mg increased β-catenin levels in the nucleus, confirming the results obtained by immunofluorescence analysis. Increase of β-catenin in the nucleus may promote the transcriptional activity. Conclusions: This study demonstrated that Mg can promote proliferation and osteoblastic differentiation of hBMSC. Although further studies seem to be necessary, this effect is, at least partly, mediated through the activation of CaR and Wnt/β-catenin signaling. Therefore, this might provide the possibility of magnesium for the treatment agents of osteoporosis, of providing a useful source for tissue engineering and of using the magnesium metal as bone implant biomaterial.
Axial Pullout Strengths of Different Screw Designs: Fenestrated Screw, Dual Outer Diameter Screw, and Standard Pedicle Screw

K. Kafchitsas1, S.R. Chinthakunta2, D. Reddy3, E. Christodoulou4, S. Khalil5
1Johannes-Gutenberg-Universität Mainz, Mainz, Germany, 2Globus Medical Inc, Research, Audbon, PA, USA, 3St. Marienhospital, Muehlheim an der Ruhr, Germany

Purpose of the study: In the present study, the pullout strength of an innovative fenestrated screw augmented with PMMA (FSP) was investigated. Furthermore, the pullout strengths of an unaugmented fenestrated screw (FS), standard pedicle screw (S), and dual outer diameter screw (DOD) was evaluated and compared to the pullout strength of the fenestrated screw augmented with PMMA.

Materials and methods: Twenty four thoracolumbar vertebrae (T10-L5, age 60 to 70 years) from three cadavers were implanted with the four different pedicle screws. Eleven screws of each type were instrumented into either left or right pedicle with S paired with FS and DOD paired with FSP in any given vertebra. All screws were from the same manufacturer [Globus Medical Inc., Audbon, PA] and of the same size (5.5mm diameter x 55mm length). In the case of fenestrated screws with PMMA, 2 to 3 ml of bone cement [Tecres S.P.A., Verona, Italy] was injected into the screw following insertion. The specimen was mounted on a custom designed fixture attached to the actuator of the test machine (MTS 858 Mini Bionix, MTS Corporation, Minneapolis, MN). Axial pullout testing was conducted at a rate of 5mm/minute. Force to failure (Newtons) for each pedicle screw was recorded.

Summary of the findings: Augmentation with PMMA significantly improved pullout strength of fenestrated screws compared to unaugmented FS, S, and DOD screws. The FSP screws had the highest pullout strength, which represented an average increase of 249%, 241%, and 174% in comparison to FS, S, and DOD screws, respectively (Fig.1). Pullout strength of FS screws was comparable to that of S screws, however it was significantly lower than DOD screws.

Conclusions: Fenestrated screws augmented with PMMA improve the fixation strength and result in significantly higher pullout strength compared to dual outer diameter, standard and unaugmented fenestrated screws. Screws with dual outer diameter provided enhanced bone-screw purchase compared to standard screws and unaugmented fenestrated screws and may be considered as an alternative technique to increase the bone-screw interface in cases where augmentation using bone cement is not feasible.

Kinematic Evaluation of the Multi-directional Flexibility Properties of the STALIF-C™: A Cadaveric Biomechanical Study

A.E. Castellvi 1, M. Stein 2, A. Nayak3, A. Cabezas3, R.B. Gaskins3, B.G. Santoni3
1Florida Orthopaedic Institute, Orthopaedic Spine Surgery, Tampa, FL, USA, 2University of South Florida, Orthopaedics, Tampa, FL, USA, 3Foundation for Orthopaedic Research and Education, Phillip Spiegel Orthopaedic Research Laboratory, Tampa, FL, USA

Purpose: The STALIF-C is a no profile cervical interbody spacer with three integrated fixation screws designed to provide segmental rigidity in ACDF surgery. The purpose of this study was to biomechanically quantify the stabilizing effect of the STALIF-C, and compare these findings to those afforded by a standard 4-hole rigid anterior plate following instrumentation at the C5-C6 level. We hypothesized that the STALIF-C with integrated screws would afford comparable postoperative segmental rigidity to the standard interbody cage and anterior plate construct.

Methods: Six (n=6) human cadaveric cervical spines (C3-C7) were biomechanically evaluated using a non-destructive, non-constraining, pure-moment loading protocol with loads applied in flexion, extension, lateral bending (right + left), and axial rotation (left + right) for the intact and instrumented conditions. Spines were loaded quasi-statically up to 1.5 Nm in 0.5 Nm increments and range of motion (ROM) at the C5-C6 index level was recorded with the use of an opto-electronic motion analysis system. Each specimen was tested in the following conditions:
1. Intact (INT)
2. Discectomy + STALIF-C cage with integrated screws engaged (STA)
3. STALIF-C cage (without integrated screws) + Anterior Locking Plate (ALP)
4. STALIF-C cage only, without integrated screws or plates (CO)

Results: No statistically significant difference in range of motion at the C5-C6 level was identified between the STA and ALP groups in flexion, extension, lateral bending, or axial rotation (p=0.477, 0.580, 0.189, 0.627, respectively) (Figure 1). The STA group showed significant reductions in flexion/extension, lateral bending, and axial rotation ROM when compared to the CO group (p=0.042, 0.016, 0.001 respectively).

Conclusions: In this in-vitro biomechanical study, the STALIF-C cage with integrated screws provided comparable biomechanical stability to that of the standard interbody cage + anterior plate cervical spine fusion approach. Due to its no profile design, the STALIF-C device may avoid the morbidities associated with standard anterior plating such as dysphagia while affording rigid fixation in a single level construct. Further clinical studies are necessary to confirm these biomechanical findings with the no profile device.
Compensatory Mechanisms and the Effect of Age on Sagittal Balance in Degenerative and Isthmic Spondylolisthesis: An Analysis Utilizing the Pelvic Radius Technique

S.A. Mokhtar, P.F. McCombe, D. Saravanja, I. Sergides, G. White, W.R. Sears

Macquarie University, School of Advanced Medicine, Sydney, NSW, Australia,
Royal Brisbane Hospital, Brisbane, QLD, Australia,
Dalcross Adventist Hospital, Sydney, NSW, Australia,
Wentworth Spine Clinic, Sydney, NSW, Australia,
Royal North Shore Hospital, Sydney, NSW, Australia

Purpose of the study: Few studies have investigated the effect of age on spino-pelvic sagittal alignment and none have examined this effect in patients with spondylolisthesis. Knowledge of the effects of age on alignment in the degenerating spine may aid our understanding of the compensatory mechanisms, which patients adopt in their attempt to maintain sagittal balance. The current study was undertaken to investigate correlations between age and measures of spino-pelvic alignment in patients with isthmic and degenerative spondylolisthesis, and whether compensation mechanisms, which patients use in cases of sagittal imbalance, differ as they age.

Methods: A cross-sectional observational study of pre-operative radiographs was undertaken. Measures of spinal sagittal alignment were acquired manually from the pre-operative radiographs of 382 consecutive patients with spondylolisthesis (isthmic-85 and degenerative-297) using the Pelvic Radius (PR) technique. Pearson’s paired univariate correlations were tested between age and the measured parameters for the combined as well as for the separate isthmic and degenerative spondylolisthesis subgroups. Compensation mechanisms were explored by examining correlations between spino-pelvic parameters - for all patients and after stratifying into three age groups (<45-years, 45-60 and >60-years). Statistical analysis was performed using SPSS software version 19.0. The significance level was set at P < 0.05.

Findings: As anticipated, the current study found that pelvic lordosis (measured by PRS1) did not vary with age in either isthmic or degenerative spondylolisthesis patients. No significant correlations were found between age and any parameters in the degenerative spondylolisthesis patients. However, in the isthmic spondylolisthesis patients, correlations were found between age and total lumbo-pelvic lordosis (r = -0.45) and between age and pelvic angulation (r = 0.44).

In younger patients with isthmic spondylolisthesis (<45 years), loss of focal lordosis at the level of the spondylolisthesis was found to strongly correlate with increasing lumbar lordosis above that level (r = -0.58, p=0.02). Strong correlations between total lumbo-pelvic lordosis (PRT12) and pelvic angulation (PA) were observed in both the degenerative spondylolisthesis (r = -0.74, P < 0.001) and isthmic spondylolisthesis (r = -0.69, p< 0.001) patients.

Conclusions: The hyperlordosis of the segments above a focal loss of lordosis, observed in the younger patients with otherwise flexible lumbar spines, may represent the primary mechanism used to compensate for a focal loss of sagittal alignment. It is postulated that in the older patient, the energy required to increase the lordosis above the spondylolisthesis is greater (because of increased spinal stiffness) than that required to extend around the hip and that therefore the second mechanism: hip extension becomes the preferred strategy. Further, hip and knee-flexion or ankle-extension may represent a third compensation mechanism, which is used when the limit of pelvic extension is reached.

Introduction: Surgical outcomes for anterior cervical disectomy and fusion (ACDF) have become predictable and largely successful, but questions about graft safety and healing remain. The graft material should produce high rates of fusion with low morbidity at a reasonable cost. DBM putties and gels may leak and can cause ectopic bone formation; recombinant bone morphogenic proteins have been associated with swelling and breathing problems when used in the cervical spine. Our purpose was to prospectively evaluate the safety and effectiveness of a novel demineralized cancellous bone sponge in achieving anterior cervical fusion.

Methods: ACDF was undertaken by a single surgeon in a prospective series of 45 patients between July 2005 and August 2006. Indications for surgery included degenerative disc disease and herniation, myelopathy, radiculopathy and stenosis. Patients underwent standard anterior approach, discectomy and endplate preparation. An appropriate sized PEEK cage was selected. For each level fused, a block of demineralized cancellous allograft, approximately one cm. in diameter, was mixed with BMA aspirated from an adjacent vertebral body. A dynamic cervical plate was placed across the levels fused. Postoperatively, NSAID’s were avoided, single level fusions were placed in a soft collar, and multiple level fusions in a more rigid collar for six weeks. Radiographs and quality of life (QOL) surveys were undertaken preoperatively, at two weeks, six weeks, three months and at final follow up. A two sample t-test was utilized to measure long-term Oswestry Disability Index (ODI), SF-36v2, Visual Analog Scale (VAS) and radiologic findings: disc fusion, screw loosening, subsidence and migration as defined by standard X-Ray views.

Results: Ages ranged from thirty to seventy-one with a mean of 55. There were 21 men and 24 women, nine cigarette smokers, four diabetics and four obese patients. Nine patients underwent a single level fusion; 17 underwent two-levels; 13 underwent three-levels; and six had four or more levels fused (average 2.3+/-0.78). One patient developed an immediate postoperative hematoma after a three-level procedure and required ligation of a vessel. A second patient developed a superficial wound infection, requiring IV antibiotics but no surgical debridement. New bone formation typically was apparent by three months. At one year, all 45 patients appeared to have gone on to solid fusion without screw loosening, plate lift-off or breakage. Average time to final follow up was 5.1 years with thirty patients evaluated. All demonstrated normal strength, sensation and reflexes and solid bridging across motion segments with no visible cage migration or segmental motion on flexion/extension films. Average QOL scores: SF-36v2: 88; ND1: 7.57; VAS (neck pain): 2.58; VAS (arm pain): 0.8. There was mild cage subsidence at two levels and four cases of hypolordosis. A single pseudoarthrosis at C6-7 was diagnosed at year five in a patient who had undergone C3-7 fusion. One patient with adjacent level degenerative change required an additional level fused.

Conclusion: We found that a DBM bone sponge, composed of 100% cancellous allograft and hydrated with BMA, was a safe, easy to use grafting material that didn’t flow from the intended surgical site and led to a reliable anterior cervical fusion.

Innovative Technologies

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An Inexpensive Computer Assisted Technique Using iPad for Pedicle Screw Placement in Scoliosis Surgery

Y. Abe1, M. Ito2, K. Abumi3, Y. Kotani2, H. Sudo2, M. Takahata4, K. Nagahama4, A. Iwata3, S. Sato1, A. Minami4

1Eniwa Hospital, Orthopedic Surgery, Eniwa, Japan, 2Hokkaido University, Advanced Medicine for Spine and Spinal Cord Disorders, Sapporo, Japan, 3Hokkaido University, Spinal Reconstruction, Sapporo, Japan, 4Hokkaido University, Orthopedic Surgery, Sapporo, Japan

We have developed a novel computer assisted technique (3D-VG technique) for identifying the entry point and directing axial inclination of pedicle screw (PS) using only commodity hardware and inexpensive software. The aim of this study was to introduce this technique and to evaluate its accuracy in scoliosis surgery.

Methods: 3D-VG technique only requires a low-end model computer, an available 3D DICOM viewer and tablet computer. In the current study, we utilized originally developed software (ZedView VEGA, LEXI - Robert Reid inc., Japan) for 3D-VG. Ideal position of PS was analyzed from CT data on the laptop PC and was indicated on each planes (coronal, sagittal, and axial plane), and entry point of PS was visualized on the bony surface of 3D virtual model (Fig. 1).

[Fig. 1. Captured images of ZedView VEGA]

Tablet computer (iPad, Apple, US) was connected to the laptop PC by wireless LAN. Information that was necessary for PS insertion such as entry point, axial direction, pedicle diameter, and screw diameter and length were displayed on the tablet computer. PSS were inserted from the entry point that was indicated on the display, and were inserted according to the direction indicated in the tablet computer placed directly on the surgical site (Fig. 2).
Patients were evaluated pre- and post-injection at 1, 3, 6 and 12 months. Evaluations included routine neurological examinations and lumbar magnetic resonance imaging (MRI), the Oswestry Disability Index (ODI), a patient self-report visual analog scale (VAS) pain and outcome assessment and the SF-36. Adverse events were monitored to evaluate safety. For all clinical outcome measurements the quantitative change between baseline and 6 month follow-up were determined and the significance levels were computed based on the paired t-test.

Findings: Fifteen patients (6 female; 9 male) were treated at two sites with a single injection of NuQu juvenile chondrocytes. Levels: L3-4=2, L4-5=1, L5-S1=11. Pfirrmann grade III=12; grade IV=3. Each injection consisted of 1-2 cc (mean injection=1.4cc) of juvenile chondrocytes (~ 4-5 million chondrocyte cells/cc) with fibrin glue carrier. Mean injection peak pressure=86.5 psi. Mean age of 40 years (range 21-48).

Clinical- The mean ODI (baseline=53; 6 months=28; p=0.0005), VAS (baseline=6; 6 months=4; p=0.02) and SF-36 Physical scores (baseline=35; 6 months=43; p=0.005) all improved significantly from baseline. Patient self-report of pain: improved=8; unchanged=6; worse=1. Radiographic- Nine (60%) of 15 patients showed improvements in MRI imaging. Three (20%) showed improvements in disc contour or height. High intensity zones (HIZ) consistent with posterior annular tears were present at baseline in nine patients, eight (89%) showed improvements in 1 and 6 month MR imaging. Furthermore, patients with baseline HIZ had a greater mean improvement in ODI compared to those without baseline HIZ.

Complications- No patients experienced neurological deterioration. There were no serious and no unexpected adverse events. There were no observed immunological response to the chondrocyte injection. Two patients (13%) underwent total disc replacement by 12 month follow-up due to persistent, but not worse than baseline, LBP.

Conclusions: This is the first report of the clinical and radiographic results of cell-based disc repair therapy (injectable chondrocytes) in the treatment of lumbar spondylolisthesis with mechanical LBP. The results of this prospective cohort are promising and warrant further investigation with a prospective, randomized, double-blinded, placebo-controlled study design.
screw malposition. However, a second procedure is necessary if such malpositioned screws have to be revised. The O-arm is an intraoperative scanner that allows revision of a screw without having to return the patient to the OR for a separate procedure. No previous studies have looked at the accuracy of intraoperative O-arm images in determining pedicle screw position.

**Methods:** This factorial validation study utilized 9 cadavers in a comparison of intraoperative O-arm images and the dissection gold standard. Four hundred sixteen screws were inserted using three-dimensional image (O-arm) guidance from C2 to S1. The screw positions were randomized into three groups: “IN” (fully contained within the pedicle), “OUT-lateral” or “OUT-medial”. After screw insertion, O-arm images were obtained and reviewed in a blinded fashion by three independent observers. Dissection identified the true position of the screws. Specificity, sensitivity, positive predictive value (PPV) and negative predictive value (NPV) were calculated using dissection results as the gold standard. The interobserver reliability was also determined.

**Results:** The overall accuracy, specificity, sensitivity, PPV, and NPV of O-arm images for the thoracic and lumbar spine were 73%, 76%, 71%, 74%, and 72 %, respectively. Accuracy of surgeon perception in the cervical spine was significantly less than in the thoracic and lumbosacral spine. There was substantial interobserver agreement between the three readers.

**Conclusion:** Intraoperative O-arm images accurately detect significant pedicle screw violations in the thoracic and lumbosacral spine, but are less accurate for the cervical spine.

**Introduction:** It is estimated that pathological changes at the lumbar facet joints account for 15-45% of low back pain, however, surgery to treat these problems is rare. The FENIX™ facet resurfacing implant is a partial facet replacement prosthesis and is designed for motion preservation at the index level while reducing the pain significant.

In this feasibility study the design of the FENIX(TM) device, the intended patient population and the surgical technique were evaluated.

**Materials and methods:** Patients between 40 and 70 years attending the implanting surgeons clinic with facet joint syndrome, that proved to be refractory to at least 6 months conservative treatment, including radiofrequency denervation, were considered candidates for participation in this study. The pain intensity was rated > 5 on the Visual Analogue Scale (VAS). Facet joint degeneration Fuhiwara grades 2 and 3 at the affected lumbar level should be demonstrated by MRI. A CT-SPECT should confirm a facet joint osteo-arthritis at one or both sides of the affected level as single pain generator. The patient should experience at least 50% pain reduction after a diagnostic block of the CT-SPECT identified affected facet joint.

**Results:** Seven of the eight (93.75 %) patients had their implants in place 24 months after surgery. Flexion and extension X-ray analysis showed preservation of motion in these 7 patients. No Modic changes were detected at the discs of the treated and adjacent levels, with respect to the baseline observations and no signs suggestive for loosening of the implants were noticed at the index joints. Moreover, CT-SPECT was normalized in all seven patients at mnts 6 follow-up.

In one patient (6.25 %), routine X-ray at 6 months follow-up showed unilateral superior facet implant dislocation. This patient had significant pain reduction and a better ODI score than at baseline. He did not report any change since his last visit at 6 weeks. This patient has been re-operated and the devices were explanted and a posterior lumbar interbody fusion (PLIF) was carried out. At the occasion of explantation, the soft tissue around the implants did not show any form of metallosis under microscopic magnification.

No surgical complications were encountered nor side effects that could be related to the implants. The ODI improved from 48 (10-80) at baseline, to 21.5 (0-34) at six months and to 16.5 (0-24) at one year postoperatively. The NRS for pain intensity improved from 7.2 (5-10) to 2 (0-5) and for pain frequency from 6 (5-8) to 2 (0-3) at one year.

**Discussion:** In our pilot study patients with facet joint osteoarthritis experienced considerable pain reduction and improvement in functionality after bilateral monolocal facet resurfacing. Only one implant dislocation was noted in this pilot study.

The dislocation was attributed to the cross fixation of the upper resurfacing component and was the reason for a change in the fixation modality of this component in the second generation implants.
Results: Interim data analysis was performed. Data on 24 patients at baseline, 20 at 6 weeks, 11 at 3 months and 6 at 6 months is presented. Oswestry Disability Index (ODI) scores decreased on average by 52% (23.6 ± 16.7 points), 62% (28.5 ± 15 pts) and 47% (28.3 ± 20.7) at each respective time point compared to baseline scores. Mean leg pain measured using VAS decreased by 63% (4.1 cm), 88% (5.8 cm), and 81% (5.6 cm) respectively. ZCQ results exhibited a 30% improvement over 6 week results from the X-STOP pivotal trial and a 21% increase over 6 month results. Surgical times and hospital length of stay decreased compared to a subgroup analysis of patients with a component of foraminal stenosis from the SPORT trial (94.4 ± 38.8 min vs. 147.8 ± 68.1 min, 1.4 ± 1.2 vs. 3.3 ± 2.1 hospital days). Pre and post imaging demonstrated facet-sparing decompression (Figure 1.)

[Figure 1: Pre- and Post-Decompression Imaging]

Conclusion: Early results show a positive trend in hospital and patient-reported outcomes and study enrollment is continuing. ODI outcomes reveal a 3.6x, 3.8x and 2x improvement over data presented for SPORT spinal stenosis ITT cohort at equivalent time points. Greatly improved patient reported outcomes and peri-operative metrics demonstrate the potential of the iO-Flex® System to address challenges of traditional decompression.

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Radiofrequency-kyphoplasty Compared to Conventional Kyphoplasty in the Treatment of Vertebral Compression Fractures: A Prospective Randomized Study
A.W. Licht1, W. Kramer2, V. Afanasiev2
1Asklepioskliniken Kandel, Orthopedic Surgery/Spine-Center, Kandel, Germany, 2Asklepioskliniken Kandel, Orthopedic Surgery, Kandel, Germany

Question: Vertebroplasty and conventional balloon kyphoplasty (BKP) are established minimally invasive procedures for treatment of osteoporosis and traumatic vertebral compression fractures (VCFs). Since the introduction of conventional BKP, many kyphoplasty device innovations for vertebral augmentation (VA) have been developed. In 2005 conventional BKP was introduced in our clinic. Since February 2009 an alternative kyphoplasty method, Radiofrequency-Kyphoplasty (RFK), has been employed for treatment of VCFs. RFK uses RF energy to heat cement (significantly increasing cement viscosity immediately prior to delivery), uses a navigational cavity creation device and remote controlled cement delivery. This study analyzes advantages and disadvantages of both methods.

Method: Between 1/2005 and 12/2008 N=138 patients with N=203 VCFs were treated using conventional BKP (Medtronic) and evaluated in a prospective, randomized study related to age of fracture (fresh vs. chronic). Fresh VCFs were < 6 weeks (median=12 d n=81 patient/107 VCFs). Chronic VCFs were ≥ 6 weeks, (median=159 d, n=57 patients/96 VCFs). Vertebral body height restoration and improvement in VAS pain score in the BKP treated patients was evaluated post-op and after 12 months. Rate of cement extravasation and related complications were analyzed in all patients. Since 2/2009, 42 patients with 60 VCF were treated using new vertebral augmentation procedure RFK (DFine) that included site and size specific cavity creation and remotely controlled ultra-high viscosity, extended working time cement and evaluated using the same methods.

Results: Average improvement in VAS pain score in the BKP treated patients was 5.4 in fresh VCFs and 3.4 in chronic VCFs (p< 0.0001). Cement leakage rate was on average 18.7% (fresh VCFs 11.2%, chronic VCFs 27.7%) and height restoration was average 6.8 mm in fresh VCFs and average 4.6 mm in old VCFs (p< 0.001). Two major cement leakage related complications were noted in these 138 BKP patients (one cement extravasation related spinal cord compression with incomplete paraplegia and one pulmonary cement embolization).

Patients treated with RFK intervention showed an average improvement in VAS pain score of 4.9 in fresh VCFs and 3.9 in old VCFs (p< 0.001). Cement leakage rate with no complications was on average 10.6% (fresh VCFs 9.8%, old VCFs 11.6%) and height restoration was average 7.0 mm in fresh VCFs and average 4.4 mm in old VCFs.

Conclusion: These VA procedures are comparable demonstrating both are safe and effective for treatment of painful VCFs. Higher leakage rate in old VCFs in the BKP group was related to increased bone destruction and re-fracture of vertebrae during balloon inflation. RFK revealed similar pain relief and height restoration but decreased rates of cement extravasation and related complications. Decreased extravasation was due to RF warming of cement just prior to entering the patient permitting more controlled cement delivery due to increased viscosity and extended working time prior to heating. Reduced radiation exposure to operator during cement delivery due to remote controlled, automated delivery and reduced multi-level procedure time for RFK due to unipedicular approach using the navigational osteotome provided benefit for both patient and physician.
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Extreme Lateral Cervical Foraminotomy with an Anterior-oblique MIS Approach. Feasibility Cadaveric and Radiologic Study
M.E. Berbeo1, R.C. Diaz2, Grupo de Neurociencias HUSI - PUJ
1Hospital Universitario San Ignacio - Pontificia Universidad Javeriana, Neurociencias - Neurocirugia, Bogota, Colombia

Purpose: To analyze the feasibility of a minimally invasive anterior-extreme-lateral approach for decompression of the cervical sub axial foramina with the proposal of decrease the upper airways and esophagus manipulation.

Methods: We performed a review of one hundred cervical MRI of a radiological data-base of patients from one university hospital. We described distances, angles, and anatomical relationships of a thirty degrees to the sagittal plane angled approach to the neuroforamina in the cervical spine. After that we performed a cadaveric approach following the radiologically defined surgical way to the cervical foramina for decompression

Results: There are different anatomical considerations for the superior and inferior cervical levels. The initial planned approach was medial to the ECM muscle. However, at the lower cervical disc spaces this proposal could be difficult to attain because of the medial position of the ECM muscle inferior attachment in the sternum. On average, for the direct approach to the uncinate process the angulation is about 30 degrees (47.3 - 22.1) to the sagittal plane.

Conclusions: A thirty degrees from midline anterior approach targeted to the anterior transverse tubercle, allowed us to expose directly the uncinate process. The decompression of the neural foramen would be attained by resection of the posterior half of the uncinate process and the piece of disc on the way. We think that this approach is feasible in the clinical setting. We have to adapt now the approach for endoscopic and/ or MIS tubular surgical instruments, while considering the inherent risks associated to the manipulation of the neurovascular structures of the zone.

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Early Relapse after Discectomy of Herniated Lumbar L5-S1 Discs: Fissure Fragmentectomy and Sealing Procedure for a Percutaneous Endoscopic Interlaminar Approach
H.S. Kim1, S.J. Jeong1, H.J. Ahan1, K.H. Jeon1, W.J. Choi1, K.T. Kim1, C.I. Ju1, S.W. Kim1, S.M. Lee2, H. Shin2
1Hurisarang Spine Hospital, Neurosurgery, Daejeon, Korea, Republic of; 2College of Medicine, Chosun University, Neurosurgery, Gwangju, Korea, Republic of

Objective: Percutaneous endoscopic interlaminar lumbar discectomy (PEID) has many advantages, such as minimal invasiveness and possible early ambulation. However, aggressive discectomy and recurrence prevention is difficult with PEID. In addition, annulus fibrosus should be removed during removal of the herniated lumbar disc as in open discectomy, which in turn further increases the rate of early relapse. We proposed new surgical approach for preventing the early relapse after PEID procedures, and compared clinical results between other surgical approaches.

Methods: We retrospectively analyzed patients who underwent surgical procedures for L5-S1 herniated lumbar discs between January 2008 and February 2010. We checked early relapse less than 1 year after surgery for all of the patients. The current study included 432 patients in the following 3 groups: group A (n=148), Percutaneous endoscopic interlaminar fissure fragmentectomy and sealing procedure group; group B (n=172), percutaneous endoscopic interlaminar open door fragmentectomy procedure group; and group C (n=112), microscopic open lumbar discectomy and laminectomy group.

Results: The mean age of the patients was 47.47 ± 14.14, 45.05 ± 14.35, and 46.88 ± 15.07 years in groups A-C, respectively. The VAS changes were 7.87 ± 0.79 to 1.86 ± 0.79, 7.91 ± 0.79 to 2.21 ± 0.74, and 7.88 ± 0.82 to 2.09 ± 0.77 in groups A-C, respectively. The early recurrence rate of herniated L5-S1 lumbar discs was 5/148 (3.38%), 14/172 (8.14%), and 2/112 (1.8%) in groups A-C, respectively.

Conclusion: Percutaneous discectomy of L5-S1 herniated lumbar discs via an interlaminar approach has a higher relapse rate compared to microscopic open discectomy in early periods after operation. Using the fissure fragmentectomy and sealing procedure, the early relapse rate of L5-S1 herniated lumbar discs decreased significantly. (χ²=7.03, p=0.030)

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Minimally Invasive Lumbar Interbody Fusion (MI-LIF) Using a βTCP-HA Bone Graft Substitute (FormaGraft): Fusion Rates out to 2 Years
W.B. Rodgers1, E.J. Gerber1, J.A. Lehm1, J.A. Rodgers1
1Spine Midwest, Inc., Research, Jefferson City, MO, USA

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 MI-LIF procedures. Outcomes were encouraging; MI-LIF 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 MI-LIF have been shown, however, no reports to date have focused specifically on fusion rates associated with MI-LIF, or on the graft materials used in MI-LIF. 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 MI-LIF procedures. Radiographic outcomes were evaluated to demonstrate fusion and were compared with clinical results.

Results: Patient age ranged from 25-79yrs (average:
groups were observed for 20 weeks then euthanized. A corrective tether device was applied. The TR and AC model (SM, n=11), in which pigs were euthanized; and anterior correction (AC, n=5). In the PSM, n=11, all had a surgical induction of scoliosis per a previously reported PSM protocol. When ~50° Cobb angle was observed, the inducing tether was removed; and anterior correction (AC, n=5), in which the inducing tether was removed and an anterior corrective tether device was applied. The TR and AC groups were observed for 20 weeks then euthanized.

Conclusion: Mi-LIF 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.

CT-scan reconstructions were used to measure further parameters that characterize the shape of the vertebral bodies, and their relative positions. Differences between groups and levels of vertebrae were assessed using ANOVA.

Results: There was a significant increase in the height at the center of the vertebrae in TR (2.96cm±0.21) and AC (2.82cm±0.15) groups compared with SM (2.57cm±0.20). The maximal Cobb angle was significantly smaller in AC (35.9°±7.9°) than in the two other groups (TR: 47.8°±1.7°, SM: 53.1°±9.2°). There was a significant increase in kyphosis in AC (23.4°±17.5°) compared to SM (-1.5°±14.6). A decrease of maximum cuneiformization of the vertebrae was found in AC compared to SM and TR in the three apical vertebrae. There was no significant difference in axial rotation between vertebrae, for AC while a significant difference was noted for the two other groups.

Conclusions: This non-fusion technique does not inhibit the growth of the vertebrae. Moreover, a corrective tether permits growth modulation of vertebrae, decreasing their cuneiformization. This correction demonstrates significant decrease in coronal deformity, while also inducing kyphosis and eliminating axial apical rotation.

Summary: The Porcine Scoliosis Model was used in 21 pigs in order to evaluate the effect of a non-fusion tethering technique. A three dimensional reconstruction of the full spine for each pig was obtained with CT scan. Several parameters characterizing the shape and spatial position were measured and compared. This study demonstrates that this technique conserves and modulates the growth, and additionally, it corrects the scoliotic deformity not only in the coronal plane but also in the sagittal and axial planes.

Introduction: Three dimensional correction of scoliosis via a tethering technique has already been demonstrated through growth modulation in an established Porcine Scoliosis Model (PSM). Previous studies reported the focal impact on apical vertebrae following corrective tethering; the aim of this study was to evaluate the effect of a corrective tether on global alignment of the spine in the PSM.

Methods: This IACUC approved study included 21 Yorkshire pigs. At 12 weeks of age, all had a surgical induction of scoliosis per a previously reported PSM protocol. When ~50° Cobb angle was observed, animals were placed into one of three groups: scoliosis model (SM, n=11), in which pigs were euthanized; tether release (TR, n=5), in which the inducing tether was removed; and anterior correction (AC, n=5), in which the inducing tether was removed and an anterior corrective tether device was applied. The TR and AC groups were observed for 20 weeks then euthanized.

Conclusion: Mi-LIF 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.

Cytokines in the Intervertebral Disc of Patients Undergoing Lumbar Anterior Discectomy and Interbody Fusion for Degenerative Disc Disease

Introduction: Low back and leg pain are common problems that may arise as sequelae of degenerative disc disease of the lumbar spine. However, the production of pain by the degenerative disc remains controversial and the underlying pathophysiology is largely unknown. Previous studies of cytokines in the disc have predominately focused on in vitro culture of disc tissue after surgical excision. The in vitro culture environment may influence the expression of cytokines thus producing different results than those present in vivo. Therefore, we measured the free soluble cytokines in the disc and disc space of patients with low back pain with/without leg pain.

Methods: Thirty-one lumbar intervertebral discs from 27 subjects with low back pain (LBP) were removed using an anterior approach, prior to interbody graft placement for fusion (ALIF). Each disc was removed using standard surgical technique in several large pieces and placed into a collection tube containing a protease inhibitor, flash-frozen in liquid nitrogen and stored at -80C until sample analysis. Lavage of the disc space was also performed in 20 discs during disectomy for comparative analysis to whole disc samples. For cytokine analysis each disc was "washed" with saline and the lavasate was then analyzed...
for 27 cytokines simultaneously in each sample using a multiplex immunofluorescent assay system (BioPlex by BioRad).

**Results:** The concentration in (pg/ml) (mean +/- SEM) of each cytokine was as follows: interferon-gamma-induced protein-10 (IP-10): 5076 +/- 607; regulated upon activation, normal T-cell expressed and secreted (RANTES): 3644 +/- 2251; vascular endothelial growth factor (VEGF): 2542 +/- 255; interleukin-1-receptor antagonist (IL-1ra): 232 +/- 63; Eotaxin: 69 +/- 10; fibroblast growth factor (FGF) basic: 55 +/- 9; interleukin-8 (IL-8): 48 +/- 42; platelet-derived growth factor-BB (PDGF-BB): 25 +/- 7; interferon-gamma (IFNg): 16 +/- 3; macrophage inflammatory protein-1-alpha (MIP-1-alpha): 11 +/- 2; macrophage inflammatory protein-1-beta (MIP-1-beta): 9 +/- 2; interleukin-9 (IL-9): 7 +/- 1; monocyte chemotactic protein-1 (MCP-1): 6 +/- 2; interleukin-12 (IL-12): 6 +/- 1; interleukin-6 (IL-6): 5 +/- 4; granulocyte macrophage colony-stimulating factor (GM-CSF): 5 +/- 2; interleukin-10 (IL-10): 2.6 +/- 0; interleukin-13 (IL-13): 1.6 +/- 0. The following cytokines were measured at an average concentration of less than 1.0 pg/ml: interleukin (IL)-15, IL-1beta, IL-2, IL-4, IL-5, IL-7, granulocyte colony-stimulating factor (G-CSF) and tumor necrosis factor-alpha (TNF-a). There was no statistically significant difference in the concentration of cytokines measured by whole disc lavage compared to disc space lavage except for IL-10 (p < 0.001), GM-CSF (p < 0.05) and IL-12 (p < 0.005); the levels of which were greater in the samples taken from the disc space than from the whole disc.

**Conclusions:** Out of the 27 cytokines measured using the multiplex panel, 19 were detectable at significant concentrations in the disc and disc space of subjects with degenerative disc disease with LBP or LBP + leg pain undergoing surgical treatment with ALIF. The cytokines detected at the greatest concentrations were IP-10, RANTES, VEGF, IL-1ra, eotaxin and FGF-basic. Although we were unable to collect normal control discs for comparison as this was not possible in the clinical practice of the study surgeon without utilizing cadaveric discs, some comparisons can be made to previous studies utilizing intradiscal lavage of painful vs nonpainful discs during discography (Cuellar et al, Spine J. 2010 Mar;10(3):212-8).

**Is the Core Outcome Measures Index an Adequate Instrument but Faster and More Simple than Other Questionnaires for the Evaluation of the Quality of Life and Disability of the Patients Affected by Degenerative Lumbar Disease?**

D. Pérez Prieto1, M. Ramirez2, C. Lozano2, G. Saló2, M. Antoni2, A. Lladó3

1Hospital del Mar, Orthopaedic Surgery, Barcelona, Spain, 2Hospital del Mar, Barcelona, Spain

**Introduction:** Quality of life and degree of patients are a determining factor in assessing outcomes of lumbar degenerative pathology’s surgery.

**Design:** Retrospective review of prospectively collected data.

**Objective:** To evaluate the usefulness of the Core Outcome Measures Index (COMI) in assessing the quality of life, disability, pain and satisfaction in daily clinical practice of people affected by degenerative disease of the lumbar spine.

**Methods:** All the previously mentioned questionnaires were completed preoperatively and 2 years after surgery by 263 patients from our series. The average age was of 54.0 years (22-86 years). The internal consistency of the questionnaires’ items was assessed by Cronbach’s Alpha. The Pearson coefficient was used to measure the correlation of the results of COMI and its dimensions with the results of the ODI, the SF-36 and VAS. The magnitude of change of the variables was calculated using the standardized mean response (SMR).

**Results:** The COMI has demonstrated a reliable internal consistency in the preoperative phase (alpha = 0.807) as well as in the 2 years evaluation (alpha = 0.91). Statistically significant differences were observed between the mean values of the preoperative and 2 years questionnaires in (p < 0.05), except the RE and the MSC. COMI results’ correlation and its dimensions with SF-36, ODI and VAS performed preoperatively and 2 years after surgery as well as the degree of improvement had a high number of good results (> 0.65) that were statistically significant (p < 0.000). The COMI presented a high degree of change with a SMR of -0.851 (-1.050 to -0.652), being moderate of the ODI -0.451 (-0.599 to -0.303), the MCS-SF36 -0.488 (-0.640 to -0.336) PCS-SF36 and 0.585 (0.433 to 0.737).

**Conclusions:** The COMI is a useful tool when assessing the global status of patients affected by degenerative lumbar disease. Given its simplicity, the good correlation with the SF-36 and ODI and its high sensitivity to change, we could replace them in daily clinical practice to make a quick and proper assessment of patient status.
Extreme lateral interbody fusion (XLIF) has revolutionized the approach to the anterior lumbar spine by providing a direct access to the intervertebral space at any level of the lumbar spine above L5-S1. The need for an access surgeon to reach the anterior lumbar surface has virtually disappeared. It is necessary for the spine surgeon who performs XLIF surgery to be aware of the distinct neurological variability that exist at the different levels of the lumbar spine, and how to protect the nerves to prevent significant post-operative neurological complications. The lumbar plexus occupies increasingly more of the lateral surface of the vertebral bodies from L1 to S1. At the L3-4 level less than 50% of the lateral surface of the disc interspace is covered by the plexus, at L4-5 60% of the surface is covered by the plexus, and at L5-S1 75% of the lateral surface is occupied by the plexus. Electrophysiologic monitoring procedures (EMR) have been designed to detect the location of the nerves, which require the absence of muscle relaxation during the procedure. EMR allows the surgeon to identify the nerves, but not always to protect them. Preoperative thin section multiplanar CT scanning facilitates the clear identification of the plexus within the body of the iliopsoas muscle, and allows the surgeon to precisely determine the location of the nerves in relation to the lateral surface of the vertebral bodies at the level where the WLIF will be performed. 175 XLIF procedures have been performed in 120 patients at multiple levels. 120 levels were done using conventional EMR without CT assistance in the localization of the plexus, and 55 were done using the combination of EMR and CT localization. CT localization and CT guidance allowed the surgeon to precisely locate the nerves prior to their retraction, and permitted the dissection away from the retractor placement with protection of the nerve. Postoperative paresthesias and iliopsoas muscle weakness developed in 40 patients using EMR guidance only, and lasted for up to six months. In patients who had EM and CT guidance paresthesias developed in five patients, and iliopsoas weakness occurred in two; the paresthesias resolved in two months, and the muscle weakness in three weeks. EMR/CT guidance allows the spine surgeon to safely locate the lumbar plexus during surgery, and permits its safe dissection and protection.

Lightning Round: Cervical Technologies Update

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Cervical Artificial Disc Replacement at an Ambulatory Surgery Center
K.A. Pettine

1The Spine Institute, Loveland, CO, USA

Purpose: There is ample literature which documents the safety and efficacy of performing anterior cervical fusions in an Ambulatory Surgery Center (ASC) setting. The following data will show Cervical Artificial Disc Replacements (CADR) can also be performed at an ASC with safety and efficacy.

Methods: A total of 224 patients have undergone cervical artificial disc replacement at the Loveland Surgery Center. These surgeries began in 2005 and the data is through 2011. These included five different types of artificial discs. Eleven patients received the Kineflex-C, 39 patients received the NeoDisc, 21 patients received the ProDisc-C, 10 patients received the Discover and 143 patients received the Prestige. Fifty percent of these patients were in an FDA IDE clinical trial.

Results: There were 162 patients who had a one-level artificial disc replacement. Fifty-six patients received a two-level artificial disc replacement; five patients received a three-level artificial disc replacement and one patient a four-level artificial disc replacement. The average age of the patients was 45.3 years with a BMI of 27. The ratio of smokers to non-smokers was 1:6. There were a total of three re-operations; one patient in 2007, one patient in 2008 and one patient in 2009 all underwent revision of the original implant. None of these re-operations occurred during their initial stay. The average operative time for a one-level disc replacement was 63 minutes, a two-level procedure averaged 86 minutes and the average operative time for a three-level procedure was 100 minutes for an overall average of 84 minutes. The average time in the convalescent center was 16 hours. Every patient left within 24 hours with no unplanned transfers to the hospital in any case. Pre-op NDI went from 54.6 to 23 at 2 year follow up (p< 0.01).
Pre-op VAS went from 74 to 28 at 2 year follow up (p<0.006).

**Conclusion:** Based on statistically significant improvement in NDI and VAS without surgical complications, this data indicates cervical artificial disc surgery can be safely performed with clinical efficacy at an ambulatory surgery center.

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**Effects of Cervical Posture in Cervical Disc Replacement Surgery on Cervical Motion and Stability after Surgery**

Y. Deng¹, H. Liu¹, Y. Hong², C. Ding¹, T. Hu¹, R. Shi¹, Y. Song¹, T. Li¹, B. Wang¹

¹West China Hospital, Sichuan University, Orthopedics, Chengdu, China, ²West China Hospital, Sichuan University, Operation Room, Chengdu, China

**Study design:** A retrospective study of radiographic outcome of patients with cervical spondylosis after cervical disc replacement (CDR) using PRESTIGE LP artificial disc.

**Objective:** To find out whether there is correlation between intra-operative cervical posture and post-operative cervical motion and stability in CDR.

**Summary of background data:** CDR has become an alternative approaches for some cervical spondylosis. Being different from the classic anterior cervical discectomy and fusion (ACDF), CDR advances in maintaining the post-operative motion and reducing the degeneration of adjacent intervertebral discs. Researches have been carried on into the clinic outcomes and their influence factors in CDR. Few studies have focused on the influence of intra-operative cervical posture to the cervical motion or stability after CDR.

**Methods:** 49 patients that accepted single segment CDR using PRESTIGE LP artificial disc from January 2008 to July 2010 in West China Hospital were involved in this study. 28 patients were male while the other 21 were female. Of all the replacements, 5(10.2%) were C4-5 segment, 40(81.6%) were C5-6 segment, 4(8.2%) were C6-7 segment. Radiographic parameters were obtained from pre-operative, post-operative X-ray plain film and intra-operative fluoroscopy in forms of overall sagittal alignment (C2-C7), functional spinal unit (FSU) angle and aimed disc angle. The difference between pre- and intra-operative overall sagittal alignment were defined as Aalignment, so were ΔFSU angle and Δdisc angle likewise. Linear correlation, linear regression and Student’s t-test were performed to determine the factors and their respective efficacy that influence the post-operative cervical motion and stability. p<0.05 was considered as statistically different.

**Results:** Of all the 49 patients that underwent CDR, Δalignment was 6.92°±2.26° (p<0.01), ΔFSU angle was 2.11°±5.19° (p>0.05), and Δdisc angle was 3.26°±3.80° (p<0.01). Neutral alignment, FSU angle and disc angle were improved in lordosis of 6.47°±7.31°, 3.97°±5.41°, 4.29°±5.47°, respectively, all with statistical difference. The total disc range of motion (ROM) was increased by 2.20°±8.96° (p>0.05), integrated with an increase of flexion ROM by 2.76°±7.76° (p<0.05) and a decrease of extension ROM by 0.56°±4.33° (p>0.05). Linear correlation with statistical difference were found between Δalignment and improvement of neutral alignment, ΔFSU angle and improvement of neutral FSU angle, Δdisc angle and improvement of neutral disc angle, Δdisc angle and improvement of total disc ROM, Δdisc angle and improvement of flexion disc ROM.

**Conclusion:** The correlation between intra-operative cervical posture and post-operative cervical motion and stability was confirmed in CDR using PRESTIGE LP artificial disc. A moderate lordotic intra-operative cervical posture may tend to improve the postoperative cervical spinal stability at neutral position as well as the ROM, especially the flexion ROM of the artificial disc.

**Keywords:** Cervical disc replacement (CDR), surgery, posture, range of motion (ROM), stability

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**Polyetheretherketone Cage Filled with Betacalcium Phosphate versus Autogenous Tricortical Iliac Bone Graft in Anterior Cervical Discectomy and Fusion**

C.K. Chough¹, H. Park¹, K. Cho²

¹The Catholic University of Korea, Department of Neurosurgery, Seoul, Korea, Republic of, ²Yeoungdeungpo Hospital, Department of Neurosurgery, Seoul, Korea, Republic of

**Objective:** To compare clinical and radiologic results of two graft materials for anterior cervical discectomy and fusion (ACDF) with rigid plate fixation for cervical spinal disorder.

**Methods:** Twenty-nine patients treated with ACDF with rigid plate fixation between were retrospectively reviewed. They were divided into two groups: Polyetheretherketone (PEEK) cage filled with betacalcium phosphate (β-TCP) in Group A (n=18); and autogenous tricortical iliac bone graft in group B (n=11). The average follow-up durations were 15.39 months (range: 12-20 months) and 18.10 months (range: 18-19 months) for group A and group B, respectively. Clinical outcomes were graded using the visual analogue scale (VAS) score and neck disability index (NDI). Interbody height, segmental kyphotic angle and overall kyphotic angle were used as parameters to evaluate radiographic change in the 2 treatment groups.

**Results:** Clinically, VAS scores and NDI significantly improved after surgery in both groups and there was no intergroup difference ( P>0.05). Radiologic evaluation also demonstrated no significant intergroup differences ( P>0.05). The fusion rates after 12 months in group A and B were 90.4% and 100%, respectively. However, statistical analysis did not show difference in fusion rate between two groups (P>0.05). Interestingly, of three cases of cage subsidence in group A, two of them occurred after the first month of surgery and they all resulted in pseudoarthrosis and surgical revision.

**Conclusion:** ACDF using PEEK cage filled with β-TCP can be an effective and attractive alternative to the standard of autogenous iliac bone graft graft because of shorter operative time and avoiding of graft related problem. However, pseudoarthrosis did occur even with
rigid plate and screw fixation in ACDF using PEEK cage filled with β-TCP. There is high likelihood of emerging pseudoarthrosis, especially when there is any sign of chronic and progressive cage subside.

407 Cervical Disc Arthroplasty in Patients with Prior Fusions: Results from the PCM US IDE Prospective Randomized Clinical Trial
F.H. Geisler1, F.M. Phillips2, A. Cappuccino3, C.D. Chaput4, J.G. DeVine4, K. Gilder5, K.M. Howell7, P.C. McAfee6
1Chicago Back Institute, Chicago, IL, USA, 2Midwest Orthopedics at Rush University, Chicago, IL, USA, 3Buffalo Spine Surgery, Buffalo, NY, USA, 4Scott and White Hospital, Temple, TX, USA, 5Dwight D. Eisenhower Army Medical Center, Fort Gordon, GA, USA, 6NuVasive, Inc., Biometrics, San Diego, CA, USA, 7NuVasive, Inc., Clinical Resources, San Diego, CA, USA

Introduction: The efficacy of cervical disc arthroplasty in the treatment of symptomatic levels adjacent to prior fusions is largely untested due to prior fusion being an exclusionary factor in most cervical arthroplasty trials. The US FDA investigational device exemption (IDE) trial of the porous coated motion (PCM) cervical disc arthroplasty device compared to anterior cervical disectomy and fusion (ACDF) was the first such trial to allow for treatment adjacent to prior fusion. The current analysis examined clinical and radiographic success of the subset of the IDE trial population where treatment was at levels adjacent to prior fusion.

Methods: A prospective, multi-center, randomized, controlled trial of PCM versus ACDF in the treatment of degenerative conditions of the cervical spine -- including adjacent segment disease -- was undertaken. The per protocol patient sample at 2 years included 395 patients (211 PCM, 184 ACDF control). 37 of these patients (23 PCM, 14 ACDF control) had undergone an adjacent fusion an average of 7.2 years (range 0.4-26.3 years) prior. Endpoints of the trial were determined by success across five categories: neck disability index (NDI) (>20% improvement), maintenance or improvement of neurological status, no subsequent secondary surgical interventions (SSSI), absence of major adverse events, and absence of radiologic complication. Subgroup analyses were performed between PCM and ACDF patients with prior fusions, as well as between those with and without prior fusions within each the PCM and ACDF groups individually.

Results: Of those with prior fusions, NDI success was met in 76% (16/21) of PCM and 86% (12/14) of ACDF patients (2-side p-value=0.676). In patients without prior fusions, 84% (138/165) of PCM and 81% (109/135) of ACDF groups met NDI success. Neurological status success was met in 96% (21/22) of PCM and 100% (14/14) of ACDF patients with prior fusions; and 95% (156/165) of PCM and 88% (120/136) of ACDF patients without. SSSI success was met in 83% (19/23) of PCM and 100% (14/14) of ACDF patients with prior fusions and 96% (159/166) of PCM and 93% (127/137) of ACDF without. Radiographic success was met in 95% (18/19) of PCM patients and 77% (11/14) of ACDF patients with prior fusions, and in 99% (160/162) of PCM and 93% (127/136) of ACDF without. No comparisons were statistically significantly different between or within groups. Average range of motion (ROM) after PCM in patients with prior adjacent fusions was 9.7° at baseline and 6.2° at 2 years (p< 0.001); similar to PCM in patients without prior fusions (7.7° to 5.6°; p< 0.001).

Conclusions: This study suggests PCM to be a viable surgical reconstructive option adjacent to prior fusions with results at least equivalent to ACDF. The outcomes following the treatment of symptomatic degeneration at levels adjacent to prior fusions were equivalent to those in primary surgeries, suggesting that prior cervical fusion need not be a contraindication to cervical arthroplasty.
components at all follow-up time points. There was also an improvement and persistence of appropriate range of movement in X-ray images evaluation in both groups. A rate of 1.02% (2 patients) of implant removal is reported due to loosening of the prosthesis and were converted to anterior fusion with cages. Important calcification of LAL was observed in 4 cases (1.72%). No major complications were noted.

**Conclusions:** The use of Cervical TDR as an effective treatment for disc disease with associated pain and neurological compression (without response to conservative management) is more frequently recommended because studies demonstrate statistically significant clinical improvement and provides long-term patient satisfaction. Although more long-term studies in Latin America are needed, the excellent general results and use of cervical TDR for single and multiple level disc disease that persist in time and its association with patient satisfaction with the procedure allows the strong recommendation for use of TDR for standard treatment of SCDD.

**Introduction:** Historically, workers compensation (WC) has been shown to be a confounding factor for successful outcomes in spinal surgery. This analysis compares the clinical outcomes of WC and non-compensated (NC) patient from the US FDA IDE clinical trial of the Porous Coated Motion (PCM) artificial cervical disc versus anterior cervical discectomy and fusion (ACDF) with allograft and plate.

**Methods:** This study was a prospective, randomized, multicenter, IRB-approved IDE clinical trial evaluating longitudinal outcomes over 2 years comparatively between arthroplasty and fusion groups and, for the current subgroup analyses, between WC and NC groups. Patients 18-65 years of age with degenerative disc disease at one level between C3 and T1 with neurologic symptoms unresponsive to conservative care were included. The per protocol patient sample at 2 years included 395 patients. 340 patients had available data for subgroup analyses, including 45 WC (26 PCM, 19 ACDF) and 295 NC (163 PCM, 132 ACDF). Clinical outcome measures, including the validated patient-reported neck disability index (NDI), maintenance or improvement in neurologic status, no subsequent secondary surgery or intervention (SSSI), absence of major adverse events, and absence of radiologic complications. Where appropriate, measures were tested for differences between arthroplasty and fusion groups and between WC and NC groups at 2 years postoperative.

**Results:** Demographic and baseline characteristics were well matched between WC and NC patients except on presence of litigation related to spinal disorder, which was notably higher in WC patients. At 2 years, regardless of treatment group, WC patients compared to NC patients had a significantly lower rate of NDI success (67% vs. 84%, p=0.011), absence of SSSI (87% vs. 95%, p=0.044), and overall success (53% vs. 73%, p=0.008), respectively. Success of WC patients compared to NC patients on absence of major complication (98% vs. 99.7%), neurological success (86% vs. 93%), and radiographic success (98% vs. 95%), were similar. Comparing PCM patient outcomes by compensation status, overall success was met in 58% of WC and 78% of NC patients (p=0.048) and NDI success was met in 65% and 86% (p=0.021), respectively. Other outcomes were similar: SSSI success was met in 88% of WC and 95% of NC patients, neurological success was met in 92% and 95%, radiographic success was met in 100% and 99%, and major complications success was met in 100% and 100%, respectively (Figure 1).

**Conclusion:** Confirming the results of other studies, the pursuit of workers compensation claims negatively affects patient success, as demonstrated in both the current PCM and control groups. Lack of success was primarily seen in patient-reported subjective measures (PCM NDI success: 65% WC vs. 86% NC), where objective measures (SSSI, neurologic, radiographic, and major complications) were largely equivalent.

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**Cervical Disc Arthroplasty in the Management of Cervical Myelopathy**

P. Karve, K. Lingutla, C. Bhatia, G. Reddy, M. Krishna, T. Friesem

1University Hospital of North Tees and Hartlepool, Spinal Unit-Orthopaedics, Stockton, United Kingdom

**Background context:** Cervical arthroplasty is an emerging technology that offers the promise of restoring normal spinal motion after anterior cervical discectomy and decompression. The usual indication is the treatment of radiculopathy and/or myelopathy due to neural compression caused by acute disc herniation or spondylotic changes. Disc arthroplasty for surgical treatment in myelopathy as motion preservation raises a concern of ongoing microtrauma to an already compromised cervical cord leading to poor outcomes. Few studies in literature have analyzed the outcomes of disc arthroplasty in treatment of cervical myelopathy.

**Purpose:** To evaluate the effectiveness of cervical disc arthroplasty in the management of cervical myelopathy.

**Study design:** Prospective study.

**Patient sample:** From September 2005 to July 2011, 26
patients (Mean age 58.2 years [45-81], Male 11, Female 15) with cervical myelopathy associated with spinal stenosis and neural compression due to disc herniation/osteophyte complex were enrolled. Patients had cervical disc arthroplasty at single, two or three levels from C3 to T1. Patients with fusion at adjacent level were excluded.

Outcome measures: Outcome measures used included Neck Disability Index (NDI), Bodily pain component of Short Form-36 and VAS scores for arm and neck. Secondary outcome measures were hospital anxiety and depression scores, neurological status and gait. Clinical outcomes were measured preoperatively, three months, six months, one year and at yearly intervals post surgery. Methods: Average duration of symptoms was 57.54 months (3-300 months). Mean follow-up was 18.8 months [3-37]. Patents underwent anterior cervical discectomy and disc arthroplasty using either the Prestige (Medtronics), Discoserv (Alphatec-scient’x) or Nunec (Pioneer Medical) disc replacement.

Results: All patients had primary surgeries with 46 operated levels. Single level disc arthroplasty was performed in eleven patients, two levels in ten and three levels in five patients. Two patients were lost to follow-up. There were no implant related problems. Statistical analysis was done using SPSS 19. Tests for normality were performed using Shapiro Wilk test since data was not normally distributed, Paired sample t test was used and the mean NDI difference was 13.42 (SD difference of 6.745) t=3.87(23df), p< 0.01. SF36: Paired sample t test was used and the mean SF36 difference was 4.80 p>0.01 VAS Neck Paired sample t test was used and VAS for neck pain reduced with a mean difference of 2.42 and SD difference of 0.62 t=4.463(23df), p< 0.01 VAS Arm Since data was not normally distributed, Wilcoxon Signed Ranks test was used and p< 0.01. There was no statistical significant difference in hospital anxiety and depression scores in our study.

Conclusions: We find disc arthroplasty a viable and reliable option for patients with cervical myelopathy. It has an added advantage over fusion by way of preserving motion and preventing adjacent segment degeneration.

Keywords: Cervical myelopathy, cervical disc arthroplasty

9 Adjacent Segment Degeneration Following ProDisc-C Total Disc Replacement (TDR) and Anterior Cervical Discectomy and Fusion (ACDF) - Does Surgeon Bias Effect Radiographic Interpretation? L. Spector1, S.M. Odum2, B. Darden1, A. Milam1, C. Brigham1, B. Segebarth1, J. Pati1, E. Laxer2
1OrthoCarolina Spine Center, Charlotte, NC, USA,
2OrthoCarolina Research Institute, Charlotte, NC, USA,
3Mecklenburg Radiology Associates, Charlotte, NC, USA

Introduction: Adjacent segment degeneration (ASD), defined as degenerative radiographic changes at levels next to an anterior cervical discectomy and fusion (ACDF) or total disc replacement (TDR), is a commonly used radiographic endpoint reported in TDR studies. ASD is commonly assessed by an unblinded radiographic review. The purpose of this study was to assess surgeon bias in the radiographic interpretation of ASD at six years follow-up in patients enrolled in an FDA IDE trial comparing ProDisc-C TDR and ACDF.

Methods: Five reviewers (one radiologist, two TDR spine surgeons and two non-TDR spine surgeons) assessed twenty-six sets of pre- and post-op films (11 ACDF and 15 TDR) for development or progression of adjacent segment degeneration (see Figure 1).

For the first review, the index level was blinded on both pre-op and post-op radiographs to minimize any potential reviewer bias. For the second review, the index level was unblinded on both pre-op and post-op radiographs to allow for any potential reviewer bias.

The order of the sets of pre- and post-op films was randomly changed between the two reviews and the reviews were performed a week apart. Each reviewer graded ASD development/progression on the levels cephalad and caudad to the index level as yes (there was development/progression of ASD), no (there was no development/progression of ASD), and not applicable (not able to evaluate an adjacent level). Intra-rater reliability was assessed between the blinded and unblinded reviews and inter-rater reliability was assessed for each review. The Kappa statistic was used to measure both intra- and inter-rater reliability. The Chi-square statistic was used to assess differences in proportions of raters grades of ASD progression.

Results: The intra-rater reliability between the blinded and unblinded reviews was substantial indicating little to no bias in assessing ASD development/progression. The Kappa statistic for TDR spine surgeons 1 and 2 was 0.58 and 0.644 (p< 0.0001), respectively. The Kappa statistic for non-TDR spine surgeons 1 and 2 was 0.718 and 0.572 (p< 0.0001), respectively. The intra-rater reliability for the radiologist was 0.642 (p< 0.0001). Inter-rater reliability for the blinded review ranged from 0.316 to
Introduction: Recently, total disc replacement (TDR) has emerged as an alternative to anterior discectomy and fusion (ACDF) for treatment of intractable symptomatic cervical degenerative disc disease (DDD) at a single level. Despite initial positive clinical outcomes from several FDA investigational device exemption (IDE) trials, reports have documented the occurrence of segmental kyphosis in segments treated with a TDR. Segmental kyphosis has been associated with axial neck pain, and new-onset of neurological symptoms. In this study we examined the effect of the pre-operative disc angle on post-operative disc angle, R.O.M and clinical outcomes of patients who participated in the FDA IDE clinical trial of Mobi-C Cervical Artificial Disc.

Methods: A prospective, randomized, multi-centered, concurrently controlled FDA IDE trial to evaluate the safety and effectiveness of TDR with Mobi-C compared to ACDF was conducted. 145 patients implanted with a TDR as part of this study were used in this analysis. The primary outcome measures are pre-operative disc angle, post-operative implanted segment angle, range of motion, anterior-posterior (AP) translation, and overall study success at 24 months. Disc/segment angle was calculated based on neutral lateral radiograph. Range of motion and AP translation were calculated using flexion/extension radiographs. All radiographs were analyzed by the independent core lab Medical Metrics, Inc. (Houston, TX) using QMA software. Sign conventions are: positive angles indicate segmental lordosis and negative angles indicate segmental kyphosis.

Results: Pre-operatively 106 (73.6%) patients had lordotic disc angles and 38 (26.4%) patients had kyphotic disc angles. Post-operatively, 11 patients with kyphotic discs pre-operatively and 101 of these patients remained in lordosis after surgery with 5 patients shifting to kyphosis. Overall the mean disc angle pre-operatively for all patients was 2.9° ±4.9° and at 24 months was 7.4° ±5.5°. This difference is statistically significant (p<0.0001) towards an increase in lordosis at the treated segment. Pre-op disc angle was correlated positively with post-op segment angle (r²= 0.56). However, overall there was no correlation of pre-op disc angle with R.O.M or AP translation at 24 months. At 24 months, there were no differences between groups of patients who had a kyphotic or lordotic segment pre-operatively, in terms of overall study success, NDI score, or VAS neck pain score. Pre-operatively patients with lordotic disc angles had significantly more movement in terms of both flexion/extension ROM and AP translation. However, this significant difference between groups of patients disappeared at 24 months. Both groups of patients demonstrated significant increases in both ROM and translation and reached similar levels of motion at the index segment (Figure 1 and 2).

Conclusions: The results of this FDA IDE trial demonstrate that the NDI, VAS neck pain, and overall study success of TDR with Mobi-C are unaffected by pre-operative disc angle. These results also demonstrate that TDR with Mobi-C can restore lordosis and motion at the treated segment regardless of pre-operative disc angle.

288 Physical and Mental Life Quality in Patients Treated with Dynamic Cervical Implant
J. Herdmann1, B. Zillner1, P. Buddenberg1, F. Floeth1
1St. Vincent Hospital, Spine Unit & Center of Pain Management Duesseldorf, Dusseldorf, Germany

Introduction: New implants for cervical disc replacement aim at maintaining or restoring function. The Dynamic Cervical Implant (DCI™, Paradigm Spine) seeks to combine the advantages of the gold standard fusion technique with the motion preservation philosophy. DCI has a constrained motion: it works like a shock absorbing spring and may help to slow down adjacent segment degeneration.

Methods: Between 2007 and 2011 we selected 121 patients aged 32 to 73 years for treatment with DCI at either one or two levels (13 patients). Indications were radiculopathies (n=69), axial pain (n=6) or spondylotic spinal stenosis (n=46) without chronic myelopathy.
Patients are followed up at 3, 6, 12, and 24 months after surgery with NDI, pain and satisfaction questionnaires as well as SF12.

**Results:** Disc surgery was performed at C3/C4 (n=2), C4/5 (n=8), at C5/6 (n=65), C6/7 (n=57) and at C7/T1 (n=2). In flexion/extension radiographs motion rapidly increased after surgery. However, 5 of 19 segments treated during the initial phase of our study were fused (seen at 6 or 12 months). After implant footprint was changed and larger sizes were provided only 7 of 99 segments fused within 12 months (7%). More than 90% of the patients rated their clinical result as excellent or good. There were no implant related complications or revision surgery. Anterior migration of the implant resulted in fusion of the operated segment (2 cases) without need for additional measures. Neck pain, arm pain, and NDI continuously decreased in successive follow-ups. SF12-measures returned to normal (physical score) and even reached scores better than normal (mental scores). Correspondingly all satisfaction scores continuously increased.

**Conclusions:** Cervical disc replacement with DCI is positioned in between ACFD and TDR. The change of implant footprint after an initial trial has significantly reduced long-term fusion-rate. Clinical results after 24 months follow up are as good as or better than in anterior cervical fusion. Adjacent segment protection may be liable for this improvement, which is associated with enhanced life quality. DCI-patients will be followed-up continuously for the next years in order to validate these findings.

**Lightning Round: Outpatient Medical Economics**

**230 Spinal Keyhole Approach to Intraspinal Pathology**

M. Westphal, F. Raimund, U. Grzyska, D. Winkler, J. Regelsberger

1UK Eppendorf, Neurosurgery, Hamburg, Germany, 2UK Eppendorf, Neuroradiology, Hamburg, Germany

Access to intraspinal, intradural pathologies has to consider the impact on the biomechanics and stability of the vertebral column. Instead of extensive approaches requiring stabilizations to prevent sequelae from compromised biomechanics, minimal keyhole approaches have been developed and reduced morbidity. We here report on our experience with minimizing approaches to intraspinal pathologies.

Over a period of 15 years, 65 spinal dural arteriovenous fistulas (SDAVF), 77 intraspinal meningiomas, 82 intraspinal neurinomas and 329 intramedullary lesions (tumorous and vascular over a period of 25 years) were treated with minimal exposures, mostly using the “spinal keyhole approach”.

For SDAVF, the radioopaque placement of a radioopacity coil in a feeding vessel allows for the exact localization of the fistula by intraoperative fluoroscopy and then a limited partial hemilaminectomy by uniaterally expanding the appropriate interlaminar window. For meningiomas, in all cases a hemilaminectomy or partial hemilaminectomy of two adjacent laminae was sufficient to get 2-3 cm access to the dural origin of the tumor and by debulking and detaching of the dural origin the tumors could be mobilized into the opening so that complete removal was possible. The same approach was taken for neurinomas. This approach is particularly useful for lumbar lesions which in the cauda equine are highly mobile and can always be pulled inside the view of the keyhole for complete removal. For intramedullary tumors, a laminotomy is placed so that the poles of the lesions can be reached and intraoperative ultrasound before opening the dura has been extremely helpful to prove that the exposure in the prone position which differs from the supine position in which the diagnostic MRI was taken is adequate so that minimal extensions on either end can be performed with the dura closed. This saves the patient the a priori removal of an extra lamina as a “safety margin”.

In no case of SDAVF, spinal meningioma or neurinoma we saw signs of instability or deformity with observation periods of maximally 15 years. In no case an attempted keyhole approach had to be extended to a laminectomy. Only in 3 cases of cervical laminotomies (of six segments) we saw a saw neck deformity which in two cases required anterior and posterior stabilization. Spinal keyhole approaches are adequate for the removal of the vast majority of intraspinal pathologies, reduce procedural time, blood loss, postoperative pain, allow immediate mobilization and ensure functional integrity of the spine without stabilization. A general extrapolation of this approach to metastatic disease depends on individual conditions but needs much more complex considerations.

**226 Minimally Invasive Lateral Interbody Fusion (MI-LIF) in Smokers**

W.B. Rodgers, E.J. Gerber, J.A. Lehmen, J.A. Rodgers

1Spine Midwest, Inc., Research, Jefferson City, MO, USA

**Summary:** In a large single-site series of MI-LIFs, 356 patients smoked at the time of surgery. Overall clinical and radiographic outcomes and are reported.

**Introduction:** The pre- and post-operative results of MI-LIF were collected to assess feasibility and clinical and radiographic success in smokers.

**Methods:** In our single-site prospective series of 1093 MI-LIF patients, 356 smoked at the time of surgery. Patient demographics and clinical/radiographic outcomes were assessed.

**Results:** Patients ranged in age from 22-84 years (average 56 years) and were treated for a variety of indications. 46% had previous spine surgery. 17% had diabetes, 34% had CAD, 8% had COPD, and 11% were chronic steroid users. 49% were obese or morbidly obese. 427 levels were treated: 296 1-levels, 49 2-levels, and 11 3-levels. Grafting materials included a composite of DBM, local bone graft, and bone marrow aspirate (81.5%), a beta-tricalcium phosphate/hydroxyapatite (FormaGraft) with bone marrow aspirate (6.5%), and allograft cellular bone matrix containing native mesenchymal stem cells (1.7%). All but two surgeries included supplemental fixation, most performed in the same surgical position. There were no infections. Complications included 1 transfusion, 2 pneumonia, 1 reintubation, 1 ileus, 2 urinary retention, 1 atrial fibrillation, 1 endplate fracture (healed without intervention), 1 sacral fracture, 3 intraoperative hardware failures (replaced without incident), 1 osteophyte fracture (required reoperation), 2 compression fractures (required vertebroplasty), and 1 quad weakness (resolved without intervention). Hospital stay averaged 1.1 days. From pre-op to 24 mos post-op, average disc height improved by 2.9mm, average slip improved by 3.6mm, average VAS pain score decreased by 5.2 points. Signs of fusion by Lenke scores of 1 or 2 were 80% at 3 mos, 94% at 6 mos, and 98% at 12 mos and 98% at 24 mos -- not significantly different from the greater non-smoking (624 pts) cohort (84%, 95%, 97% and 98%, respectively).
Aims: There are growing demands for quality assessment in spine care. To date there is no registry or national standards widely employed to address this need. The purpose of this study was to describe the implementation of a spine surgery quality assurance (QA) program within a multi-site spine practice.

Methods: Data collected for the QA program included type of procedure, surgeon, assistant, hospital, intra-operative complications (with particular focus on dural tears) or unanticipated events (designated as “other”) for reporting purposes and included items such as inability to remove instrumentation as planned, change in surgical plan due to anatomy or intra-operative findings, etc.), post-operative complications /events, and re-operations. All operative notes were reviewed and entered into an Access file that serves as a surgery log by a staff member. During each post-operative patient visit, the clinical staff completed a form providing information on any complications /events occurring since surgery. The form was returned to be entered into the data file. Each quarter, a summary report was generated and provided to the peer review committee and each surgeon (see figure for overview of process). The report contained the incidence rate of each of these four categories for the entire practice to allow comparisons of the individual surgeon to the overall practice and to each other. At the end of each year, a composite report was prepared reporting the cumulative experience. A similar report was prepared for the first two-year cumulative experience.

Results: QA reports were successfully generated, reviewed by the peer review committee, and then by each individual surgeon. Any value that appeared to be an outlier compared with the overall practice value was investigated in greater detail and reviewed with the individual surgeon. An example of the type of data generated from the QA reporting follows: the report covering the first 2-year cumulative data found that the infection rate was 1.7% for the practice, ranging from 0.0% to 4.7% among individual surgeons.

Discussion: A QA program can be successfully implemented and maintained in a spine practice. There must be staff and resources dedicated to maintain the data file, monitor completion of the follow-up forms, and generate reports. Benchmarking surgeon performance is possible within the practice. External benchmarking can loosely be performed using published rates for complications such as dural tears and infections; however, differences in patient populations and procedures performed pose a challenge to performing exact comparisons. Trending individual surgeon’s performance allows for peer analysis, and remedial measures for consistent outliers within the practice. It is thought that this program can serve as a model for other clinics and can be implemented on a larger scale as a step toward comprehensive QA monitoring for spine surgery.

496 Mitigation of Investigator Bias in Adverse Event Reporting from an Industry-sponsored Spine Surgery Study: Utilization of an Independent Clinical Events Committee

J.D. Auerbach1, K. McGowan1, M. Halevi3, G. Maislin4
1Bronx-Lebanon Hospital Center, Department of Orthopaedics, Bronx, NY, USA, 2MCRA, New York, NY, USA, 3Paradigm Spine, New York, NY, USA, 4Biomedical Statistical Consulting, Wynnewood, PA, USA

Introduction: Recent articles in the lay press and in peer-reviewed publications have raised concerns about the ability to report high quality, unbiased adverse event data from an industry-sponsored spine surgery study where investigators may have a perceived conflict of interest. To address this, many clinical trials utilize an independent clinical events committee (CEC) to review adverse events and re-adjudicate the severity and relatedness accordingly. No study to date has demonstrated or quantified the degree to which bias is present in adverse event reporting, nor the effect that a CEC has on mitigating this potential bias.

Methods: The coflex® IDE study is a prospective, randomized, multicenter trial comparing coflex® device (n=140 patients) to laminectomy and posterolateral fusion (n=72 patients) for the treatment of spinal stenosis with spondylolisthesis. Investigators classified the severity of each adverse event (mild, moderate, or severe), and the relationship to surgery and device (unrelated, unlikely, possibly, probably, or definitely). An independent CEC, composed of 3 independent, blinded spinal surgeons without affiliation to the study sponsor, reviewed and re-adjudicated all adverse events. All CEC adjudications were binding to the sponsor.

Results: The CEC reclassified the level of severity, relation to surgery, and/or relation to device of 394 of the 1,056 (37.3%) adverse events. A similar proportion of adverse events were reclassified in the coflex® and fusion groups (37.9% vs. 36.0%, p=0.56). Similar rates of reclassification were also observed between the coflex® and fusion groups with respect to level of severity (6.3% vs 3.3%, p=0.06), relation to surgery (28.7% vs 27.1%, p=0.59), and relation to device (25.8% vs 27.4%, p=0.59). Conditional on CEC revising the investigators’ original rating, it was 5.3 (95% CI 2.6 to 10.7) times more likely for the CEC to upgrade the adverse event than to downgrade the adverse event. Similarly, it was 7.3 (95% CI 5.1 to 10.6) times more likely for the CEC to upgrade the relationship to surgery and 11.6 (95% CI 7.5 to 18.8) times more likely for the CEC to upgrade rather than downgrade the relationship to the device (Table).
Further break-down of the adverse event reports of the coflex® trial demonstrated that the status of the investigator’s financial interest in the company had little effect on the reclassification of adverse events. Similar rates of adverse events were reclassified in both investor and non-investor groups (37.2% and 37.4%, respectively).

Conclusions: Our results demonstrate substantial investigator bias in the reporting of adverse events. A total of 37% of adverse events were revised by the CEC, the vast majority of which were upgrades in the level of severity, or a designation of greater relatedness to surgery or device. An independent CEC can identify and mitigate potential inherent investigator bias and facilitate an accurate assessment of investigational device safety profile, and further, should be considered a requisite component of future clinical trials.

110 Anterior Cervical Discectomy and Fusion versus Cervical Disc Arthroplasty: Cost-utility Analysis Based on an Institutional Financial Data Economic Model

D.T. Warren1, C.M. Hoelscher1, T.M. Andres1, P.A. Ricart Hoffiz1,2, J.A. Bendo1, J.A. Godstein1
1NYU Hospital for Joint Diseases, New York, NY, USA, 2Westchester Medical Center, Valhalla, NY, USA

Purpose: Patients with cervical disc herniations resulting in radiculopathy or myelopathy from single-level disease have traditionally been treated with Anterior Cervical Discectomy and Fusion (ACDF) with excellent results. Cervical Disc Arthroplasty (CDA) has been shown to result in similar clinical outcomes. Expert suggestion of reduced adjacent segment degeneration is a promising future result. The purpose of this study is to compare the cost-utility of ACDF versus CDA in single level cervical disc disease using institutional financial data. We aim to structure future research of cost-utility over a long term follow-up for these alternative surgical options; this information is of particular interest when compared to our previously reported Medicare-based economic model.

Methods: We reviewed single institution prospective data from a randomized controlled trial comparing single-level ACDF and CDA in cervical disc disease. 28 patients (ACDF n=10, CDA n=18) underwent surgery as part of a randomized controlled trial. Data collected included demographics, HRQOL outcome scores (NDI and SF-36) and utility scores. The financial records of a separate cohort of 28 patients (ACDF n=15, CDA n=13) were reviewed to establish actual hospital cost, charge and payment data for each procedure. QALYs were calculated at 1 and 2 years after surgery, allowing for cost/QALY assessments utilizing both types of outcome scores. We then performed a cost-utility analysis based on incremental cost-effectiveness ratios.

Summary of results: RCT patients undergoing either ACDF or CDA were not significantly different in their demographic data; patients of the financial cohort were demographically similar to the trial patients. At two years, total QALYs gained when using NDI scores were 0.37 and 0.27 for ACDF and CDA, respectively; with SF-36 scores, total QALYs gained after two years were 0.47 and 0.32 for ACDF and CDA, respectively. The hospital cost of ACDF was $16,108, while the cost of CDA was $16,004; the total costs of these procedures, which included surgeons and anesthesiologist fees, were $19,811 and $18,440, respectively. Total Cost/QALY at 2 years using NDI scores was $53,543 for ACDF and $68,295 for CDA; Total Cost/QALY at 2 years using SF-36 scores was $42,151 and $57,624, respectively. The incremental cost-effectiveness ratio (ICER) of ACDF versus CDA at 2 years was $1,043 with NDI scores and $695 with SF-36.

Conclusions: We confirm the efficacy of ACDF and CDA in the treatment of cervical disc disease. Our results suggest similar clinical outcomes at one and two year follow-up. Both modalities demonstrate cost-effectiveness. However, the additional QALYs gained by ACDF in this study demonstrate a potentially more cost-effective profile for this procedure at two years. The ICERs suggest that the added benefit via ACDF comes at a reasonable cost. In comparison with our previously reported findings using a Medicare-based financial model, the ICERs are significantly lower when using hospital costs. This difference highlights the way in which cost-effectiveness research is influenced by the chosen financial model. Long-term follow-up may illustrate greater cost-effectiveness via CDA due to lower hospital costs and the possibility of reduced adjacent segment degeneration and revision surgery in the CDA population.

269 Lumbar Artificial Disc Replacement at an Ambulatory Surgery Center

K.A. Pettine1
1The Spine Institute, Loveland, CO, USA

Purpose: The purpose of this study is to determine if Lumbar Artificial Disc Replacements can be performed at an ASC with safety and efficacy.

Methods: Two hundred twenty-three patients underwent a lumbar artificial disc replacement at an ASC from 2005 to 2011. There were four types of lumbar artificial discs implanted; the Kineflex in 41 patients, the Charité in 84 patients, the ProDisc-L in 61 patients and the Freedom disc in 37 patients. Seventy-five percent of these patients were involved in an FDA IDE study and have had their medical records extensively monitored.

Results: The mean age of these patients was 42.1 and their mean BMI was 26.5. There were 115 females and 108 males. There were 195 patients who had a one-level artificial disc implanted, 10 patients had a two-level artificial disc and 18 patients had an anterior lumbar interbody fusion at one level and an artificial disc replacement at one level. OR time averaged 119 minutes at L4-5, 64 minutes at L5-S1 and 128 minutes for two levels. Time in the PACU was 83 minutes and time in the convalescent center averaged 18 hours. Every patient except two left the convalescent center within the 24-hour timeframe. Average ODI went from a 57.7 at pre-op to 25.9 at 12 months post-op for an average improvement of 55.1% (p < 0.001). Average VAS at pre-op was 78.0 and improved to 26.1 at 12 months follow-up for an average improvement of 66.5% (p < 0.001). Two patients had a re-operation within 24 hours and there was one unplanned hospital transfer. These cases will be discussed.

Conclusion: These results indicate lumbar artificial discs can be performed with safety and efficacy at an outpatient ambulatory surgery center.
INSIDE:

REGULAR POSTERS

POSTER AREA MAP

ALL POSTER TITLES LISTED
(IN NUMERICAL ORDER)

ORAL POSTER FULL ABSTRACTS
(LOCATED WITHIN THURSDAY PODIUM ABSTRACTS)

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**POSTER INFORMATION**

**The poster viewing hours are:**

- Tuesday, March 20  5:00 p.m. - 7:00 p.m.
- Wednesday, March 21  9:00 a.m. - 6:00 p.m.
- Thursday, March 22  9:00 a.m. - 6:00 p.m.
- Friday, March 23  9:00 a.m. - 2:00 p.m.

Posters are designed to provide attendees with an in-depth learning experience. New investigations, new methods, and innovative research are featured in Poster Exhibits.

**Awards will be presented on Friday morning, March 23, 2012 from 10:15 a.m. - 10:30 p.m.**
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Lumbar Therapies and Outcomes

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Can Dynamic Non-fusion Stabilization Make up for the Disadvantage of Decompression Alone for Unstable Lumbar Canal Stenosis?

T. Sakai1, H. Ohta1, Y. Matsumoto1, Y. Nakayama1, Y. Iguchi2, Y. Takemitsu1, H. Kida1
1Oita Orthopedic Hospital, Oita, Japan

Purpose: To compare clinical outcome and effects on operated and adjacent segments of patients with unstable lumbar canal stenosis treated with non-fusion stabilization and decompression surgery.

Materials: 68 patients underwent a surgery for unstable L4/5 lumbar canal stenosis. Decompression surgery was applied to 27 patients (Decompression group) and non-fusion stabilization in use of SSCS (Spinal Segmental Correction System, ulrich, Germany) (SSCS group) was applied to 41 patients.

Method: Preoperative and final follow-up JOA score and the improvement rate (Hirabayashi method) were used to assess clinical outcome. For imaging assessment, preoperative and final follow-up 1) lumbar kinematics at each segment [% segmental mobility (each segment ROM / total lumbar ROM) x 100] evaluated with functional radiographs, 2) progress of disc degeneration at each segment evaluated with MRI T2 weighted image (Pfirmann classification system) were used.

Results: Improvement of the JOA score showed a significant difference (48.2% in Decompression group and 70.6% in SSCS group). In SSCS group, the lumbar kinematic distribution at operated segments was significantly reduced but increased at proximal adjacent segment. Decompression group did not have significant difference but it tended to increase at operated segments. Between two groups, SSCS group showed significantly low kinematic distribution at operated segments, compared with Decompression group but no significant difference at proximal/distal adjacent segments. There was no significant difference in disc degeneration at all segments between two groups.

Conclusion: For unstable lumbar canal stenosis, non-fusion stabilization with SSCS may make up the disadvantages of decompression alone.

Lumbar Therapies and Outcomes

13
Correlation between Significant Cortical Signal Changes on Intraoperative Spinal Cord Monitoring and Blood Pressure during Lumbar Surgery

H.C. Gogineni1, E. Young1, J. Stover2, M. Windom2, C. Biro2, T. Syed2, N.U. Ahn1
1Case Western Reserve University School of Medicine, Cleveland, OH, USA, 2University Hospitals Case Medical Center, Cleveland, OH, USA

Summary of background data: The objective of our study is to determine if blood pressures commonly found in controlled hypotension adversely affect cerebral blood flow. Our study was a retrospective and observational study. During lumbar surgery, hypotensive anesthesia to achieve controlled hypotension is requested by many spine surgeons to decrease blood loss and to improve visualization. Naturally, anesthesiologists are resistive to lowering blood pressure due to the risk of cerebral hypoperfusion and possible stroke. These impending adverse events can be monitored in the intraoperative setting with somatosensory evoked potentials (SSEP). With this SSEP data, we can monitor in real time whether blood pressures commonly found in controlled hypotension adversely affect cortical signals and subsequent cerebral blood flow.

Methods: Upon obtaining IRB approval, we conducted a chart review of 123 patients who underwent lumbar surgery by one spine surgeon within the last 5 years at one institution. We obtained blood pressure data and recorded significant cortical signal changes in a binary format, i.e., whether a patient had significant cortical signal changes or not. The 4 blood pressure variables we obtained were minimum, average, and maximum systolic pressures, and average mean arterial pressure. We then performed logistic regression analyses between the various blood pressure data and cortical signal changes to identify any significant associations.

Results: Twelve out of the 123 patients had significant cortical signal changes. The lowest minimum systolic blood pressure recorded was 55 mmHg and the lowest average mean arterial pressure recorded was 59 mmHg. We found no significant associations between cortical signal changes and these four blood pressure variables (lowest p-value=0.156).

Conclusions: Controlled hypotensive anesthesia is an effective means of minimizing blood loss and decreasing operative time by allowing better visualization of the surgical field. We already know that cortical signal changes are representative of cerebral hypoperfusion, in the absence of other factors such as surgical manipulation of the spine that can cause cortical signal changes. Our study suggests that there is no significant association between the usual blood pressure variation of lumbar surgery and cortical signal changes. This information should allow anesthesiologists to employ hypotensive anesthesia to achieve controlled hypotension more frequently. We do recognize that more and larger studies might be needed to confirm our findings. Specifically, we understand that thorough neurological and cognitive testing postoperatively would be more definitive in determining if the patient had any lasting adverse effects due to their blood pressures during the lumbar surgery.
**Introduction:** The objective of our study is to determine if operative blood loss and postoperative recovery period length, in lumbar surgery, are correlated. Our study was a retrospective and observational study. The issue of rising health care cost has captured the attention of our nation in recent times. There are many factors that can add to the problem of rising health care cost. One such factor is the extensive number of postoperative recovery days spent in the hospital. Extensive postoperative recovery periods are sometimes necessary depending on factors such as the surgery performed and complications faced, among others. One such complication is high blood loss during the surgery. Some studies have shown a link between high blood loss and increased number of recovery days in the hospital. Our study was conducted to investigate this link specifically in lumbar surgery. Current evidence documenting the link between high blood loss and increased numbers of postoperative recovery days in the hospital specifically for lumbar surgery is scarce.

**Methods:** Upon obtaining IRB approval, we conducted a retrospective chart review of 115 patients who had undergone lumbar surgery at one institution by one spine surgeon within the last 5 years. We obtained their anesthesiology and operative records to retrieve their blood loss data during lumbar surgery. We also obtained their hospital records to retrieve data about the length of their postoperative hospital stay in days. We created a database and used linear regression analyses to find statistically significant correlations in our data.

**Results:** The estimated blood loss ranged from 100 ml to 3700 ml with a mean of 700 ml. The length of stay ranged from 2 to 22 days with a mean of 4.4 days. Using a linear regression analysis, while correcting for age and sex, we found a statistically significant positive correlation between operative blood loss and postoperative length of stay in the hospital after lumbar surgery (p-value=0.001).

**Discussion:** Increased health care costs arise from many factors, one of which is the increased postoperative recovery period. Our study suggests a link between increased postoperative recovery periods and higher operative blood loss, specifically in lumbar surgery. Using this study as a start, we can begin to tease out the factors that lead to increased postoperative recovery periods in the hospital. High operative blood losses obviously need to be curtailed to improve patient morbidity and mortality, our study provides another reason for that need. We do recognize that larger studies need to be conducted to verify our findings.

**Conclusion:** Kivaplasty represents an advanced kyphoplasty techniques with the additional benefit of avoiding additional bone damage. Furthermore it allows to minimise the cement volume which is reducing local and systemic cement toxicity effect. Clinical outcomes are adequate to other kypho- or vertebroplasty techniques.
Lumbar Therapies and Outcomes

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Changes of Segmental Motion in Lumbar Total Disc Replacement Using ProDisc-L: Their Impact on Facet Joint Degeneration and Clinical Outcomes

C.-K. Park¹, K.-S. Ryu¹, M.-H. Shin¹

¹Seoul St. Mary’s Hospital, The Catholic University, Seoul, Korea, Republic of

Objective: The purpose of this retrospective study is to observe postoperative changes of segmental motion at the index level and to evaluate possible factors that could affect postoperative segmental translation and to identify their relations with facet joint degeneration after lumbar total disc replacement (TDR) using the ProDisc-L.

Methods: Thirty-five consecutive patients, who underwent lumbar TDR using ProDisc-L, completed at least 24 months follow-up. Segmental lordosis, range of motion (ROM) and translation were assessed postoperatively 1 month and at least 24 months by using dynamic plain radiograph. They were assessed in relation to patient age, sex, levels with implants, the change of functional spinal unit (FSU) height, global ROM, prosthesis size, and prosthesis position. The changes of facet joint degeneration were also determined in relation to the change of segmental motion, clinical outcome and prosthesis factors.

Results: The postoperative changes of segmental lordosis, ROM, and translation degree were listed on table 1. Mean segmental lordosis was postoperatively increased at L4-5 (p=0.000) and L5-S1 (p=0.000). Mean segmental ROM was also increased postoperatively at L4-5 (p=0.000), however at L5-S1, there was no significant change (p=0.687). Mean segmental translation was significantly increased at L4-5 (p=0.03), however at L5-S1, the change was not significant (p=0.617). Relative size of prosthesis, the amount of changes in FSU, and global ROM was the significant factor among the variables related to segmental motion that authors assessed (p=0.042, p=0.032, and p=0.000, respectively). The progression of facet degeneration (PFA) at the index segments was positively related with female in gender (p=0.005), the malposition of prosthesis on frontal plane (p=0.022), however, there were no significant differences of segmental translation, segmental angle, and segmental ROM at index level between PFA group and non-PFA group (p=0.586, 0.625, and 0.650, respectively).

Table 1. Summary of the time course of changes in translation, segmental ROM, segmental angle after lumbar TDR

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<th>Segment</th>
<th>L4-5</th>
<th>L5-S1</th>
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<tr>
<td>Translation</td>
<td></td>
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<tr>
<td>PostOP</td>
<td>4.56±1.39</td>
<td>4.21±4.70</td>
</tr>
<tr>
<td>Last F/U</td>
<td>4.39±2.36</td>
<td>4.20±1.95</td>
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<tr>
<td>Segmental ROM</td>
<td>6.31±1.78</td>
<td>6.33±5.06</td>
</tr>
<tr>
<td>PostOP</td>
<td>13.78±5.07</td>
<td>13.91±4.44</td>
</tr>
<tr>
<td>Last F/U</td>
<td>18.26±5.95</td>
<td>16.25±5.06</td>
</tr>
<tr>
<td>Segmental angle</td>
<td>20.38±2.25</td>
<td>16.78±1.65</td>
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Conclusions: The present study demonstrated that after TDR using ProDisc-L, there were significant differences in segmental motion at index level including segmental angle and segmental translation regarding to the level implanted, and these differences were significantly correlated with the relative size of implant, the amount of post-operative change of FSU, and global ROM. However, it seems that the changes of segmental motion did not significantly affect to facet joint degeneration.
Regular Posters

MIS Technique and Results

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Self-closing Nitinol Clips for Minimally Invasive Spinal Dural Closure

N.P. Patel1, B.D. Birch1, M.K. Lyons1, S.E. Dement1, G.A. Elbert1

1Mayo Clinic, Phoenix, AZ, USA

Introduction: Minimally invasive approaches have been used to treat a variety of spinal conditions including degenerative disk/joint disease, bone pathology, epidural tumors, and infection. Benign intradural lesions such as schwannomas and dural arteriovenous fistulas (DAVF) have traditionally been approached through a bilateral laminectomy procedure with intradural exploration and resection of tumor or ligation of the fistulae. Newer minimally invasive approaches for these pathologies seem attractive, but dural closure remains problematic. The authors describe the use of self closing nitinol clips for dural closure for minimally invasive spine surgery and use illustrations to describe the technique.

Methods: Five patients with thoracic DAVF and 3 patients with lumbar intradural schwannomas were microsurgically treated with a minimally invasive technique. The procedure entailed localization using fluoroscopy followed by a midline 2.5 cm skin opening. Exposure was facilitated using single blade unilateral muscle retraction or tubular retractor. A hemilaminectomy was carried out under the microscope exposing the lateral aspect of the thecal sac on the appropriate side. The dura was opened in a paramedian fashion and stay sutures were placed. The pathology was then addressed in standard fashion. Dural closure was facilitated using self-closing dural spring sutures and fibrin sealant. The cases were retrospectively reviewed to determine the incidence of post-operative complications.

Results: Each patient tolerated the procedure well. There were no SSEP changes and no intraoperative or postoperative complications. Specifically, there were no new neurological deficits and no cerebrospinal fluid leaks. Each patient was ambulatory either the same day of surgery or the next morning with only minimal incisional back pain. There were no reactions to the nitinol clips.

Conclusions: The minimally invasive approach for intradural pathology is reasonable in selected cases. The dura is quite difficult to suture through tubular retractors, but the use of self closing nitinol spring clips is technically simple and obviates the need for suture. Our initial experience with this dural closure technique is promising.

MIS Technique and Results

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A Feasibility Research of Unilateral Incision MIS-TLIF Using Pedicle Screws and a Translaminar Screw Hybrid Fixation

K. Mao1, Y. Wang1

1General Hospital of People’s Liberation Army, Department of Orthopedics, Beijing, China

Objective: To investigate the feasibility and safety of unilateral incision hybrid fixation using pedicle screws and a translaminar screw in minimally invasive (MIS) transforaminal lumbar interbody fusion (TLIF).

Methods: 18 patients with single-level lumbar disc disease were treated with MIS-TLIF under METRx™ X-tube. After decompression and fixation using unilateral pedicle screws, a translaminar screw was inserted from the same incision to the other side. The results of perioperative parameters, radiographic images and clinical outcomes were assessed.

Results: All patients underwent MIS-TLIF were accomplished unilateral hybrid fixation without any neural complication. The average operative time was 106.67±18.79min, the average operative blood loss was 61.94±21.36ml, and the average postoperative ambulation time was 20.77±5.43h. The average length of translaminar facets screw was 52.33±2.3mm, and the postoperative X-ray and CT images showed all screws penetrate through facets joint. The postoperative VAS and ODI scores were significant improved compared with preoperative.

Conclusion: Bilateral hybrid fixation could be completed through unilateral incision by pedicule screws and a translaminar screw in MIS-TLIF, and the advantage including less invasion, quickly recovery, short operative time, and saving fixation cost.

Cervical Therapies and Outcomes

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Clinical Comparison of Two Implantation Systems for Single Level BRYAN Artificial Cervical Disc Replacement

R. Shi1, H. Liu1, C. Ding1, T. Hu1, Y. Song1, F. Pei1

1West China Hospital, Sichuan University, Department of Orthopedic, Chengdu, China

Background context: The BRYAN® cervical disc is widely used for cervical arthroplasty. Its two implanting instrumentation systems, the BRYAN® cervical system and the ACCEL® system, have not been compared clinically for their safety and effectiveness.

Purpose: To clinically evaluate the safety and efficacy of two implantation instrument systems for BRYAN cervical artificial disc single-segment replacement.

Study design/setting: A prospective non-randomized clinical controlled study in consecutive patients from November 2004 to April 2008, with minimum two-year follow-up.

Patient sample: Thirty patients with single-level cervical disc degeneration who responded poorly to conservative treatment and who accepted BRYAN artificial disc replacement.

Outcome measures:

Self-report Measures: Visual analogue scale (VAS), Odom score and neck disability index (NDI) were used to rate the pain, surgery outcome and neck disability.

Physiologic Measures: Range of motion (ROM) of cervical spine and replaced disc on plain radiographs were measured. Computerized tomography (CT) scan and magnetic resonance imaging (MRI) were reviewed.

Functional Measure: SF-36 was used to assess quality
of life.

**Methods:** The first 14 cases were operated with the BRYAN cervical system (Group A), and the next 16 patients with the ACCEL system (Group B). All those measurements were conducted before the surgery, and two weeks, six, 12, and 24 months after operation.

**Results:** Patients’ male-to-female-ratio was 3:2. The average age was 43.7±7.3 years. Patients’ baseline statuses were similar between two groups (P<0.05). VAS for neck pain and arm pain, NDI, and SF-36 were significantly improved after surgery (P<0.05) in both groups, and no clinical differences were found between groups (P>0.05). All Odom scores were better than good. The mean operation time and blood loss in Group A (173±42.5 minutes and 250±159.8 ml) were respectively significantly higher than the values for Group B (137.5±19.3 minutes and 138.1±86.7 ml, P<0.05). Motion of the prostheses and cervical spine were found similar between two groups during follow-up (P<0.05).

**Conclusions:** Both the BRYAN cervical system and the ACCEL system achieved satisfactory outcomes for artificial disc single-segmental replacement for cervical disc degeneration. The ACCEL system had the advantages of greater surgical efficiency and less blood loss. Similar clinical efficacy, cervical motion and prosthesis movement were obtained with the BRYAN cervical disc system and the ACCEL system.

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**MIS Technique and Results**

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**Least Invasive Decompression, Interbody Fusion, and Pedicle Screw Implantation of the Lumbar Spine - A Case Series Report**

S.G. Osman

1American Spine Center, Surgery, Frederick, MD, USA

**Background context:** The open surgical procedures of the lumbar spine, while addressing the pathology adequately may lead to complications which may be crippling. Complications apart, major dissections of the spine may lead to prolonged duration under anesthesia; 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. Hence, the need to develop the least invasive approach which adequately addresses the pathology.

**Purpose:** 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 techniques.

**Study design:** Prospective Study of case series treated by one surgeon. Outcome Measures include 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:** Surgical procedures included arthroscopic decompression of the foramina and the discs; interbody fusion with allograft bone chips and BMP-2 on collagen carrier; and percutaneous implantation of pedicle screws. Post-operatively the patients completed the questionnaires. Charts were reviewed for operative notes, hospital stay, medications, and imaging studies.

**Results:** 60 patients met the inclusion criteria. The average age is 52.8 years. 58% of patients were older than 50 years, and 20% older than 70 years of age. Most patients complained of both back and leg pain. Follow-up ranged 6-25 months with average of 12 months. Pre-operative diagnoses included: degenerative disc disease; degenerative motion-segment with stenosis; and spondylolisthesis. Levels fused: 1 = 22 (36.7%); 2 = 28 (46.6%); 3 = 7 (11.7%); 4 = 1 (1.7%); and 5 = 2 (3.3%). The average time in OR was 2:90 hours. Estimated blood loss averaged 57.6 cc. The duration of hospital stay averaged 2.6 days. Pre-operative and post-op back pain averaged 7.5 and 2 on VAS respectively. Paired t test was used for statistical analysis and the difference between pre-operative and post-operative back pain was significant (p < 0.005). Pre-operative and post-op leg pain averaged 7.0, and 1.7 respectively (p < 0.005). 47 images were available at the last visits, including x-ray and CT scans which showed solid fusion in 28 (59.6%) patients, stable fixation in 17 (36.2%), and osteolysis in 2 patients (4.2%). All patients had improvement of 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 developed pain due to loose pedicle screws and required removal of hardware. Both patients had satisfactory outcome after their second operations.

**Conclusion:** The procedure consistently produced satisfactory results in all demographics. The results of this study demonstrate how drastically the surgery related morbidity, and the treatment cost, can be reduced. The out-comes relating to patients in the age group of 71-90 years are particularly encouraging given that the population is getting older, and yet with the desire to continue with physical activities generally enjoyed by the younger generation.

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**MIS Technique and Results**

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**Arthroscopic Disectomy and Interbody Fusion of the Thoracic Spine a Report of Ipsilateral Two Portal Approach**

S.G. Osman

1American Spine Center, Surgery, Frederick, MD, USA

**Background data:** The standard approach to the Thoracic disc is through Thoracotomy. Video-assisted thoracoscopic approach has been used as an alternative to the open approach for nearly two decades, and more recently thoracic XLIF and extracavitary, posterolateral approaches have been introduced. The transthoracic procedures involve deflating the lung for access to the
spine, and post-operative thoracic drainage is necessary, and post-operative morbidity can be significant. The retro-pleural procedures are in their infancy, but the published results are promising. The purpose of this study is to introduce posterolateral arthroscopic thoracic decompression and fusion procedure, which is extra-pleural, least disruptive to normal anatomy, performed on the based on observational hospital stay for less than 24 hours in cost-effective manner.

**Methods:** 15 consecutive patients who underwent arthroscopic decompression and interbody fusion of the thoracic spine were prospectively studied according the hospitals IRB protocol. The SF-36 and VAS questionnaires were completed pre- and post-operatively. Paired t-test was used for statistical analysis. The patient was placed in prone position on a radiolucent table and instrumentation was performed under fluoroscopic control. Two portals were developed ipsilaterally (one for the arthroscope and the other for instruments) on the side of disc herniation, and a single portal was used on the contralateral side. Various instruments were used for disc excision and exploration of the spinal canal. Fusion was accomplished with bilateral cortico-cancellous dowels obtained from the iliac crests. Infiltration of the access channel and facet injections of the contiguous joints were performed with bupivacaine, for immediate post-operative pain control.

**Results:** 15 patients with the average age of 54 years were followed-up for 28 months post-operatively. Overall back pain score decreased from 7.2 (+1.5) to 3 (+2) following the procedure - P < 0.005. 11 patients were satisfied with their current life-style post-operatively as opposed to one pre-operatively. 2 patients had reoccurrences. Hospital stay averaged 18.5 hours. The operative room cost and the cost for hospital stay was 51.9% of cost of anterior open disectomy.

**Conclusion:** The extra-pleural, bi-portal ipsilateral, arthroscopic approach for the decompression and interbody fusion of the thoracic spine is feasible, cost effective, least traumatic, and associated with minimal complications. Patients with single level thoracic disc herniation obtained the best results. The technique is applicable for most thoracic disc herniations.

**Keywords:** Posterolateral, Endoscopic, retropleural, disectomy, bone dowels, fusion.

### Biomechanics/Basic Science

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**Improved Positive Identification of the Causative Bacteria in Pyogenic Spondylitis by Use of Multiple Tissue Samples and Prolonged Incubation**

*P. Buechin-Emunds*, C.R. *Schaetz*

1Orthopädische Klinik Markgröningen, Spine Centre, Markgröningen, Germany

**Introduction:** According to the literature the identification of responsible micro-organism in pyogenic spondylitis is successful only in 49-79%.

Therefore, we started a prospective study to assess the efficiency of using multiple tissue samples obtained by biopsy instead of smear tests plus prolonged incubation on the rate of positive bacterial cultures. The leading micro-organism in all published studies is *Staphylococcus aureus*.

**Methods:** All pat. with clinically fulminant pyogenic spondylitis were surgically treated. A dorsoventral spondylodesis with dorsal decompression, surgical debridement of necrotic tissue and spinal fusion was done. During surgery 5 tissue samples for microbiological examination were obtained. Aerobic and anaerobic incubation on different agar plates for 14 days. The culture was declared positive, if an agent could be detect in at least 2 cultures, and negatively if no growth was visible after 14 days. A histological testing was done as well. Tissue samples were also collected in a control group (surgical pat. without any signs of infection). Pat. considered for conservative treatment were subjected to a ct-guided biopsy of the inflammatory focus.

**Results:** We included 82 pat. with the clinical diagnosis of pyogenic spondylitis, 6 pat. were treated conservatively, 76 were treated surgically. 42 pat. with no history of infection were used as a control.

In 87% of the spondylitis group at least two cultures were positive for the same bacteria. The method of tissue sampling had a statistically significant, strong effect on the microbiological result. In the surgically treated group sensitivity of the method was 91 % versus 33 % in the CT-biopsy group (p=0.0044).

Also a variable with strong influence on the microbiological test result is prior antibiotic therapy. 32 pat. were treated with antibiotics before admission in our department. In pat. with previous treatment with antibiotics the microbiological test result was positive in only 57%. In the surgical spondylitis group more than 70% had 5 cultures positive for the same bacteria, an additional 10% had 4 positive cultures out of 5 samples. In total, 80% of cases had at least three positive cultures. In the control group only 4 patients showed three or more positive cultures. Thus, the specificity is 85% and the risk of false positive cultures 15%. In ROC-Analyses the threshold was 3 positive cultures, contrary to our definition given at the beginning. Leading bacteria was *S.aureus* detected in 21 pat. (25,6%). In 15 pat. (17,1%) *S.epidermidis* und 7 pat. (8,54%) *E.coli* in was identified. In the Control-Group only Propionibacterium acnes could be detected in 3 or more samples. In 14 pat. a bacterial resistance against Clindamycin (35,9%) was identified, in 13 pat. against Ciprofloxacin (33,3%).

**Discussion:** The rate of pos. results in microbiological diagnosis of pyogenic spondylitis significantly increased by using 5 tissue samples obtained by biopsy and prolonged incubation. Contrary to the studies about spondylitis published so far, in our presenting study *S.aureus* was encountered in a lower rate and *S.epidermidis* was detected in a higher rated as reported. The existence of types of bacteria with a high degree of preexisting bacterial resistance against commonly used first-line antibiotics strongly suggests to obtain a positive identification of the causative agent before beginning medical treatment.
MIS Technique and Results

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Conservative Care versus Cross-over to Radiofrequency Kyphoplasty: A Comparative Effectiveness Study on the Treatment of Vertebral Body Fractures
R. Bornemann1, L.A. Otten1, K. Kabir1, D.C. Wirtz1, R. Pflugmacher1
1Universitätsklinikum Bonn, Klinik und Poliklinik für Orthopädie und Unfallchirurgie, Bonn, Germany

Background: There is controversy about how to treat vertebral fractures. Conservative care is the default approach, despite lack of evidence. Radiofrequency kyphoplasty uses ultrahigh viscosity cement to restore spinal posture and stabilize the fracture. The aims of this study were to compare radiofrequency kyphoplasty to conservative care and assess the usual algorithm of starting all patients on conservative care for 6 weeks before offering surgery.

Methods: Elderly patients with painful osteoporotic vertebral compression fractures were all treated with 6 weeks of conservative care (analgesics, bracing, and physiotherapy). They were then offered the choice of continuing conservative care or crossing over to radiofrequency kyphoplasty, at 6 and 12 weeks. Clinical success was defined as: 1) VAS pain improvement ≥ 2, 2) final VAS pain ≤ 5, 3) no functional worsening on ODI.

Results: After the initial 6 weeks of conservative care, only 1 of 65 patients met the criteria for clinical success, and median VAS improvement was 0. After 12 weeks of conservative care, only 5 of 38 patients met the criteria for clinical success, and median VAS improvement was 1. At the 6 week follow-up after radiofrequency kyphoplasty, 31 of 33 surgery patients met the criteria for clinical success, and median VAS improvement was 5.

Conclusion: For the vast majority of patients, conservative care did not provide meaningful clinical improvement. By contrast, nearly all patients who underwent radiofrequency kyphoplasty had rapid substantial improvement. Surgery was clearly much more effective than conservative care and should be offered to patients much sooner.

Cervical Therapies and Outcomes

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Occipitocervical Fusion with Transpedicular Fixtion System
R. Zhu1, H. Yang1
1The First Affiliated Hospital of Suzhou University, Suzhou, China

Objective: To evaluate the effects of an occipitocervical fusion with transpedicular fixation system in a large and diverse patient population, the authors prospectively studied a consecutive group of 43 patients. 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. 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%. Transpedicular internal fixation system has multiaxial screw of three-column fixation and plastic rods, which offer strong fixation 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.

Cervical Therapies and Outcomes

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Cervical Percutaneous Nucleotomy and Decompression
M. Schubert1
1APEX Spine Center, Spine, München, Germany

Background and purpose: Because of the fear of complications related to conventional treatment for cervical disc herniations, minimal invasive procedures gain significant interest in patients and spine surgeons. The purpose of this study was to evaluate the effectiveness and complication rate of an anterior percutaneous minimal invasive surgical treatment.

Study design: A prospective clinical study.

Patient sample: 267 consecutive patients over a 4 year period with a MRI or CT proven disc-herniation, with or without foraminal stenosis, predominantly radicular symptoms, no previous neck surgery and not responding to conservative treatment. All patients had a two year follow up.

Outcome measures: The patients had a clinical evaluation 3 months after surgery and returned at two years an extensive questionnaire including VAS Score, MacNab Score as well as subjective satisfaction.

Methods: In all cases a confirmative discography of the affected level was performed. If discography did not reveal massive epidural dye leakage, 500 I.U. chymopapain was injected. Subsequently a mechanical percutaneous foraminal decompression was performed with a two millimetre reamer and mechanical forceps removal of protruded and extruded disc material under control of a X-image intesifier.

Results: After two years 89.8% of the patients reported excellent or good results. 9% of the patients had a fair or unaltered result and 1.2% reported no improvement at all. Recording to the VAS scale the patients reported a significant improvement for arm pain (6,7pts) as well as neck pain (6,2pts). In 3 cases an early recurrent disc herniation (< 3month) appeared (1,2%). 11 patients (4,3%) had a recurrence within 2 years. 3 patients (1,2%) had again a percutaneous treatment, 1 patient (0,4%) had a mikrodiscectomie and 7 patients had a fusion. One patient had to be hospitalized because of bleeding from...
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the upper thyroid artery. There was one dural puncture and two cases with subcutaneous haematoma. One patient had temporary hoarseness for 2 weeks. One patient developed a stress-ulcer from previous long term steroid use. All patients recovered without residual symptoms. There were no infections. **Conclusion:** This procedure is a delicate but save and effective treatment for cervical disc herniations even in case of foraminal stenosis.

**Lumbar Therapies and Outcomes**

78 Microscopically Assisted vs. Standard Laparotomy L5-S1 Circumferential Fusion 1 Year Follow-up J. Buric1, D. Bombardieri1, C. Del Gaizo1, M. Pulidon1 1cddc Villa Torri, Bologna, Italy

**Background:** Antero-Posterior (360°) lumbar fusion as compared to Postero-Lateral fusion showed to be superior on a long term follow-up in terms of higher fusion rate and better clinical outcome. Main limit to the approach is a higher rate of visceral and vascular complications.

**Objective:** To prospectively evaluate the usefulness of microscopically assisted L5-S1 retroperitoneal approach as compared to the standard anterior retroperitoneal approach.

**Methods and materials:** Twenty patients affected by low back and leg pain due to degenerative disc disease and/or spondylolisthesis were included in the study. Ten patients were submitted to a single-stage microscopically assisted left-retroperitoneal anterior lumbar interbody fusion and posterior pedicle instrumentation and 10 patients were submitted to a single-stage standard laparotomy left retroperitoneal anterior interbody fusion and posterior pedicle instrumentation. Technical difference between the two approaches lays mainly in a significantly smaller skin incision (mean 6 cm) in the microscopically assisted group as compared to the standard group (mean 20 cm). The microscopical view permitted a better and more detailed control of great and small para and pre-vertebral vessel as well as of the nerves of hypo gastric plexus.

**Results:** In the microscopically assisted group no complications were observed during the peri-op and post-op period while in the standard group two major vascular complications and a transient hypogastric plexus lesion occurred. Blood loss in the microscopically assisted group was negligible (< 10 cc) while in the standard group was significantly higher (mean 250 cc). On 1 year follow-up, clinical outcomes for both groups were identical, however, patients from the microscopically assisted group had a faster post-operative mobilization (mean 12 hours) as compared to the standard group (mean 36 hours). The microscopically assisted group of patients reported less pain in the first 48 hours (VAS 2.5) as compared to the standard group (mean VAS 5.5) and required less analgesics as compared to the standard group. In the microscopically assisted group no cases of permanent or transitory ileus was ever observed while in the standard group a mean of 30 hours was needed before the bowels function was restored. The fusion rate, as evaluated by an independent observer, was 100% for both groups. Mean operation time for the microscopically assisted group was slightly longer (100 minutes) as compared to the standard group (85 minutes). No complications related to posterior pedicle instrumentation was observed in either group.

**Conclusions:** Use of microscope permits better visualization of vessels and a proper positioning of the retractor blades particularly in regard to veins that frequently and inadvertently may slip under the retractor and be lesioned. Small nerves of the hypo gastric plexus can be precisely isolated and retracted with less damage. The approach itself requires less retraction and thus compression on the peritoneum and a better control of the ureter. The incision of the anterior annulus can be done more precisely with a better control of the margins of incision. The use of microsurgical techniques during the anterior approaches to the L5-S1 interbody discectomy and fusion showed to be advantageous in all aspects except the time interval.

**Biomechanics/Basic Science**

80 Biomechanical Comparison of Cervical Disc Replacement and Fusion Using Bi-level and Hybrid Constructs: A Finite Element Study A. Gandhi1, S. Kode1, D. Fredericks1, J. Smucker1, N. Grosland1 1University of Iowa, Iowa City, IA, USA

**Objective:** To compare the kinematics of the cervical spine following a bi-level total disc replacement (TDR), a bi-level fusion, and a hybrid (TDR adjacent to fusion) procedure.

**Methods:** A previously validated specimen-specific 3D finite element model of the cervical spine (C2-T1; Figure-1A) [1] was modified to simulate moderate degeneration at levels C5-C6 and C6-C7 [2]. The degenerative model was then altered to accommodate the three surgical procedures outlined below:

**Bi-level Fusion Model:** A fusion at C5-C6 and C6-C7 was modeled by changing the material properties of the intervertebral disc to that of bone [3].

**Bi-level TDR Model:** A TDR with Prestige LP (Medtronic, Memphis, TN) cervical disc was introduced at C5-C6 and C6-C7 (Figure-1A) [4]. Prestige LP has two articulating components; a ball on the upper and a trough on the lower component which were meshed with hexahedral elements.

**Hybrid Model:** A hybrid model was created to simulate a TDR at C5-C6 and fusion at C6-C7 (Figure-1A). The original, healthy model was subjected to pure moments (up to ±2.0 Nm) in flexion-extension, lateral bending, and axial rotation. Thereafter, the degenerative and three surgical models were analyzed by increasing the moment until the motion (C2-T1) matched that of the healthy model. The analysis was performed using ABAQUS 6.9. Range of Motion (ROM) and disc stresses were used for analysis.
Results: Figure-1B compares the intersegmental motions for all five models in flexion-extension. As compared to the healthy model, each model predicted a decrease in motion at the modified (i.e., degenerative, implant, or fused) levels and an increase in motion at the unaltered, or adjacent, levels. During flexion/extension the bi-level fusion exhibited a 98% decrease in motion at the fused levels which was accompanied by a 61% increase in adjacent segment motion. The motion at the operative bi-level TDR segments were reduced by 22%, while the adjacent level motions increased by 12%. The change in adjacent level disc stresses for the modified models corresponded with the changes in intersegmental motion, where the adjacent levels were least affected by the bi-level TDR (+7%), moderately affected by the hybrid construct (+32%), and largely affected with the bi-level fusion (+88%). Similar trends were observed in lateral bending and axial rotation.

Conclusion: Bi-level TDR model predicted motion and stresses close to a healthy model and better than the degenerative and fusion model indicating that it is a superior biomechanical alternative to fusion. The hybrid model showed that the Prestige LP disc was good at handling the increased stresses adjacent to fusion, thus showing that Hybrid construct is a better biomechanical alternative to bi-level fusion.

References:

Biomechanics/Basic Science

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Biomechanical Evaluation of Balloon-kyphoplasty and Radiofrequency-kyphoplasty in a Bisegmental Osteoporotic Human Spine Model
H.-J. Riesner¹, H.-J. Wilke², B. Friemert³, N. Graf³, R. Ihler³, G. Achatz⁴, R. Lechner⁵
¹Armed Forces Hospital Ulm, Surgery, Ulm, Germany, ²Institute of Orthopaedic Research and Biomechanics, University of Ulm, Ulm, Germany

Aim: To treat vertebral body compression fractures (VCF) cement augmentation is a common practice. Besides balloon-kyphoplasty (BK), the most used kyphoplasty system worldwide, several new developments had been introduced to the market recently, among them radiofrequency-kyphoplasty (RFK) which uses an ultra high viscose bone cement, which is applied hydraulically controlled. This technique is supposed to increase the working time of the cement, paired with a lower risk of cement extravasation and a reduced destruction of trabecular bone compared to BK. However similar results concerning stabilization and reduction of the fracture are promoted. Aim of this study was to biomechanically analyze and compare those two methods concerning stabilization of VCF and height restoration.

Methods: Twelve human osteoporotic bisegmental spine specimens were divided into two groups, each consisting of 3 x T9-11 and 3 x T12-L2 segments. A VCF (A1.2) with height reduction of 30% of the anterior vertebral edge was created in the middle vertebra. After kyphoplasty, either with BK or RFK, a complex cyclic loading of 100.000 cycles was performed. The Range of Motion (RoM in Flexion/Extension (Ex/Flex), lateral bending and rotation (Rot)) was measured with a spine tester; the height of the vertebral body was assessed radiologically. Significance was set at p< 0.05.

Results: A significant increase of RoM was seen after fracture (all results in median, related to intact condition; BK/RFK) (Ex/Flex: 230/243 %, lateral bending: 171/182 %, rotation: 135/146 %). Both kyphoplasty methods created a significant stabilization of the fracture. (Ex/Flex: 204/208 %, lateral bending: 144/161 %, rotation: 120/119 %), however a significant larger RoM compared to the intact status remained. After cyclic loading a significant rise in RoM was seen (Ex/Flex: 399/416 %, lateral bending: 241/252 %, rotation: 257/263 %), largest in the first 20.000 cycles. The compression fracture caused a height reduction at the anterior edge (BK/RFK) of 5.8 mm in BK and 4.9 mm in RFK specimens. Height increased after augmentation by 2.3 respectively 2.1 mm, yet the original height was not restored. Cyclic loading caused a significant height reduction of 3.7 and 1.9 mm. There were no significant differences between BK and RFK concerning RoM and height.

Conclusion: The stabilization and reduction of a VCF is similar with BK and RFK, however there remained significant differences compared to the intact specimens with both techniques. Therefore both methods seem equal concerning stabilization and height restoration.

MIS Technique and Results

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Minimally Invasive Multi-level Posterior Lumbar Interbody Fusion Using the Modified Mini-open and Trans-facet Approach with the Rimmed Head Type Percutaneous Transpedicular Screw System Characterized by a Combination of Axis Guidance and Detachable Extender Systems for Degenerative Spinal Disease Requiring Posterior Decompression
H.S. Kim¹, S.J. Jeong³, H.J. Ahan¹, K.H. Jeon¹, W.J. Choi¹, K.T. Kim¹, C.J. Ju¹, S.W. Kim¹, S.M. Lee², H. Shin²
¹Hurisarang Spine Hospital, Neurosurgery, Daejeon, Korea, Republic of, ²College of Medicine, Chosun University, Neurosurgery, Gwangju, Korea, Republic of
Objective: Minimally invasive percutaneous transpedicular screw fixation allows for significantly less blood loss and tissue disruption. However, there are technical limitations with multi-level procedures via the percutaneous technique, especially when using axis guidance. The purpose of this study was to describe the surgical technique and outcome of minimally invasive multi-level posterior lumbar interbody fusion (PLIF) using the axis guided percutaneous transpedicular screw fixation system.

Methods: The current study included 84 patients and divided into the following two groups: A (n=68), mini-open two-level PLIF; and B (n=16), mini-open three-level PLIF. The mean age: 64.41 (44 ~ 78 years) in group A, and 64.88 (50 ~ 79 years) in group B. The mean follow-up period: 28.65 (15 ~ 45 months) for group A and 29.19 (14 ~ 38 months) for group B.

Patients received multi-level PLIF using a modified mini-open and trans-facet approach with the percutaneous transpedicular screw fixation system (Apollon System®, Solco Biomedical Co., South Korea). This method uses an percutaneous transpedicular screw fixation system with rimmed screw heads and is characterized by the combined use of the vertical axis guidance and a detachable extender.

Under epidural anesthesia, decompression underwent via a trans-facet approach and screws were inserted into paraspinal route after subdermal paraspinal dissection. To evaluate the surgical results, we assessed the epidural anesthesia, operation time, intra-operative blood loss, midline skin incision and procedure-related complications. To evaluate the clinical outcome, we assessed the postoperative ambulation time, the Visual Analog Scale (VAS) and Low Back Outcome Score (LBOS) at the final follow-up.

Results: Epidural anesthesia was used in 66 group A cases (97.06%), and 14 group B cases (88.89%). Operation times were 159.41 min (120 ~ 200 min) for group A and 198.13 min (160 ~ 250 min) for group B. Intra-operative blood loss was 249.26 ml (140 ~ 350 ml) in group A, and 386.86 ml (250 ~ 700 ml) in group B. Midline surgical scars were 6.38 cm (4 ~ 9 cm) in group A, and 8.13 cm (6 ~ 12 cm) in group B. Postoperative ambulation time was 1.93 days (1 ~ 4 days) for group A, and 2.31 days (1 ~ 4 days) for group B. The mean pain score (VAS) prior to surgery was decreased at the last follow-up from 7.53 (6 ~ 9) to 2.31 (1 ~ 4) in group A, and from 7.56 (7 ~ 9) to 2.81 (2 ~ 4) in group B. The mean LBOS prior to surgery improved at the last follow-up from 7.53 (6 ~ 9) to 2.31 (1 ~ 4) in group A, and 29.88 (18 ~ 40) to 58.18 (52~64) in group B. The mean LBOS prior to surgery improved at the last follow-up from 7.53 (6 ~ 9) to 2.31 (1 ~ 4) in group A, and 29.88 (18 ~ 40) to 58.18 (52~64) in group B.

Conclusion: Multi-level minimally-invasive PLIF was effectively performed using the percutaneous transpedicular screw fixation system with a modified mini-open and trans-facet approach under epidural anesthesia. This method can be used effectively with the percutaneous transpedicular screw fixation system with rimmed screw heads characterized by the combined use of vertical axis guidance and detachable extender system.

Lumbar Therapies and Outcomes

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Extreme Lateral Interbody Fusion (XLIF) of the Initial Consecutive Case Series. Learning Curve at 1 Year Follow-up
J. Buric1, C. Del Gaizo1, D. Bombardieri1
1cdc Villa Torri, Bologna, Italy

Background: Anterior interbody lumbar fusions as compared to posterolateral fusion showed to be superior on a long term follow-up in terms of fusion rate, re-operations, sagittal alignment and clinical outcome. Main limit of the anterior approach is a higher rate of potentially serious complications as vascular and visceral injuries. Extreme lateral lumbar interbody (XLIF) fusion is a novel concept of anterior lumbar interbody fusion techniques. While maintaining all the advantages it is less invasive, with lower complication rate and shorter times of surgery. Main limit to the approach is the L5-S1 level, unreachable due to iliac crest morphology.

Objective: Retrospective outcome evaluation of initial consecutive case series.

Methods and materials: Thirty-four consecutive patients affected by degenerative disc disease and/or spondylolisthesis of the lumbar spine. All of the patients presented with a long-standing low back and/or leg pain. Thirteen patients were previously operated. One level pathology was treated in 15 patients, two levels in 11 patients and more than 2 levels in 8 patients. Five patients were submitted to stand-alone XLIF and 29 to circumferential fusion with bilateral pedicle screw instrumentation. The patients were followed-up for 1 year with Visual Analog Scale and with multiple questions interview.

Results: The mean pre-op VAS values were 6.3 (±2.4) and 4.7 (±2.8) for back and leg pain, respectively. On 1 year follow-up the mean VAS values were 2.4 (±2.2) and 1.4 (±2.1) for back and leg pain, respectively. The difference between pre-op and 1 year follow-up was statistically significant (-3.9 and -3.3). Four patients (11.8%) reported unchanged and 2 patients (2.9%) reported worst clinical outcomes as compared to pre-op clinical status. All of the other patients reported better
(10 pts.; 29.4%) and much better (18 pts.; 52.9%) clinical outcomes. Twenty eight patients were satisfied with the surgery and would do it again, 2 patients were satisfied with the surgery but would not do it again while 4 patients were not satisfied and would not do it again. Mean operating time for the sole lateral approach was 57.5 minutes by level although the result could be biased as with the gain in experience the time shortened to 30 minutes for the last 15 patients. The mean blood loss regarding the sole lateral approach was < 50 ml. No major visceral or vascular injuries occurred. In one case a psoas muscle hematoma was observed. There was 1 case of skin layer post-op infection resolved with 1 month antibiotic therapy. In one case an intra-op fracture of the body of L4 occurred. In 2 cases of stand-alone XLIF, subsidence of the upper vertebrae was observed. Useful fusion, as seen at 1 year follow-up X-rays, was achieved in 94% of patients.

**Conclusions:** Clinical and radiological results of XLIF at 1 year follow-up were found satisfactory and super imposable to other types of circumferential fusions. The learning curve showed to be short and only the time consumption changed between the first and the last case done. Absence of major visceral and vascular lesions and lower surgical time makes it a useful alternative to anterior interbody fusion. Its major limit is the L5-S1 level.

**Lumbar Therapies and Outcomes**

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10-year Experience in Autologous Disc Chondrocyte Transplantation (ADCT): A Critical Clinical Review of 115 Cases

H.J. Meisel¹, C. Hohaus¹, T. Ganey², U. Mansmann³

¹BG Clinic Bergmannstrost, Department of Neurosurgery, Halle, Germany, ²Atlanta Medical Center, Atlanta, GA, USA, ³LMU Munich, Munich, Germany

This report details a clinical series of 115 ADCT cases that were enrolled from January 2000 to June 2011. Discectomy treatment for disc herniation results in a significant loss of nucleus material and subsequently in disc height. Morphological restoration through the use of ADCT represents a strategy that offers a potential to accentuate disc metabolism that will achieve mechanic function. The clinical goal was to provide long term pain relief, prevent adjacent segment disease, and reduce recurrent disc herniation. Oswestry low back pain disability questionnaire (OPDQ), Prolo and VAS scores were used for the evaluation. Disc height and water content were assessed by MRI. Demographic data, neurological status and BMI were collected from the patients. 6, 12 and 24 months postoperatively.

The mean age of the patients was 34.6 years; the mean BMI 23.9. Significant improvement in OPDQ total sum score persisted through the two-year assessment. Reherniation rate was reduced by 63%. Clinical durability as well as pain and disability gains of these ADCT patients was defined under strict regimen of inclusion/exclusion criteria for this minimally-invasive percutaneous disc repair.

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Long-term Outcomes Following Lumbar Spine Fusion for Adult Isthmic Spondylolisthesis: A Comparison of Posterior Lumbar Interbody Fusion with Posterolateral Fusion

P.A. Robertson¹, J.E. Cunningham²

¹The Orthopaedic Clinic, Mercy Specialist Centre, Auckland, New Zealand, ²Royal Melbourne Hospital, Melbourne, VIC, Australia

**Purpose of the study:** Posterior lumbar interbody fusion (PLIF) has the theoretical advantage of optimising foraminal decompression, improving sagittal alignment and providing a more consistent fusion mass in adult patients with isthmic spondylolisthesis (IS) compared to posterolateral fusion (PLF). Previous studies with only short-term follow-up have not shown a difference between fusion techniques.

**Methods:** An observational cohort study was performed of a single surgeon’s patients treating IS over a ten year period (52 patients), using either PLF (21 pts) or PLIF (31 pts). The PLIF group had surgical intervention with R90/Hourglass interbody lordotic spacers, interbody autologous cancellous bone graft and posterior pedicle screw instrumentation with the TSRH system. The procedure was the same for the PLF group but no interbody instrumentation or fusion was performed. Preoperative and 12-month data were collected prospectively, and long-term follow-up was by mailed questionnaire. Preoperative patient characteristics between the two groups were not significantly different. Average follow-up was 7 years, 10 months, and 81% of questionnaires were returned. Outcome measures were Roland Morris Disability Questionnaire (RMDQ), Low Back Outcome Score (LBOS), SF-12v2 and SF-6D R2. The SF-6D R2 is a “whole of health” measure.

**Results:** PLIF provided better short- and long-term results than PLF. The PLIF group had significantly better LBOS scores in the long term, and non-significantly better RMDQ scores in the long term. As measured by RMDQ Minimum Clinically Important Difference (MCID) set at 4, RMDQ MCID set at 8, the LBOS MCID set at 7.5 points and by SF-12v2 physical component score (PCS), PLIF patients performed better than PLF patients. When analysing single level fusions alone, the difference is more pronounced, with PCS, mental component scores and SF-6D R2 all being significantly better in the PLIF group rather than the PLF group.

**Discussion and conclusions:** This paper strongly supports the use of PLIF to obtain equivalent or superior clinical outcomes when compared to PLF for spinal fusion for lumbar isthmic spondylolisthesis. The results of this study are the first to report to such long-term follow-up comparing these two procedures.
Lumbar Vertebral Reconstruction Using Dual Expandable Corpectomy Spacer in a Posterior Spondylectomy Model: A Biomechanical Cadaver Study
A. Muzumdar¹, B. Bucklen¹, M. Chen², R. Jandial², B. Kelly², D. Reddy¹, S. Khalil¹
¹Globus Medical, Inc., Research, Audubon, PA, USA, ²City of Hope, Division of Neurosurgery, Duarte, CA, USA

Surgical intervention of the anterior and posterior columns is often required for management of trauma, infection or malignancy. Posterior-only approaches have become increasingly used to perform segmental resection and reconstruction in these circumstances. Typical reconstruction involves posterior instrumentation 2 levels above and below with a single central expandable spacer. In the lumbar region, the nerve roots increase the technical difficulty and often prevent placement of a large corpectomy device. To facilitate delivery through the posterior lumbar approach, as well as potentially add greater anterior column support, the authors explored a reconstruction method using two parallel expandable cages reinforced with pedicle screw fixation. The biomechanical stability of the smaller bilateral expandable cages (which can be inserted with a single-stage posterior approach) was compared to a traditional larger corpectomy device (which is usually inserted through an anterior or lateral approach) in lumbar spondylectomy model. In both scenarios long posterior pedicle screw and rod fixation was included 2 levels above and below the spondylectomy. Additionally the effect of adding torsional cross-connectors to the rods of the treated level was examined.

Five human cadaver T12-S1 spines were tested using a multi-directional, six degree-of-freedom spine tester [Globus Medical, Audubon, PA]. Each spine was tested to 8 N-m in flexion-extension (FE), lateral bending (LB), and axial rotation (AR) using a load-control protocol. Subsequently, spondylectomy was performed at L3, and two, parallel corpectomy spacers [X-PAND, Globus Medical] were inserted. Posterior pedicle screws and rods [REVERE, Globus Medical] were applied from L1-L5, with cross-connectors at L3. Various derivations of this base construct were performed and shown in Figure 1, changing the number of spacers, the size of the spacers, and the addition of cross-connectors. All constructs demonstrated improved stability when compared to the intact, or pre-op condition. In LB, all constructs demonstrated rigidity less than 6% of intact motion. In FE, cross-connectors provided a constant amount of “extra-stability” of 2-3.5 degrees less than the corresponding condition without cross-connectors. Similarly, in AR, cross-connectors decreased range-of-motion from 7-12 degrees. The number or sizes of corpectomy spacers led to minor differences in LB or AR. However, in FE, two bilateral devices placed near the cortical rim reduced motion when compared to a single medium or even a large sized device. In conclusion, long posterior fixation is necessary to provide adequate stability in a lumbar spondylectomy model. Further addition of cross-connectors is beneficial in axial rotation. Biomechanically, using two parallel expandable corpectomy spacers on the cortical rim leads to improved stability in flexion-extension and is clinically conducive to a single-stage posterior approach.

Biomechanics/Basic Science

Transforaminal & Posterior Decompression of the Lumbar Spine - A Comparative Study of Stability and Intervertebral Foraminal Area
S.G. Osman¹,²
¹American Spine Center, Orthopedic Surgery, Frederick, MD, USA, ²Frederick Memorial Hospital, Surgery, Frederick, MD, USA

Background: Adequate posterior decompression with laminectomy and partial facetectomies may, without guaranteeing adequate foraminal decompression, lead to excessive removal of stabilizing structures which may in turn lead to acute or chronic instability; recurrent neural compression; violation of the spinal canal and subsequent fibrosis; and risk of dural tear and nerve injury in subsequent surgeries. Clinically, endoscopic foraminoplasty is not associated with instability of the spine, and there is less risk of intra-spinal fibrosis.

Purpose: To study the feasibility of transforaminal endoscopic foraminoplasty; compare the spinal stability following transforaminal and posterior decompression; assess the adequacy of foraminal decompression by comparing the foraminal area after decompressions using the two methods; and to compare anatomic changes following the two procedures.

Materials and methods: 10 lumbar spinal functional units obtained from five fresh human cadavers (3 male
Treatment has failed. Nevertheless, rigid fixation has several disadvantages, such as stress-shielding, adjacent level hyper mobility, and reduced load-sharing which may lead to pseudoarthrosis. Consequently, an ideal implant will demonstrate an optimum stiffness which would minimize the above issues. As the stiffness of the spinal unit is a combination of the implant stiffness and fusion mass stiffness, the response of the surrounding tissue to the implanted construct is paramount. Semi-rigid fixation devices such as Polyetheretherketone (PEEK) rods, titanium rods with helical grooves, and polymeric spacers with an interwoven cord tethered between pedicle screws have been designed to provide an intermediate level of stabilization and increase load sharing with the anterior column.

The authors evaluated the kinematic differences between semi-rigid PEEK rods and a pre-loaded, pre-assembled polymeric cord and spacer-based system (TRANSITION, Globus Medical, Audubon, PA) Ten human cadaver lumbosacral spines (L3-S1) were tested under a pure moment of 7 Nm, using a 6-degree-of-freedom spine tester (Globus Medical), in flexion-extension (FE), lateral bending (LB), and axial rotation (AR). The specimens were divided into two groups of five, according to the type of semi-rigid fixation applied. Each type of transpedicular semi-rigid instrumentation utilized pedicle screws of a different design and could not be re-used on the same specimen without sacrificing screw purchase. Posterior fixation was tested with and without a lateral interbody spacer [TransContinental, Globus Medical]. Results are presented as a percentage of intact range-of-motion (ROM).

In the without-interbody group, rigid rods achieved the highest level of fixation (FE: 25%, LB: 33%, AR: 52%), with both semi-rigid systems demonstrating equivalence (TRANSITION FE: 34%, LB: 54%, AR: 82%; PEEK Rods FE: 35%, LB: 51%, AR: 65%). The addition of a lateral interbody spacer provided much stability, similar to that of semi-rigid instrumentation without interbody, in all three loading modes. In the interbody group, rigid rods achieved the highest level of fixation (FE: 16%, LB: 23%, AR: 40%) compared to the semi-rigid systems (TRANSITION FE: 20%, LB: 30%, AR: 48%; PEEK Rods FE: 18%, LB: 30%, AR: 47%). The stiffness of the spine after surgery is a combination of the applied instrumentation and fusion mass. With difficulty in predicting the contribution of the fusion mass, this study investigated the rigidity of posterior instrumentation imparted on the spine. The perceived benefits of semi-rigid systems may further contribute to the stiffness of the fusion mass, but could not be evaluated. Semi-rigid systems led to gradual decrease of stiffness of 10%, 20%, and 20% in FE, LB, and AR, respectively when compared to rigid systems without interbody. With the addition of a lateral interbody device, range-of-motion of semi-rigid systems was reduced by 16%, 22%, and 26%. There were no detectable differences between the semi-rigid devices tested.

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The Comparative Stability of Rigid and Semi-rigid Systems in a Lumbar Cadaveric Model

B. Bucklen1, M. Moldavsky1, S. Khalil1, P. McAfee2

1Globus Medical, Inc., Research, Audubon, PA, USA, 2Towson Orthopaedic Associates, Sparks, MD, USA

Fusion using rigid pedicle screw-rod instrumentation is a conventional surgical treatment for several conditions related to degenerative disc disease when non-operative treatment has failed. Nevertheless, rigid fixation has been designed to provide an intermediate level of stabilization and increase load sharing with the anterior column.

Regular Posters
Results: The structural properties and appearance of the device remained intact at 30, 90 and 180 days. The material remained flexible, hydrophilic, and soft, without visible resorption or decomposition. The material was well tolerated by the animal, with minimal histological signs of inflammation or rejection. Tissue plane of dissection scores were significantly lower at the device sites than the control sites for each timepoint. Animals in the 180 day group underwent MRI scans at 102 days post implant. No depression of the spinal cord was observed at the test site in one sheep and a slight depression of the spinal cord was observed in the second sheep with however no abnormal neurological finding.

Conclusions: The PVA vessel shield effectively protected the structures overlying the sheep spine during revision, providing a clear dissection plane for resection at repeat surgery. The overlying structures separated from the previous surgical site with no adhesion and allowed safe separation of adjacent tissues without the use of sharp dissection.

Cervical Therapies and Outcomes

109 Does Maintenance/Restoration of Segmental Lordosis Contribute to the Outcome of ACDF Patients? A Pilot Study

I.H. Lieberman1, X. Hu1

1Texas Back Institute, Scoliosis & Spine Tumor Center, Plano, TX, USA

Introduction: Anterior cervical discectomy and fusion (ACDF) remains the standard of care for patients with cervical radiculopathy who are unresponsive to conservative medical care. Normal cervical lordosis (C2-C7) is measured approximately at 34 degrees. The maintenance/restoration of segmental lordosis is usually ignored as an outcome factor in ACDF surgeries. The aim of this study is to review a series of ACDF patients and to evaluate the relationship between segmental lordosis maintenance/restoration and clinical outcome.

Methods: Data were collected prospectively from the ACDF (control) group of randomized clinical trials comparing total disc replacement with ACDF at a single site. A database of 31 patients that received ACDF was established as the study group. The patients had reached an average of 22.3 months (range from 3 to 60 months) follow-up. Kyphosis angles were measured preoperatively and at the latest follow-up. On lateral radiographs, the angle between the lines drawn at the posterior margin of the most cranial and caudal vertebral bodies forming the local kyphosis was determined as the kyphosis angle. The visual analog scale (VAS) for neck pain, arm pain, and neck disability index (NDI) were obtained for each patient. The correlation between segmental lordosis maintance/restoration and clinical outcome of ACDF surgeries was analyzed.

Results: A total of 31 patients were included in this study. The mean age of the patients at surgery was 43.4 years (range 27-60). Sixteen (51.6%) of which were female and fifteen (48.4%) were male. Twenty seven patients (87.1%) had one-level ACDF and four patients (12.9%) had two-level ACDF. Nine patients (group 1) had...
and they were corrected to cervical lordosis at the follow-up visit. Six patients (group 2) had cervical kyphosis and their kyphosis was similar postoperatively. Sixteen patients (group 3) had cervical lordosis and their lordosis was maintained at follow-up. On average at 22.3 months (range from 3 to 60 months) follow-up, all three groups had improved neck VAS scores, arm VAS scores and NDI scores. The neck VAS scores improved 47.3%, 67.9%, and 56.2% respectively in three groups. The arm VAS scores improved 48.9%, 63.6%, and 57.2% respectively in three groups. The NDI scores improved 64.1%, 81.0%, and 61.8% respectively in three groups (Fig. 1).

Discussion and conclusions: Unexpectedly, from the above results, it appears that the patients that presented with cervical kyphosis had relatively better outcome compared to the other groups, even where surgery provided for no restoration to cervical lordosis (Fig. 1). This study still does not clearly answer if the maintenance/restoration of segmental lordosis contributes to the clinical outcome of ACDF patients.

MIS Technique and Results

121 Radiographic, Surgical Outcome of Percutaneous Sacroiliac Joint Fusion with Porous Plasma-coated Triangular Titanium Implants: An Independent Review

J. Glaser1, L. Rudolf1, T. Horst1, W. Barfield2
1Medical University South Carolina, Charleston, SC, USA,
2Alice Peck Day Medical Center, Lebanon, NH, USA

Background: Diagnosis and treatment of a dysfunctional sacroiliac joint is challenging as well as controversial. We describe a new technique involving percutaneous placement of porous plasma-coated triangular titanium implants across the sacroiliac joint.

Purpose: The purpose is to independently review the surgical and radiographic results of this procedure.

Study design: We reviewed 31 consecutive patients who underwent the procedure by one orthopaedic surgeon. The reviewers have no relationship with the patients or with the company producing the implants.

Patient sample: 31 patients underwent sacroiliac fixation between 10/24/2007 to 10/14/2009, 7 men and 24 women. Mean age was 54.3 years at the time of surgery (34-85). Mean follow-up period was 13.7 months (6-30). 29 of 31 patients had a minimum of 12 months of follow-up. All patients had pain unresponsive to prolonged nonoperative treatment and had complete or near complete pain relief with CT-guided sacroiliac injection. Implants produced by SI-BONE, Inc., San Jose, California.

Outcome measures: Radiographic and surgical assessments.

Methods: After appropriate Institutional Review Board approval, medical charts, plain radiographs, and CT scans were deidentified and randomized. They were then reviewed by investigators not involved with the care of the patients to determine the surgical and radiographic outcomes. Radiographic outcome consisted of evaluating osseous ingrowth into the implant surface, bone growth across the sacroiliac joint, and radiographic complications.

Results: 27 patients expressed satisfaction, and 4 patients did not. There were no recorded intraoperative complications. Estimated blood loss was none to minimal in all patients. Each patient was discharged home on postoperative day one. Patients began walking full weight bearing by 8-9 weeks (8 patients), 12 weeks (21 patients), and 16 weeks (2 patients). Pain relief was noted to be Complete (16 patients), Excellent (5 patients), Good (9 patients), and Fair (1 patients). There were 4 patients with postoperative complication. These were infected hematoma (2), L5 nerve root irritation by implant (1), and L5-S1 discitis (1). One patient required revision. On 6 mo. postop CT scan, 18/19 patients had radiographic evidence of bone ingrowth and bone into or across the SI joint was evident in 8/19 patients. There also was lucency around at least one implant in 5/19 patients.

Conclusions: Preliminary results are promising for the use of this percutaneous sacroiliac joint fusion implant for a carefully selected group of patients with disabling SI dysfunction.

Keywords: Sacroiliac dysfunction, Sacroiliac joint fusion, Porous Titanium Implants

Biomechanics/Basic Science

122 Comparison of the Biomechanical Effect of Pedicle-based Dynamic Stabilization: A Study with Finite Element Analysis

T.-A. Jahng1, Y. Kim2, K. Moon3
1Seoul National University College of Medicine, Neurological Surgery, Jongno-Gu, Seoul, Korea, Republic of, 2Dankook University, Department of Mechanical Engineering, Yongin, Korea, Republic of, 321 Century Hospital, Neurosurgery, Siheung, Korea, Republic of

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™ (Synthes Spine, West Chester, PA. USA), Dynesys™ (Zimmer Spine, Warsaw, IN. USA), and PEEK rod were chosen as the representative PBDS and compared with the intact spine and rigid rod fixation model of functional spinal unit.

Objective: To investigate the effect of implantation of PBDSs to spinal functional unit and to elucidate the differences in biomechanical characteristics according to different materials and design.
Lumbar Therapies and Outcomes

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Is it Possible to Increase and Maintain Disc Height when Performing a New Technique in Instrumented Lumbar Posterolateral Fusion (PLF)? Results from a Consecutive Prospective Study

S. Berg1, P. Dahlemar Sterner1

1Stockholm Spine Center, Upplands Väsby, Stockholm, Sweden

Purpose of the study: Lumbar fusion is considered the “gold standard” treatment for chronic low back pain (CLBP) that is believed to be due to degenerative disc disease (DDD) and is not relieved by prolonged conservative treatment. Instrumented intercorporal fusion is believed to better restore disc height and prevent postoperative kyphosis than instrumented posterolateral fusion (PLF). A new technique to perform PLF, utilizing the possibilities of modern pedicle screw systems, challenges this belief, why this study is performed.

Material and methods: 89 consecutive patients age 20-73, all with CLBP. 50 patients were female. 79 patients were diagnosed as DDD only, 10 patients had a spondylolisthesis with concurrent DDD. 45 patients were treated at one segment, 43 at two and one patient at three segments. PLF’s were performed in all patients using a pretension-distraction technique. All patients had pre-and immediate post-operative as late follow-up X-rays taken. Disc height and lordosis were calculated for all treated segments according to evaluated methods. The values on disc height and lordosis were compared for each patient from pre- to immediate post-operative and follow-up.

Summary of the findings: All treated segments had an increase of disc height from preoperative to postoperative examinations. Despite some reduction of this increase at late control follow-up, the increase was still significant for L3-L4 segment (men) and L4-L5, L5-S1 segments (women). Lordosis was reduced postoperatively with less than the measurement error for the method.

Conclusion: When this method to perform PLF was used, long-term increase in disc height and maintenance of lordosis was at least as favorable as reported on intercorporal fusions.
complications including major blood vessel injury, neurological damage, or nerve root injury. Quality of life was assessed with EQ-5D VAS and EuroQol-5D. The follow-up schedule was 6 weeks, 3, 6, 12, and 24 months. To account for missing followup data, longitudinal values were compared with a repeated measures ANOVA model with a compound symmetric covariance structure. To assess outcome differences from baseline, an estimated least-square means from the fitted model was used. The 95% confidence intervals and p-values for pairwise comparisons of pre-operative and post-operative visits were adjusted for multiple comparisons using a mixed effect model. The Dunnet procedure was used for post hoc analysis.

**Results:** Thirty-seven patients have been treated with 34 available for follow-up at 6 months (90.1%) and 26 (67.4%) at 12 months. Two patients were lost to follow-up after 6 weeks. The average age was 61.7±11.1 years with 49% male patients. Surgery time was 87.3±29.8 minutes with an EBL of 216.0±107.9 mL. Thirty-nine levels were implanted: 2 at L2-L3, 13 at L3-L4, 21 at L4-L5 and 3 at L5-S1. There were 3 double-levels, with the remainder single-levels, and one level adjacent to a three-level fusion. There were no major intra-operative complications. There was one reoperation for compromised wound healing, one motor weakness one day postoperatively (leg, resolved) and one device removal at 12 months. Significant improvement (p≤ 0.001) was noted in all effectiveness outcome measures through 12 months, with ZCQ-PS significant (p= 0.02) at 12 months as compared to 6 weeks (Figure 1). Improvement in quality of life was also noted (Figure 2). Patient satisfaction was 60% at 6 months and 12 months.

**Conclusion:** While this data represents short term follow-up, and is limited to a single site and patient numbers, it appears that treatment of NIC secondary to LSS using this device via a unilateral approach represents a safe and effective alternative to traditional treatments. However, longer patient followup is required.

### Cervical Therapies and Outcomes

#### En Bloc Cervical Laminoplasty Using Trans-laminar Screw (T-laminoplasty): New Procedure of Cervical Laminoplasty

*T.A. Jahng*, *S.E. Lee*

**Background:** Cervical laminoplasty is a popular surgical procedure for patients with multilevel compressive cervical lesions. However, several reports have noted its limitations and shortcomings.

**Objective:** The authors have newly developed an en bloc cervical laminoplasty procedure using a trans-laminar screw to preserve the posterior midline structures so as to maintain spinal stability and prevent postoperative axial pain and deformity.

**Methods:** In brief, after standard exposure of posterior cervical spine with preserving the midline ligamentous structure, en bloc laminotomy was made. The trans-laminar trajectory from the lamina to the contralateral lateral mass was prepared. Then, a long trans-laminar screw was inserted through the lamina with suspension of the laminotomized block to expand the spinal canal, passed through the allograft laminar spacer, and finally was inserted in the contralateral lateral mass. Next, using the same method a following screw was inserted to the adjacent segment from the opposite side; further screw fixations were made using this alternating fashion.

**Results:** The levels of laminoplasty totaled 47 in 11 patients. C3-C6 laminoplasty was the most common (7 patients). Clinical outcomes were statistically improved during the mean follow-up period of 13 months. Radiologic outcomes of cervical lordosis and range of motion were preserved with expansion of the cross-sectional area of the spinal canal.

**Conclusion:** En bloc cervical laminoplasty using trans-laminar screw can be a surgical option for multilevel compressive cervical lesions. With this novel procedure, it was possible to preserve the midline ligamentous structures while obtaining good clinical and radiologic outcomes.

### Lumbar Therapies and Outcomes

#### Non-fusion Dynamic Stabilization in Addition to Decompressive Laminectomy for Spinal Stenosis with Degenerative Lumbar Scoliosis

*T.A. Jahng*, *S.E. Lee*

**Background:** Spinal stenosis with degenerative lumbar scoliosis is a challenging condition that often requires complex surgical interventions.

**Objective:** The authors propose a novel approach combining non-fusion dynamic stabilization with decompressive laminectomy to address both stenosis and scoliosis.

**Methods:** The procedure involves decompression of the stenotic levels followed by placement of dynamic stabilization implants. These devices are designed to provide segmental stabilization while allowing motion at the treated segments.

**Results:** In a series of 15 cases, the authors demonstrated significant improvement in symptomatic relief and radiographic outcome measures. Patients reported reductions in pain and improved quality of life.

**Conclusion:** This combined approach offers a safe and effective option for patients with degenerative lumbar scoliosis and stenosis, potentially reducing the need for major fusion surgery.
Summary of background data: Spinal stenosis with degenerative lumbar scoliosis mostly occurs in the elderly population causing pain in the legs and back, claudication, and spinal deformity. Surgical management includes decompression and fixation with fusion either with an anterior or posterior approach to prevent further progression of the deformity.

Objective: To analyze surgical outcomes after non-fusion stabilization in addition to decompressive laminectomy for spinal stenosis with a mild to moderate degree of degenerative lumbar scoliosis.

Methods: Twenty-eight patients (21 women and 7 men with a mean age of 65.3 years) with spinal stenosis and degenerative lumbar scoliosis who underwent non-fusion stabilization with the Dynesys™ system (Zimmer Spine, Minneapolis, MN) in addition to decompressive laminectomy were included in this study. Medical records and radiographic studies were reviewed to access clinical and radiological outcomes and surgery-related complications.

Results: The mean follow-up period was 25.56 months. Fifty-six segments were decompressed in 28 patients. The segments for decompressive laminectomy were as follows: one segment in 6 patients (21.4%; L4/5), 2 segments in 16 patients (57.1%; L3/4/5 in 15, L4/5/S1 in 1), and 3 segments in 6 patients (21.4%; L2/3/4/5 in 5, L1/2/3/4 in 1). There were 59 stabilized segments without fusion in 28 patients: One segmental stabilization in 8 patients (28.6%; L4/5), 2 segmental stabilizations in 11 patients (39.3%; L3/4/5), 3 segmental stabilizations in 7 patients (25.0%; L2/3/4/5 in 6, L3/4/5/S1 in 1), and 4 segmental stabilizations in 2 patients (7.1%; L2/3/4/5/S1 in 1, L1/2/3/4/5 in 1). Radiographically, the global lumbar scoliosis angle was 12.39° ± 5.00° before surgery, 4.47° ± 3.83° after surgery, and 7.22° ± 6.66° at last follow-up with a statistically significant correction for the scoliosis angle (p < 0.001). Lumbar lordosis and range of motion (ROM) at each segment was preserved. The visual analog scale (VAS) for leg and back pain decreased, and Oswestry disability index (ODI) improved after surgery with statistically significant change. There were no newly developed neurological deficits or aggravation of neurological symptoms.

Conclusion: Non-fusion stabilization in addition to decompressive laminectomy resulted in a safe and effective procedure for elderly patients with lumbar stenosis with a mild to moderate degree of scoliosis angle (< 30°). Statistically significant improvement of the clinical outcome was obtained at last follow-up with no progression of the degenerative scoliosis.

Lumbar Therapies and Outcomes

150 Endoscopic Herniated Discectomy with Saline Flow

J. Rigal1, S. Aunoble1, R. Saddiki1, F. Sibilla1, J.-C. Le Huec1
1University Victor Segalen Bordeaux 2, Bordeaux, France

Introduction: Discectomy is one of the most common spinal surgeries. Open discectomy remains the standard method for treatment of lumbar disc herniation, but can traumatize spinal structure and leaves symptomatic epidural scarring in more than 10% of cases. The video-assisted surgery, described by Destandaeu and K.Foley, is an alternative because of its benefits during surgery: bleeding decreased, better view and after surgery: pain and decreased fibrosis compared with the conventional method. S.Ruetten has recently proposed an endoscopic technique with saline flow. His study compared the endoscopic technique to open technique. The last article of PEUL published in JAMA (Journal of the American Medical Association) does not show the superiority of the endoscopic technique compared with the minimally invasive technique. The purpose of our study was to analyse the long-term results of the endoscopic herniated discectomy with saline flow and compare the technique feasibility, safety and efficacy of this one.

Materials and methods: It is a prospective study. 30 patients have been operated (17 males and 13 females) between april 2009 and april 2011 by two spine surgeons in one medical center. Our indications were herniated discs L4-L5 or L5-S1 excluded or under-ligament.

Installation in prone position, marking the surgical

Lumbar Therapies and Outcomes

139 Clinical Value of Nerve Root Sedimentation Sign in Lumbar Spinal Stenosis

K. Y. Lee1, L. Wang1, H. J. Kim1, Y. S. Oh1
1College of Medicine, Dong-A University, Orthopedic Surgery, Busan, Korea, Republic of

Aims: To assess the diagnostic value of sedimentation sign shown on MRI with lumbar spinal stenosis and comparison of postoperative clinical results.

Methods: Three hundred two patients diagnosed with lumbar spinal stenosis by MRI were reviewed to indentify a sedimentation sign and all of them were performed the operative treatment. 142 patients who did not be confirmed as spinal stenosis by MRI were selected as control group to estimate the diagnostic value of nerve root sedimentation sign. Correlation with the duration of preoperative symptom and the number of involved segments were compared and analyzed between sedimentation sign positive (Group I) and negative (Group II). We estimated Million Visual Analogue Score (MVAS) and Korean Oswestry Disability Index (KODI) for the assessment of the pain and the functional disability.

Results: A positive sedimentation sign was found in 265 patients (87.7%) and diagnostic value was statistically significant (p < 0.001). 2 or more segments involved were significantly correlated with sedimentation sign positive group (p < 0.001). MVAS presented the improvement of 64.5±4.6%, KODI, 62.9±3.9% after surgical treatment in Group I in Group II, each scores showed the improvement of 34.6±2.3% (MVAS), 37.1±1.8% (KODI). The improvement of these scores in Group I was better than in Group II.

Conclusion: Nerve root sedimentation sign is an additional tool to diagnose lumbar spinal stenosis and the considerable factor to decide the operation.
window and lateral fluoroscopic. The surgery was possible by use of Ellman bipolar and Wolf instruments. Incision of 7mm. Visual analog scale scores for back pain and leg pain, Oswestry Disability Index and Roland-Morris score were recorded preoperatively, and at 3, 6, 9 and 12 months postoperatively. Recurrence and complication rate were recorded too.

**Results:** Mean operative time was 54 min (30-110 min) Intra-operative complications were one case of dural tear, 3 conversions in open technique. Postoperatively, we had an early recurrence of disc herniation causing a cauda equina syndrome taken urgently with recovery underway.

VAS scores for back pain and leg pain, Oswestry and Roland-Morris score revealed statistically significant improvement when they were compared with preoperative values. Mean hospital stay was statistically shorter with the endoscopic technique. There were no major surgical complications, and no medical or infectious complication. The recurrence rate was 6.6%.

Our study shows similar results to those of S.Ruetten but side effects increased mainly due to the learning curve.

**Conclusion:** The advantages of the endoscopic technique are very interesting, especially with regard to the postoperative. Indeed two MRI systematic monitoring showed the complete absence of muscle damage and the lack of post-operative fibrosis. In addition, the complication rate decreases with experience, compared with the open technique, and there is an early recovery activities.

**Cervical Therapies and Outcomes**

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**Efficacy and Safety of an Absorbable Cervical Cage with and without Plating: A Multicenter Case Study**  
*B. de Germay¹, L. Boissiere², S. Aunoble², J.-C. Le Huec³*  
¹Clinique de l’Union, Toulouse, France, ²Bordeaux Segalen, Bordeaux, France

**Purpose:** The objective of the present study is to evaluate the clinical results of an absorbable cervical cage (TCP/PLLA) in anterior cervical discectomy and fusion (ACDF).

**Methods:** The study subjects were 89 consecutive patients who underwent single or multi level anterior cervical discectomy and fusion with a Duocage® absorbable cage, with or without plate fixation.

**Results:** Cervical interbody fusion is excellent with stable dynamic X-rays for 98.0% of the operated levels, good resorption, and without clinical inflammatory reaction, at latest follow-up. Functional results and return to activities are also good. This study confirms that patients with a fixation plate have better outcomes in terms of migration, loss of disc height, and functional results and pain when operated on several levels.

**Conclusions:** The Duocage® absorbable cage is capable of achieving fusion without inflammatory reaction during resorption. Furthermore, these findings confirm that the fixation plate can decrease the risk of migration and subsidence of the cage.
Introduction: The Dynesys® system (Zimmer, Winterthur, Switzerland) has been used as a dynamic lumbar stabilisation device for more than 15 years. Even if good short term results have been reported little is known about the long-term outcome especially in the most common indication of degenerative spondylolisthesis at L4/5.

Materials and methods: All patients with a monosegmental degenerative lumbar spondylolisthesis at L4/5 which were treated with the Dynesys stabilisation system between 2000 and 2006 were re-assessed. In all patients bilateral decompression of index segment was performed. At a mean follow-up interval of 7.2 years (range 4.8-11.2), 39 patients (female: 30; male: 9) returned for a review. For Outcome measurement the «Spine Tango» (including SF-12, EQ-5D, Oswestry Disability index) for the assessment of the Quality of Life and a Questionnaire based on Grob et al containing questions about changes in back and leg-syndroms after surgery, duration of improvement, reoperations, changes in workstatus, quality of life and free time activities, global outcome after surgery and the willing of undergoing surgery again with hindsight was used. Radiographic assessment included a.p., lateral and functional x-rays of the lumbar spine. Complications regarding the implant, i.e. screw loosening, as well as signs of adjacent segment degeneration and persisting motion in the stabilized segement were specifically registered.

Results: At latest follow-up 8 of 39 patients (21%) had undergone further surgeries. The reasons for re-intervention were symptomatic adjacent segment disease in 6 cases, late onset infection in one case and implant breakage in another case. Backpain had improved in 89 % of patients, legpain in 86%. Work status had improved in 82%, free time activities in 84% following index surgery. 84% reported an improvement of overall quality of life, 83% stated a global subjective improvement judging the success of the surgery in general. 92% of the patients would undergo the surgery again with hindsight. In 9 cases progression of spondylolisthesis could be found in the stabilized segment. Moreover we found 4 cases of asymptomatic screw loosening. 29 of 39 (74%) operated segments showed a limited flexion-extension angle of less than 4° in the functional x-rays, which is clinically defined as a fusion. 17.9%(7/39) of the adjacent segments L5/S1 and 28.2%(11/39) of the adjacent segments L3/4 showed signs of adjacent segement pathology with reduction of disc height even though there was no clinical correlation.

Conclusion: Long-term results after monosegmental instrumentation of degenerative spondylolisthesis L4/5 with the Dynesys-System are favourable. The revision rate is low and seems comparable to other dorsal instrumentation devices. Although the remaining motion in the stabilized segment is reduced, the rate of radiologically visible as well as clinically symptomatic adjacent segment degeneration appears low. Dynesys instrumentation seems a valuable alternative to formal fusion in cases of L4/5 degenerative spondylolisthesis also in the long-term.
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Lumbar Spinal Stenosis Treatment with Aperius® Percutaneous Interspinous Spacer (INCA Trial)

F. Bonte1, J.K. Van Meirhaeghe1, P. Fransen2, D. Morelli3, N. Craig4, G. Godde5, F. Collignon6

1AZ Sint-Jan Brugge-Oostende AV, Dienst Orthopedie en Traumatologie, Brugge, Belgium, 2Clinique du Parc Leopold, Centre Neurochirurgical, Brussels, Belgium, 3CHU Tivoli La Louviere, Service de Neurochirurgie, La Louviere, Belgium, 4Woodend Hospital, NHS Grampian, Orthopedic Suite, Aberdeen, United Kingdom, 5Zentrum für Molekulare Orthopädie, Gemeinschaftspraxis Königsallee, Düsseldorf, Germany

Introduction: Degenerative lumbar spinal stenosis (DLSS) is a disease with Neurogenic Intermittent Claudication (NIC) -a position-dependant complaint- being its cardinal symptom. Patients usually present with leg pain and possibly back and/or buttock groin pain. Interspinous Process 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, thus relieving symptoms. The APERIUS® Percutaneous Interspinous Spacer is the first percutaneous IPD to treat DLSS with NIC.

Material and methods: The INCA trial, a multicenter single arm post-marketing study evaluated the safety and effectiveness of the APERIUS. One hundred fifty-six patients with a history of DLSS at one or maximum two levels (L1-L5) with confirmed symptoms of NIC were included and followed for 12 months with visits at 48hours, 7days, 6 weeks, 6 and 12 months. Primary effectiveness endpoint was assessed as the mean % change from baseline in Zurich Claudication Questionnaire (ZCQ) Symptom Severity at 6 weeks. The % of patients reaching the Minimal Clinical Important Difference (MCID) for ZCQ (≥0.5 points increase in Symptom Severity and Physical Function) and clinical important VAS leg pain (≥30% improvement)[1, 2] were assessed. Procedure and device related SAE were assessed throughout the complete study.

Results: A total of 128 patients completed the full follow-up. Mean age was 65 years (range 19 to 84) with mean complaint duration 41.3 months. Surgery was done at 1 level in 72 patients, 2 levels in 74 patients and 10 patients received 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. Six weeks post operative the MCID was reached in 77% of the patients for ZCQ symptom severity and 65% for physical function. At 12 months, these numbers decreased slightly to 60% and 58 % respectively. Clinically important leg pain improvement is reported in 62% of patients at 12 months. A total of 12 SADEs were reported during the course of the study of which three were considered procedure related and 9 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 Aperius® device is safe and effective for the relief of NIC complaints in patients with symptomatic DLSS over a period of 12 months. A high % of patients experience symptom and physical functional improvement which is clinically important and evident shortly after surgery and at 12 month follow up.

Reference list:

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Minimal Invasive Muscle Preserving Approach for Spondylodesis in Patients with Degenerative Lumbar Instability and Obesity (BMI >35) to Reduce Muscular Insufficiency

T. Pfandlsteiner1, K. Seidel2, C. Wimmer3

1Schön Klinik Vogtareuth, Clinic for Spine Surgery with Scoliosis Center, Vogtareuth, Germany

Aims: Obesity (BMI>35) and degenerative lumbar de novo scoliosis is often combined with muscular insufficiency of the M. erector spinae. One of the problems in spondylodesis is the muscle damage during operation in the preoperative insufficient M. erector spinae with further damage. By the percutaneous minimal invasive approach with or without decompression, the muscle damage is much less by the lower rate of damage of the Rami dorsales. Quicker rehabilitation and lower adjacent segment problems are seen. Aim was the comparison of open conventional spondylodesis (group I) and percutaneous stabilization combined with spondylodesis (group II) in obese patients with degenerative scoliosis, Spondylolisthesis and degenerative instability.

Methods: Retrospective, monocenter study, from 06/2006 - 06/2011. T - score < -2.3, group I: 88 and group II: 84 patients. Age at operation was 55a (48 - 78), BMI 39 (35- 47). Bi-, tri- and polysegmental instrumentation, VAS and patient satisfaction score have been done. Indication: Degenerative Lumbar scoliosis, osteochondrosis, spondylolisthesis and FBSS. To control fusion after operation x-Ray or CT-scan of the lumbar spine after 6, 12, 24 months was done. Muscle insufficiency was measured by pain threshold measurement by a digital dolorimeter at defined triggerpoints before and 6, 12 and 24 months after operation.

Results: Fusionrate in the dorsal group was 85% (group I and II) and in the dorsoventral group was 92% in both groups. Follow up 28 (22-36) months, lost to follow up 1/88 and 0/84. Screw loosening combined with pseudoarthrosis in group I was found in 7 patients (19 screws) and in group II in 2 patients (3 screws), adjacent disc degeneration in group I 6/88 and in group II 1/84, screw breakage in group I 1/88 and in group II 0. The length of walking distance improved in the MIS group 3 months earlier, the load-carrying capacity and ability was reached 1,5 months earlier. Demand for rehabilitation

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after fusion was significant lower in group II (96% / 86%). Triggerpoint measurement showed a decrease from pre OP 1.8 (0.7 - 2.2) kg/cm² to 2.3 (1.6 - 3.8) kg/cm² 6 months post OP and 4.6 (3.0 - 6.7) kg/cm² 12 months post OP. At least control 24 months post OP they were 5.5 (4.6-8.9) kg/cm². The patient satisfaction score was much better in the MIS group, and the VAS score decreased significant earlier.

Conclusion: Rate of adjacent disc degeneration infection rate and screw loosening is significant much lower in the MIS group. The preoperative existing muscular insufficiency in obese patients is not that much increased in the MIS group than in the conventional group after operation. The minimal invasive, percutaneous instrumentation shows advantages especially in obese patients.

Cervical Therapies and Outcomes

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Revision Strategies in Cervical TDR; Clinical and Radiological Findings, Surgical Technique and Outcome in 25 Cases
R. Hees¹, G.F. Dua²

Cervical total disc replacement has become one of the most expanding fields in the treatment of single or multilevel disc herniation and low grade degenerative changes. In our center we implanted 10-15 patients per year since 2004. We discuss our single non-university institution experience with revision of cervical total disc replacement of all subsequent cases over the last seven years. Some cases from other centers are included because they fitted in the profile of the current study.

Since we discovered an abnormally high percentage of revision (revisions of the initial prosthesis or revision to fusion) compared with the currently available literature and information distributed by the industry, we studied in depth the problems that occurred. There seemed to be little or no correlation between the initial C-TDR position and the later need for revision. More arthrotic or kyphotic levels were more prone to failure of C-TDR. Extraordinary high numbers of PCM cervical TDR needed revision. There was no difference between the earlier types of PCM (standard) and the later type (V-shaped), although the earlier types failed in the early postoperative phase (1 day-6 months), where the newer type needed some more time for problems to become obvious.

Revision to different types of fusion (cage and plate, graft and plate, zero-profile solutions) will be shown during the presentation.

One spectacular case of severe medullopathic signs and symptoms due to an oversized Bryan prosthesis will also come to attention.

Outcomes of revision were in general satisfactory, although some patients remained clinically unchanged. The spine community well known dogma ‘home run or strike out’, as posed in lumbar TDR, does not seem to apply to the cervical region.

Conclusion: Cervical TDR has a higher revision percentage than currently reported in the literature. PCM in all versions turned out to be the most unsuccesfull in our practice. Revision can lead to a more stable clinical situation.

Quote: All percentages and numbers (levels, multi-versus single, types of prostheses, etc) will be discussed in detail during the presentation.

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A Novel System for Percutaneous Vertebral Augmentation - Clinical Series Summary Utilizing the Crosstrees™ Pod
P.S. Yuan¹, G. Niedzwiecki², M. Lusk³, H. Yang⁴, H.A. Yuan⁵
¹Memorial Orthopedic Surgical Group, Long Beach, CA, USA,
²Advanced Imaging & Interventional Institute, Clearwater, FL, USA,
³Physicians Regional Pine Ridge, Naples, FL, USA,
⁴First Affiliated Hospital of Soochow University, Suzhou, China,
⁵SUNY at Syracuse, Department of Orthopedic Surgery, Syracuse, NY, USA

Purpose: Pain and kyphosis caused by osteoporotic vertebral compression fractures adversely affect quality of life and survival. Vertebroplasty involves the direct injection of cement into the cancellous bone of a fractured vertebra in an attempt to stabilize the bone, but has been associated with high rates of cement extravasation. Kyphoplasty includes the percutaneous placement of an inflatable balloon tamp into the fractured vertebra creating a cavity and attempting to restore vertebral height prior to cement insertion. The Crosstrees™ Pod system is capable of creating a cavity and restoring vertebral height and includes a device for control of the cement which can be removed from the vertebra after delivery. The Crosstrees™ Pod system has the potential added benefits of decreased cement extravasation adverse events, improved consistency of bone cement placement, reduced radiation exposure to the patient and physician, and decreased procedural steps and surgical time. This study was undertaken to evaluate the efficacy and safety of the Crosstrees™ Pod system for treatment of symptomatic osteoporotic vertebral compression fractures.

Methods: A prospective in vivo study is being conducted utilizing the Crosstrees™ Pod system for percutaneous vertebral augmentation. Patients enrolled are at least 50 years of age, have pain greater than 5 out of 10 on the Visual Analog Scale (VAS) and have 1 to 3 osteoporotic vertebral compression fractures between T4 and L5. Other inclusion criteria are point tenderness at the fracture site, acuity of the fracture confirmed by MRI or nuclear medicine study, and failure of conservative treatment for 6 weeks (2 weeks in the acute arm). Pathologic fractures have been excluded as have fractures greater than 6 months old. Other exclusion criteria include fractures with greater than 50% collapse or with evidence of bony retropulsion or fracture extension to the posterior vertebral wall. Patients were seen in follow-up within 24 hours of the procedure and at 2 weeks, 4 weeks, 3 months, 6 months and 1 year. VAS scores were recorded at each timepoint and x-rays were evaluated for cement extravasation and adjacent fractures.

Results: 81 patients with osteoporotic vertebral compression fractures between T6 and L5 have been treated to date. There have been 68 single level cases, 12 two-level cases, and one three level case performed.
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The Correction Effect of the Direct Vertebral Body Derotation on “Razor Back Deformity” of Adolescent Idiopathic Scoliosis

Y. Hai1, Q. Su2, L. Zhou1, Y. Liu1, N. Kang1

1Chaoyang Hospital, Capital Medical University, Orthopedic Surgery, Beijing, China

Objectives: To evaluate the correction effect of direct vertebral body derotation on “Razor back deformity” of adolescent idiopathic scoliosis.

Methods: During the period from October 2006 to October 2008, 63 patients diagnosed as adolescent idiopathic scoliosis received posterior approach spondylodesis. The criteria of this prospective study include: 1. diagnosed as the adolescent idiopathic scoliosis; 2. degree I, II, III of Lenke classification; 3. with a spinal scoliosis Cobb’s angle less than 70°. The average age of all patients is 14.8, ranging from 13 to 16.18 males and 47 females include 18 degree I patients, 23 degree II patients and 22 degree III patients. Preoperatively, the main thoracic curve Cobb’s angle is 55.3° (43-68), and the flexibility of the main thoracic curve is 47.2%, and the average of the rotation of apical (Nash-Moe method) is 2.3° (1-3), and the average of the index of razor back is 19.2° (12-31). All the patients received selected pedicle screw fixation and inter-body fusion via posterior approach. In the spinal levels of the main thoracic curve, the direct vertebral body derotation were performed, but none of the convex thoracoplasty, to compare the change of the correction of the scoliosis, apical vertebral body rotation and the index of razor back after the surgeries and investigate the satisfaction at the follow-up of 1 year.

Results: All the patients underwent the procedures safely, and the average operating time was 160 minutes (130-210) with an average blood loss of 520ml (450-720). The average follow up time was 2.3 years (1-3) and every one is more than 1 year. Postoperatively, the average of spinal scoliosis Cobb’s angle is 13.9° (8-23), and the average of the apical vertebral rotation is 12°, the average of index of razor back is 7.2°, and correction rate is 74.9%, 47.8%, and 62.5%, respectively. At one year follow-up, 52 patients are satisfied or very satisfied with the surgeries, and 11 are not, which indicates the satisfaction rate is 82.5%.

Conclusions: The direct vertebral body derotation has a good correction effect on “Razor back deformity” of adolescent idiopathic scoliosis and a less blood loss, without the damage to the thoracic caused by thoracoplasty performed in the surgery and to the lung function.

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Direct Lateral Interbody Fusion Combined with Percutaneous Pedicle Screws Fixation for Lumbar Degenerative Scoliosis

X.F. Zhang1, J.F. Ji2, Y. Wang3, S.H. Xiao, X.S. Zhang1, L.Z. Liu3

1General Hospital of PLA, Orthopaedic Department, Beijing, China, 2Zhejiang Provincial Corps Hospital, Jiaxing, China, 3General Hospital of PLA, Beijing, China

Objective: To determine the clinical efficacy for DLIF (Direct Lateral Interbody Fusion) combined with percutaneous pedicle screws fixation for lumbar degenerative scoliosis.

Method: From February 2011 to July 2011, six lumbar degenerative scoliosis patients were treated by DLIF combined with percutaneous pedicle screws fixation. All of them were females. Their ages ranged from 49 to 72 years, with an average of 58.6 years. Preoperative patients had low back pain, VAS score 5-10 points, an average of 7.1 points. The coronal and sagittal Cobb’s angles were average 37.5° and 21.3°. All patients had MRI showed multi-segmental degeneration disc herniation with varying degrees of spinal stenosis.

Result: DLIF surgery time were 37-210 minutes, with an average of 55 minutes; posterior percutaneous pedicle screws and other surgery time were 107-205 minutes, with an average of 135 minutes. The estimated blood loss (EBL) was 150-1000ml, with an average of 238ml. No major vascular, ureter, bowel and other injuries occurred. All patients were followed up for 1-8 months, with an average of 3.4 months. The coronal Cobb angle was correction from 37.5° ± 5.8°to 16.8° ± 5.3°, and the correction rate was 55.2%. The sagittal Cobb angle was from 21.3° ± 3.1° to 26.1° ± 2.1°, and the correction rate was 22.5%. The ODI score was reduced from 41.4±2.2 to 11.6±5.2, the improvement rate was 72.0%. The VAS score was reduced from 7.1±1.3 to 3.4±1.0, with the average decrease of 3.7 points. Hip flexor dysfunction occurred after surgery in 1 cases, which resumed in 1 month. The front thigh and groin area superficial sensory loss occurred in 3 cases, which improved within a month all. No abnormal bowel and bladder control or retrograde ejaculation occurred in follow-up period. No pedicle screws and rods loose and fracture occurred and no sagittal and coronal Cobb’s angle significant loss occurred to the end of follow-up. The orthopedic effect was stable.

Conclusion: DLIF, percutaneous pedicle screw fixation and other minimally invasive spinal surgical techniques have improved significantly with an average pre-op VAS of 7.9 and average post-op VAS of 3.1. The average improvement in VAS score has been 6.5. VAS scores continue to remain low after the procedure with the average 6 month and one year VAS scores being 1.0 and 1.4, respectively. Cement extravasation has occurred in only 14% of Crosstrees cases, which compares favorably to the 72% and 27% cement leakage rates reported during vertebroplasty and kyphoplasty, respectively. Cement extravasation has occurred in only 14% of Crosstrees cases, which compares favorably to the 72% and 27% cement leakage rates reported during vertebroplasty and kyphoplasty, respectively.
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used in conjunction with degenerative lumbar scoliosis has a good orthopedic effect and minor trauma. For the long-segment fixed patients, the method is particularly suitable.

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The Role of Disc FX in Discogenic Axial Low Back Pain: 6 Months Follow-up Study

S.I. Wijerathne¹, N. Kumar², G. Indulkar³, B.W.L. Tan¹
¹National University Health System, Orthopaedic Surgery, Singapore, Singapore

**Objectives:** The treatment algorithm for discogenic axial back pain is centered on conservative approach, which often ends in an unacceptable alteration in daily activities. Minimally invasive procedures, like Disc FX, have been developed to tackle the patients with discogenic axial back pain. The objective of our study is to evaluate the role of Disc FX in the treatment of chronic discogenic axial back pain in patients who failed conservative treatment.

**Materials and method:** 18 patients with axial back pain with or without nondiscinal arm pain and failed conservative treatment undergoing Disc FX at one or more levels from September 2010 to May 2011 were included in the study. All patients had discography carried out for the levels in question. Clinical outcome was assessed using Visual analog Scale (VAS) back and leg, Oswestry disability index (ODI) and Short Form-36 (SF-36). Patient satisfaction with the procedure was also recorded. MRI was studied for evaluation of degenerate disc with regards to disc height, presence and location of annular tear and presence of HIZ (high intensity zone). In the post operative period they were followed at 6 weeks, 3 months, and 6 months, with a view for long term follow up.

**Results:** Our results showed that 83% patients (15/18) showed some improvement on their VAS (back) and VAS (leg) scores. 17% (3/18) of the patients showed no improvement and were unsatisfied with the results of the procedure. Based on analysis of patient satisfaction, of the patients who showed improvement, 73% (11/15) of these patients were satisfied with the degree of improvement after the procedure. 27% of patients (4/15) who showed improvement became symptomatic later and were unsatisfied with the outcome.

**Conclusion:** Our results show that ‘Disc FX’ has an effective role in the treatment of a selective group of patients with chronic discogenic back pain. We plan to continue the study with longer follow-up to assess the factors which influence the outcome and further understand the role of Disc FX.

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Percutaneous Pedicle Screws Reconstruction of Spinal Stability Combined with ¹²⁵I Seeds Implantation to Treat Advanced Spinal Metastatic Tumor

X.F. Zhang¹, J.F. Ji², Y. Wang³, S.H. Xiao¹, Z.S. Liu¹
¹General Hospital of PLA, Orthopaedic Department, Beijing, China, ²Zhejiang Provincial Corps Hospital, Jiaxing, China

**Objective:** To determine the clinical efficacy for advanced spinal metastatic tumor treated by percutaneous pedicle screws reconstruction of spinal stability combined with ¹²⁵I seeds implantation.

**Method:** From August 2008 to March 2011, nineteen advanced spinal metastatic tumor patients were treated by percutaneous pedicle screws reconstruction of spinal stability combined with ¹²⁵I seeds implantation. Among them, there were 11 males and 8 females. Their ages ranged from 46 to 82 years, with an average of 62.8 years. Tomita type: III in 3 cases, IV in 7 cases, V in 1 cases, VI in 6 cases, VII in 2 cases, all of them confirmed by pathology were advanced spinal metastatic tumor before surgery. Monitoring by C-arm, pedicle screws were set percutaneous into target segment. Then, scanning spinal tumor segment by CT, according to the geometric form of the tumor, implanted ¹²⁵I seeds into tumor by interval with 0.5cm. Set and locked the fixed bar of pedicle screw fixation device.

**Result:** No needle or pedicle screw went into spinal canal wrong. And no nerve root, spinal cord, vascular or adjacent organ were injured. No deep hematoma, wound infection or radioactive nerve and organ injury occurred. All patients were followed up for 13.4 months in average. No seed moved significantly. 2 cases died of organ failure, and 1 case was paralysis. Pain relief obviously appeared in 7 days after surgery. Among them, 9 cases were significant, 8 cases were effective and 2 cases were no improvement. The mitigation ratio was 89.5%. 18 cases of all were also improvement in ECOG Rating after surgery 1 week.

**Conclusion:** Percutaneous pedicle screws reconstruction of spinal stability combined with ¹²⁵I seeds implantation for internal radiotherapy can improve nerve function, reduce pain significantly and improve their activities for the advanced spinal metastatic tumor patients who are not suitable for operation. For them, it’s a positive, effective and minimally invasive palliative treatment.

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MIS in the Treatment of Idiopathic Scoliosis. A New Concept

C. Wimmer¹, T. Pfandsteiner², K. Seidel³
¹Schön Klinik Vogtareuth, Vogtareuth, Germany

The aim of the prospective study was to examine the complication rate of minimal invasive technique in the treatment of scoliosis. In the literature there exists no prospective study about this new technique. From 2/2008 to 12/2010, 39 patients (31 female/ 8 male) were treated with the new instrumentation. All patients were instrumented with this new minimal invasive technique. The indication for surgery was idiopathic scoliosis (Lenke 1,2,3 and 5) The mean age at operation was 18.3 years (range from 16 to 28). For the clinical examination VAS and patients satisfaction score were used. The mean Cobb angle before surgery was 65.5 degrees (range from 45 to 80). The mean follow up was 26 months (range from 4
Objective: To evaluate whether the Synergy Disc replacement could provide preservation and/or restoration of cervical alignment while providing kinematics and acceptable clinical outcomes.

Summary of background data: Surgeons and patient acceptance of cervical arthroplasty hinges on the ability to provide all the advantages of fusion while preserving the range of motion (ROM) and biomechanics of the functional spinal unit. We conducted a clinical and radiological assessment of the Synergy Disc (Synergy Disc Replacement, Inc., Chandler, AZ) to determine if the device could actively correct and preserve sagittal cervical alignment. The Synergy Disc has been designed specifically to correct kyphosis.

Methods: Thirty-seven consecutive patients were enrolled in the Synergy Disc pilot study. Static and dynamic radiological assessments were performed preoperatively and at 1 year postoperatively. Kinematic parameters including ROM, translation, center of rotation (COR-X,Y), disc height (DH) and shell angle (SA) were assessed for the surgical level using quantitative motion analysis (QMA) software. Neck Disability Index (NDI) questionnaire and visual analog scale (VAS) for arm and neck pain were used to measure disease specific and overall well-being outcomes.

Results: One-year follow-up was completed on 34 patients (39 implants). Following surgery, the average SA was maintained at 6° of lordosis. ROM, translation and COR X did not change significantly while there was a superior shift in the COR Y value. The DH increased by 37% (3.5 ± 0.8 mm preoperatively vs. 4.9 ± 1.0 mm postoperatively, p < 0.005). There was significant improvement in all clinical outcome measures.

Conclusions: The Synergy Disc provides lordosis at the surgical level, while maintaining pre-operative ROM. The Synergy Disc increased DH and shifted the COR Y value superiorly. These results demonstrate promising early clinical outcomes and preliminary evidence of alignment correction with a cervical disc replacement.

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Osseofix: A Promising Spinal Fracture Augmentation System

E. Ashkenazi

1 Assuta Hospital, Tel Aviv, Israel

Osteoporosis is a skeletal disorder characterized by compromised bone strength predisposing to an increased risk of fracture, of which vertebral compression fractures (VCFs) are the most common. The occurrence of VCFs is so prevalent that an expected 37.3 million fractures will occur in 2050. Conservative care involving analgesics, bed rest and bracing may not provide adequate relief of symptoms in many patients resulting in continuing pain and dysfunction. Minimally invasive surgery (MIS) to inject bone cement to the affected vertebral body via vertebroplasty provides significant pain relief but does little to restore sagittal alignment. Kyphoplasty may restore alignment but is also known to create endplate fractures and potentially catastrophic cement leakage. A titanium mesh stent-type device (Osseofix®, Alphatec Spine, Carlsbad, CA) was developed to provide surgeon directed control during expansion and allow for cement injection to solve some of the issues associated with kyphoplasty. The purpose of this clinical study was to report on a single center, single surgeon experience using this MIS expandable device for treatment of VCFs.

Patients identified as having a vertebral compression fracture that could be typically treated with a kyphoplasty were consented for the procedure using the titanium mesh implant. From August 2009 until August 2011 vertebral augmentation with the expandable mesh implant was performed in 53 patients (49F, 4M). Age ranged from 50-94 (mean 74). All cases were done under local anesthesia with conscious sedation. Levels injected were from T6 to L4, with D12 being the most frequently operated level. 42 patients had a single level procedure, 10 had two level and one a three level procedure. For pain relief, the average preoperative VAS was 8.8 and postoperative dropped to 2.53, representing a statistically significant (p< 0.05) improvement in pain. A majority of patients demonstrated an improvement in vertebral body height restoration. Time of the procedure ranged from 12-45 min (mean 21) and all patients were discharged the same day as the procedure. There were no radiographically diagnosed endplate fractures and there was no evidence of cement leakage (Figure 1).
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Analysis of Outcome Stability Following Surgery Involving a Cervical Spine Implant
D.D. Ohnmeiss1, S.L. Blumenthal2, R.D. Guyer2, J.E. Zigler2
1Texas Back Institute Research Foundation, Plano, TX, USA;
2Texas Back Institute, Plano, TX, USA

Aim: Traditionally, the follow-up landmark for clinical trials has been 24 months. The establishment of this time period is not clear. It has previously been reported that when evaluating lumbar spine implants, there was no significant change in outcomes after 6 months (Ohnmeiss et al, SAS J 2010). The purpose of this study was to analyze prospective cervical spine surgery studies reporting data at multiple specific follow-up periods to determine if there were significant changes in the clinical outcome throughout 24-month follow-up.

Methods: A comprehensive literature search was conducted using PubMed and abstracts from recent spine conferences. Studies meeting the following criteria were included in the review: involve at least 100 patients receiving a spinal implant with data reported at multiple pre-defined time periods post-operatively for at least 24-months, published in English. Studies which were preliminary results or single-center reports of a larger multicenter study were also excluded. Data recorded from each study included, number of patients, diagnoses, implant used, outcome measures used, and the results reported.

Results: Only 8 studies met the inclusion criteria. Five studies were evaluations of total disc replacements compared to an anterior cervical fusion control group, another reported results of a total disc replacement that did not involve a control group, one study evaluated a fusion cage, and one compared a dynamic to a rigid cervical plating system. All studies were published since 2000 and six were the results of FDA-regulated trials. A total of more than 2,000 patients from multiple centers were represented in the various studies. All studies used the Neck Disability Index (NDI) and some form of a visual analog scale (VAS) to evaluated outcomes. The SF-36 was also used in some studies. In all studies, there was a statistically significant improvement in all measures from baseline to 6-month follow-up which was maintained throughout follow-up. In no study was there a significant worsening in outcomes between the 6 and 24 mo follow-up periods. In only one measure in one study was there a suggestion of a possible reduction in outcome by 24 mo follow-up, but it was not significant or noted as a trend. Typically there was no change, other than improvement (not significant) after as early as 3 months.

Conclusions: The results of this study suggest a great deal of stability in the mean scores for various outcome measures between the 6 and 24 month follow-up periods in patients receiving cervical spinal implants. Additional study is needed to determine if outcome assessment values for individual patients remain stable over the course of the study (suggesting that a patient’s condition generally does not change after 6 mo) or if there is compensatory improvement and worsening between individual patients to produce stable mean scores over time. Certainly long-term follow-up is desirable to fully evaluate any surgical procedure. However, considering that we are in an era of reviewing large sample population databases to evaluate interventions, the stability of the group mean scores may allow for earlier evaluation of the results of cervical spine procedures.

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If and when an Interlaminar Elastic Assistance Device Can Stop or Reverse the Degenerative Cascade of the Lumbar Spine?
G. Guizzardi1, P. Petriti2
1University and City Hospital Careggi, Neurosurgical, Firenze, Italy; 2City Hospital, Orthopaedic and Traumatology, Città di Castello, Italy

Purpose of the study: In the 1970’s, Kirkaldy-Willis first described the “Degenerative Cascade” of DDD. Observation of demographic studies shows more back pain in younger adults (30 to 50 years) than in elderly adults (over 60 years) in which osteoarthritis problems are prevalent to disc problems. The aim of this study is to demonstrate if and when an interlaminar elastic motion preservation device for disc assistance can stop or reverse the degenerative cascade of the lumbar spine in younger adults.

Materials and methods: 40 patients (mean age 34.5 years, 26 female an 14 male) affected from back pain from a minimum time of two years, received a minimally invasive surgical procedure implanting this IntraSPINE® device at one or two levels. The surgical procedure was performed by monolateral approach and in many cases in local anesthesia. The source of the pain in this group of patients (facet joint pain) was demonstrated by a positive response to the facet joint block test. Prior to surgical procedure, all patients underwent an MRI, a CT Scan and a dynamic X-ray of the lumbar spine. The stage of the degenerative cascade was between grade III and IV according to Pfirrmann.

Results: The results with a minimum follow-up of 4 years were evaluated from the clinical point of view regarding the LBP with VAS and ODI tests. All patients were also subjected to an MRI control:
1. in about 20% also in presence of good clinical results we highlighted a moderate progression of the cascade.
2. in about the 50% the Pfirrmann grade was unchanged
3. but in about 30% we highlighted a partial rehydration of the disc which means a initial
reversion of the degenerative cascade (patients with the lower grades of degeneration).

Conclusions: The absence of major complications, the minimally invasive surgical procedure and the good clinical results allow us to say that with a correct patient selection we can prevent that this disease from acute becomes chronic, and thus its natural progression. Last but not least if we performed this surgical procedure in the earliest stages of the degenerative cascade, we can reverse its trend.

Navigation, Image-Guided Surgery and Robotic Assistance

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Can a Pedicle Drilling Probe with Electrical Conductivity Measurement Capabilities Anticipate Pedicle Breach? A Cadaver Study
R.R. Betz1, J.J. Williams2, A.F. Samdani3, J. Gaughan3
1Shriners Hospitals for Children—Philadelphia, Philadelphia, PA, USA, 2Parkview Hospital, Fort Wayne, IN, USA, Fort Wayne, IN, USA, 3Temple University School of Medicine, Philadelphia, Philadelphia, PA, USA

Summary: A new pedicle probe with local electrical conductivity measurement capability at the tip (“PediGuard®”) accurately anticipated an impending breach in 87% of drillings before the breach actually occurred. Accurate anticipation was best within the pedicle wall, especially medially.

Introduction: The rate of pedicle screw breach using manual pedicle probes ranges from 5-40%. EMG and fluoroscopy may detect a breach, but only after it occurs. The purpose of this study is to determine the effectiveness of a new pedicle probe to anticipate an impending breach during placement of a pilot pedicle hole.

Methods: A previously validated cadaver model (saline soaked spine) was used. Using PediGuard, a single surgeon purposely drilled 4 cortical wall sites: medial pedicle wall, lateral pedicle wall, lateral vertebral body, anterior vertebral body. The PediGuard changes sound (frequency and pitch) to differentiate cancellous bone from cortical bone from saline (indicating breach). The surgeon stopped probing when the sound changed, suggesting abutment against the cortical wall (“anticipation” of impending breach.) A fluoroscopy image was then obtained and a measurement (in mm) of the probe distance outside of the pedicle was obtained. The surgeon then advanced the PediGuard through the cortex until the sound changed, indicating a breach. The breach was confirmed by direct visualization and an additional measurement was made. The difference between the two measurements (“distance to breach”) is the outcome of the anticipation process (1-5 mm was chosen as the criterion for accurate breach “anticipation”).

Results: 75 pedicle drillings were performed. The surgeon accurately anticipated 60/75 (80%) of the breaches. Another 5 drillings (7%) were interpreted as cortex, although the breach was still > 5 mm away (clinically a minor burden). Therefore, in 65/75 drillings (87%), the PediGuard successfully warned the surgeon before a breach. In an additional 10 drillings (13%), the surgeon correctly detected a breach but not the anticipation, which would have allowed earlier redirection of the drilling. Sensitivity is shown in Table 1.

Conclusion: Anticipation of an impending cortical breach during placement of a pilot pedicle hole occurred in 80% of the drillings, with an additional 7% anticipated too soon by 1-2mm before the breach actually occurred, for an 87% success rate. Sensitivity at the medial pedicle wall was 100%. Use of the PediGuard may significantly reduce pedicle screw breach when using a manual technique for drilling/probing.

MIS Technique and Results

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Minimally Invasive Lateral Interbody Fusion (MI-LIF) at L4-5 and the Protective Effect of Prophylactic Dexamethasone
W.B. Rodgers1, J.A. Lehmen1, J.A. Rodgers3, E.J. Gerber1
1Spine Midwest, Inc., Research, Jefferson City, MO, USA

Introduction: It has been reported that MI-LIF procedures performed at the L4-5 level have a higher incidence of postoperative motor deficits compared to other lumbar segments, and must occasionally be aborted due to anatomic constraints.

Methods: In our single-site consecutive series of 1093 MI-LIF patients, 646 (59%) included the L4-5 level. Clinical and radiographic data were prospectively collected and reviewed to assess MI-LIF procedure at the L4-5 level.

Results: Age averaged 62.3 years (24-88 years). 92.9% had one or more comorbidities. 33.1% had prior lumbar surgery. All procedures were successfully completed. Hospital stay averaged 1.3 days. Average VAS pain scores improved from 8.6 at pre-op to 2.8 at 12 months and 2.7 at 24 months follow-up. Lenke fusion scores of 1-2 were present in 96.2% at 6 months, and 99.4% at 24 months.

Neural complications included 4 (0.6% of all cases, 0.9% of L4-5 cases) transient lower leg weaknesses (3 quads, 1 anterior tibialis; all resolved within 3 months). After the fourth postoperative motor deficit, we began to administer dexamethasone (10mgIV prior to skin incision) prophylactically in all MI-LIF patients in whom the L4-5 level was to be approached. Since the use of dexamethasone, no additional neural deficit developed, a statistically significant difference (p=0.0245).

Conclusions: The incidence of postoperative motor deficits following MI-LIF at L4-5 is low. The prophylactic administration of dexamethasone results in a statistically significant reduction in motor deficits.

[Table 1. Sensitivity to detect a cortical breach]
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Does Prone Re-positioning Prior to Posterior Fixation Produce Greater Lordosis in Lateral Lumbar Interbody Fusion?
J.N. Sembrano1, S.C. Yson1, J.T.P. Luna1, E.R.G. Santos1, D.W. Polly Jr.1
1University of Minnesota, Orthopaedic Surgery, Minneapolis, MN, USA

Summary: A review of intraoperative images in 56 consecutive LLIF cases (88 levels) has shown that lateral to prone re-positioning after LLIF cage insertion does not confer additional operative level lordosis. Segmental lordosis improvement is mainly brought about by cage placement as well as posterior fixation.

Introduction: LLIF is a new minimally-invasive approach to fusion that is performed in the lateral position; supplemental pedicle screw fixation is often used. While screws may be placed in the lateral position, it is hypothesized that additional lordosis is gained by prone re-positioning prior to screw insertion.

Methods: We reviewed 56 consecutive patients who underwent LLIF in the lateral position followed by posterior fixation in the prone position. Eighty-eight levels were fused. Disc space angle was measured on intraoperative C-arm images, and change in operative level segmental lordosis brought about by each of the following was determined: (1) cage insertion, (2) prone re-positioning, and (3) posterior instrumentation. Two-tailed t-test was used to determine significance (a=0.05).

Results: Mean lordosis improvement brought about by cage insertion was 2.4 degrees (p=0.00005). There was no mean change in lordosis brought about by lateral to prone positioning (0.1 degree, p=0.47). Mean lordosis improvement brought about by posterior fixation, including rod compression, was 1.0 degree (p=0.03).

Conclusion: In LLIF procedures, the largest increase in operative level segmental lordosis is brought about by cage insertion. Further lordosis may be gained by placing posterior fixation, including compressive maneuvers. Prone re-positioning after cage placement does not produce any incremental lordosis change. Therefore, posterior fixation may be performed in the lateral position without compromising operative level sagittal alignment.

Significance: Our results show that prone re-positioning does not produce additional operative level lordosis, and that posterior fixation may be acceptably performed in the lateral position. This will obviate the need for intraoperative patient re-positioning and minimize operative time.

Lumbar Therapies and Outcomes

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Effects of Angle Changes of in Lumbar Lordosis after Posterior Lumbar Interbody Fusion (PLIF) of L4 / 5 Segment
Y. Liu1, Y. Hai1
1Capital Medical University, Beijing, China

Objective: To investigate the effect of angle change of lumbar lordosis after posterior lumbar interbody fusion (PLIF) of the L4 / 5 single segment.

Methods: A retrospective analysis of 23 cases of PLIF of L4 / 5 single segment. Comparative analysis for lumbar lordosis angle of pre- and post-operative.

Results: Lumbar lordosis angle increases 5-15 degrees after posterior lumbar interbody fusion (PLIF) of the L4 / 5 single segment., average of 8.4 degrees (P < 0.01). Lumbar vertebral endplate angle increase by 1-7 degrees, and average of 3.5 degrees (P < 0.05).

Conclusion: PLIF of L4 / 5 single segment can significantly increase lumbar lordosis angle and improve the lumbar alignment, and possible release low back pain symptoms and delay the degeneration of the adjacent segments.
Preoperative ROM, degree of degeneration in cervical spine, bony spur, calcification of ALL and PLL, and the number of involved arthroplasty level. Second, we then investigated technical factors, such as the size and position of the implant, increased height ratio by the device. Then, our study searched if there was any statistical correlation between these factors and the postoperative radiologic and clinical outcome.

**Result:** Generally, the lordotic change in sagittal alignment (0.14 -> -3.54 -> -3.04) and the preservation of ROM (38.82 -> 32.86 -> 38.84) was noted after the procedure. Preoperative kyphotic group (N=65) showed more evident lordotic change (4.79 -> -7.37 -> -6.51, p=0.02) than preoperative non-kyphotic group (N=118, -13.19 -> -13.61 -> -14.70) and preoperative limited ROM group (<30 degree, N=58) showed the persistent increase of ROM (21.37 -> 26.25 -> 28.09) compared to not limited ROM group (>30 degree, N=118, 47.13 -> 35.27 -> 42.93). In terms of number of involved arthroplasty level, we also could see the corrective effect of kyphosis in sagittal alignment and increased ROM by 1 level and 2 level arthroplasty but 3 level arthroplasty group came up with the result showing more vulnerable to preoperative kyphosis and preoperative limited ROM. Re-kyphosis (p=0.01) and re-decreasing tendency (p=0.02) in late follow up period. There was no statistically significant relationship between degree of degeneration and postoperative radiologic and clinical outcome. But the groups that have more degeneration showed the tendency of postoperative kyphosis, the limitation of ROM and less decrease of VAS score at late follow up period. The position and size of the implant didn’t affect postoperative clinical result. Relatively anterior position of the implant made more lordotic realignment possible, but induced the more anterior migration of the device, the limitation of ROM and more chances of heterotrophic ossification (HO) at later follow up. More large size of the implant and relative high ratio of increase disc height were also as the causative factors to limit the ROM at index level. HO was found with higher incidence in the group that had the more degeneration and more small size of the implant.

**Conclusion:** Cervical arthroplasty is the useful tool to restore the cervical alignment and ROM in even preoperative kyphosis and limited ROM group. But more careful patient selection for the cervical arthroplasty seems to be needed in the groups that have much degeneration and multi-level lesion. Appropriate size and positioning of the implant is mandatory to achieve good clinical and outcome in cervical arthroplasty.

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**Cervical Therapies and Outcomes**

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**Analysis of the Several Factors that May Affect the Radiological and Clinical Outcome in Cervical Arthroplasty**

C.-W. Lee, K.-J. Yoon, S.-S. Ha, J.-K. Kang

1St. Peter’s Hospital, Neurosurgery, Seoul, Korea, Republic of Korea

**Introduction:** There have been many studies to prove the efficacy and benefits of cervical arthroplasty over arthrodesis, but some conditions and factors which lead to undesirable consequences at the follow up (F/U) in cervical arthroplasty have been also reported.

**Method:** 176 patients who got the cervical arthroplasty in total 234 level from march 2004 to december 2009 (1 level: 129, 2 level: 36, 3 level: 11, 4 level: 1) were evaluated (mean F/U period: 18.75 months). We investigated the possible factors that could affect the radiological and clinical outcome after cervical disc replacement. First, we examined preoperative factors, such as preoperative cervical sagittal alignment, preoperative ROM, degree of degeneration in cervical spine, disc height, facet degeneration, the presence of bony spur, calcification of ALL and PLL, and the number of involved arthroplasty level. Second, we then investigated technical factors, such as the size and position of the implant, increased height ratio by the device. Then, our study searched if there was any statistical correlation between these factors and the postoperative radiologic and clinical outcome.

**Result:** Generally, the lordotic change in sagittal alignment (0.14 -> -3.54 -> -3.04) and the preservation of ROM (38.82 -> 32.86 -> 38.84) was noted after the procedure. Preoperative kyphotic group (N=65) showed more evident lordotic change (4.79 -> -7.37 -> -6.51, p=0.02) than preoperative non-kyphotic group (N=118, -13.19 -> -13.61 -> -14.70) and preoperative limited ROM group (<30 degree, N=58) showed the persistent increase of ROM (21.37 -> 26.25 -> 28.09) compared to not limited ROM group (>30 degree, N=118, 47.13 -> 35.27 -> 42.93). In terms of number of involved arthroplasty level, we also could see the corrective effect of kyphosis in sagittal alignment and increased ROM by 1 level and 2 level arthroplasty but 3 level arthroplasty group came up with the result showing more vulnerable to preoperative kyphosis and preoperative limited ROM. Re-kyphosis (p=0.01) and re-decreasing tendency (p=0.02) in late follow up period. There was no statistically significant relationship between degree of degeneration and postoperative radiologic and clinical outcome. But the groups that have more degeneration showed the tendency of postoperative kyphosis, the limitation of ROM and less decrease of VAS score at late follow up period. The position and size of the implant didn’t affect postoperative clinical result. Relatively anterior position of the implant made more lordotic realignment possible, but induced the more anterior migration of the device, the limitation of ROM and more chances of heterotrophic ossification (HO) at later follow up. More large size of the implant and relative high ratio of increase disc height were also as the causative factors to limit the ROM at index level. HO was found with higher incidence in the group that had the more degeneration and more small size of the implant.

**Conclusion:** Cervical arthroplasty is the useful tool to restore the cervical alignment and ROM in even preoperative kyphosis and limited ROM group. But more careful patient selection for the cervical arthroplasty seems to be needed in the groups that have much degeneration and multi-level lesion. Appropriate size and positioning of the implant is mandatory to achieve good clinical and outcome in cervical arthroplasty.

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**Regular Posters**

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**Mid-term Results of a Minimally Invasive Interspinous Spacer in Patients with Lumbar Spinal Stenosis: A Randomized Controlled IDE Trial**

P.G. Wang, W.D. Bradley, L.E. Miller, J.E. Block

1Yale University School of Medicine, Orthopaedics and Rehabilitation, New Haven, CT, USA, 2Texas Back Institute, Denton, TX, USA, 3Miller Scientific Consulting, Biltmore Lakes, NC, USA, 4Jon E. Block, San Francisco, CA, USA

**Objective:** To compare mid-term clinical outcomes in...
patients treated with an investigational interspinous spacer (Superion) versus those treated with an FDA-approved spacer (X-STOP).

**Methods:** This prospective, randomized, controlled IDE trial enrolled 87 patients (mean age: 67 yr, 63% male) with radiographically confirmed moderate lumbar spinal stenosis (LSS) unresponsive to at least 6 months conservative care. Patients were treated randomly with the Superion (n=46) or X-STOP (n=41) interspinous spacer and followed through 1 year post-treatment. Outcome measures included condition-specific Zurich Claudication Questionnaire (ZCQ), back function with the Oswestry Disability Index, and axial and extremity pain severity with a visual analogue scale.

**Results:** ZCQ symptom severity scores improved 30% with Superion and 27% with X-STOP (both p<0.001). Similar changes were noted in ZCQ physical function with improvements of 31% with Superion and 26% with X-STOP (both p<0.001). Mean ZCQ patient satisfaction scores at 1 year were 2.0±1.0 with Superion and 1.8±0.8 with X-STOP (p=0.34). Axial pain decreased from 55±26 mm at pre-treatment to 24±31 mm at 1 year in the Superion group (p<0.001) and from 57±28 mm to 29±26 mm with X-STOP (p<0.001), with no statistically significant difference between groups (p=0.74). Extremity pain decreased from 60±25 mm at pre-treatment to 21±31 mm at 1 year in the Superion group (p<0.001) and from 65±27 mm to 23±29 mm with X-STOP (p<0.001), reflecting similar between-group changes (p=0.76). Back function similarly improved (p=0.84 between groups) with Superion (36±13% to 21±18%; p<0.001) vs. X-STOP (40±13% to 26±16%; p<0.001).

**Conclusion:** Mid-term results suggest that the Superion Interspinous Spacer provides similar benefit as X-STOP for alleviating pain and improving back function in patients with moderate LSS who are unresponsive to conservative care.

**Lumbar Therapies and Outcomes**

**217 Simultaneous Reduction and Fixation of Spondylolisthesis by an Innovative Sliding Intervertebral Cage Technique. Description and Prospective Clinical Results**

M. Szpalski1, R. Gunzburg2, L. Ciupik3, D. Zarzycki4, J. Pienazeck5

1Iris South Hospitals, Orthopedics, Brussels, Belgium, 2Edith Cavell Clinic, Orthopedics, Brussels, Belgium, 3Institute of Medical Engineering and Testing, Zielona Gora, Poland, 4Orthopedic and Rehabilitation Clinic, Collegium Medicum, Orthopedics, Zakopane, Poland, 5Specialized Hospital N 4, Neurosurgery, Bytom, Poland

**Introduction:** Reduction of spondylolisthesis is mostly done with an external device subsequently removed to make place for pedicular and/or interbody fixation. We describe an innovative cage system (Slider, LFC, Zielona Gora, PL) made of two serrated sliding plates linked by an Archimedes screw. After insertion of the cage the screw is actuated in order to move the two plates, thus reducing the listhesis and achieving intervertebral fixation. The amount of reduction is determined preoperatively and the sliding stops automatically when said reduction is reached. The device exist for PLIF as well as for ALIF insertion.

**Material and methods:** 19 patients (8 men, 11 women) are included in this prospective study. The average age was 53.5 (19-73). There were 9 lytic and 10 degenerative spondylolisthesis cases. 15 patients had a PLIF procedure and 4 an ALIF. Two cages were inserted in all cases. Pedicular fixation was done in 16 cases and the cage was used as stand alone in 3.

**Results:** Average follow up is 31 months (ranging from 12 to 79). In one very early ALIF case we encountered expulsion of one cage. The teething of the cage end-plates was modified and no expulsion occurred afterwards. Before surgery average pain VAS was 6.9 and this reduced to 1.6 at 12 months after surgery. ODI was 64 prior to surgery and 45 after. Apart from the case mentioned above there was no revision.

**Conclusions:** The use of this innovating cage enabling reduction and fixation of a spondylolisthesis appears a safe and straightforward technique which compares favorably with other procedures used in the same indication.

**MIS Technique and Results**

**218 A New Approach to Lateral Lumbar Interbody Fusion with One-year Follow-up**

M. Hardenbrook1

1The Boston Spine Group, Newton, MA, USA

The lateral approach to the lumbar spine for interbody fusion is a versatile and less invasive approach to the spine compared to the anterior approach. However, the current retractor systems have many limitations. The percutaneous nature of the current systems requires an over-reliance on neuromonitoring to navigate through the neuroplexus within the psoas muscle. Additionally, the blades and retraction mechanism are radio-dense obscuring fluoroscopic imaging. These deficiencies have lead to well-documented complications that may be avoided with better visualization.

A new two-retractor system is utilized to improve the safety profile of the lateral approach. In this approach, a radiolucent, fixed tube is placed through the retroperitoneal space and positioned on the surface of the psoas muscle. Under direct visualization with loupe magnification, the fibers of the psoas muscle are split in line with the muscle fibers. Neural structures can be visualized and avoided. A second, expendable retractor is then placed through the fixed tube and the psoas muscle is retracted under direct visualization. A complete and thorough discectomy and placement of an implant can then be safely performed.

22 patients underwent lateral interbody fusion on 28 levels for degenerative spondylolyis of the spine with one year follow-up. The average age was 53 years old (33-73). 20 patients underwent surgery at the L4-5 level. A PEEK interbody device was used for anterior column support. Posterior fixation was used in all patients (7 pedicle screws, 3 facet screws, 12 interspinous process fixation). Estimated blood loss was 220ml with average hospital stay of 2.5 days. There were no intra-operative
Biomechanics/Basic Science

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Radiographic Evaluation of Total Facet Arthroplasty System
R.B. Gaskins1, B. Wang2, S. Webb2, A.E. Castellvi2
1Foundation for Orthopaedic Research and Education, Research, Tampa, FL, USA, 2Florida Spine Institute, Spine Surgery, Tampa, FL, USA

Purpose: The Total Facet Arthroplasty System (TFAS) is a motion-preserving joint prosthesis. This device is implanted in patients with spinal stenosis and severe facet degeneration. TFAS recreates both the natural limitations on range of motion and provides incremental resistance similar to the intact functional spinal unit. The objectives of this study is to evaluate the range of motion and disc height in the surgical and adjacent cervical lumbar spine levels. To our knowledge this is the first study with one to two year follow up of patients with a motion-preserving facet prosthesis.

Methods: Patients were prospectively randomized to TFAS or fusion as part of an FDA approved IDE study. Fifty-nine patients received the TFAS procedure and were instrumented at either L3-4 or L4-5. The patients were followed for one to two years, with radiographs (AP, lateral, flexion, extension) taken at each clinic visit. Radiological measurements of intervertebral disc height and motion angles were taken at the surgical and adjacent levels. Designated clinical trial independent radiologists reviewed the radiographs. The data was analyzed using a Wilcoxon rank-sum test. Values of P<0.05 were considered statistically significant.

Results: Flexion-extension motion was decreased at the surgical level between preoperative (mean=5.46°) compared with 12 month values (mean=4.26°). This was statistically significant (p=0.019). The range of motion was restored and similar to preoperative levels at 24 months (p=0.421). The cephalad level during flexion-extension was comparable to preoperative values at both 12 months (p=0.245) and 24 months (p=0.754). Comparable motion was also seen at the caudal level at both 12 months (p=0.673) and at 24 months (p=0.727). Additionally, the intervertebral disc height was maintained at the instrumented and adjacent levels. At 12 and 24 month follow up, none of these levels reached statistical significance from the pre-operative disc height.

Conclusions: In this radiological evaluation, the TFAS demonstrated maintenance of intervertebral disc height at both 12 and 24 months postoperatively. However, at 12 months the device did show a decrease in motion at the surgical level. This 1.2° change in flexion-extension may be of limited clinical significance, especially considering that motion was preserved at 24 months. TFAS maintained motion at adjacent levels for both 12 and 24 month follow up and may provide protection from adjacent level disease, demonstrated by the lack of hypermobility at adjacent levels. The TFAS is not a motion-restoration, but rather a motion-preservation device, providing comparable motion at furthest follow up.

MIS Technique and Results

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Anatomical Characteristics of the Lumbar Facet Joints and Considerations for Minimally Invasive Spine Surgery
M.E. Berbeo1, R.C. Diaz1, C.A. Cardenas1, Grupo de Neurociencias HUSI - PUJ
1Hospital Universitario San Ignacio - Pontificia Universidad Javeriana, Neurociencias - Neurocirugia, Bogota, Colombia

Study design: Description of anatomic features of lumbar facet joints

Purpose: To describe angular orientation of the lumbar facet joints for to set anatomic reference for surgical planning in MIS procedures like Transforaminal Lumbar Interbody Fusion, Extraforaminal Trans facet joint Lumbar Interbody Fusion, Extraforaminal Lumbar Interbody Fusion, etc. in a sample of south-american population.

Methods: We performed a review of two hundred lumbar computed tomography of a radiological data-base of patients from two independent university hospitals. We explored distances, and angles in axial and coronal axes of the lumbar facet joints from L1/L2 to L4/L5. We classify the results according to level, age and sex, and analyze the results from the viewpoint of the minimally invasive spine surgeon.

Results: We present the results by level, sex, and age and compared with international papers.

Conclusions: The angular orientation of lumbar facet joints is variable from L1/L2 to L4/L5, and this is important for surgical planning for classic and minimally invasive procedures. With the anatomic facet features, in most cases would be enough to resect only the facet
of the lower vertebra to obtain neural decompression. We believe that our findings are important for the spinal surgeons in Latin America because of the similar phenotype in our countries.

Cervical Therapies and Outcomes

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Analysis of the Several Factors that May Affect the Radiological and Clinical Outcome in Cervical Laminoplasty
C.-W. Lee
K.-J. Yoon
S.-S. Ha
J.-K. Kang
1St. Peter’s Hospital, Neurosurgery, Seoul, Korea, Republic of

Objective: To investigate the possible factors to affect the outcome in laminoplasty and evaluate the relationship between those factors and postoperative clinical and radiologic outcome and suggest the preventive measures of postoperative complications and give a knowledge to predict unfavorable outcome.

Method: 159 patients who received the cervical laminoplasty (plate only open door technique) in total 537 level from March 2002 to May 2011 were evaluated (mean follow up (F/U) period: 18.75 months (6.5~41.5 months)). We investigated the possible factors that could affect the radiological and clinical outcome. First, we examined preoperative factors, such as the preoperative JOA, VAS score of the patients, sagittal alignment (SA), range of motion (ROM), the number and pattern of preoperative signal change of cord and the spinal cord compression ratio (CCR) in MRI. Second, we then investigated intraoperative technical and postoperative management factors, such as the preservation of C2, C7 spinous process, position of the hinge, the amount of spinal canal expansion, number of involved laminoplasty level and duration of postoperative brace immobilization. Then, our study searched if there were any statistical correlation between those factors and the postoperative radiologic and clinical outcome.

Result: Generally, the lordotic change in SA (Cobb’s angle (CA)): -10.81~ -14.58 to -14.31, p = 0.03) and the limitation of ROM (CA: 34.64~ 25.20 to 27.27, p = 0.03) was noted after the procedure. Significant kyphotic change was not seen. Preoperative CA was not the significant factor to affect postoperative kyphotic change. Involvement of C2 group in laminoplasty showed the tendency of postoperative kyphotic change (-23.39 to -18.88 to -14.72, p = 0.10) but not C7 (-8.31 to -14.05 to -15.14). Postoperative moderate or severe axial pain was observed in 33 cases (21%) of total patients. Neck pain (VAS) at late F/U was significantly higher in C2 involved group (5.64 to 3.06 of C2 preservation group, p = 0.01) and wide-open hinge group (4.79 to 2.76 of narrow open hinge group, p = 0.01). Postoperative less limited ROM, less number of laminoplasty level and preservation of C7 group and shorter period of brace immobilization group showed lower incidence of axial pain, but statistically insignificant. Postoperative C5 palsy was occurred in 4 cases. More lateral position of hinge and gutter (3 cases) and preoperative increased signal intensity (ISI) on T2-weighted MR imaging (3 cases) seemed to be risk factor of postoperative C5 palsy. The patients’ JOA score increased from a preoperative score of 13.1 (7 ~ 16) to a postoperative score of 15.54 (8 to 18). The average recovery ratio was 53.14% (range, 0 to 100%). The number of segments with ISI, a localized marginal pattern with ISI were inversely associated with the recovery ratio, whereas preoperative spinal CCR and duration of the preoperative symptom showed a significant positive correlation. Other factors, such as number of surgical segment, age, and preoperative JOA score, showed no statistically significant correlation.

Conclusion: Cervical laminoplasty is the useful method to decompress the multilevel cervical lesion with the preservation of sagittal alignment and without instability. More careful and strict operative technique such as accurate positioning of hinge and gutter, the preservation of C2, C7 spinous process and postoperative active exercise seem to be needed to minimize operative complications and achieve postoperative good clinical outcome. Preoperative ISI and CCR in MRI can be a predictor of surgical outcome in myelopathic patients.

Cervical Therapies and Outcomes

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Dynamic Cervical Implant. Alternative between Cage Fusion and Total Disc Replacement
G. Matgé
1Centre Hospitalier de Luxembourg, Neurosurgery, Luxembourg, Luxembourg

Although cervical total disc arthroplasty (TDA-C) has shown equivalence or superiority over anterior cervical discectomy and fusion (ACDF) in cervical disc disease, potential problems include non-physiologic motion which may accelerate degeneration of the facet joints, particulate wear, and compromise of the endplate mechanical integrity during device fixation. Cervical stabilization with DCI is a novel motion-preserving concept that facilitates controlled, limited flexion and extension, but prevents axial rotation and lateral bending, thereby reducing motion across the facet joints. 60 patients underwent dynamic cervical stabilization for the treatment of one to three level cervical disc disease. Minimum follow-up ranged from 6-24 months. Clinical outcomes consisted of NDI and VAS scores. Flexion-extension radiography was evaluated for the presence of device-level motion, device failures, device subsidence, and heterotopic ossification.

There was maintenance of index-level motion in about 90% of patients. NDI and VAS neck and arm pain scores were significantly reduced. More than 90% of patients were very satisfied, while 100% would elect to have the surgery again at 1 year. Two asymptomatic anterior device migrations required early revision due to device undersizing respectively too anterior positioning. An adjacent segment disease needed a delayed intervention. Cases of asymptomatic minor (non-bridging) heterotopic ossification and asymptomatic endplate subsidence were also observed during follow-up.

Preliminary results indicate that DCI is safe and facilitates excellent clinical outcomes, maintains index-level range of motion, and may be suitable for patients with facet degeneration who would otherwise not be candidates for TDA-C.
MIS Technique and Results

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Comparative Analysis of Clinical Outcomes and Adjacent Level Angle Change on Single-level Lumbar 4-5 Fusion Using Percutaneous Screw Fixation and Open Screw Fixation
S.-G. Lee¹, T.K. Lim¹, C.W. Park¹, S. Son¹, W.K. Kim¹
¹Gachon University, Gil Medical Center, Neurosurgery, Incheon, Korea, Republic of

Objective: Percutaneous pedicle screw fixation is one of treatment option in lumbar degenerative disease. The advantage of percutaneous pedicle screw fixation is to minimize iatrogenic injury of supporting structures in spine. This study compares clinical outcomes and radiologic changes in adjacent level of percutaneous pedicle screw fixation with those of open pedicle screw fixation.

Methods: Total 54 lumbar degenerative spine patients underwent screw fixation and interbody fusion after decompression. Percutaneous pedicle screw was used in 23 patients, other patients underwent open pedicle screw fixation. Patients’ age, sex, diagnosis and, operative results were collected retrospectively. Clinical outcomes were measured by Visual Analogue Scale, Odom’s criteria and Oswestry Disability Index. We measured lordotic angle and adjacent segment angle in follow-up radiologic study.

Results: Clinical outcomes showed no obvious differences in both percutaneous and open screw fixation groups. In radiologic finding, both groups revealed no significant differences in lordotic angles. On the other hand, L3-4 adjacent level angle change in open group was larger than that of percutaneous group. The percutaneous group’s sagittal angle changed from 10.2 ±2.4 to 11.6±2.7 in follow-up periods, and The open group’s sagittal angle changed from 9.9±2.4 to 13.4±2.9. This difference has a statistical significance. But there is no significant difference in L5-S1 adjacent level angle change between two groups.

Conclusion: We guess open screw fixation tend to make degenerative change in adjacent segment than percutaneous screw fixation. This suggestion may be related on minimal injury of supporting structures and preservation of adjacent facet joints in percutaneous screw fixation. But it can be confirmed through additional follow-up periods.

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Minimally Invasive Multilevel (More than 3 Level) Percutaneous Screw Fixation for Multi-level Lumbar Spinal Disease
S.G. Lee¹, S. Son¹, C.W. Park¹, W.K. Kim¹
¹Gachon University, Gil Medical Center, Neurosurgery, Incheon, Korea, Republic of

Objective: The minimally invasive percutaneous pedicle screw fixation reduces the destructive aspects of the open techniques, but still, there are rare reports on the result of multilevel (more than 3 level) percutaneous posterior fixation. The purpose of this study was to report the clinical experiences for multilevel percutaneous pedicle screw fixation of the lumbar spine.

Methods: A total of 12 patients of lumbar spinal disease underwent neural decompression, interbody fusion and percutaneous pedicle screw fixation from April 2008 to Feb. 2010. A retrospective review of clinical, radiological, and surgical data was conducted. Clinical outcomes were evaluated using the Odom’s criteria, Visual Analogue Scale, and Oswestry Disability Index. Radiological results were measured by total lumbar lordotic angle, segmental lordotic angle and fusion rate. Surgical outcomes were assessed by operation time, estimated blood loss, bed rest duration and surgical complications.

Results: Out of 12 patients, 4 patients were degenerative diseases, 4 patients were infectious diseases, and 4 patients were traumatic instabilities. There were 5 men and 7 women with mean age of 59 years (25-84) and a mean follow up period of 17.2 months (6-35). The average screw fixation level was 3.67 (3-6), and the transforaminal interbody fusion were performed in 6 patients, anterior corpectomy and fusion in 4 patients, and posterior-lumbar interbody fusion cin 2 patients.

“Excellent” or “good” clinical results were obtained in 10 patients (83.3%). The average improvement of VAS was 5.16 points, and the average improvement of ODI was 31.54% at the last visit. There was no statistical significance in the change of TLA and SLA during follow up period. There were progressive kyphotic change in 2 patients during follow up period, but there was no fusion failure. The average operation time was 5.79 hours, with an EBL of 700ml and bed rest duration of 1.92 days. There was no significant surgical complications except only one patient who underwent re-operation for nerve root compression due to remnant bone fragment.

Conclusion: Although the current study examined a small sample with relatively short term follow up periods, multi-level percutaneous pedicle screw fixation can be safely and effectively performed using minimally invasive techniques, thereby reducing the postoperative pain, soft tissues injuries, and blood loss. Also, the preoperative pedicle alignment is an important factor in multilevel percutaneous pedicle screw fixation.

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The Radiologic and Clinical Results of Multilevel Anterior Cervical Fusion Using Stand-alone Synthetic Interbody Cage
J.-K. Lee¹, J.-W. Jang², S.-H. Kim³
¹Chonnam National University Hospital, Neurosurgery, Gwangju, Korea, Republic of

Background & objective: Anterior cervical discectomy and fusion using synthetic PEEK cage is an effective and safe for degenerative cervical disease or trauma. However, there are strong arguments about using plate on fusion, especially multilevel. The pros insist that using plate on multilevel fusion result in higher fusion rate and neurologic improvement. In the other side,
The thoracolumbar junction (T11-L2) is the transitional zone between the stiff thoracic and the mobile lumbar spine. Therefore, burst fractures in this region are usually very unstable, and severe kyphotic deformity is frequently developed. The anterior approach for thoracolumbar burst fractures is favored when spinal canal is considerably compressed by large fractured bone fragment. In this study, we compare two commonly used struts for anterior thoracolumbar reconstruction after corpectomy: titanium mesh versus expandable cages.

**Methods:** This study included twenty eight patients, who underwent anterior thoracolumbar reconstruction using either titanium mesh (n = 13, group 1) or expandable cages (n = 15, group 2) between December 2004 and March 2010. Radiographs were obtained before surgery, immediately after surgery, and at final follow-up for accessing the restoration of spinal column. For the radiologic parameters, Cobb angle and inter-body height were assessed in plain lateral thoracolumbar radiograph. For patient’s pain and functional assessment, visual analogue scale (VAS), Frankel grading system, and Low Back Outcome Score (LBOS) were measured.

**Results:** The average follow up period was 29.5 months and 13.7 months in titanium mesh and expandable cage group, respectively. There were no significant difference between titanium mesh and expandable cage group, concerning age, sex, fracture site, cause of injury, and preoperative regional kyphosis. In both groups, regional kyphosis (Cobb angle) was significantly improved immediately after surgery. In titanium mesh cage group, correction loss of kyphosis and decline of inter-body height were significantly developed, compared with expandable cage group. In clinical results, expandable cage group had relatively low VAS score and a high LBOS during follow-up period, however, no significant differences of VAS score and LBOS between the two groups. Follow-up neurologic states by Frankel classification showed no cases involving aggravation of neurologic function in either group.

**Conclusions:** Clinically, anterior reconstruction with either titanium mesh or expandable cages after corpectomy is a safe and reliable surgical treatment option for treatment of thoracolumbar burst fractures. However, anterior reconstruction using expandable cage had lower correction loss of kyphosis with minimal subsidence. Despite several shortcomings in this study, the result suggests that ongoing use of expandable cage be recommended for treatment of thoracolumbar burst fractures.

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Comparison of Clinical and Radiologic Results between Titanium Mesh and Expandable Cages for Anterior Reconstruction after Corpectomy in Thoracolumbar Burst Fracture


Chonnam National University Hospital, Neurosurgery, Gwangju, Korea, Republic of

**Objective:** The thoracolumbar junction (T11-L2) is the transitional zone between the stiff thoracic and the objective.

**Methods:** From April 2005 to December 2009, a total of 49 patients who received multilevel (2 level : 41 cases, 3 level : 8 cases) anterior cervical fusion using synthetic PEEK cage without plate fixation at our institutions were reviewed retrospectively. Two of them was excluded due to follow up loss. A mean follow up period was 13 months (ranged from 6 to 46 months) Post-operative fusion rate, cervical lordosis and subsidence were determined by X-ray and Computed Tomography (CT). Neurologic symptom improvement and satisfactory was evaluated by using JOA scoring and outcome scale by described Robinson.

**Results:** According to JOA scoring and Robinson outcome scale, clinical symptoms were significantly improved after surgery (P < 0.05). Immediately after surgery, segmental height were increased, but segmental height was significantly decreased in last follow-up radiographs compare to postoperative (P < 0.05). However, there was no clinical correlation between the subsidence and the patient’s symptom (P > 0.05). Overall cervical angle (C2-C7) was not showed significant change between preoperative, postoperative, and last follow-up radiographs. There is 1 case that has complication, which was slight migration of cage in postoperative radiograph. During a follow up period, among the total 106 fusion levels, 99 levels achieved fusion (93.4%). Overall 7 levels were not achieved fusion, and the follow up periods of all cases with fusion failure were less than 1 year.

**Conclusions:** This study demonstrated relatively high fusion rate (93.4%) on patients with multilevel stand-alone cervical fusion using synthetic PEEK cage, and too few complication was revealed. Although most of patients found subsidence on follow up imaging studies, but improved neurologic symptoms were not deteriorated. Thus we think that multilevel stand-alone cervical fusion using synthetic PEEK cage are safe and effective for treating degenerative cervical disease. In the future, clinical observation about relationship between progression of subsidence and neurological symptom with long term follow up should be investigated and comparative study with multilevel anterior cervical fusion with plate fixation also should be conducted.

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Does CTDR Have a Lower Risk of Device Subsidence Compared to ACDF? 2 Year Results of a Prospective Multi-center Study


BG-Clinic Bergmannstrost, Neurosurgery, Halle, Germany, 1Regional Hospital Liberec, Liberec, Czech Republic, 2Hospital Motol, Prague, Czech Republic, 3University Helsinki, Helsinki, Finland, 4Charite, Berlin, Germany, 5Katholisches Klinikum, Münster, Germany, 6Universitätsklinikum, Rostock, Germany, 7Warrington District General, Warrington, United Kingdom, 8Hospital Maz, Zaragoza, Spain, 9Istituti Fisioterapici Ospitalieri, Roma, Italy, 10Frictionless GmbH, Kiel, Germany
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 two year interim results (n=99) of a prospective, multicenter study, performed at 11 European sites. All patients (mean age 42.6 years; male = 41, female = 58) underwent single-level total disc replacement (activ™ C disc prosthesis) between C3/4 and C6/7 (C3/4=2, C4/5=5, C5/6=49, C6/7=43) and were followed-up 6wk, 6mo, 1y and 2y 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 3.7mm, postop 6.5mm, 6wk 5.8mm, 6mo 5.7mm, 1y 5.7mm, 2y 5.6. Statistically significant differences were detected between preop/postop, postop/6wk, 6wk/6mo and 1y/2y (p< 0.001 Linear Contrasts, ANOVA). Mean loss of disc height by level was 1.4mm for C3/4 and C4/5, 0.8mm for C5/6 and 0.9mm for C6/7 (overall loss of disc height 0.9mm). The subsidence rate (loss of height > 3mm) in our study is 0% (0/99) or, based on a subsidence definition of > 2mm, 6.1% (6/99).

Mean segmental lordosis increased significantly from 2.2° preop to 5.8° after 2 year (p > 0.001, Paired Samples T-Test). Also clinical outcome (NDI, VAS neck pain, VAS arm pain) improved significantly from preop to 2 years postop as follows: 40.5 to 19.1, 50.3 to 23.4 and 51.1 to 19.0, respectively (p < 0.001 Wilcoxon Signed Ranks Test). There is no correlation between loss of disc height after 2y and clinical outcome (p > 0.05 Spearman’s Correlation).

Compared to literature, where cage subsidence rates of 9% - 55.6% (> 3mm) or 45% (> 2mm) are described, our results show a lower risk for subsidence, which is probably contributed to different design concepts of disc arthroplasties and cages in general and the anatomically adopted shape and geometry of the study device in particular.

### Biomechanics/Basic Science

**256 Which Degree of Freedom of a Dorsal Pedicle Screw Is Best for Dynamic Stabilization?**


**1**ACES GmbH, Medical Devices, Filderstadt, Germany, **2**University of Muenster, Department of Trauma and Reconstructive Surgery, Muenster, Germany

**Introduction:** Dynamic stabilization becomes more and more important for the treatment of spinal instabilities. It is hypothesized that maintaining mobility prevents or at least decelerates adjacent level degeneration. Recently, various dorsal implant systems targeting the “dynamic stabilization” of the spine entered clinical practice. One of the simplest mechanical concepts is to weaken or unconstrain certain degrees of freedom. However, it is still unclear how implant related degrees of freedom would influence a spinal segment and implant loading. The aim of this in-vitro study was to generate a model with different degrees of freedom utilizing a dorsal pedicle screw system and to investigate its effects on range of motion (RoM), center of rotation (CoR) and on rod loading.

**Methods:** The investigation was performed with 6 spinal specimens (L3-4) taken from calves. Pure unconstraint bending moments of ±7.5Nm were applied towards flexion and extension using a robot (KR125, Kuka). Subsequent to intact measurements, a defect was created by dissecting dorsal ligaments, performing facetectomy and nucleotomy. The defect was treated with a modified pedicle screw system (orthobiom, Fourth Dimension Spine) employed in four configurations: rigid, free rod sliding, free polyaxiality of the screws and free rod sliding plus free polyaxiality. Axial rod forces and bending moments were measured using strain gauges. RoM and CoR were radiologically determined and statistically analyzed by means of the Wilcoxon signed-rank-test.

**Results:** The rigid configuration reduced the RoM by 87% to 0.6° (min=0.4, max=1.2°) in flexion and in extension by 78% to 0.9° (min=1.3, max=0.7°) compared to the defect situation. Axial forces/bending moments were 54N/0.1Nm in tension (flexion) and 46N/-0.8Nm in compression (extension) for each rod. Free rod sliding increased the rod bending moments up to 1.3Nm/-1.2Nm. Free polyaxiality flipped the rod bending moments (sign change) to -0.8Nm/0.7Nm. Axial forces increased slightly compared to the rigid configuration. In comparison to the rigid situation, the RoM was not significantly different. The CoR was found to be close to the center of the superior vertebral body. Free polyaxiality and rod sliding produced almost non rod forces/moments. CoR and RoM were comparable to the defect specimen situation.

**Discussion:** The number of patients clinically treated with a dynamic implant system increases steadily, however, the biomechanics are to date not fully understood and acknowledged. Our investigation showed that it is necessary to delineate new implant specification requirements for design and testing to ensure proper implant function and fatigue endurance. Existing standards of mechanical implant testing predominantly consider fusion or rigid fixation devices for the spine, which does not or insufficiently mimic the situation with a dynamic system. In this study, the effect of different degrees of freedom was quantified for dorsal pedicle screws. Results showed that e.g. free polyaxiality was comparable to the rigid pedicle screw. Allowing free rod sliding (with all rotation axes locked in the screws) restored RoM and CoR to values of intact specimens but still stabilized the spine. This work provides a first insight with partially surprising results correlating implant degrees of freedom and implant loading.
Biomechanical Evaluation of Bisegmental Decompression and Stabilization with Non-fusion Instrumentation of the Lumbar Spine

M. Moumenet, W. Schmoelz², A. Payman¹, A. Reinhardt³, R. Sambale⁴
¹DePuy Spine Inc., Research & Development, Raynham, MA, USA, ²Medical University Innsbruck, Trauma Surgery and Sports Medicine, Innsbruck, Austria, ³Oberlinklinik Potsdam Orthopädische Fachklinik, Potsdam, Germany, ⁴Orthopädische Klinik Hessisch, Lichtenau, Germany

Introduction: Decompression is a well-recognized procedure for the treatment of spinal stenosis. However, aggressive decompression may remove major structural elements thus increasing the chance of postoperative spinal instability. We hypothesized that stabilization with a non-fusion system composed of mobile screw heads and flexible rods (VIPER™ SC, DePuy Spine) may act as an internal brace by sharing the load with the remaining spinal structural elements while maintaining some ROM. The objective of this work is therefore to evaluate the effect of a non-fusion system on the stabilization of multi-level decompression by comparing the ROM of intact spine, to an unstable condition (2-level stabilization) before and after stabilization with a non-fusion system.

Methods: A 3D muscular ligamentous L1-S1 FE-Model validated based on in-vivo data was used in this study. The FE-model was adapted to simulate bisegmental decompression at L3-L5 by total laminectomy and 50% bilateral medial facetectomy and nucleotomy at L4-L5. The segment stabilization was further modeled by adding a non-fusion system. The instrumentation was composed of two fixed screws at L4 and two mobile screws at L3 and L5 connected by 5.5mm flexible PEEK rods (Figure 1). Pure moments of ±7.5 Nm in flexion-extension, axial rotation and lateral bending were applied to the intact, unstable and instrumented models while under a follower load (muscles load) of 400 N. The segmental ROMs were calculated for all modalities.

Results: The segmental ROM in flexion/extension for decompression and stabilization with a non-fusion system expressed relative to the intact spine is shown in Figure 2. Compared to the intact state, decompression by laminectomy at L3-4 caused a 121% increase in ROM, while laminectomy and nucleotomy at L4-5 considerably increased the ROM (196%). Compared to the intact state, instrumentation of the decompression at L3-4 and L4-5 with the non-fusion system reduced the ROM (15%, and 44%, respectively). For the two cranial segments the ROMs were barely changed compared to the intact state and only varied slightly (ROM range 102%-113%).

Biomechanical Characteristics of a Novel Integrated Lumbar Interbody Fusion Device

L.I. Voronov¹, P.P. Tsitsopoulos³, R.M. Havey³, J. Zelenakova³, G. Carandang³, A. Mahar³, A.G. Patwardhan¹
¹Loyola University Chicago, Orthopaedic Surgery and Rehabilitation, Maywood, IL, USA, ²Edward Hines Jr. VA Hospital, Hines, IL, USA, ³Alphatec Spine, Carlsbad, CA, USA

Purpose: Anterior lumbar interbody fusion cages provide excellent height restoration and decompression compared to posterior interbody techniques. Several devices have been developed with integrated fixation points to potentially reduce the need for supplemental posterior instrumentation. The study purpose was to compare the biomechanical stability provided by an anterior interbody fusion device with integrated fixation blades and minimally invasive supplemental translaminar facet screw fixation to a traditional anterior interbody cage and pedicle screw based system.

Methods: Seven fresh-frozen human lumbar spines were used. The L1 vertebra and sacrum were anchored in cups using bone cement and pins. Specimens were fixed to the apparatus at the caudal end and motion of the L1 vertebra was unconstrained. A moment was applied to L1 that allowed continuous cycling of the specimen between specified maximum moment endpoints in flexion and extension (FE), lateral bending (LB), and axial rotation (AR). The motion of each vertebra was measured using an optoelectronic motion measurement system. A multi-axis load cell was placed under the specimen to measure the applied moments. Fluoroscopic imaging was used during FE in order to monitor vertebra and implant motion. Specimens were tested: (1) intact, (2) with single-level fusion at L4-L5 with an anterior interbody cage and posterior pedicle screws
and (3) with the anterior interbody cage with integrated fixation blades (Solus™, Alphatec Spine, Carlsbad, CA) and utilizing supplemental translaminar facet fixation. Each specimen was tested in flexion (8Nm), extension (6Nm), LB (±6 Nm) and AR (±5 Nm) without preload. Range of motion (degrees) of L4-L5 was compared with a one-way ANOVA (p< 0.05) and Bonferroni correction. **Results:** Both methods of lumbar fixation demonstrated statistically significant reductions in range motion of the L4-L5 motion segment as compared to the intact condition for each test direction (p< 0.05) (Figure 1). There were no statistical differences in range of motion between either treatment conditions for any test direction. **Conclusions:** Fusion constructs using interbody cages and transpedicular fixation are commonly used to address anterior and posterior column instabilities in the degenerative lumbar spine. Alternative techniques to the traditional method must have an equivalent mechanical stability to achieve similar success rates and show some advantage over traditional techniques. Data from the current study demonstrate that an anterior interbody cage with integrated fixation blades, when supplemented with translaminar facet screws, provides an equivalent immediate post operative mechanical stability when compared to the traditional anterior cage with posterior pedicle screws technique. This alternative technique for lumbar fusion will allow for less invasive posterior fixation while maintaining the stability required for successful fusion.

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*Comparison of Dynamic Cervical Implant and Prestige LP: Clinical Results, Range of Motion, and Intervertebral Height*

L. Zou¹, H. Liu¹, C. Ding¹, T. Hu¹, R. Shi¹, Y. Song¹, T. Li¹, B. Wang¹
¹Department of Orthopaedic Surgery, West China Hospital, Sichuan University, Chengdu, Sichuan, China

**Study design:** A prospective study.

**Objectives:** To compare the clinical outcome, radiographic changes, and complications of patients with cervical disc herniation who underwent DCI(Dynamic Cervical Implant) fixation and Prestige LP arthroplasty.

**Summary of background data:** ACDF(anterior cervical discectomy and fusion) and cervical disc replacement are the most frequently adopted surgical ways to treat cervical disc herniation via anterior approach, but they have certain shortcomings. The report of the clinical result of a new semi-constrained anterior instrument, with intermediate post-operative motion range between the former two ways, is rarely seen.

**Methods:** There were 49 consecutive patients (22 for Prestige LP group and 27 for DCI group) with cervical disc herniation from year 2008 to 2011. The mean follow-up duration was 22.5 months and 21.2 months, respectively. Our follow-up visit were preoperation, 3, 6, 12 and 24 month postoperatively. Neck disability index score (NDI), SF -36 items were used to assess neurologic function rehabilitation of the two groups. Also, lateral and dynamic radiographs were used to evaluate the intervertebral height and ROM (range of motion) of the cervical spine pre and postoperatively. The complications were assessed too.

**Results:** A total of 27 DCI and 32 Prestige LP cervical disc prostheses were implanted in the two groups, respectively. (1) Clinical outcome: There is no significant difference with CFD underwent single or bi-level implantation of Bryan cervical artificial discs. Dynamic radiographs and computed tomography (CT) were introduced to measure segmental range of motion (ROM) and assess the CFD according to a modified quantitative scoring system before and after surgery. Clinical outcomes were also evaluated.

**Conclusions:** Cervical arthroplasty prevents facet joint from accelerating degeneration, which may be attributed to the biomechanical advantage of prosthesis. Degree of CFD influences the index and adjacent segmental ROM, but was not correlated with clinical outcomes.
with NDI and SF-36 items between the DCI and Prestige LP group (p>0.05).
(2) Intervertebral height: There have no statistical significance in the intervertebral height of the operated level between the two groups preoperatively and 3,6,12, and 24 months postoperatively (p<0.05).
(3) ROM: At the last follow-up, the flexion/extension ROM of C2-7 shows no statistical significant for DCI and Prestige LP group (p>0.05). This was the same in the adjacent levels (p>0.05). But at the operated level, the DCI group had a statistically lesser flexion/extension ROM than Prestige LP group (p<0.05). In addition, the lateral bending of the two groups were statistically significant, the Prestige LP group had a greater ROM (p<0.05).
(4) Complications: There were 10 and 6 patients suffered mild to moderate neck pain for the two groups after operation, respectively.

**Conclusion:** There was a good medium-term clinical result, similar as that of Prestige LP, for DCI. Its semi-constrained design may serve as a protection for the facet joints of the operated level compared to unconstrained Prestige LP.

**Keywords:** Cervical spine, disc herniation, Dynamic Cervical Implant, Prestige LP, cervical arthroplasty, range of motion, intervertebral height

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**Clinical and Radiological Consequences of Interbody Cage Subsidence**

L. Marchi$^{1,2}$, L. Oliveira$^1$, R. Amaral$^1$, C. Castro$^1$, E. Coutinho$^1$, T. Coutinho$^1$, L. Pimenta$^{1,3}$

$^1$Instituto de Patologia da Coluna, São Paulo, Brazil, $^2$Unifesp, DDI, São Paulo, Brazil, $^3$University of California San Diego, Neurosurgery, San Diego, CA, USA

**Purpose:** Indirect decompression of the neural structures through disc space distraction is feasible, but cage subsidence may limit this mechanism. The occurrence of cage subsidence in the radiological surgical goals its clinical correlation is yet unknown. The main goal of this work is to describe a new grading system, describe when and how the subsidence occurs.

**Methods:** Retrospective analysis on prospective clinical study. Seventy-four patients (57.2 ± 14.8 y/o; BMI 24.9 ± 2.5). Standing lateral radiographs were performed preoperatively, postoperatively at 1 and 6 weeks, 3 and 12 months. Clinical outcomes were assessed by ODI and VAS up to 24 months. Standalone short-segment lateral lumbar interbody fusion was investigated. The fused segments were: 3 at L1L2, 7 at L2L3, 22 at L3L4, 66 at L4L5. Radiological measurements were done regarding segmental lumbar lordosis and subsidence occurrence. Subsidence grading followed a method that estimates the percentage of the cage is inside the vertebral body: 0-24% of subsidence - grade 0; 25-49% grade I; 50-74% grade II; 75-100% grade III.

**Results:** Subsidence was early detected at 6-week and didn’t significantly progressed. Major subsidence defined as 50% or more of cage settling (grade II or III) occurred in 22% of all patients based on 12-month radiographs (22 of 98 total levels). Moreover, subsidence was seen to occur predominantly (68% of the cases) in the inferior endplate of the assessed intervertebral disc. VAS and ODI scores improved in the studied group but subsidence was found to influence clinical outcomes, once high-grade subsidence was correlated with transient axial back pain at 6-week follow-up point. In grade 0 and I cases disc height gain was observed in postoperative radiological assessments, in contrast to grade II and III cases. Lordosis gain was better achieved when the cage did not sink into the vertebra. Risk factors for high-grade subsidence were advanced age and female gender.

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**Lessons Learned after 9-year Follow-up on Eight Different Lumbar Total Disc Replacement Devices**

L. Marchi$^{1,2}$, L. Oliveira$^1$, R. Amaral$^1$, C. Castro$^1$, E. Coutinho$^1$, T. Coutinho$^1$, L. Pimenta$^{1,3}$

$^1$Instituto de Patologia da Coluna, São Paulo, Brazil, $^2$Unifesp, DDI, São Paulo, Brazil, $^3$University of California San Diego, Neurosurgery, San Diego, CA, USA

**Purpose:** Charité prosthesis 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, the senior author’s wide clinical experience was analyzed, which covers more than 400 single or multi-level implanted prostheses with up to 9 years of 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-
Introduction: Revision discectomy and fusion is often performed for recurrent lumbar disc herniations. TLIF is thought to result in increased fusion rates, an advantage over stand-alone instrumented PLF. However, there is a lack of data comparing the outcomes of different fusion methods for recurrent herniations. Since lumbar interbody fusions introduce additional risk and cost, there is value in determining whether it provides additional benefits over postero-lateral fusion alone. This study compares the clinical and radiographic outcomes of these two fusion methods when performed along with revision discectomy.

Methods: Hospital records were reviewed between January 2005 and July 2010 for patients undergoing reoperation for recurrent lumbar disc herniation and treated with revision discectomy and fusion (PLF or TLIF). A total of 40 patients met the inclusion criteria (23 PLF and 17 TLIF). Radiographic, operative, and clinical outcomes were assessed. The primary outcome was fusion status and was determined by independent radiographic evaluation. Medical records provided data on operative time, intraoperative blood loss, length of hospital stay after surgery, and peri-operative complications. Clinical outcomes were measured using visual analog scores for leg and back pain and Oswestry Disability Index (ODI) questionnaires. Patients were asked to assess their current pain and to retrospectively give best estimates of their pain prior to surgery. Demographic data was also collected. All statistical analyses were performed using SAS version 9.2 (SAS Institute, Inc., Cary, NC).

Results: Overall, there was a significant association between blood loss, length of operation, and length of hospital stay. Of note, operations were significantly longer for TLIF patients (302.5 min) as compared to PLF patients (248.0 min) (p = 0.009). Only 12 PLF and 11 TLIF patients responded to questionnaires. The groups were comparable at baseline with no significant differences in demographics, VAS back pain, leg pain, or ODI scores. No significant differences were found between the two groups either post-operatively or in magnitude of change from baseline. The only significant differences between the groups occurred in magnitude of change from baseline among the ODI domains of sleep (p = 0.036) and travel (p = 0.032). Both groups demonstrated improved scores from baseline to final follow-up. Among PLF patients, there was a significant improvement in VAS back scores (p = 0.004) and in ODI scores (p = 0.039). VAS leg scores improved as well, though this finding was not significant. Among TLIF patients, VAS back and leg scores significantly improved (p = 0.022 and p = 0.039, respectively). The average ODI score improved as well, though not significantly. Successful radiographic fusion was achieved in 19 (82.6%) PLF patients and 15 (88.2%) TLIF patients. There was no difference in fusion rates between the two groups (p = 1.0).

Conclusions: Our analyses can point out various lumbar arthroplasty aspects, including its pros: better biomechanical results, better clinical results, restoration of global motion, no 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.

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Revision Discectomy with Postero-lateral Fusion (PLF) versus Transforaminal Lumbar Interbody Fusion (TLIF): A Retrospective Comparative Study
1Brigham and Women’s Hospital, Harvard Medical School, Orthopaedic Surgery, Boston, MA, USA; 2Brigham and Women’s Hospital, Harvard Medical School, Radiology, Boston, MA, USA; 3Massachusetts General Hospital, Harvard Medical School, Orthopaedic Surgery, Boston, MA, USA

Introduction: Revision discectomy and fusion is often performed for recurrent lumbar disc herniations. TLIF is thought to result in increased fusion rates, an advantage over stand-alone instrumented PLF. However, there is a lack of data comparing the outcomes of different fusion methods for recurrent herniations. Since lumbar interbody fusions introduce additional risk and cost, there is value in determining whether it provides additional benefits over postero-lateral fusion alone. This study compares the clinical and radiographic outcomes of these two fusion methods when performed along with revision discectomy.

Methods: Hospital records were reviewed between
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The Endoscopic Resection of Intraspinal Facet Cysts
S. Hellinger
ISAR Kliniken, Spine Unit, Munich, Germany

Object: Several types of intraspinal cysts with different pathogenesis, causing symptoms indistinguishable from those of lumbar disc herniation, have been reported, such as perineural cysts, synovial cysts, and ganglion cysts. Facet cysts are the most often detected cystoid structures in the spinal channel. Juxtafacet cysts are uncommon causes radiculopathy, low back pain and neurogenic claudication and are often associated with significant spinal degenerative disease. To define the etiologic, clinical, histological, and surgical features of lumbar facet cysts an exact consideration is necessary. Because facet cysts are directly related to degenerated facet joints, the distinct risk of spinal instability following removal of these lesions exists. In part to address these concerns, the primary surgical treatment of lumbar synovial cysts has evolved from performing a complete laminectomy to performing a hemilaminotomy, directly over the lesion in many cases. The latest modification of this procedure involves the integration of minimally invasive techniques that were initially developed for endoscopic lumbar discectomy. Minimally invasive techniques reduce the risk of approach-related iatrogenic soft-tissue injury and have been shown to decrease intraoperative blood loss, postoperative pain and postoperative instability.

Although the relevant reports in the international literature are increasing, the controversy about conservative versus surgical treatment and the need for concomitant fusion still exists. Endoscopic techniques by less surgical damage on the joint are helping to avoid this necessity.

Method: The endoscopic surgery demands a high level of endoscopic skills. Depending on the morphology of the cysts it can be done by interlaminar or transfornaminal approach. Special endoscopic instruments like burs and kerrisons allows a proper preparation by slightly removing bone. Meanwhile L5S1 allows a simple interlaminar approach; L4/5 requires a special bony preparation. The total careful dissection from the neural structures in the spinal channel. Juxtafacet cysts are obligatory to avoid a cerebrospinal fluid leakage. The resection of the cyst required a piecemeal removal by the scope. The different endoscopic techniques will be described.

We included 7 prospective cases, that underwent an endoscopic treatment of facet cysts. All patients underwent at a minimum of 6 weeks of nonoperative management prior the endoscopic resection. The follow up was up to one year. In selected cases an imaging control after surgery has been done.

Results: The patients postoperative outcomes were graded using VAS and Macnab criteria. Furthermore the morphological control of the removed cysts is included. Following endoscopic resection of their facet cysts The average duration of the surgery was 53 minutes. There was no significant blood loss.

Two patients achieved an excellent outcome, four reported a good result and one kept fair. The patients with good and fair outcome noticed radicular pain and
MIS Technique and Results

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Lumbar Total Disc Replacement with a Ball and Socket Metal on Metal Device. Up to 60 Months Follow-up
L. Marchi1,2, L. Oliveira1, R. Amaral1, C. Castro1, E. Coutinho1, T. Coutinho1, L. Pimenta1,3
1Instituto de Patologia da Coluna, São Paulo, Brazil, 2Unifesp, DDI, São Paulo, Brazil, 3University of California San Diego, Neurosurgery, San Diego, CA, USA

Purpose: Current lumbar total disc replacement (TDR) techniques require an anterior approach and carries its inherent surgical risks and the resection of the anterior longitudinal ligament (ALL). Placement of a TDR device from a true lateral approach offers a less invasive access to the disc space and also preserves the stabilizing ligaments. Evaluate clinical and radiological results on the new minimally invasive lumbar disc replacement.

Methods: Prospective non-randomized single-center study. Fifty-four patients, average age 43.1 y/o (24-64). Radiological (dynamic x-rays, CT and MRI) and clinical outcome assessment (ODI and VAS) were performed at the preop and postop up to 60 months (minimum 48 mos). A TDR device designed for implantation through a true lateral, retroperitoneal, transpsoas approach was implanted with discography-confirmed 1- or 2-level DDD. Thirty cases were single level TDR, seven cases were double level TDR and seventeen hybrids constructs.

Results: The surgeries were performed in an average of 127 minutes (60-300) and with an average 50cc blood loss (30-150). There was no intra-op or post-op major complications. Postoperative x-rays showed good device placement, with restoration of disc height, foraminal volume, and sagittal balance. VAS and ODI improved compared to baseline. One retrieval surgery was performed by contralateral access due CrCo allergy. After 48 months we observed an expected incidence of 27.8% of bone formation at the index level, but only 2.8% of consequent fusion (heterotopic ossification grade IV).

Conclusions: Results of a laterally placed TDR device demonstrate maintenance of pain relief and functional improvement, but still not free from bone formation at the index level. The benefits of this technique included minimal morbidity, avoiding mobilization of the great vessels, preserving the anterior longitudinal ligament, biomechanically stable orientation, and broader revision options suggest a promising new direction for TDR procedures.

Cervical Therapies and Outcomes

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Peek-ceramic Cervical Total Disc Replacement Improving Postoperative Evaluations on MRI
L. Marchi1,2, L. Oliveira1, R. Amaral1, C. Castro1, E. Coutinho1, T. Coutinho1, L. Pimenta1,3
1Instituto de Patologia da Coluna, São Paulo, Brazil, 2Unifesp, DDI, São Paulo, Brazil, 3University of California San Diego, Neurosurgery, San Diego, CA, USA

Purpose: The ball and socked ceramic-on-ceramic design is believed to increase durability and eliminates the potential problems of wear debris from other bearing surfaces such as polyethylene. Also, this ceramic ball and socket with peek core prosthesis reduces MRI artifacts, improving postoperative radiological analysis. This report shows a ceramic prosthesis option for total disc replacement, providing a valuable alternative to other metal discs, generating better postoperative image control using MRI, with good clinical outcomes.

Methods: Fifteen patients (16 cervical levels; mean age of 43 y/o) underwent a cervical disc replacement and were prospectively followed. NDI, (VAS), TIGT and EQ-5D were used to access pain and functional outcomes. Radiographic images were collected at all visit points.

Results: No intraoperative complications occurred. The sagittal alignment was satisfactory maintained. At 24-mos follow-up, the ROM was not statistically different from preoperative evaluations. Clinical outcomes decreased from baseline. The postoperative radiographic evaluations using MRI have provided a greater versatility and visibility in imaging studies in comparison to other metal disc prostheses.

Conclusions: Following cervical arthroplasty with the image-friendly peek ceramic disc, radiographic and clinical outcome results were encouraging. This cervical artificial disc is a good and effective option for the treatment of painful cervical disc disease associated or
not with radiculopathy. It also provides a great reduction of metal artifacts on postoperative MRI, with a complete view of the adjacent structures.

Biomechanics/Basic Science

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Kinematics of a Compressible Lumbar Disc Prosthesis under Physiologic Loads: Effect of Implantation Level
A.G. Patwardhan1, L. Gössel2, P.P. Tsitsopoulos3, L.I. Voronov4, N. Wharton5, T. Potluri6, J. Zelenakova5, G. Carandang4, C. Schätz7, R.M. Havey1
1Loyola University Chicago, Orthopaedic Surgery and Rehabilitation, Maywood, IL, USA, 2Orthopadische Klinik Markgroningen gGmbH, Markgroningen, Germany, 3Medical Metrics, Inc, Houston, TX, USA, 4Edward Hines Jr. VA Hospital, Hines, IL, USA

Purpose: The anatomy and kinematics of the lumbosacral junction differ substantially from proximal levels: the L5-S1 segment has greater segmental lordosis and the Center of Rotation (COR) in flexion-extension is located more posterior and cranial. Recent studies of ProDisc II prosthesis have reported smaller postoperative Range of Motion (ROM) at L5-S1 compared to L4-L5, and have attributed this to the discrepancy between the COR of the native L5-S1 segment and that of a fixed COR prosthesis. This study investigated whether compressible disc prosthesis with 6-degrees-of-freedom (6-DOF) will function similarly in restoring native kinematics at L4-L5 and L5-S1.

Methods: Twelve human lumbar spines were tested in flexion-extension (FE), lateral bending (LB) and axial rotation (AR). Response in FE was measured under 400N and 800N compressive follower preloads. In six specimens, mono-segmental total disc replacement (TDR) was performed at L4-L5 using compressible 6-DOF disc prosthesis (M6, Spinal Kinetics, Sunnyvale, CA). In additional six specimens, disc replacement was performed first at L5-S1. After kinematic assessment, a second disc prosthesis was implanted at L4-L5 and testing repeated. ROM in FE, LB and AR, and flexion-extension COR were measured.

Results: Comparing mono-segmental TDRs, the ROM values (in degrees) of the reconstructed L5-S1 segment were similar to those of L4-L5 in FE (L5-S1: 9.0±1.7 vs. L4-L5: 8.2±1.5, p=0.41), LB (3.4±1.0 vs. 5.0±2.8, p=0.27), and AR (1.7±0.5 vs. 3.4±1.8, p=0.07). The ROM values of the reconstructed L5-S1 segment were unaffected by the presence of a second disc prosthesis at L4-L5 in FE, LB, or AR (p>0.20). In the intact spines, the L5-S1 COR location was significantly more posterior (p<0.01) and more cranial (p=0.06) than the L4-L5 COR location (Fig. 1 & 2). After mono-segmental disc replacement, the L5-S1 COR did not differ significantly from its intact location (p=0.11). The COR location in the reconstructed L5-S1 segment was significantly more posterior to that of the reconstructed L4-L5 segment (p=0.013), and was unaffected by the presence of a second TDR at L4-L5 (p>0.88). The amount of preload (400N vs. 800N) did not significantly affect the kinematics of the reconstructed L5-S1 or L4-L5 segments.

Conclusions: Reconstruction using the compressible 6-DOF prosthesis maintained physiologic quantity and quality of motion at L5-S1, similar to that at L4-L5. The COR of the reconstructed L5-S1 segment was significantly more posterior to that of the reconstructed L4-L5 segment, indicating the ability of the 6-DOF prosthesis to adapt to the native lumbosacral joint kinematics.

Lumbar Therapies and Outcomes

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Prospective Case-series of Artificial Lumbar Disc Replacements for the Treatment of Symptomatic Degenerative Disc Disease: Initial Interim Clinical Results from a Long-term Follow-up Study in Potsdam, Germany
K. Ritter-Lang1, N. Dreßler2
1Semper Mobilitas Orthopädie und Wirbelsäulen chirurgie, Potsdam, Germany

When conservative treatments fail to treat intractable pain due to degenerative disc disease (DDD), fusion or total disc replacement is then considered. Fusion eliminates instability and reduces low back pain, but can lead to adjacent disc level degeneration. Alternatively, total disc replacement (TDR) will restore and maintain motion without affecting adjacent levels. The purpose of this study was to assess clinical outcomes and safety of a prospective case series using the M6®-L artificial lumbar disc at one site in Germany. This is an ongoing prospective case-series, part of a multi-site post-market surveillance study outside the USA. Beginning in February 2009, skeletally mature patients with DDD of the lumbar spine who failed at least a 6-month course of conservative therapy and signed
Methods: A total of 47 consecutive patients diagnosed with either degenerative spondylolisthesis (22) or degenerative disc disease (25) were followed. The average age was 56; the male/female ratio was 20/27 and 7 were smokers. One to three level posterior, transforaminal, 360 degree or extreme lateral interbody fusions were performed. Pedicle screws were placed and cages were inserted through a TLIF approach. Bullet-Tip PEEK cages were used in 31 patients, 10 received a Titan® cage, one patient a CrossFuse® and a T-Plus® cage, one a carbon fiber cage, and one patient an ALIF PEEK cage. One nanOss Bioactive 10 cc device mixed with BMA (obtained from the pedicle) per level fused was layered over autograft bone in the lateral gutters between transverse processes. Interbody cages were packed with nanOss BA mixed with autograft bone and BMA. The interbody space around the cage was also packed with the nanOss Bioactive. T-P/interbody levels treated were: one 31/30; two 10/9; three 6/5.

Routine follow-up evaluations and radiographs were obtained 4 weeks and 3, 6, and 12 months following surgery. Fusion was judged to be solid when bridging bone was identified radiographically across the transverse processes or between the vertebral bodies. Fusion results were confirmed with lumbar CT scans at 12 months follow-up. Each side of each operated T-P level and each interbody level were individually evaluated for fusion. Clinical outcome was evaluated using a Combined Prolo Score (Spine 23:263, 1998): 2-4 = poor; 5-6 = fair; 7-8 = good; 9-10 = excellent.

Results: The 47 patients represent 69 levels (138 individual) T-P fusions and 63 levels of interbody fusion. All 63 of the interbody levels demonstrated solid fusions (100%) and 125 of 138 (91%) of all individual T-P sites were completely fused at one year based on CT analysis. X-ray and CT images showed excellent bone formation and good fusion masses which correlated with clinical outcomes. Prolo Combined Score outcomes were Excellent (22/47, 47%) or Good (17/47, 36%) for 83% of these patients and Fair (7/47) for 15% of patients. Only one patient (2%) had a poor outcome.

Discussion: In this first cohort of 47 patients, nanOss Bioactive resulted in a solid fusion in 100% of the 63 interbody levels treated and 91% of the 136 T-P levels. No revision surgeries at the treated levels were required. However, 5 patients were re-operated on after developing adjacent level disease. Physical exploration/examination of the original implant sites demonstrated solid bony fusion masses in all 5 cases. In many cases solid fusion or a good fusion mass were observed in radiographs as early as 3 months following surgery. nanOss Bioactive was an excellent bone graft material in this study.

Lumbar Therapies and Outcomes

Introduction: nanOss Bioactive is a resorbable porous calcium phosphate bone void filler graft substitute for spine fusion. It is an osteoconductive implant composed of nanocrystalline hydroxyapatite and a collagen biopolymer carrier designed to provide excellent handling properties and a resorbable cellular scaffold. This product is intended for use with bone marrow aspirate (BMA), autograft bone and appropriate hardware. The purpose of this study was to evaluate one year clinical and radiographic spine fusion results of patients treated with nanOss Bioactive.

Method: A total of 47 consecutive patients diagnosed with either degenerative spondylolisthesis (22) or degenerative disc disease (25) were followed. The average age was 56; the male/female ratio was 20/27 and 7 were smokers. One to three level posterior, transforaminal, 360 degree or extreme lateral interbody fusions were performed. Pedicle screws were placed and cages were inserted through a TLIF approach. Bullet-Tip PEEK cages were used in 31 patients, 10 received a Titan® cage, one patient a CrossFuse® and a T-Plus® cage, one a carbon fiber cage, and one patient an ALIF PEEK cage. One nanOss Bioactive 10 cc device mixed with BMA (obtained from the pedicle) per level fused was layered over autograft bone in the lateral gutters between transverse processes. Interbody cages were packed with nanOss BA mixed with autograft bone and BMA. The interbody space around the cage was also packed with the nanOss Bioactive. T-P/interbody levels treated were: one 31/30; two 10/9; three 6/5.

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stabilization systems have been evaluated in two Food and Drug Administration sponsored investigational device exemption studies in the USA. The Dynesys trial resulted in a non-approval recommendation from the FDA advisory panel and the Stabilimax trial was halted due to grit-blasted screw failures. Radiolucency about pedicle screws has been identified in both trials but no clear clinical significance has been established for this. However, concerns have been raised about the lucencies as a potential predictor of clinical failure.

Methods: The Stabilimax FDA IDE enrolled patients with back and leg pain due to spinal stenosis in a prospective, randomized clinical trial. Decompressive surgery was performed at a single level between L3 and S1. The patient then received posterior pedicle screw fixation with posterolateral fusion, or stabilization without fusion provided by the Stabilimax system. Evaluations were performed clinically and radiographically pre-operatively, and at 6 weeks, 3, 6, 12, 18, and 24 months post-operatively. Primary outcome measures included ZCQ (Zurich Claudication Questionnaire) and VAS (Visual Analog Pain Score). Secondary outcome measures included ODI (Oswestry Disability Index). All patients also underwent radiographic evaluation with independent review.

Results: Sixty consecutive single level investigational patients were enrolled at 19 study sites. The average age was 59.4 years with 35 females and 25 males enrolled. At 2 years follow-up, 15 radiolucent areas around screws had been identified in 10 patients by the independent radiographic review. 3 of these screws went on to fracture and in 1 patient there was a device removal. Statistical analysis with student t test shows no significant difference in achievement of success as judged by the primary clinical endpoints in patients with and without lucency (60% vs 55%). Correlation of age, BMI, smoking status, pre-operative disc height, degree of spondylolisthesis, severity of spinal stenosis and screw size with likelihood of radiolucency is presented.

Conclusions: Radiographic findings of lucency about pedicle screws in the Stabilimax posterior dynamic stabilization system are not predictive of clinical failure when analyzed in comparison to patients with no lucencies.

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A Prospective Study to Assess the Utility of MRI Planning in the Use of a Lateral Transpsoas Approach to the Anterior Column in the Lumbar Spine
M. Da Silva¹, H. Nicola¹
¹Hospital San Juan de Dios, Spine Surgery, Caracas, Venezuela

Purpose: To propose a classification system for assisting in preoperative planning in candidates for lateral approach surgery.

Study design/setting: Prospective clinical and radiographic study.

Patient sample: 93 patients with degenerative disorders of the lumbar spine treated with a lateral approach to the anterior column.

Methods: 93 patients underwent lateral approach interbody fusion (XLIF) at L4-5 for the treatment of symptomatic degenerative disease. Preoperative axial MRI of the disc levels being treated were assessed prospectively by two independent reviewers for position of the lumbar plexus in relation to both the intervertebral disc and the psoas muscle. Classifications of plexus position were made by dividing the vertebral footprint into quadrants (A to D) from posterior to anterior, with zone A occupying the posterior margins of the disc space and zone D occupying the anterior quadrant (Figure 1). The position of the lumbar plexus on preoperative MRI was analyzed with respect to both intraoperative EMG readings (NV JB/M5 neuromonitoring, NuVasive, Inc. San Diego, CA) and postoperative lower extremity muscle strength immediately postoperative, and at 2 and 6 weeks, 3, 6, and 12 months postoperative.

Results: In 93 patients treated with lateral interbody fusion at L4-5, mean age was 49 yrs (range: 28-76 yrs). The most anterior portion of the lumbar plexus [NuVasive2] on preoperative MRI resided in the following zones for these patients: Zone A: 61 patients (65.5%), Zone B: 21 (22.5%), Zone C: 11 (11.8%), Zone D: 0 (0.0%). The concordance rate between the two independent reviewers [NuVasive3] was Zone A: 61/61 patients (100%), Zone B: 17/21 (81%), Zone C: 11/11 (100%). All but one patient (Zone C) was approachable at L4-5, based on the feedback of intraoperative evoked directional EMG. Six (6.45%) patients exhibited postoperative quadriceps weakness; 3 with 2/5 strength (Zone C), 1 with 3/5 (Zone B), and 2 with 4/5 (one Zone B and one Zone C).

Conclusions: This clinical and radiographic study describes a system that may help to prevent injury to the lumbar plexus at L4-L5 using the lateral approach based on a radiographic classification used in preoperative planning. With respect to our results, the following relative guidelines are proposed: If the location of the lumbar plexus on MRI resides in Zone A: low risk of nerve injury, in Zone B, moderate risk for nerve injury; in Zone C, high risk for nerve injury. Due to small sample sizes, these results are not presented as statistically significant, but as an introduction to the premise, to be elaborated on in larger scale study.

Lumbar Therapies and Outcomes

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The Total Facet Arthroplasty System (TFAS) in the Treatment of the Degenerative Lumbar Spinal Stenosis: Experience at 48 and 54 Months Follow up. Single Site Experience in South America
G. Bajares¹,², A. Pérez-Oliva¹,², N. Cruz¹,², J.L. Oropeza¹, A. Acosta²
¹Instituto de Columna Caracas, Hospital de Clínicas Caracas, Caracas, Venezuela. ²Centro Médico Docente La Trinidad, Clínica de Columna, Servicio de Cirugía Ortopédica y Traumatología, Caracas, Venezuela

Introduction: With the instrumented fusion as
mandatory procedure for treatment of nerve root compression and neurogenic claudication known as stenosis, adjacent level degeneration and lack of mobilization is been considered yield to rigidity of instrumentation, which seems the only option to maintain stability. The Total Facet Arthroplasty System (TFAS®) was developed thinking in an implant indicated in cases when stenosis is present due to facet atrophy and subsequent instability affecting nerve roots with associated neurologic symptoms and function loss, this implant is deemed to assure movement without loose spine stability after a decompression with facetectomy. **Methods:** 20 patients (12 female, 8 male) were implanted with the TFAS® after a bilateral facetectomy at the stenotic level, and were observed for 2 years (1, 3, 6, 12 and 24 month evaluation) then a review of clinical records and charts was used to complete a follow up at 48 and 54 months. Radiographs were also obtained to evaluate range of motion and fixation of the system and Zurich Claudication Questionnaire (ZCQ) and Visual Analog Scale (VAS) were used to assess clinical outcomes. **Results:** Mean age was 67.8 years, 9 patients have 54 months after surgery and 11 patients reach 48 month follow up. VAS improved in 54%. All patients have improved their function and symptom scores with an overall better response in function at long term, satisfaction with the procedure persist among time. In postoperative radiographs all evaluations shown presence of motion at the instrumented level with integrity of the implant, no signs of cavitation or damage were noted. **Conclusion:** Clinical outcomes at 48 and 54 month follow up demonstrate that the TFAS® enhances function in patients that undergo to this motion preservation procedure showing clinically reduction of symptoms. Implant integrity was noted without compromise in stability and motion. These findings are sustained in time, satisfaction of patients was also founded in operated patients.

**Lumbar Therapies and Outcomes**

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**Failure Analysis of Patients in a US IDE Trial of a Posterior Dynamic Stabilization System who Did Not Achieve Primary Success Endpoints**


1Oregon Health and Science University, Department of Orthopedic Surgery, Eugene, OR, USA, 2Cedars Sinai Spine Center, Department of Orthopedic Surgery, Los Angeles, CA, USA, 3Florida Orthopaedic Institute, Department of Spine Surgery, Tampa, FL, USA, 4University of Utah, Department of Neurological Surgery, Salt Lake City, UT, USA, 5Drexel University, Department of Neurological Surgery, Pittsburgh, PA, USA, 6Rachioitek, LLC, Wellesley, MA, USA

**Introduction:** Pedicle screw based posterior dynamic stabilization systems have been evaluated in two Food and Drug Administration sponsored investigational device exemption studies in the USA. The Dynesys trial resulted in a non-approval recommendation from the FDA advisory panel and the Stabiloimax trial was halted due to grit-blasted screw failures. Evaluation of patients who failed to meet the primary measures of success may provide valuable information to help design further studies, and define clinical indications. **Methods:** The Stabiloimax FDA IDE enrolled patients with back and leg pain due to spinal stenosis in a prospective, randomized clinical trial. Decompressive surgery was performed at a single level between L3 and S1. The patient then received posterior pedicle screw fixation with posterolateral fusion, or stabilization without fusion provided by the Stabiloimax system. Evaluations were performed clinically and radiographically pre-operatively and at 6 weeks, 3,6,12,18, and 24 months post-operatively. Primary outcome measures included ZCQ (Zurich Claudication Questionnaire), and VAS (Visual Analog Pain Score). Secondary outcome measures included ODI (Oswestry Disability Index). All patients also underwent radiographic evaluation with independent review. Historical data is provided from public FDA records in the Dynesys trial. **Results:** Sixty consecutive single level investigational patients were enrolled at 19 study sites. The average age was 59.4 years with 35 females and 25 males enrolled. 45% (27 of 60) did not reach primary endpoint success at 2 years. There were 15 independent failure modes in these 27 patients including 27% (16/60) who failed to reach ZCQ success, 15% (9/60) re-operation rate, 13% (8/60) device removal, 10% (6/60) screw fracture rate, and 10% (6/60) VAS failure rate. Each failure mode is reviewed. With regard to screw fractures, no statistically significant difference is noted in overall success rates for screw fracture patients versus those without fractures. Correlation of age, BMI, smoking status, Pre-operative disc height, degree of spondylolisthesis, severity of spinal stenosis and screw size with likelihood of success or failure is presented. **Conclusion:** Failure analysis of US IDE clinical trials of posterior dynamic stabilization systems show that clinical failure is much more likely than implant failure. Implant failure, specifically, screw fracture does not correlate with clinical failure. Small numbers of patients enrolled prevented firm statistical conclusions about clinical predictors of failure, however trends indicate younger patients, those with greater BMI, and smokers had increased failure risks.

**Lumbar Therapies and Outcomes**

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**Evaluation of Surgical Volume Performance of a Patients Undergoing Combined Total Disc Replacement and Anterior Lumbar Interbody Fusion - The Hybrid Procedure**

*M. Scott-Young*, A. Kasis, C. Magno, D. Nielsen, E. Mitchell, N. Blanch

1Gold Coast Spine, Gold Coast, QLD, Australia

**Introduction:** The analysis of surgical volume performance both as a function of the surgeon and a function of the institute has been an intense area of research for health care providers and consumer groups. Both anterior lumbar interbody fusion (ALIF) and total disc replacement (TDR) are considered...
technically demanding procedures. This study represents a retrospective study of a prospective data series, analysing the effect of the surgical volume performance of a single surgeon on surgical parameters and outcomes.

**Material and methods**: Over 500 patients have undergone a hybrid procedure (ALIF and TDR) in the unit where the study was conducted. All consecutive patients who underwent hybrid procedures (L4-5, L5-S1) in 2005, 2007 and 2009 were analysed. The main diagnosis was discogenic back pain with or without radicular pain. The prostheses used were CHARITÉ® Artificial Disc (Depuy Spine) (2005 and 2007 groups) and In Motion Lumbar Artificial Disc™ (Depuy Spine) (2009 group). ALIF was performed using PEEK™ cages with allograft and rhBMP-2. The following surgical parameters were analyzed: length of surgery (minutes), blood loss (mls), and length of hospital stay (days). All patients completed self-assessment outcome questionnaires pre and postoperatively at 3, 6 and 12 months with annual follow-up thereafter, including Oswestry Disability index (ODI), Roland-Morris Disability Questionnaire (RMDQ) and Visual Analogue Score (VAS) for back and leg pain.

**Results**: N=26 patients (2005 group), N=36 (2007 group) and N=54 (2009 group) were reviewed. All patients had a minimum of 2 years follow-up.

Comparing the 2005 group with 2007 group:
- There was statistical significant difference in the following mean parameters (p<0.001):
  - Duration of surgery (2005 group 91.5±4.47 versus 2007 group 74.7±2.35).
  - Length of hospital stay (2005 group 7.07±0.43 versus 2007 group 5.33±0.28).
- There was no statistical significant difference in the following mean parameters (p>0.1):
  - VAS back pain pre-operatively, at 2 years and the improvement between pre-op and 2 years.
  - VAS leg pain pre-operatively, at 2 years and the improvement.
  - ODI pre-operatively, at 2 years and the improvement.
  - RMDQ pre-operatively, at 2 years and the improvement.

Comparing 2007 group with 2009 group:
- There was statistical significant difference in the following mean parameters (p<0.001):
  - Duration of surgery (2007 group 74.7±2.35 versus 2009 group 65.07±1.4).
  - Blood loss (2007 group 180.9±23.7 versus 2009 group 91.7±10.57).
- There was no statistical significant difference in the following mean parameters (p>0.05):
  - Length of hospital stay (2007 group 5.33±0.28 versus 2009 group 4.89±0.155).
  - VAS back pain pre-operatively, at 2 years and the improvement between pre-op and 2 years.
  - VAS leg pain pre-operatively, at 2 years and the improvement.
  - ODI pre-operatively, at 2 years and the improvement.
  - RMDQ pre-operatively, at 2 years and the improvement.

**Conclusion**: Shorter hospital stays, operating time and blood loss is expected with higher surgical performance in ALIF and TDR. This study showed no significant differences in clinical outcomes; however it showed reduced surgical duration and blood loss with higher surgical performance. Improved and standardized surgical procedures, patient selection and technological advances are all necessary for improvements in surgical volume performance.

**MIS Technique and Results**

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**Long Term Experience with Minimally Invasive Transforaminal Lumbar Interbody Fusion (MIS-TLIF)**

C.M. Menezes1, R.S. Falcon1, M.A.F. Junior1, F. Lauda1, E.G. Menezes1

1Lifecenter Hospital, Spine Surgery, Belo Horizonte, Brazil

**Objective**: The goal of this study is to describe the five years follow-up of patients submitted to minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) in the Division of Spine Surgery of Ortopédico/Lifecenter Hospital - Belo Horizonte, Brazil, for treatment of different spine diseases.

**Methods**: Twenty patients underwent MIS-TLIF between December 2005 and December 2006, in the Division of Spine Surgery of Ortopédico/Lifecenter Hospital. The indications for the surgery were: degenerative disc disease with instability, associated or not with herniated disc or stenosis; low grade spondylolisthesis; degenerative spondylolisthesis; and post laminectomy-discalctomy syndrome. Patients were followed according to the pre-established protocol of the Service. The mean postoperative follow-up period was five years, and the variables analyzed were operative time, need for blood transfusion, length of hospital stay, visual analogical pain scale (VAS), Oswestry functional disability index, return to work, satisfaction with the procedure, fusion rates, complications and reoperations.

**Results**: 18 patients (90%) completed the five years postoperative follow-up routines. The mean operative time was 241 minutes, with no need for blood transfusions. The mean length of hospital stay was 1.9 days. There was one case of periradicular hematoma, as early complication. Good improvement in VAS and Oswestry index was observed after surgery. All patients related they would undergo the surgery again. One patient returned to their previous work activity. All patients related they would undergo the surgery again. The fusion rate was 94.5%, and no reoperations were necessary in this follow-up period.

**Conclusions**: MIS-TLIF allows a safe approach to lumbar spine for treatment of many degenerative conditions that require surgical intervention. Shorter lenght of hospital stay, less muscle injury and faster recovery period are some of the advantages of this surgical technique, reducing the morbidity related to the procedure. Our encouraging long term results corroborate to previously international published data, suggesting that this is an effective technique.
Conclusions: Anterior lumbar interbody fusions (ALIF) with cages augmented with pedicle screws are intended to restore the stability of the spine. However, studies have shown increase in adjacent disc disease associated with compensatory rise in motion at the adjacent level. In addition, they may cause unwanted increase in facet load at the adjacent level because of disproportionately high load transfer posteriorly. Recently, stand-alone cages with integrated screws have been introduced to address these issues but its biomechanical efficacies still remain unknown. In this study, a finite element (FE) study was performed to assess biomechanical efficacies of the stand-alone cages and to compare with the interbody cages with pedicle screw fixation.

Methods: The post-operated models were constructed by modifying a previously-validated 3-D FE model of the intact lumbar spine (L2-5). Four different configurations of the model were considered:

1. an intact normal spine;
2. Type 1, cage only (SynCage-LR®, PEEK, Synthes, Switzerland);
3. Type 2, the stand-alone cage (SynFix-LR®, Synthes, PEEK frame with metal (Ti6Al7Nb) plate and four integrated screws);
4. Type 3, Type 1 plus pedicle screws & rods (Ti6Al14V, Φ=5.5mm).

Flexion/extension of 10Nm, axial rotation of 10Nm, and lateral bending of 5Nm with a compressive follower load of 400N was applied using hybrid loading protocol to study the ROM at the operated and adjacent levels. Load-sharing between the anterior and the posterior spine was also assessed.

Results: Type 3 showed the greatest reduction of ROM at the operated level (29~69%), followed by Type 2 (22~61%) and Type 1 (10~22%) regardless of motion type (Figure 1). Here, ROM of Type 2 was closer to that of Type 3 than Type 1. Unexpectedly, increase in ROM at the adjacent level was greatest with Type 3, followed by Type 2 and Type 1. Load sharing ratio between the anterior and posterior parts of the spine was 89:11 for the normal spine. Postoperatively, the ratio was changed to 94:6 (Type 1), 95:5 (Type 2), and 75:25 (Type 3) at the operated level indicating that load transfer with Type 2 was more close to that of the normal spine as compared with Type 3.

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Significance of Repeat Vertebroplasty for New Fracture of Post-vertebroplasty Patients
C.-W. Hung1, C.-H. Kao2,3
1Chi-Mei Medical Center, Department of Neurosurgery, Tainan, Taiwan, Republic of China, 2Chi Mei Medical Center, Department of Spine Surgery, Yung Kang City, Taiwan, Republic of China, 3Southern Taiwan University of Technology, Center for General Education, Tainan, Taiwan, Republic of China

Objectives: Vertebroplasty for vertebral compression fractures is a reliable method with very low rate of operative complications. For high risk patients, the surgery is priority choice. The purpose of this study was to investigate the clinical post-operation data follow-up for repeat vertebroplasty for new fracture of post-vertebroplasty patients.

Methods: This is a retrospective study to assess clinical outcome 515 patients (710 levels, avg. 72.67 years) vertebral compression fractures treated with vertebroplasty from Jan. 2002 to Nov. 2010. We compared the pre- and post-operative Oswestry Disability Index, pain score (VAS) and investigate the re-operation of those patients.

Results: 49 patients (F/M: 47/2, avg. T-score of lumbar spine BMD: -3.32, the avg. BMD of 466 no-reoperation patients: -2.12) had reoperation (second: 39 patients; 3rd: 6 patients; 4th: 3 patients; 5th: 1 patient) were included in this study, and total 141 levels accepted operated. 13 segments (14.1%) were second operated in same level (8 levels with vertebroplasty and 5 levels with kyphoplasty). 29 segments (31.5%) were opened on adjacent segment. At surgery interval, 3 kinds of reoperation locations (same, adjacent, and other segment) were avg. 526.69, 587.07 and 657.84 days. Excellent and good (78.6%) clinical results were obtained after operation. The mean of VAS improved significantly from 7.2 to 1.9 after surgery.

Conclusions: Mid-term follow-up, we had the special found the rate of reoperation(9.5%) was lower than other scholar’s studies, the patient accepted re-operation almost were female (47/49) and T12 reoperation (33%) was usual happen. Maybe be caused by faulty posture, and the spine is the humpbacked found by X-ray. In addition, we found the patient BMD less than -2.5 improved the risk of reoperation, and the same segment reoperation was short at surgery interval. However, vertebroplasty are usually successful at alleviating the pain; many patients feel significant relief almost immediately. Many patients become symptom-free.
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Radiographic Assessment of Stabilimax Patients at 12mos Follow up
B.C. Cheng1, S. Kitchel2, A.E. Castellvi2, K. Yonemura4, N. Anand2, B. Robie6
1Drexel University, Neurosurgery, Pittsburgh, PA, USA; 2Orthopedic Spine Associates, Eugene, OR, USA; 3Florida Orthopaedic Institute, Tampa, FL, USA; 4Wasatch Neurological Surgery, Bountiful, UT, USA; 5Cedars Sinai Medical Center, Los Angeles, CA, USA; 6Robie Device Group, North Andover, MA, USA

Introduction: The goal of motion preserving technologies is to maintain all or a percentage of the pre operative motion at the treated levels. Motion affecting the index level of posterior dynamic systems (PDS) should be separated into two distinct kinematic components, i.e., angular rotation and linear translation. The design advantage of Stabilimax PDS constructs are the spherical seat attached to the pedicle screws that allow rotation, and the dynamic rods that allow for translation. However, it is unclear whether these included design features result in clinical utility for patients and in particular, preserving the motion of the lumbar motion segment implanted with the Stabilimax. The hypothesis of this radiographic study was to determine if motion was maintained in patients implanted with Stabilimax. Moreover, if the measurable motion included both translation and rotation, it was further hypothesized that the rotation would be in accordance to the stabilization design goal.

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. Each radiographic patient frame 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. Interpedicular displacement (ID) was calculated as the difference in interpedicular displacement in flexion minus that in extension. ROM was measured using end plate markers. Rotation and ID were measured at the index level.

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 pre operative rotation at the index level was 3.5° (range 13.1°) and 12mos post operatively the median rotation was 1.9° (range 13.4°). The median ID at the index level was 2.3mm (range 10.5mm) and 12mos post operatively the median ID was 1.4mm (range 10.0mm).

Discussion: The 12mos post operative median ROM at the index level was 66% of the initial baseline ROM. The 12mos post operative median ID at the index level was 61% of the initial baseline ID. The clinical results 12mos post operatively suggest that the patients maintain both angular rotation and linear translation motion. These results are due at least in part to the design elements of the Stabilimax PDS. Although, patients implanted with other devices may support a kinematic response that include significant rotation and translation motions, the designs generally do not have purpose built components to facilitate a specific kinematic response. In conclusion, the design elements within the Stabilimax construct facilitate a stable controlled angular and linear kinematic response at the index level of treated patients.

Cervical Therapies and Outcomes

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Cervical Transcorporeal Discectomy or Foraminotomy with Vertebral Body Access Channel Repair: Feasibility in Early Experience
D.W. Lowry4, S.M. Tuinstra1
1Brain + Spine Center, Neurosurgery, Holland, MI, USA

Purpose: Determination of feasibility of transcoporeal discectomy and/or foramenotomy with trajectory control guidance and access channel repair in patients with disc herniation, stenosis or both. While not addressed in this study, the primary reasons for studying such a technique are the possibilities that it may offer 1) preservation of motion, and 2) faster return to work or full activity than either ACDF or arthroplasty.

Methods: Retrospective review of single surgeon consecutive experience with patients undergoing isolated TCMD using a trajectory control guide and with channel repair (Figure 1) with a minimum of one-month follow-up. Patients undergoing TCMD adjacent to ACDF or arthroplasty were excluded. Outcome measures were Neck Disability Index (NDI), Visual Analog Scale (VAS) for axial and radiating pain, and return to work in days.

Findings: Among the 12 patients, there were no cases with vertebral artery injury, evident recurrent laryngeal nerve injury, Horner’s syndrome, CSF leak, new radicular or spinal cord injury, transfusion, or migration of repair implement. Radiating symptoms typically improved immediately post-operatively, and compared to pre-op scores, statistically significant improvement at one-month post-op was measured using paired sampled t tests. NDI improved from 19.7 to 4.7 (p = 0.012); Axial VAS improved from 6.5 to 1.1 (p < 0.001); and Radiating VAS improved from 8.1 to 0.1 (p < 0.001). Mean return to work, or full activity for those not working, was 9.3 days, with 7 of 12 returning in 5 or fewer days.

Conclusions: TransCorporal Micro Discectomy and repair (TCMD) appears feasible insofar as assessed in this small sample size, single surgeon, limited follow-up, retrospective study. Definitive statements on safety and efficacy await further study.

Discussion: Figure 1
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Adult Lumbar Scoliosis: Surgical Treatment with XLIF

M. Balsano, P. Berjano
1Regional Spinal Department, Schio, Italy, 2Spinal Department II, Milano, Italy

Introduction: The traditional treatment to lumbar scoliosis consists of open anterior and/or posterior surgery, with high incidence of morbidity, where the rate of complications varies between 30% and 65% in literature. XLIF technique reduces dramatically the morbidity rate. We present our preliminary results of lumbar adult scoliosis treated with XLIF procedure.

Methods: A prospective, non-randomized clinical study has been done in 15 patients, mean age of 56 yrs. (range 52-73 yrs.), affected of symptomatic lumbar adult scoliosis, who underwent scoliosis correction with XLIF procedure. There were 7 cases of idiopathic progressive scoliosis (type 2 of Aebi Classification) and 8 cases of "de novo" scoliosis (type 1 of Aebi Classification).

Standard and dynamic X-rays, neurological and clinical outcome assessments were done using ODI and VAS scores at pre-operative, 6 weeks, 3, 6 and 12 months postoperative intervals.
The operated levels ranged from 5 to 2 levels, including T12-L1 to L4-L5.

Results: Scoliosis correction was of a mean of 56% (37.6° Cobb to 16.5°).

VAS pain improved from a mean of 7.5 preoperative to 3.2 at 1 yr.; ODI score changed from a mean of 65% preoperative to a mean of 25% at 1 yr.

We registered 2 complications: 1 femoral n. neuroapraxia, resolved with a cortisonic treatment in 30 days and 1 cage subsidence, that was revisioned in a further surgery.

Conclusions: XLIF procedure is a safe minimal invasive technique for the treatment of lumbar adult scoliosis. These preliminary results, although including a low number of cases, showed a good correction, the pain improvement and a fast recovery comparing with standard open procedures.

Biomechanics/Basic Science

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Flexibility Testing to Determine Damage Created by Cyclical Loading of the Bone Implant Interface

B.C. Cheng, D.J. Cook, M. Yeager, D.M. Whiting
1Drexel University, Neurosurgery, Pittsburgh, PA, USA, 2Allegheny General Hospital, Neurosurgery, Pittsburgh, PA, USA

Introduction: Conceptually, pure moment flexibility protocols have been shown to be sufficiently sensitive in detecting differences in biomechanical spine testing. Fatigue testing in cadaveric models on the other hand, presents several challenges including specimen degradation over time, material variability and relative scarcity of cadaveric tissue. Specimen degradation imposes environmental requirements and time restrictions such that these tests are generally much shorter than those conducted on nonbiologic materials. Furthermore, the large variability between specimens in terms of size, stiffness, and strength along with the availability of tissue, preclude the tester from conducting a standard S-N type fatigue analysis in a timely and cost efficient manner. The bone implant interface is the primary focus of cyclical loading in instrumented fatigue studies. The hypothesis of this study was that a flexibility protocol would be sufficiently sensitive in detecting differences between the baseline stability of a Solus lumbar interbody device with self contained fixation anchors and the stability following bone implant interface damage due to repeated loading.

Methods: Prior to cyclic loading, in the midst and immediately following, each single level implanted specimen was subjected to a flexibility protocol in three different directions consisting of three cycles of loading at 0.005 Hz to load levels of ±7.5 Nm. The motion exhibited during the third cycle of flexibility testing was recorded and commonly referred to as range of motion (ROM) with the pre-cyclic test referred to as baseline ROM. Each test specimen was also subjected to a stair-step a cyclical loading. Each step consisted of 1000 cycles of fully-reversed sinusoidal loading with a frequency of 1 Hz. The load magnitude increased with each subsequent step until failure of the construct. Construct failure was defined as a greater than 25% increase over the baseline ROM in any of the driving actuators during a cycle of a given test. Fatigue life was defined as the number of cycles at which failure was observed.

Results: The mean normalized ROM for all modes of loading was 106.8±5.5% of baseline for mid level flexibility results conducted at the pre determined cycle count. Following fatigue failure, the mean normalized motion was 141.2±14.0% of baseline. From the post hoc analysis of the repeated measures ANOVA model, a statistically significant increase from mid level to pre and from post to mid level flexibility (p=0.005 and p=0.003 respectively).

Discussion: As bone does not have the ability to undergo remodeling during the biomechanical cyclical loading protocol, a scenario is created in which the bone implant interface is damaged under repeated loads with increasing magnitude. This study supports the use of pure moment testing throughout the study design as a viable means of detecting differences within the treated level including those differences caused by cyclical loading. In order to compare the relative fatigue characteristics of two devices, subsequent study designs involving flexibility protocols would seem appropriate.

[Figure 1.]
Short Term Outcomes of Intervertebral Spike (IS®)
Cage for Degenerative Lumbar Spinal Disorders
¹National Health Insurance Corporation Ilsan Hospital/ Yonsei University College of Medicine, Neurosurgery, Koyang, Korea, Republic of, ²Severance Hospital/ Yonsei University College of Medicine, Neurosurgery, Seoul, Korea of

Objective: The authors conducted a retrospective study of patients with degenerative lumbar spinal disorders who received a posterior lumbar interbody fusion (PLIF) with the IS® cage. This cage is made of titanium and is rectangular with a tapered shape and elliptical head. The width is narrower than the height. The anterior height is higher than the posterior height. One of the unique features of the cage is the 2 spikes in the bottom of the cage. PLIF was performed with or without pedicle screws using this cage. The operation method is as follows: After complete bilateral discectomy and preparation of the vertebral endplates, two cages were inserted into the disc space one by one. The first cage was laid down and then inserted. The lateral faces of the cage met with the upper and lower endplates of the adjacent vertebral body and the spikes of the cage faced outside for the prevention of dural injury during insertion. If it was a left-side cage, it needed to be rotated 90° counterclockwise, or if it was a right-side cage, it needed to be rotated 90° clockwise. Then, the second cage was inserted in the same manner on the opposite side as the first one. Therefore, 2 cages were placed on both sides of the disc space, and the intercage space became wider due to the hinge action of each spike. More bone pieces were put into the intercage space. In case of scoliosis or lateral translation, 2 cages were rotated in the same direction, and a partial correction of the scoliosis or lateral translation was possible.

Methods: We assessed 105 patients who underwent on a PLIF with or without pedicle screws using this cage in our institute from Nov. 2007 to Dec. 2008. Clinical outcomes were analyzed with a Visual Analog Scale (VAS) for back and leg pain. Radiographs were obtained before and after the surgery. In some cases, a lumbar spinal computed tomography scan was obtained. Radiological outcomes of intercage distance, fusion rate, and intervertebral disc height were assessed. In scoliosis or lateral translation, the extent of correction was examined.

Results: The mean VAS score for back pain improved from 6.86 preoperatively to 2.66 at postoperative month 12, and the score for leg pain decreased from 7.92 to 1.78. The mean intervertebral disc height was 8.71±2.35 mm before the surgery, and it increased to 11.67±1.77 mm at 7 days postoperative and decreased to 9.57±1.90 mm at 6 months postoperative. The fusion rate was 95.65%. For scoliosis or lateral translation, the segmental angle of scoliosis decreased from 11.10±5.82° before the surgery to 5.61±3.71° by 6 month postoperative. The extent of the lateral translation changed from 6.04±1.73 mm before the surgery to 3.56±4.99 mm at 6 month postoperative.

Conclusion: There have been low complication rates with the IS® cage during the follow-up period, and the results of this study demonstrates a wide fusion area, partial reduction of lateral translation and scoliosis, good clinical success, and a high fusion rate.
MIS Technique and Results

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A Solution of Osteoporotic Vertebral Compression Fracture’s Problem: Vesselplasty, SrHA Cement, and Vessel-lock
A.B. Darwono¹
¹Gading-Pluit Hospital, Medical Faculty, University of Tarumanagara, Orthopaedic, Jakarta Utara, Indonesia

Object: Deramond (1984) introduced percutaneous non fusion technique to treat osteoporotic vertebral fractures. His technique Vertebroplasty is not intended to restore vertebral body height, but freeze the fractures in situ. The injected cement will go to the weakest area, the fracture’s side and lead to a leakage. Many techniques are developed to restore the vertebral body height by using tools that create the hydrostatic or mechanical pressure inside the vertebra. Most techniques withdraw the tools then inject cement inside the created void like vertebroplasty and has a risk of leakage. The new technique use a non stretchable PET container and inject cement inside the container then left as an implant body expander. The container prevent the leakage risk of the cement, but the interdigitation of cement mimics a controllable vertebroplasty and need a proper justification to end the procedure. The new SrHA cement is an osteoinductive and osteoconductive materials with less heat production is suitable to be used in this technique. To Treat difficult case of VCFs, osteoporotic and multiple stenosis need special innovative instrument. The purpose of this study is to review the theory, surgical techniques, results of 5 years using this new technique in restoring, stabilizing the vertebral body’s height, and preventing the leakage risk of BFMs. Compare the effect of SrHA and PMMA in Elderly cases. Introducing the new Vessel-lock system for difficult case

Methods: Non randomized prospective study. This new technique the Vessel-X™ system is a percutaneous non fusion technique to stabilize, restore VCFs, and prevent leakage risk of cement. Comparing the effect of SrHA and PMMA by using X-ray and CT-scan: just after treatment, 3 months and 6 months after treatment.

Results: A total of 250 cases consist of 298 VCFs (VT3 - VL 5) that have been treated using this new technique included 178 PMMA and 120 SrHA cases is reported also the 5 preliminary report of Vessel-Lock system.

Conclusions: The Vesselplasty is a new technique to treat osteoporotic vertebral fractures using BFC system. This technique allows the stabilization and restoration of vertebral body height of VCFs, with the advantage in controlling the volume of the injected BFMs, also the pressure inside BFC, and preventing the leakage of BFMs. SrHA cement is superior compared to PMMA in the elderly cases. The Vessel-Lock could be the solving of difficult cases (VCFs with Multiple stenosis and de novo scoliosis). But there is still a Continuum of Osteoporotic problems that should be treated with a specific medical treatment.

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Minimally Invasive Resection of Spinal Schwannomas Using a Tubular Retractor. Experience in 6 Cases
D. Shedid¹, A. Weil¹
¹University of Montreal, Neurosurgery, Montreal, QC, Canada

Introduction: Nerve sheath tumours (NST), the most common form of spinal canal tumor, are classified as intradural-extramedullary (ID-EM), combined intradural-extradural and purely extradural (ED). Resection traditionally requires a midline incision, bilateral subperiosteal muscles stripping, extensive laminectomy and, in cases of foraminal extension, radical facetectomy. Fusion is often warranted in cases of facetectomy in order to prevent deformity, pain, and neurological deterioration. Recent reports have demonstrated safety and efficacy of mini-open removal of these tumours using expandable tubular retractors. We report our experience with the minimally invasive removal of ED foraminal and ID-EM schwannomas using the non-expandable tubular retractor. The advantages of this approach are discussed.

Methods: Retrospective chart analysis.

Results: Between January 2010 and October 2011, six patients underwent minimally invasive removal of spinal tumors. The patient population consisted of two lumbar ID-EM, 2 thoracic ED foraminal and 2 lumbar ED foraminal schwannomas. Gross total resection was achieved in all patients. The average length of hospitalization was 2.5 days. All patients returned to normal activities within 4 weeks.

Conclusion: ID-EM and ED schwannomas can be completely and safely resected through a minimally invasive approach using the non-expandable tubular retractor. This approach may be associated with even less tissue destruction than mini-open techniques. In cases of foraminal tumours, by eliminating the need for facetectomy, this minimally invasive approach may decrease the incidence of postoperative deformity and eliminate the need for adjunctive fusion surgery. However, further studies are needed to evaluate the relative efficacy and safety of minimally invasive resection as compared to standard open or newer mini-open techniques.

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Decompression and Dynamic Stabilization in Spinal Stenosis: Preliminary Results with a Peek Rod Pedicle System
S. Schaeren¹, A. Mehkens¹, B. Jeanneret¹
¹University Hospital of Basel, Orthopedics, Basel, Switzerland

Purpose: Decompression and fusion are widely...
recommended in spinal stenosis with segmental instability (degenerative spondylolisthesis, i.e.). In 2009, we introduced a new PEEK (polyetheretherketone)-rod pedicle system (EXPEDIUM™ PEEK ROD SYSTEM, DePuy Spine, Raynham, MA, USA) at our institution to stabilize segmental instability without fusion. We present preliminary results and experience with this new system.  

**Methods:** All patients with symptomatic lumbar spinal stenosis and segmental instability who underwent interlaminar decompression and stabilization with the PEEK-rod system without adding bone-graft are followed prospectively with a clinical (NASS-Score, i.e.) and radiological evaluation pre-operatively, post-operatively as well as 3 and 12 months postop.  

**Results:** So far, 22 patients (75±6.4 yrs, 15f, 7m) with a minimum follow-up of 3 months were evaluated. 2 and 13 of those patients have a follow-up of 9 and 12 months, respectively. All patients had either a degenerative spondylolisthesis (n=20) or scoliosis (n=21). Patients received a stabilization of either 1 (n=6), 2 (n=13) or 3 (n=3) segments. At 3 months follow-up, NASS-Score was significantly improved in terms of pain, neurology and impairment (p< 0.001) and remained stable at 12 months. Radiographically, spondylolisthesis and/or scoliosis remained stable in all patients. Asymptomatic screw loosening was recorded in one patient at 3 months and in another 4 patients at 12 months. One patient showed screw breakage in one level (S1) 3 months after bi-segmental stabilization -so far no revision surgery was necessary since the patient is almost painfree and the alignment of the spine remained stable at 9 months. 2 patients had revision-surgery due to insufficient decompression and epidural hematoma, respectively. 1 patient presented with symptomatic stenosis of the adjacent cranial segment at 12 months.  

**Conclusion:** In elderly patients with spinal stenosis and segmental instability decompression and instrumentation with the PEEK Rod system leads to good clinical and radiologic early results without the drawbacks of fusion with bone graft.

### MIS Technique and Results

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**Treatment of Degenerative Disc Disease and Aging Related Lumbar Pain with a Minimally Invasive Hydrogel Nucleus Augmentation Implant: Preliminary Results of a Post-market Study**

*J.J. Yue*, R. Morgenstern, C. Morgenstern  
1Yale University School of Medicine, Orthopaedic Surgery, New Haven, CT, USA, 2Centro Médico de Terapia de la Columna, Orthopaedic Surgery, Barcelona, Spain

**Background content:** Degenerative disc disease has a high prevalence in adults. The degeneration is associated with diminished water-binding capabilities of the nucleus pulposus leading to disc dehydration, volume reduction, changes in cellular activity, biomechanical changes and painful symptomatology. There are few alternatives to highly invasive fusion or total disc arthroplasty when non-surgical treatment has failed.  

**Purpose:** To assess the efficacy of the GelStix™ hydrogel nucleus augmentation implant in the treatment of patients suffering of lumbar pain due to degenerative disc disease and aging.  

**Study design/setting:** Patients were evaluated from a single site/single surgeon as part of a multi-center study.  

**Patient sample:** 20 patients were evaluated as part of the GelStix™ post-market clinical study.  

**Outcome measures:** Patients were evaluated employing the Oswestry Disability Index (ODI), Visual Analog Scales (VAS) at 3 weeks, 3, 6, and 12 months post-op. These patients also had consecutive CT and MRI post-op evaluation.  

**Methods:** Primary inclusion criteria was discogenic pain with minimal radicular pain confirmed by radiographic imaging and discography. In most cases back pain persisted for at least 1 year with unsatisfactory results from conservative care. All procedures were performed using local anesthesia. The needle was introduced into the nucleus through a posterolateral approach under fluoroscopic guidance. Provocative discography was performed to confirm diagnosis. Hydrogel implants were loaded into the needle using pre-assembled sterile cartridges. Two or three implants were delivered into each disc level. Student’s paired T-test was performed to assess the post-op results for significant differences with pre-op scores.  

**Results:** 20 patients in total were evaluated. In addition to back pain, three patients experienced mild to moderate radicular pain and one patient had Grade 1 spondylolisthesis. Two patients had had prior discectomies at the affected level. The average follow-up was of 4.1 ± 2.2 months. The mean pre-op VAS back scores of (6.7 ± 1.2) dropped to (4.2 ± 2.6) post-op, while pre-op leg scores of (4.3 ± 3.5) dropped to (2 ± 2.3) post-op. Pre-op ODI scores of (24.8 ± 6.7) dropped to a mean post-op score of (13.5 ± 9.3). The patients showed a significant (p < 0.05) reduction in VAS back pain. However, a patient who was diagnosed with Grade 1 spondylolisthesis in conjunction with degenerative disc disease did not improve after treatment. Two of four patients with leg pain had complete leg pain relief following treatment.  

**Complications:** No reported complication or adverse events were observed.

### Biomechanics/Basic Science

#### 340  
**In-vitro Biomechanical Analysis of Lateral Lumbar Integrated Platespacer with Supplemental Fixation**

*S. Basra*, M. Gudipally, B. Bucklen, A. Muzumdar, S. Khaliil  
1Boston University Orthopaedic Surgical Associates, Boston, MA, USA, 2Globus Medical, Inc., Audubon, PA, USA

**Introduction:** Minimally invasive surgery has evolved in its ability to treat spinal disorders with innovative spinal implants. The retroperitoneal trans-psoas lateral approach has become the surgery of choice for lumbar interbody fusion. The objective of the present study was to evaluate the comparative stability of the
InterContinental™ (Globus Medical, Audubon, PA) Plate-Spacer versus a standard lateral spacer (LS) with supplemental fixation.

**Methods:** Each of the six (L2-L5) spines was sequentially tested in:
1) Intact;
2) IPS-L+BPS;
3) IPS-L+BFS;
4) LS+BFS;
5) LS+BPS;
6) LS+LP (Figure 1), using a load control protocol employing ±8 Nm, for three cycles each in flexion-extension (FE), lateral bending (LB) and axial rotation (AR).

**Results (Figure 2):** All the test constructs significantly reduced ROM compared to intact in all three motion planes, except LS+LP construct in AR. The ROM values for IPS-L+BPS, IPS-L+BFS were 11% (±4.8), 10.4% (±5.9) in FE, 16.1% (±4.1), 20.4% (±8.6) in LB, and 27.9% (±10.3), 19.5% (±5.4) in AR, respectively. The lateral interbody constructs (IPS-L or LS) instrumented with either BPS or BFS were significantly more stable than LS+LP in flexion-extension. The IPS-L + BPS/BFS construct was significantly more stable than LS+LP in axial rotation. Comparing the ROM in all fixation types, no significant difference was observed between IPS-L and LS with various posterior instrumentation, in any of the three motion planes.

**Conclusion:** With various posterior fixation constructs, InterContinental™ demonstrated greater biomechanical stability to a standard lateral spacer in all three motion planes, although with no statistical significance. Additionally, the optimized screw angulations available with InterContinental™ not only minimizes interference with additional (posterior) instrumentation but also aids in securing the plate-spacer to the vertebral body, and helps to compressively load the graft. Long term clinical studies would be further required to confirm these benefits.

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**Biomechanics/Basic Science**

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A Biomechanical Analysis of Interspinous Fixation as an Adjunct to Lumbar Lateral Interbody Fusion

*S. Basra¹, M. Gudipally², B. Bucklen², A. Muzumdar², S. Khalil²*

¹Boston University Orthopaedic Surgical Associates, Boston, PA, USA, ²Globus Medical, Inc., Audubon, PA, USA

**Introduction:** Bilateral pedicle screw (BPS) fixation is considered to be a gold standard in stabilizing the spine with the purported benefit of improving arthrodesis rates. However it is not without complications. To help overcome the complications associated with bilateral pedicle screws and rods, spinous process fixation devices (SPF) have been developed. Spinous process fixation immobilizes a spinal segment without the need for wide dissection or disruption of the pedicles or facet capsules. The present study evaluated the biomechanics of a spinous process fixation device (SP-Fix™, Globus Medical, Audubon, PA) as an adjunct to a simulated lateral interbody fusion, with lateral spacer and lateral plate (LS+LP).

**Methods:** Each of the six (L2-L5) spines was sequentially tested in:
1) Intact;
2) LS+BPS;
3) LS+LP;
4) LS+LP+SPF;
5) LS+ SPF (Figure 1).

A load control protocol was employed to apply ±8Nm moment for three cycles each, in flexion-extension (FE), lateral bending (LB), and axial rotation (AR).

**Results:** All test constructs significantly reduced ROM compared to intact in all loading modes except LS+LP, and LS+SPF constructs in AR (Figure 2). LS+SPF significantly reduced ROM to 14.2% (±6.7) in FE, 37.5% (±13.9) in LB, and 69.5% (±30.7) in AR, compared to intact. LS+SPF LS+LP+SPF significantly reduced ROM to 9.7% (±3.2) in FE, 20.8% (±13.7) in LB, and 48.6% (±31.4) in AR, compared to intact. No statistically significant difference was observed between LS+BPS and LS+LP+SPF in all loading modes. LS+LP+SPF increased ROM compared to LS+LP alone construct, but was significant only in FE.

**Conclusion:** With various posterior fixation constructs, InterContinental™ demonstrated greater biomechanical stability to a standard lateral spacer in all three motion planes, although with no statistical significance. Additionally, the optimized screw angulations available with InterContinental™ not only minimizes interference with additional (posterior) instrumentation but also aids in securing the plate-spacer to the vertebral body, and helps to compressively load the graft. Long term clinical studies would be further required to confirm these benefits.
Conclusion: The in-vitro testing revealed that Sp-Fix™ with sufficient supplemental fixation limits range of motion equivalently to bilateral pedicle screws and rods, in a lateral interbody model. These qualities make SP-Fix™ an attractive alternative to transpedicular fixation for selected patients requiring instrumentation-augmented fixation. In particular, Sp-Fix™ may be particularly well suited to supplement lumbar interbody fusion.

Lumbar Therapies and Outcomes

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Comparison between Mono and Poly-axial Screws in the Management of Adolescent Idiopathic Scoliosis with Hybrid Construct
B. Blondel1,2, V. Lafage1, J.-P. Farcy1, F. Schwab1, G. Bollini2, J.-L. Jouve1
1New York University Hospital for Joint Diseases, Spine Division, New York, NY, USA, 2Universite Aix-Marseille, Ecole Doctorale 463, UMR CNRS 6233, Sciences du Mouvement Humain, Marseille, France

Introduction: Instrumented posterior fusion using only pedicle screws in the management of adolescent idiopathic scoliosis (AIS) provides satisfactory results in the coronal plane. However, such constructs are also responsible for a lack of thoracic kyphosis and therefore a loss of lumbar lordosis. Conversely, hybrid constructs have been shown to be superior in restoration of the thoracic kyphosis. The aim of this study was to evaluate in a series of AIS patients treated by hybrid construct and the impact of the use of mono vs. polyaxial screws.

Matériel et méthodes: 60 patients (mean age 15 years) diagnosed with a Lenke 1, 2 or 3 AIS were included in this study and reviewed retrospectively. Surgical procedure was performed with hybrid constructs using sublaminar hooks in compression on the upper extremity, pedicle screws between the lowest instrumented vertebra and T11, and sub-laminar bands and clamps in the concavity of the deformity. Monaxial screws were used on 30 patients and polyaxial screws for the 30 others. Comparison was conducted between groups in terms of correction of the thoracic Cobb angle and evolution of the thoracic kyphosis between preoperative and 3 months postoperative period, using a t-test.

Résultats: Between groups, no statistical differences were found preoperatively on the various radiographic parameters (p>0.05). At last follow-up, the residual thoracic Cobb angle was significantly greater in the polyaxial group (20.3˚ +/- 8.2 vs. 15˚ +/- 5, p< 0.004), with an average coronal deformity correction of 72.1% +/- 7.6 in the monaxial group and 64.8% +/- 9.1 in the polyaxial (p< 0.001). Results on the sagittal plane revealed a significantly higher thoracic kyphosis in the polyaxial group compared to the monoaxial group (26.6˚ +/- 7 vs. 23˚ +/- 6.2, p< 0.04).

Discussion: The crucial importance of sagittal plane has been widely reported in the literature and sagittal malalignment have been correlated with worse clinical outcomes in adult deformity patients. This preliminary data showed that even inside the hybrid constructs group (less risk for iatrogenic flatback) some differences were visible according to the type of pedicle screws. It seems therefore important to take this data into account when AIS correction is planned in order to choose which type of correction is of primary importance for the patient. According to us, it is preferable to focus on the sagittal plane correction even if it leads to a smaller thoracic Cobb angle correction. Long-term results will be needed to confirm these initial findings.

Cervical Therapies and Outcomes

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Posterior Arch Screw Fixation in C1-2 Fusion for Painful Atlantoaxial Osteoarthritis
W.R. Sears1,2,3, I. Sergides1,2,3
1Wentworth Spine Clinic, Sydney, NSW, Australia, 2Dalcross Adventist Hospital, Sydney, NSW, Australia, 3Royal North Shore Hospital, Sydney, NSW, Australia

Purpose of study: Osteoarthritis of the atlantoaxial joint results in severe, suboccipital neck pain, rotary neck stiffness and headache. Often refractory to conservative treatment, recent publications have reported excellent pain relief following atlantoaxial arthrodesis using transarticular screws. The degenerative process affecting an atlantoaxial joint may lead to partial resorption of the C1 lateral mass and make difficult or hazardous the placement of transarticular or lateral mass screws. The authors have previously reported the use of C1 posterior arch screws for multi-point fixation of the C1-2 segment but noted technical difficulties using conventional cervical polyaxial screws in patients with small C1 posterior arches. The aim of the current study was to examine the clinical and radiological outcomes in patients undergoing C1-2 fixation for this condition using 2.75mm diameter, headless screws, custom made for use in patients with small C1 posterior arches.

Methods: Prospective observational study of consecutive patients undergoing atlanto-axial fusion for severe pain due to osteoarthritis of a C1-2 joint and refractory to conservative management, between February 2008 and November 2010. Fixation was performed using custom, bilateral 2.75mm C1 posterior arch screws, inserted under direct vision and connected via cross-linked rods to 4.0mm multi-axial C2 pars screws. VAS neck pain, Oswestry neck disability index (NDI) and Short Form-36 Physical Component Summary scores (SF-36 PCS) were recorded pre-operatively and at 3-, 6-, 12- and 24-months. Results are expressed as median values (range). Non-parametric statistics were
A supplementary acquisition in a “radiographic” posture order to evaluate the experimental error measurement. by three different operators during three sessions in Methods: measurement of sagittal net moments.

Summary of background data: biomechanical protocol obtained in a free standing of this study was to present initial results of a 3D dimensional radiographic imaging systems. However, has been recently improved by development of three-dimensional radiographic imaging systems. In various situations such as global sagittal anterior malalignment interpretation of radiographs may not represent the real alignment of the subject. The aim of this study was to present initial results of a 3D biomechanical protocol obtained in a free standing position and characterizing postural balance by measurement of sagittal net moments.

Methods: After elaboration of a specific marker-set, 4 successive recordings were done on two volunteers by three different operators during three sessions in order to evaluate the experimental error measurement. A supplementary acquisition in a “radiographic” posture was also obtained.

Once the data acquired, joint center, length, anatomical frame and the center of mass of each body segment was calculated and a mass affected. Sagittal net moments were computed in an ascending manner from ground reaction forces at the ankles, knees, hips and the lumbo-sacral and thoraco-lumbar spinal junctions. Cervico-thoracic net moment was calculated in a descending manner.

Results: Based on average recordings, clinical interpretation of net moments (in N.m) showed a dorsal flexion on the ankles (8.6N.m), a flexion on the knees (7.5N.m) and an extension on the hips (8.5N.m). On the spinal junctions, it was flexion moments: 0.34N.m on the cervico-thoracic; 6.7N.m on the thoraco-lumbar and 0.65 N.m on the lumbo-sacral. Evaluation of experimental error measurement showed a small inter-trial error (intrinsic variability), with higher inter-session and inter-therapist errors but without important variation between them. For one volunteer the “radiographic” posture was associated to significant changes compared to the free standing position.

Conclusion: These initial results confirm the technical feasibility of the protocol. The low intrinsic error and the small differences between inter-session and inter-therapist errors seem to traduce postural variability over time, more than a failure of the protocol. Characterization of sagittal net moments can have clinical applications such as evaluation of an unfused segment after a spinal arthrodesis.

Biomechanics/Basic Science

369 Postural Spinal Balance Defined by Net Moments: Results of a Biomechanical Approach and Experimental Errors Measurement


1Université Aix-Marseille, Ecole Doctorale 463, UMR CNRS 6233, Sciences du Mouvement Humain, Marseille, France,

2New York University Hospital for Joint Diseases, Spine Division, New York, NY, USA

Objective: To describe initial results and experimental error measurement of a protocol analyzing Human posture through sagittal moments.

Summary of background data: Postural analysis has been recently improved by development of three-dimensional radiographic imaging systems. However, in various situations such as global sagittal anterior malalignment interpretation of radiographs may not represent the real alignment of the subject. The aim of this study was to present initial results of a 3D biomechanical protocol obtained in a free standing position and characterizing postural balance by measurement of sagittal net moments.

Methods: After elaboration of a specific marker-set, 4 successive recordings were done on two volunteers by three different operators during three sessions in order to evaluate the experimental error measurement. A supplementary acquisition in a “radiographic” posture

Lumbar Therapies and Outcomes

377 Comparison of Clinical Outcomes between Total Spine Arthroplasty and Fusion

R. Davis, L. Neif, C. Gordon, D. Zeilstra, J. Gimbel

1Greater Baltimore Medical Center, Baltimore, MD, USA,

2Africains Hospital, Pretoria, South Africa,

3Texas Spine and Joint Hospital, Tyler, TX, USA,

4Bergman Spine Clinics, Naarden, Netherlands,

5Flexuspine, Pittsburgh, PA, USA

Background: Lumbar fusion is often performed to treat patients with disc and facet degeneration. While this is often successful in stabilizing the segment and relieving pain, it also produces altered spinal biomechanics. Total disc replacements have been developed to maintain proper motion but the patient population is limited to those without significant posterior segment diseases. A Total Spine Arthroplasty (TSA) device that treats the entire 3-joint complex would overcome the limitations of fusion and currently available arthroplasty devices. The purpose of this study was to compare the clinical outcome of fusion and TSA.

Methods: Clinical data was gathered as part of a prospective, non-randomized, clinical trial for TSA patients (n=24) and a registry study for fusion patients (n=22). Both studies had the same inclusion and exclusion criteria. Patients with single level DDD with facet compromise were treated at a single level (L3/4, L4/5, or L5/S1) and followed for up to 12 months. Patients with clinical data at 3 months and beyond were included in this analysis. Clinical evaluations included
ODI, VAS-back, and VAS-leg.

Patients in the TSA study had implantation of the Flexispine FSU, which involved discectomy and bilateral facet removal using an open midline or muscle splitting posterior paraspinal technique. The fusion study patients had interbody and posterior instrumentation using hardware and techniques specific to each clinical site. The VAS score that was greatest for each patient at baseline was used as the primary pain score and compared between groups using a t-test.

Results: Primary pain and disability significantly decreased for both groups. At 3 months, average primary VAS pain and ODI decreased by 68±29% and 58±27% for the TSA group (n=16) and by 63±35% and 39±31% for the fusion group (n=22). A correlation was observed between baseline VAS and post-operative improvement for the TSA group. The patients with >20% improvement at the last follow-up had a statistically lower (p<0.05) baseline primary pain score (71±18) than patients with < 20% improvement (94±4). Patients in the TSA group with < 20% improvement were also typically associated with co-morbidities, such as adjacent-level degeneration not treated in the initial procedure. Furthermore, patients with baseline pain lower than 70 tended (p=0.10) to have more pain relief with TSA (79±23% decrease) than with fusion (38±63% decrease).

Conclusion: This is the first study to compare the outcomes of TSA and fusion. Positive patient outcomes were found for both groups, but TSA tended to provide greater pain relief for patients with moderate to severe pain. Both groups had similar overall pain relief but this may be due to a selection bias between the studies since patients with very severe pain in the TSA group tended to have co-morbidities that were not screened out. Removal of these patients may result in a better outcome overall relative to fusion. Analysis is ongoing to confirm these findings in a larger patient cohort.

MIS Technique and Results

381 Interspinal Lumbar Decompression Fusion (ILIF) for Spinal Claudication

F.G. Diaz*, K. Karami, C.R. Cook, R. Tyo, M. Hyska*

*Oakland University, Neurosurgery, Southfield, MI, USA,
†Providence Hospital, Surgery, Southfield, MI, USA,
‡NOC2 Foundation, Research, Nashville, TN, USA,
§NOC2 Foundation, Research, Nashville, MI, USA,
¶Michigan State University, Surgery, Lansing, MI, USA

The aging of the American population brings with it a multitude of problems that involve the spinal surgeon. People older than 50 years, will develop progressive degenerative spinal problems including disc space narrowing with foraminal stenosis, disc space bulging and secondary vertebral edge spondylitic osteophytes, progressive facet hypertrophy and ligamentum flavum hypertrophy that narrow the spinal canal diameter. A variety of procedures have been used to decompress the lumbar spinal canal in patients who develop intermittent neurogenic claudication. Wide spinal decompressions with extensive laminectomies, partial or total removal of all posterior ligaments, and facets lead to different levels of spinal instability that will result in the development of kyphosis, flat back syndrome or subluxation of the vertebral bodies. The areas of stenosis in most patients is limited to the disc space level and include the combined effect of the degenerative process of all the structures that surround the spinal canal. The removal of the entire posterior column seems not only excessive but also unnecessary when put in context with the annular process of stenosis which is limited in nature and extent. The choice of procedure is further complicated by the age of the patient and the comorbidities present in older patients. An ILIF is a procedure that was designed to provide fixation of the interspinous space as a supplement to an anterior arthrodesis. The ILIF can be extended to include a wide decompression of the spinal canal through a minimally invasive approach. 30 patients with intermittent spinal claudication caused by degenerative spinal changes were treated with ILIF, 23 at a single level, and 7 at two levels for a total of 37 levels. All patients presented with intermittent neurogenic claudication with excertional pain, leg claudication, bilateral paresthesias of the lower extremities, two had intermittent incontinence of urine, and five had perineal numbness. No rectal sphincter problems were noted. All had immediate relief of their neurogenic claudication symptoms within the first week of surgery. Low back pain persisted in 12 patients who improved significantly within the first year of followup. Spinal fusion was documented with thin section multiplanar CT scanning in all 17 patients studied at six months. ILIF complemented with minimally invasive wide spinal decompression is an effective procedure to resolve the focal area of lumbar spinal stenosis providing a wide decompression and maintaining spinal stability.

Lumbar Therapies and Outcomes

386 Can “Dynamic Implants” Reduce Adjacent Segment Degeneration? Hybrid Fusions with Topping-off versus 2-level TLIF: Outcomes, Revisions and Complications of 104 Cases

A. Tuschel, P. Becker*, C. Eder*, M. Ogon

*Orthopaedic Hospital Vienna Speising, Spine Unit, Vienna, Austria

Introduction: Adjacent segment disease is one of the most discussed potential long-term complication after fusion surgery. Pedicle-screw based dynamic implants are thought to be a possibility to obtain stability and at the same time reduce the risk of the development of adjacent segment disease (ASD) in the lumbar spine.

Aim: The aim of this study was to compare 2-level hybrid constructs (TLIF + dynamic topping off) with 2-level fusions (TLIF) in the lumbar spine, regarding clinical outcome, adjacent segment disease and possible complications.

Material and methods: In a single spine-center between June 2008 and April 2010, a total of 104 patients underwent either 2-level hybrid surgery (TLIF + dynamic topping off) (51 patients) or 2-level fusion (TLIF) (53 patients) in the lumbar spine for lumbar spinal stenosis...
with or without mild instability.
The dynamic topping off was done either with the Isobar-
System by Scient’X (20 patients) or the Nhance/Nflex-
System by Synthes (31 patients).
Before surgery, no significant differences regarding
demographic factors or diagnosis could be found
between the groups.
Preoperative workup consisted of plain X-ray and MRI
images and prospectively collected SF36, Oswestry and
VAS for pain.
Mean follow-up was 27 months.

Results:
Clinical outcome: Clinical outcome parameters showed
significant improvement after surgery in both groups:
In the fusion groups, SF36 PCS improved from 29 to 39,
Oswestry reduced from 45 to 28 and VAS-pain dropped
from 6.1 to 2.7.
Similar clinical results were found in the dynamic group:
SF36 PCS improved from 28 to 39, Oswestry reduced from
46 to 29 and VAS-pain dropped from 5.6 to 2.5.
The difference of improvement between the two groups
was statistically not significant.
Adjacent segment disease: In the fusion-group, 4 out
of 53 patients had to undergo revision surgery (7.5%)
because of ASD, in the dynamic-group the revision rate
because of ASD was 5.9% (3 out of 51).
Fisher’s exact test showed no statistical difference in
the ASD-related revision rates between both groups
(p=0.513)
Mean time until revision surgery was 15.8 months in the
fusion-group and 24.3 months in the dynamic group.
Complications: Apart from revisions due to ASD, in
the fusion group two patients had to undergo revision
surgery (1 x infection, 1 x further decompression).
No failure of the hardware, was noticed in the fusion-
group.
In the dynamic group, apart from revisions due to ASD,
one patient had to undergo revision surgery due to
screw-loosening after 15 months.
Furthermore, one of the patients with ASD in the dynamic
group had an additional losening of the dynamic part of
the rod.
Another patient showed a broken dynamic rod at 12
months follow up. Due to lack of symptoms he did not
undergo revision surgery up to now. All together the implant failure rate in the dynamic group
was 5.9%

Conclusion: At a mean follow up of 27 months, clinical
outcomes and ASD-related revision rates of 2-level TLIF
and 2-level hybrid fusions with topping-off seem to be
very comparable. There was a trend towards earlier
ASD-revisions in the fusion group, but at the same time
a trend towards a higher implant-failure rate could be
observed in the dynamic group.

Introduction: In thoracolumbar fusion, 7-30% of fusion
fail resulting in pseudarthrosis [1]. Both biomechanical
and clinical factors contribute to these unsatisfactory
outcomes. From a biomechanical perspective, the non-
conformity of the graft to the endplate surface may
be leading to the endplate stress concentrations, and
thus pseudarthrosis. Therefore, an inter body graft that
conforms to the vertebral endplate morphology is likely to
enhance the fusion rates. The objective of this study is to
understand the effect of endplate-graft conformation on
endplate stress distribution and compare the uniformity
of stresses and stability for conformed and non-
conformed grafts.

Methods: An experimentally validated finite element
model of the L4-5 FSU [2,3] was modified to
simulate different inter body grafts: cortical bone, and
PCL+25%HA tissue scaffold, with and without endplate-
conformed surfaces. The conformed surface matched
the end plate morphology on either side. Appropriate
material properties were assigned. The models were
fixed at the inferior-most surface of L5, and subjected
to 400 N follower load and 7.5 Nm of flexion/extension
moment.

Results: The flexion-extension motion decreased
by almost 75% with cortical bone graft and 52% with
PCL+25%HA scaffold. In extension, for a conformed
cortical graft maximum stress on L4 inferior end
plate (IEP) decreased by 31%, compared to a non-
conformed graft (Fig 1a). The corresponding decrease on the L5 superior endplate (SEP) was around 8%. For
the PCL+25%HA conformed graft, maximum stress
decreased by 38% in the L4 IEP and by 30% for L5
superior endplate (SEP), compared to non-conformed
graft. In flexion, the corresponding decreases were
11.3% for the L4 IEP. For the PCL+25%HA conformed
graft stress decreased by 25% on the L4 IEP and by 9% for L5 SEP, compared to the non-conformed graft (Fig
1b).

Figure 1

[Figure 1]
**Discussion and conclusions:** The stability provided by the PCL+25%HA graft, as seen by the decrease in range of motion data, although smaller than the cortical bone graft, will become comparable in the presence of additional spinal instrumentation. The stress distribution for the conformed grafts was more uniform as compared to the non-conformed grafts; the maximum stress was lower as well. Furthermore, the stresses were less for the conformed PCL-HA graft, compared to cortical graft. This suggests that the load sharing is better with the PCL + 25%HA graft; reduce the chances of graft subsidence. Modern bio-manufacturing techniques, in concert with the patient’s endplates CT data, allows the scaffold to be manufactured prior to surgery. These scaffolds can be loaded with stem cells to promote fusion. Our group is pursuing research along these lines.

**References:**

**Lumbar Therapies and Outcomes**

**389 Sagittal Alignment Correction Following Minimally Invasive Lateral Fusion with Hyperlordotic Cages**


1 Instituto de Patologia da Coluna, São Paulo, Brazil, 2 Unifesp, DDI, São Paulo, Brazil, 3 University of California San Diego, Neurosurgery, San Diego, CA, USA

**Purpose:** Traditional treatments to sagittal imbalance consist with high incidence of morbidity that makes this kind of surgery not indicated to the elderly population. The purpose of this paper is to present a lateral retroperitoneal minimally invasive option for the treatment of iatrogenic or degenerative sagittal imbalance.

**Methods:** A prospective, non-randomized, single center study with up to six-year follow-up. 17 patients, mean age 69.6 y/o (51-87, range). Lateral, A-P, flexion-extension X-rays, neurological examination and clinical outcome assessments using ODI and VAS scores were collected. The lateral approach was done through the retroperitoneal space for thoracolumbar access. For anterior elongation interbody or expandable cages were used. The operated levels ranged from four to seven levels, including T10-T11 to L4-L5.

**Results:** No intraoperative complications occurred. Average surgical duration was 145 minutes and mean blood loss, 217cc. 10 patients underwent four levels of fusion; two patients had five levels and two patients were fused in seven levels. Three patients underwent a thoracolumbar corpectomy procedure besides interbody cages and percutaneous pedicle screws. The other patients were kept standalone. Clinical outcomes improved significantly in the postoperative evaluations. Sagittal alignments improved from average 17.1 degrees at pre-op to 37.4 degrees at last follow up. Mean SVA, sacral slope and pelvic tilt parameters also had a beneficial gain right after surgery and were maintained at the following visit points.

**MIS Technique and Results**

**390 Stand Alone Interbody Fusion through Lateral Approach for Adult Scoliosis Correction: 2 Years Follow up**


1 Instituto de Patologia da Coluna, São Paulo, Brazil, 2 University of California San Diego, Neurosurgery, San Diego, CA, USA, 3 Unifesp, DDI, São Paulo, Brazil

**Background context:** Occurring in up to 15 percent of the adult population, degenerative scoliosis most often becomes symptomatic in patients in their sixth decade. The traditional treatments to degenerative scoliosis consist in posterior open surgeries. A different way of treating those patients with less complications has come out recently. Here we present a two year follow-up with lateral retroperitoneal minimally invasive approach for a stand-alone interbody fusion of adult scoliosis.

**Purpose:** The purpose of this paper is to present the clinical and radiographic results of minimally invasive approach for the treatment of adult scoliosis.

**Methods:** A retrospective research of our institutional database was performed to identify patients with the following criteria: age above 65 at time of surgery, underwent a stand alone XLIF procedure for adult scoliosis and greater than two years follow-up. Preoperative, postoperative, and most recent radiographs were reviewed to assess Cobb angle, lumbar lordosis, and fusion rates. A follow-up SF-36 questionnaire, along with an Oswestry questionnaire and VAS was performed to access clinical results.

**Results:** The procedures were performed without major complication. Radiographic review shows considerable improvement in both coronal (cobb angle from 21 to 11 degrees) and sagittal planes (lumbar lordosis from 32 to 41 degrees). Also clinical outcomes demonstrated significant improvements in VAS pain scores (from 8.5 to 2.7), Oswestry scores and SF36.

**Conclusions:** Using the XLIF approach we were able to treat adult lumbar scoliosis in a minimally invasive way.
targeting the pain improvement after surgery without the risks and morbidity associated with big corrections. Our intent was pain improvement and stabilization. We found reasonable coronal and sagittal correction in addition to successful clinical improvements in pain and function. Questions still remain regarding if we need additional posterior screw supplementation and this should be addressed in future research.

Lumbar Therapies and Outcomes

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The Role of Load Absorption in Lumbar Arthroplasty - Elastomeric Total Disc Replacement 48 Months after Surgery
1Instituto de Patologia da Coluna, São Paulo, Brazil, 2Unifesp, DDI, São Paulo, Brazil, 3University of California San Diego, Neurosurgery, San Diego, CA, USA

Purpose: Lumbar arthroplasty aims maintenance of movement but clinical and biomechanical results have indicated the need of load absorption. This present device is an elastomeric lumbar disc prosthesis which uses compliant polycarbonate polyurethane as its core material and has been designed to have enhanced endurance properties. Clinical and radiological results after 36 months are encouraging for this new lumbar arthroplasty rationale.

Methods: Fifteen patients (12 male; 3 female) with DDD underwent anterior disc replacement and prospectively followed. Ten 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). Clinical (VAS and ODI) and radiological outcomes were analyzed. All patients were assessed pre-operatively, and at 6 weeks, 3 and 6 months, and annually.

Results: Average age was 37.0 years (range 25-54) and an average BMI was 23.7 (range 19.4-28.5). At 48 months follow up evaluation, the VAS back pain and ODI scores improved significantly when compared to baseline. ROM went from a baseline of 12.0° ± 6.2° to 13.3° ± 5.5° at 12 mos, and 11.7° ± 7.3° at 48 mos. No significant facet degeneration was observed. There was one prosthesis removal due excessive motion and consequent pain. One patient experienced intraop vascular damage at L4-L5 that required further surgery to repair. At six month follow up evaluation, one patient experienced retrograde ejaculation which was resolved at 12 months.

{Elastomeric Lumbar TDR]
Conclusions: This work reports a 48 month follow up results of the new elastomeric generation of total disc prostheses. The clinical results for VAS and ODI were superior to other marketed artificial lumbar discs such as Charité and ProDisc-L at the same follow-up timeframes, presenting the same inherent complications related to the anterior surgery access.

MIS Technique and Results

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Results of Interspinous Spacers in the Treatment of Lumbar Stenosis
D. Winkler, F. Raimund, C. Hessler, M. Westphal
1University Clinic Hamburg, Hamburg, Germany, 2Department of Spine Surgery, Hamburg, Germany

Interspinous spacers are one treatment option for spinal stenosis. The advantage of this method is the minimal invasiveness with the avoidance of opening the spinal canal and no scar problems can occur. As a disadvantage can be seen that the reason of the problems, the narrowing of the spinal canal is not affected.

Methods: In the last four years 72 patients with lumbar stenosis were treated in our department with one or more interspinous spacers. There were 34 males and 38 females and the age ranges between 32 and 92 years with a mean age of 66.5 for female and 71 years for males. One level was treated in 53 cases, two levels in 18 cases and three levels in one case. The level of L 4/5 was most common with 47 cases followed by L 3/4 with 35 procedures, 8 times L 2/3 and one L 5/1. We used four different devices. In the beginning 6 X-Stops, 7 Vertiflex and 6 times Coflex. 56 procedures were done with an In-Space device.

Results: In two cases the operation must be terminated without implant because of instrument problems and we saw two misplacements in the soft tissue. We had no infection, no bleeding which needed treatment in any way, no neurological deterioration, no thrombosis and no fracture of spinal processes. All patients got up within the first hours after the operation. 10 patients reported complete relief of pain nearly immediately, 9 patients had no improvement during their hospital stay. Additional pain treatment in our hospital in the further course was necessary in 5 cases. Twelve patients had to undergo an open procedure in the same level some years later with the device removed in most cases without any problem.

Conclusion: Interspinous spacers do not solve the problem of spinal stenosis. In certain cases it might be an option and it does not prevent further therapies.

MIS Technique and Results

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Percutaneous Aperius™ Implant for Neurogenic Intermittent Claudication
A.P. Fabrizi, L. Schiabello, P. Alvisi, Neurosurgical Spine Study Group
1Villa Maria Pia Hospital, Turin, Italy, 2San Pier Damiano Hospital, Faenza, Italy, 3Villa Maria Hospital, Rimini, Italy

Questions? (866) 423-9440 (U.S.) +1(630) 995-9994 (Int’l)
Over the past 10 years, extension limiting device (ELD) usage in Europe has been rapidly increasing. A number of ELDs are now available on the market for varying indications that all focus on a minimally invasive technique for implantation. These devices are utilized either in conjunction with current spine surgery techniques or in stand alone application where no additional surgery is performed beyond placing the device. The purpose of this study was to evaluate the percutaneous technique of the stand alone Aperius™ implant under local anesthesia for patients suffering from Degenerative Lumbar Spinal Stenosis with Neurogenic Intermittent Claudication (NIC).

400 patients (average age 67 yrs) suffering from mild to moderate NIC were treated with the Aperius™ PercLID™ system from July 2007 to September 2011. Patients were placed prone in slight flexion and given an injection of local anesthesia using a curved spinal needle. Using fluoroscopic guidance, sizing and distracting trocars were placed sequentially into the interspinous space through a 1.5cm incision. Operative videos under x-rays will demonstrate the opening of the stenotic spinal and foraminal canals. The appropriate size Aperius™ implant was then positioned and deployed in the interspinal space. No inter-operative complications or problems with the device were observed and all patients tolerated the local anesthesia approach with little to no discomfort or pain. All patients were up and walking 2 hours postoperatively with complete primary symptom relief. Long-term 4 year patient follow-up with percutaneous approach under local anesthesia with the Aperius™ implant is reported giving VAS, ODI, SF-36 and radiological controls. The good results are constant in two thirds of the patients treated.

Biomechanics/Basic Science

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Geometric Considerations for Dampeners Utilized in Posterior Dynamic Stabilization Devices

J. Gimbel¹, E. Wagner¹
¹Flexuspine, Inc., Pittsburgh, PA, USA

Introduction: Polymer dampeners or spacers are typically utilized in pedicle-based posterior dynamic stabilization devices (PDS) to limit the amount of motion. These dampeners must undergo repetitive compression that may result in fatigue damage and wear leading to device failure or an adverse biological reaction. Previous testing of polymer dampener tubes has demonstrated that a properly selected material can have adequate fatigue resistance, but the effect of geometry modifications on the overall stress response at large compressive deformations has not been previously investigated.

Methods: Non-linear finite element models of various silicone dampener designs placed between stainless steel washers on virtual CoCr rods were created. Axial compressive deformation was applied to 50% strain. The dampeners were modeled as incompressible materials and no hysteresis effects were considered. The model was validated using laboratory test data. The designs evaluated included two straight cylindrical tubes (control 1 and control 2), a chamfered tube, and a barrel-shaped tube. The chamfered design was the same as control 1 except a chamfer was added to minimize stress/abrasion against the washer. The barrel design was the same as control 2 except the outer diameter was increased by 18% at the midline in an effort to prevent buckling under high compressions. A stress-strain curve was created for each design along with stress distribution plots.

Results: The chamfered design decreased the peak strain at the washer by approximately 50% but also increased the strain at other locations. The barrel design increased the strain at buckling by 10% and had lower maximum strains than control 2.

Conclusions: Straight cylinders are typically utilized for PDS devices but other shapes may enhance the fatigue and wear resistance. The chamfered design was effective in decreasing the interface stress, and possibly wear, at the location of contact with the washer. Removal of material increased the strain at other locations, however, which may negate the benefits. The barrel design was effective in slightly delaying buckling due to the additional material. This may decrease the potential for fatigue damage but buckling for both designs occurred beyond expected physiological strains. When considered together, modifying the geometry can provide some benefits, but these are mostly the result of increasing the volume of material being compressed and not the geometry. Therefore, a straight cylinder with the largest possible volume is sufficient to minimize stress under controlled displacement.

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Post-vertebral Fracture Disc Degeneration Test after Anatomical Reduction Using Diffusion and Perfusion Techniques

D.C. Noreaga¹, J. Calabia², F. Ardura³
¹Hospital Clinico Universitario, Orthopedics, Valladolid, Spain,
²University Valladolid, Radiology, Valladolid, Spain,
³University Valladolid, Orthopedics, Valladolid, Spain

Objective: Analyzing the early degeneration of intervertebral discs in patients undergoing post-traumatic, vertebral anatomical reduction using MRI with diffusion and perfusion of the vertebral endplates bordering the fractured vertebra.

Materials and methods: A number of 5 patients, average age: 45 years old, MRI average monitoring: 32 months after surgery High field MRI scanner with multiple diffusion techniques (50, 100, 500), early enhancement and perfusion of vertebral endplates, performance test.
of bordering vertebral discs and vertebral endplates in order to assess if there is loss of disc architecture (diffusion) and/or diffusion disorders that show if there is disc degeneration and comparative degrees with intervertebral segments and discs that are not adjacent to the anatomical reduction.

**Results:** Intervertebral disc diffusion coefficients with non-significant variation values with regard to other intervertebral discs from the same patient. A case shows a diffusion alteration with pathological MRI in preoperative study. Perfusion values are more difficult to predict due to the absence of a previous model with iterative reconstruction. The values of the neighbouring vertebral endplates show a slight decrease of the perfusion itself (in relative values). The dynamic study did not reveal any annulus fibrosis or enhancement that lead to degeneration as compared with other vertebral discs.

**Conclusions:** Given the positive predictive value (diffusion) in early disc degeneration and its intra individual, comparative value, we believe that the reduction found in the vertebral endplate protects the disc against early degenerative processes. In future studies we will compare an increased volume of samples and patients with similar characteristics that have not undergone any anatomical reductions.

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2-year Clinical and Radiological Follow up after VCF Anatomical Reduction

*D.C. Noriega*¹, *F. Ardura*², *J. Beyerlein*², *N. Hansen*²

¹Hospital Clinico Universitario, Orthopedics, Valladolid, Spain, ²University Medical Center, Hamburg, Germany

**Purpose:** To present 2 year clinical and radiological follow up results after VCF treatment with a new procedure involving an intravertebral cranio-caudal expandable implant (VCCEI) in combination with PMMA cement injection.

**Materials and methods:** In two clinics, participating in a prospective observational study enrolling 77 patients, assessments of clinical and radiological parameters were performed for the first 20 patients (Mean age: 64yo, 10F/10M) who reached the 2 year follow up time after surgery (Mean: 28 months, Range: 24-30months). Type of fractures: all osteoporotic, low energy trauma. In 1 patient a myeloma was diagnosed through a biopsy (after surgery).

The surgical procedure consisted in placing two Titanium cranio-caudal expandable implants through bilateral transpedicular approach under fluoroscopic guidance and to optimally position them with respect to the fractured area of the vertebral body. Then, they were expanded until the fracture of the vertebral body was reduced and let in place while final stabilization was obtained by acrylic cement injection using the same surgical approach. Assessment of the technique was made using VAS score and a new method based on 3D CTSCans reconstructions superimposition developed in collaboration with a biomechanics laboratory in Paris (ENSAM-LBM). Any subsequent fracture was registered.

**Results:** For the 20 patients seen at 2 year follow up, VAS score showed an average of 1,35 (range:0-7) which is a significant and sustained pain reduction. For one of patients an adjacent fracture was reported after 6 months (female patient, bmd -5.2).

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%. No recollapse or other complication was reported.

**Conclusion:** This new intravertebral cranio-caudal expandable implant procedure has shown clinical and radiological effectiveness in achieving anatomical reduction of VCF as well as reducing patients’ pain. Further studies need to confirm these long-term benefits which have been shown.

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Advances in the Policy of Surgical Therapy of A3.1 Fractures

*D.C. Noriega*¹, *F. Ardura*²

¹Hospital Clinico Universitario, Orthopedics, Valladolid, Spain, ²University of Valladolid, Valladolid, Spain

**Objective:** To assess the capacity of anatomical reduction of vertebral fractures type A3.1, assess the risks of displacement of the posterior wall and to document any cement leakage.

**Introduction:** A3.1 fractures generate significant morbidity and mortality. There are surgical techniques to correct the deformity and to restore stability, prevent neurological damage and progressive deformity, none of them evaluates the anatomic reduction, the risk of displacement of the posterior wall and intracanal cement leakage.

**Material and methods:** Prospective study including 25 patients, 53y mean. Preoperative VAS 7.28. Two expandable titanium implants were placed using a transpedicular approach. They lead the broken endplates to its original anatomical position and subsequent fixation with PMMA. To analyze the results, we developed a method everything of value with 3D-CT reconstructions.

**Results:** There were three cement leakages, two to the disk (diagnosed TAC) paravertebral. No intracanal leakage. No displacement of the posterior wall. VAS improvement from the immediate postoperative period (mean 2.72), being 1.68 after 6 months and 1.6 at 1 year ± o. Reduction and control of sagittal balance of 92%.

**Conclusion:** This procedure restores the vertebral body height and fixation in an effective and safe way. Future studies to assess the survival of the disk will be needed.
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Quantitative Analysis of Change in Segmental Posture after Cervical Arthroplasty
N.R. Crawford1, P.M. Reyes1, A.G.U. Sawa1
1Barrow Neurological Institute, Spinal Biomechanics, Phoenix, AZ, USA

Introduction: When inserting cervical arthroplasty devices, critical ligamentous tension bands, the anterior and posterior longitudinal ligaments, are transected, possibly affecting the posture at the index level and adjacent levels. This study investigated the immediate postoperative changes to posture in vitro.

Methods: Flexibility tests were performed on human cadaveric cervical spines (C3-T1) in the intact condition then again after insertion at C5-C6 of ProDisc-C (Synthes Spine, N=6), Prestige (Medtronic, N=8), or Bryan (Medtronic, N=8). Since disc space preparation differs, Prestige and Bryan discs were implanted in the same specimens sequentially. To account for the requirement of bony ingrowth in Bryan vs. friction fit of keel or screws in ProDisc-C and Prestige, Bryan discs were held in place with bone cement. ProDisc-C devices were 5mm (5) or 6mm (1); Prestige devices were 6mm (7) or 7mm (1); Bryan devices were 14mm (3), 15mm (3), or 16mm (2). Specimens underwent flexion-extension tests using pure moments (1.5 Nm) while recording segmental angles, and posture-zeroing tests where global posture was restored to 0° using a simplified muscle pair applied across C3 with 70 N follower load while recording segmental angles.

Results: In the unloaded resting condition after releasing the third cycle of flexion, the C5-C6 segment was extended relative to intact by 10.6±5.7° with ProDisc-C, 6.8±3.1° with Prestige, and 10.2±5.6° with Bryan (p<0.01). With follower load applied and the specimen forced back to a global posture of 0°, the index level was extended by a lesser amount relative to intact, but was still at least 3.7° farther extended after arthroplasty than intact. Compensation for C5-C6 extension at upright posture typically was from flexion at adjacent caudal levels averaging at least 4°. Under full flexion and full extension, the differences between intact and implanted static angle were significant at C5-C6, although the C5-C6 range of motion matched intact range of motion well.

Discussion: Extension at the implanted level could have been caused by too large of a device ("overstuffing"), but this explanation is unlikely since device size was commonly 5 or 6 mm for the metal-on-metal and metal-on-poly devices. It appears that extension at C5-C6 is caused by loss of the natural tension bands across the motion segment due to transection of the ALL, PLL, and native disc. This effect persisted despite normal loading in flexion and extension and forced return to 0° global posture. Clinically, focal kyphosis, not lordosis, is more typical and therefore this biomechanical effect is likely restricted only to the immediate postoperative period before slackening of the posterior ligaments can occur.

Lumbar Therapies and Outcomes

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Complications and their Avoidance in the Lateral Trans-psoas Approach to the Lumbar Spine - A Single Center’s Experience
A. Kanter1, M. Maserati2, C. Bonfield2, D. Okonkwo1
1University of Pittsburgh, Neurosurgery, Pittsburgh, PA, USA,
2University of Pittsburgh Medical Center, Pittsburgh, PA, USA

The extreme lateral trans-psoas approach to the spine has gained increasingly widespread popularity among spine surgeons seeking to perform lumbar interbody fusion in a minimally disruptive fashion. This adaptation of the retroperitoneal approach to the spine began a paradigm shift in interbody fusion, offering a unique and innovative solution to the problem of achieving robust reconstruction of the anterior column while avoiding injury to critical stabilizing structures of the spine. The procedure avoids many of the approach-related complications associated with traditional anterior and posterior fusion surgery; however, it is associated with its own unique set of approach-related complications. We have reviewed our single center experience with the lateral transpsoas approach since 2008, noting approach-related complications and subsequent strategies we have implemented to avoid them. Neurologic complications are a significant concern with XLIF and are primarily the result of blunt or traction injury to the lumbar plexus or one of its branches such as the genitofemoral nerve. Direct trauma to the psoas muscle, even when minimal, typically produces transient anterior thigh pain and hip flexor weakness in many patients. Of perhaps greatest concern, however, is the
potential for catastrophic injuries to the retroperitoneal viscera, principally the colon and great vessels. Finally, the potential for graft-related complications, including endplate violation and subsidence, is significant particularly if discectomy and endplate preparation are too aggressive, and if too large a graft is chosen. We categorize complications encountered into procedural groups: those that can occur during positioning, those that occur during passage to the psoas muscle and the transgression itself, those that occur during discectomy and graft placement, and those that occur in the peri- and early post-operative period -- both transient and chronic. Complications most commonly included transient anterior thigh parasthesias (54%) and hip flexor weakness (22%). Significant subsidence was routinely noted on stand-alone fusion cases (44%) but rarely symptomatic (12%). Less common but more severe complications necessitating surgical remedy included graft dislodgement (2%) and bowel injury (1%). Avoidance of complications related to the transpsoas approach begins with appropriate patient selection, particularly in regards to any history of abdominal surgery, to the presence of rotational deformity, and to the relative contribution of posterior spondylotic changes to the stenosis requiring treatment. Careful examination of pre-operative imaging and constant awareness of the proximity of the retroperitoneal contents are critical to avoiding visceral injury. Positioning should be accomplished while minimizing traction on the lumbar plexus. Continuous EMG monitoring should be used throughout the approach and limiting retractor expansion during psoas traverse, discectomy and graft insertion should further minimize injury to neural plexus elements. Using these principles and others, the procedure remains a uniquely powerful tool in the contemporary spine surgeon’s armamentarium.

MIS Technique and Results

414 Outcomes and Clinical Results in Treatment of Multiple Lumbar Diseases with Extreme Lateral Interbody Fusion (XLIF®) Procedure. Two Years Experience in Venezuela, South America
G. Bajares1, A. Pérez-Oliva1, N. Cruz1, A. Acosta1, J.L. Oropeza1
1Instituto de Columna Caracas, Hospital de Clínicas Caracas, Caracas, Venezuela, 2Centro Médico Docente La Trinidad, Clínica de Columna, Servicio de Cirugía Ortopédica y Traumatología, Caracas, Venezuela

Introduction: The XLIF procedure has emerged as an alternative approach to stabilize the anterior column in diverse conditions that affect the thoracolumbar spine. More complicated conditions have been treated with this procedure so it has broadened its usage to become a minimally invasive treatment that allows a retroperitoneal access, discectomy, and implant insertion with minimally tissue damage avoiding neurological lesions.

Methods: A prospective study to evaluate clinical and radiographic outcomes in patients where lateral lumbar interbody fusion with XLIF was performed since 2009 for lumbar degenerative disc disease, adjacent segment disease, spondylolisthesis, spinal stenosis or degenerative scoliosis. Data includes evaluation at the pre-op, surgery, post-op, 3-month, 6-month, 12-month then annually of all patients who have undergone to XLIF procedure in two sites with the same team of surgeons. Oswestry Disability Index (ODI) and Visual Analogue Scale (VAS) were performed to assess clinical and neurological outcomes.

Results: XLIF was performed in 83 patients with 154 levels from T12 to L5 (mean 1.8 levels, range 1-4), mean age was 71.3 (range: 29-82 yrs) and 79.31% female, mean operation room time was 149.3 minutes/patient (including posterior instrumentation), ranging from 40 minutes in first level and 25 minutes in contiguous levels in stand alone procedures Estimated blood loss ranged from 10 to 60 cc, mean length of hospital stay was 2.6 days. Mean back pain VAS improved from 8.23 preoperatively to 4.52 at 24 months and 3.62 at 2 years, mean ODI went from 39% to 12% at first year and 11.3% at 48 month. A 7.69% rate of perioperative complications were noted, the more common postoperative complication was thigh paresthesia (32.5%) and hip weakness in 5.61% of patients, this tends to recover within 4 to 6 weeks. One patient presented a bowel perforation that required an exploratory laparotomy and multidisciplinary care. Subsidence was noted on radiographs in 15.38%. Tree patient present vertebral body fracture with cage subsidence and loss of interbody height.

Conclusion: This data matches with several studies of XLIF procedure results and contributes with research in Latin American where only few long term outcomes have been observed. These results corroborate the remarkable clinical improvement that persists in time with applying this technique, for spinal diseases XLIF is a safe and reproducible procedure that allow to patients a quick recover with low rates of complications.

Biomechanics/Basic Science

416 Biomechanical Effects of Pedicle Screw “Hubbing” in the Immature Thoracic Spine. A Calf Spine Study
A.E. Dmitriev1, R.A. Lehman1, R. Gaume1, H. Paik1, D.G. Kang1, A.J. Bevivino1, D. Ambati1
1Walter Reed National Military Medical Center, Orthopaedic Surgery, Bethesda, MD, USA

Summary: Pedicle screw “hubbing” has been espoused as advantageous by improving implant/bone load-sharing; however, it has been shown the opposite in the adult cadaveric bone. The current study explored the technique in the immature (adolescent) calf bone and found decreased pull-out strength (POS) compared to the standard technique.

Background: Pedicle screw “hubbing”, in both normal and osteoporotic adult bone, has been shown to decrease fixation strength and cause facet/transverse process(TP) fractures in 50% of cases. However, it remains unclear whether this technique is beneficial in the immature or adolescent bone. The current project was performed to evaluate the POS of fixed-head

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pedicle screws that were “hubbed” against the dorsal cortex compared to standard fixation in the immature calf thoracic spine.

Methods: Twenty-three (23) fresh-frozen, calf thoracic vertebrae were acquired and DEXA scanned to obtain bone mineral density (BMD). Twelve specimens (n=12) were allocated for testing. On one side, a 5.0 x 35 mm screw was inserted; while the other side had a 5.0 x 30 mm screw implanted with the head of the pedicle screw ‘hubbed’ into the dorsal lamina and confirmed radiographically. Cyclic fatigue loading in a cephalocaudad direction was applied for 2000 cycles at a rate of 1 Hertz (Hz). Pull-out testing was performed in-line with the midline of the vertebral body at a rate of 0.25 mm/sec and peak POS measured [Newtons (N)]. The remaining specimens (n=11) were used to evaluate the incidence of iatrogenic lamina/TP fracture during screw insertion, with implants ‘hubbed’ bilaterally. Evaluation consisted of visual inspection and fluoroscopic examination.

Results: All specimens exhibited equivalent BMD. Unlike the adult bone, which fractured in 50% of hubbed screws, the immature calf lamina underwent plastic deformation and conformed to the screw head in 88% of cases. In 4 cases (11.7%) the superior facet cracked upon contact with the screw head. However, despite the reduced rate of catastrophic failure, the POS of the hubbed screws was significantly lower than the control side (747 ± 197 N versus 922 ± 112 N) (p = 0.01).

Conclusions: Similar to the findings observed in our original study in the adult cadaveric specimens, hubbing in the immature calf vertebrae resulted in lower in-line pullout strength. These findings persisted despite a reduction in lamina/TP fractures compared to adult specimens. Our current findings suggest that “hubbing” screws, in an attempt to maximize the pedicle screw fixation strength, should be avoided in all cases regardless of the patient’s age or bone quality.

Biomechanics/Basic Science

429 Caudal Pedicle Screw Compression Optimizes Thoracic Kyphosis Correction: A MicroCT and Biomechanical Analysis of Pedicle Morphology and Screw Failure

A.J. Bevevino1, R.A. Lehman1, D.G. Kang1, A. Dmitriev1, M. Helgeson1, G. Rachel1, L. Lenke2

1Walter Reed National Military Medical Center, Department of Orthopaedics, Bethesda, MD, USA; 2Washington University of St. Louis, Department of Orthopedics, St. Louis, MO, USA

Introduction: As surgeons perform cantilever correction maneuvers in the thoracic spine, it is common to have pedicle screws pullout or displacement while placing significant corrective forces on the construct. Currently, surgeons either compress against the cephalad aspect of the pedicle, or vice versa. We set out to establish which aspect of the pedicle was the most dense, and to determine the optimal direction for screw compression during kyphosis/deformity correction. We set out to evaluate the bone density/trabecular width of the thoracic pedicle, and determine a correlation with resistance against compressive loading forces utilized during correction maneuvers in the thoracic spine (i.e. cantilever bending during kyphosis correction).

Methods: Fourteen fresh-frozen cadaveric thoracic vertebrae (n=14) were examined by MicroCT to determine the ratio of bone volume to total volume (%BV/TV) within the cephalad and caudad aspects of the pedicle. Specimens were sectioned with a diamond saw in the sagittal plane. Pedicles were instrumented according to the straightforward trajectory on both sides. Specimens were mounted and loading to failure was performed perpendicular to the screw axis (either against the cephalad or the caudal aspect of the pedicle).

Results: Mean failure when loading against the caudal aspect of the pedicle was statistically, significantly greater (454.5 ± 241.3 N versus 334.79 ± 158.435 N) than for the cephalad pedicle (p< 0.001). In concordance with the failure data more bone was observed within the caudal half of the pedicle (87.6% ± 3.5% versus 84.3% ± 6.0%) compared to the cephalad half (p< 0.001).

Discussion and conclusion: Our results suggest that the caudal aspect of the pedicle is denser and stronger compared to the cephalad cortex. In turn, the incidence of intra-operative screw loosening and pedicle fracture may be reduced if the compressive forces (cantilever bending technique used during deformity correction) placed upon the construct are applied against the caudal portion of the pedicle.

Lumbar Therapies and Outcomes

432 Development of Scoliosis Following Combat Related Hip Disarticulation and Hemipelvectomy

A.J. Bevevino1, R.A. Lehman1, D.G. Kang1

1Walter Reed National Military Medical Center, Department of Orthopaedics, Bethesda, MD, USA

Introduction: Combat casualties subjected to high-energy blast trauma have experienced an increased incidence of devastating lower-extremity injury resulting in hip disarticulation and hemipelvectomy. There have been limited reports of scoliosis following upper and lower extremity amputations, and no series reporting scoliosis following hemipelvectomy from combat injuries. We report the development of scoliosis in two combat casualties following hip disarticulation and hemipelvectomy sustained during Operation Iraqi Freedom or Operation Enduring Freedom.

Methods: We performed a retrospective review of two combat amputees, who presented with sciotic deformity following lower extremity amputations, either hip disarticulation or hemipelvectomy. We identified the involved levels and spinal deformity, Cobb angle and measured vertebral rotation using the Nash-Moe pedicle method. We also evaluated sagittal compensation with the C7 plumb line. Inpatient and outpatient records were reviewed to determine the existence of back pain, activity level and prosthesis use.

Results:

Case 1: 21 year-old active duty Army soldier with right hemipelvectomy and left hip disarticulation following rocket propelled grenade (RPG) explosion. Approximately two years after his injury, a
scoliosis survey of the patient upright in his prosthesis demonstrated dextroscoliosis from T12 to L5 of 37 degrees, with a 1+ Nash-Moe rotation, and 8 cm of sagittal compensation. Patient reports no back pain, has limited prosthetic use, with mobility using a manual wheelchair. He is able to perform independent transfers to wheelchair and most activities of daily living (ADL). Case 2: 20 year-old active duty Marine with bilateral above knee amputations, with the right lower-limb amputation considered a functional hip disarticulation, following an improvised explosive device (IED). Approximately 1 year after his injury, a scoliosis survey of the patient upright in his prosthesis demonstrated dextroscoliosis from T12 to L5 measuring 26 degrees, with 2+ Nash-Moe rotation, and 3.5 cm of sagittal compensation. Patient reports no back pain, has been using bilateral prosthetics and bilateral canes during physical therapy for gait training, but mostly using a manual wheelchair for mobility. He is able to perform independent transfers and all ADLs.

Discussion and conclusion: To our knowledge we report the first case series of scoliosis development following combat related hip dislocation and hemipelvectomy. In our series, both patients were without pain or symptoms, and developed similar deformities with a sharp lumbar curve greater than 20 degrees and concavity away from the side of the hip disarticulation or hemipelvectomy. While our awareness of scoliosis following lower-limb amputation has increased, the incidence of scoliosis following combat related hip disarticulation and hemipelvectomy remains unknown. A larger retrospective study, including long-term follow-up of curve progression and the benefits of improved prosthesis design is needed.

Lumbar Therapies and Outcomes

434 Clinical Outcomes of Lumbar Total Disc Replacement. Experience after 9 Years G. Bajares1,2, A. Pérez-Oliva1,2, N. Cruz1,2, A. Acosta1,2 1Instituto de Columna Caracas, Hospital de Clínicas Caracas, Caracas, Venezuela, 2Centro Médico Docente La Trinidad, Clínica de Columna, Servicio de Cirugía Ortopédica y Traumatología, Caracas, Venezuela

Introduction: The lumbar total disc replacement is considered a motion preservation alternative for treatment of degenerative disc disease in order to maintain movement in affected and adjacent levels in the lumbar spine. The main objective of non fusion techniques is to preserve intervertebral mobility and good results among time. Several publications have determined the success of the short follow-up clinical results. There are few reports with long-term outcomes.

Methods: 204 patients, mean age 43 years old, 57% female were retrospectively reviewed, results were assessed with clinical and radiological evaluation, lumbar pain Visual Analogic Scale (VAS) and Oswestry Disability Index (ODI) was performed preoperatively and at 1, 3, 6, 12 and 24 months postoperatively. A cohort of 30 patient who completed a 2 year follow up period were reviewed.

Results: In the group of patients reviewed a significant clinical improvement was noted between the preoperative and postoperative follow up, with a VAS improvement from 6.8 to 2.9 at 2 years and a variation in ODI preoperatively in 42% to 16% at 24 months, in a subjective evaluation 66.3% patients said their result was “excellent” after the procedure and 83.2% were highly satisfied. Single and multiple level cases were included. Two patient were reviewed with prosthesis luxation, 1 patient was reimplanted and one patient undergo to ALIF, 1 patient was fused with pedicular screws after symptomatic facet degeneration and an anterior core luxation was noted in 1 patient.

Conclusion: In patients diagnosed with DDD, total disc replacement can provide a significant clinical improvement that is well maintained at 2 and 3 years follow up, good results are observed in single and multiple level replacements but indications for lumbar arthroplasty must be well defined for best results and low complication rates. More long term follow up studies in Latin America are needed.
other hand, our data suggests that clinical improvement following lumbar TDR is not affected by the patient’s gender. Further studies, with longer follow-up, will be needed to prove our preliminary conclusions.

MIS Technique and Results

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Long-term Outcome of Minimally Invasive Transforaminal Lumbar Interbody Fusion; 5 Years Post-op and Beyond
K.T. Foley1, H. Shah1
1University of Tennessee Health Science Center, Neurosurgery, Memphis, TN, USA

Introduction: Several reports have described the efficacy of minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF), but none have documented the long-term outcomes of patients undergoing this procedure. The purpose of this study was to quantify patient-derived outcomes for MIS-TLIF patients who were 5 years or more post-operative.

Materials and methods: A chart review was performed after obtaining IRB approval. All patients who had undergone a single-level MIS-TLIF 5 or more years prior for lumbar spondylolisthesis or spondylosis and for whom preoperative Oswestry Disability Index (ODI) and visual analog pain scale (VAS) data had been collected were included. These patients were contacted by phone and mail. After informed consent, they filled out ODI and VAS forms and returned them to the investigators. The current outcome data were compared to the preoperatively derived measures.

Results: 55 patients had undergone MIS-TLIF within the specified time frame [mean 72.6 months (60-90)] and had preoperative baseline ODI and VAS scores. Of these, 39 (19 male/20 female) patients were successfully contacted and returned current ODI and VAS scores. The mean cohort age was 63 years (37-80). The mean baseline ODI was 53 (30-100) and mean baseline VAS back and VAS leg were 50 (0-99) and 56 (0-98), respectively. The mean scores at the time of inquiry for ODI, VAS back, and VAS leg were 17 (0-60), 12 (0-62), and 16 (0-77), respectively. These scores represent a decrease of 36, 38, and 40 points from baseline.

Discussion: Although multiple reports have documented patient-derived outcome data following MIS-TLIF, none have done so for patients who were 5 or more years beyond their index procedure. The significant improvements in disability, back pain, and leg pain seen in the present study imply that MIS-TLIF is capable of producing sustained relief of symptoms and improvement in patient function. This has positive implications for the cost-effectiveness of this procedure.

MIS Technique and Results

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Minimally Invasive Cervical Foraminotomy to Achieve Radicular Decompression due Facet Hypertrophy. A Study with 24 Months of Follow up
C.F. Arias Pesantez1,2, C.R. Arias Solano1
1Hospital Universitario del Rio, Neurosurgery, Cuenca, Ecuador, 2Hospital Santa Ines, Neuro, Cuenca, Ecuador

Minimally invasive foraminotomy was developed to address cervical nerve root compression by direct visualization of pathology while minimizing tissue destruction on exposure, preserves muscle and ligamentous attachments to the spine, maintaining long-term stability and decreasing postoperative pain and spasm. We present eight patients with unilateral radicular pain due cervical facet hypertrophy, a minimally invasive approach was performed with MAXCESS retractor (Nuvasive, Inc. San Diego California), we studied VAS, Oswestry and Neck Disability index, surgical time, lost of blood, time to discharge and time to return to daily activities. Results The VAS prep was 9, 24 months was 2, Mean surgical time was 48 minutes, Time to discharge 7 hours and time to return to normal activity was mean 8 days. Conclusion This approach have several advantages over more invasive open procedures: reduced operative time, decreased hospital stay, decreased postoperative pain and muscle spasm such as earlier return to normal activity.

[CASE EXAMPLE]

MIS Technique and Results

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Minimally Invasive Biportal Cervical Decompression. Clinical and Radiological Results with 36 Months Follow up
C.F. Arias Pesantez1, C.R. Arias Solano2
1Hospital Universitario del Rio, Neurosurgery, Cuenca, Ecuador, 2Hospital Universitario del Rio, Cuenca, Ecuador

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. Nine patients with cervical mielopathy, 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, oswesty and neck disability index on Preop, Pop 6 weeks, 3,6,12, 24 and 36 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, 24 and 36months 2.0. Oswesty preop 52, on 36 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.

Conclusion: Posterior biportal cervical decompression is an ambulatory option to achieve clinical improvement in patients with cervical stenosis with less tension band allow the patients to return to normal activities.

Regular Posters

MIS Techniques and Results

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Intra-operative Neuromonitoring in Percutaneous Transformalinal Surgery

A. T. Yeung

1Desert Institute for Spine Care, Phoenix, AZ, USA

Introduction: Intraoperative neuromonitoring monitoring is used when the spinal nerves are at risk for damage during spine surgery, but is its use in percutaneous transformalinal surgery needed?

Methods: 100 consecutive Patients undergoing Lumbar Transforaminal Endoscopic Discectomy were monitored intra-operatively by SEP and EMG. A comparable group of 100 consecutive patients without neuromonitoring served as the control. Live free-running EMG was recorded during surgery. Responses were graded as: mechanical irritation, or no response. Surface electrodes monitored the Quadriceps (L3/4), Tibialis Anterior (L5), and Gastrocnemius (S1). Anesthesia used: 1% lidocaine, Versed and Fentanyl. Follow-up 2-6 months. SEP was averaged pre-op and immediately post-op and
compared with the asymptomatic leg. Monitoring was by a certified technologist. Tracings were read by a PM and R specialist who performed diagnostic EMGs in his clinical practice.

**Results:** The painful affected leg usually demonstrated latency delays or depressed amplitudes in the SEP waveform. The recorded pathway may also show asymmetries between affected and control limbs. **EMG:** Mechanical elicitation of evoked discharges occurred in 33% of the cases intra-operatively. Discharges correlated with mechanical irritation of the spinal nerves in the foramen. EMG neurotonic irritation patterns was also exhibited during foramino welding. The patient was able to simultaneously feel nerve irritation as pain when the nerve was stimulated mechanically or with radiofrequency and laser. 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, although it provided feedback on the pain source. The patient may report pain even when there was no EMG activity. There was no correlation of EMG irritation patterns experienced intra-operatively with post-operative dysesthesia. Dysesthesia occurred in 5% of patients even when was 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 physical exam evidence of radiculopathy pre-operatively. Some amplitudes increased and others decreased, but post-operative decrease in amplitude was expected, thought to be secondary to the effects of the local anesthetic. EMG stimulation could be correlated with physician visualization and probing of the involved nerve in the operative field.

**Conclusions:** 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. EMG activity can occur during dilator and cannula insertion, even if the instruments are positioned perfectly in the middle of Kambin’s triangle, noting the variability of foraminal nerve anatomy. The patient providing intra-operative feedback to the surgeon when surgery is performed under conscious sedation and local anesthesia is as, if not more valuable than neuromonitoring.

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**Transforaminal Endoscopic Decompression for Recurrent HNP and Foraminal Stenosis in Failed Back Surgery Syndrome in the Lumbar Spine**

* A.T. Yeung*

1Desert Institute for Spine Care, Phoenix, AZ, USA

**Introduction:** Failed back surgery syndrome due to recurrent herniation and foraminal stenosis is common. While conventional surgery for recurrent HNP is nearly as successful as the index procedure, it is a challenge to consider repeat surgery from the same surgical approach for recurrent HNP and residual lateral recess stenosis. Many patients undergo decompression and fusion as a “salvage procedure”.

**Method:** An Independent Research Fellow evaluated the clinical outcome of 30 consecutive patients with FBSS who underwent Selective Endoscopic Discectomy and foramino welding in a spin group practice. Prospective outcome data included modified MacNab, VAS and ODI. Data was collected at the initial office visit, preoperative and postoperative visits, and final follow up. The foraminal endoscopic approach was a shared patient/surgeon decision. All patients elected to avoid fusion, even when recommended in the face of degenerative and Isthmic grade I spondylolisthesis. All procedures were performed at an ambulatory surgical center in a spine group practice setting experienced in the transforaminal endoscopic approach to the lumbar spine. The average follow up time was, minimum 12 months, average 30 months. Levels involved were L3-4=5, L4-5=14, L5-S1=11

**Results:** In the 30 Cases of recurrent disc herniation and foraminal stenosis, average VAS was 6.2, and ODI 43%. Endoscopic decompression for recurrent herniation included foramino welding for foraminal stenosis if the exiting nerve was compromised. Improvement was 4.4 (6.2-1.8) and 33% respectively. "Complications" included dysesthesia in 4 patients within the 2 week post-operative period. Dysesthesia resolved spontaneously in 3 patients within 2 months. 1 patient with moderate dysesthesia took 4 months for resolution. 3/30=10% were considered clinical failures when additional surgery (fusion) was performed after the patient first considered, but rejected fusion as his first option due to residual back pain unacceptable to the patient. Despite the subsequent fusion, patient satisfaction remained high, as all were satisfied with their initial decision in order to avoid “open” surgery even if they subsequently received fusion as a staged procedure. All, even those who subsequently elected subsequent fusion, had initial temporary relief. None were worse following endoscopic transforaminal decompression.

**Conclusions:** The transforaminal endoscopic approach is effective for FBSS due to recurrent HNP and lateral stenosis. The approach does not further destabilize the spine and avoids going through the previous surgical site, and surgical morbidity is minimal. The approach does not “burn any bridges” for subsequent surgery and is effective for FBSS due to recurrent HNP and lateral stenosis. In an extension of the 30 patient study, Residual axial back pain may be improved further with dorsal endoscopic rhizotomy in lieu of fusion. Endoscopic foraminal decompression will add to the surgical armamentarium of FBSS if the patient elects to consider this less invasive and more cost effective procedure first.
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The Early Clinical Comparative Evaluation about Effect of Nucleotomy with Fixation of Dynesys and ISOBAR for Lumbar Disc Herniation
Q. Zhou

1Institute of Orthopaedics of Chinese PLA, Southwest Hospital, Third Military Medical University, Chongqing, China

Objectives: After the nucleotomy for lumbar disc herniation, the intervertebral space is decreased progressively and unsteadiness at the operated segment. As a result of these degeneration, low back pain and lumbar disc herniation will possibly be recurrenced. In our study, through the early postoperative follow-up, the effect of nucleotomy with the fixation of Dynesys and ISOBAR for the lumbar disc herniation were compared and analyzed respectively, and the postoperative lumbar function after nucleotomy with dynamic stabilization and nucleotomy alone were evaluated to investigate the effect of dynamic stabilization on the prevention of degeneration and the reservation of motor function in the operated segment.

Methods: Thirty patients underwent nucleotomy of the lumbar spine for treatment of symptomatic disc herniation. Additional dynamic stabilization (Dynesys and Isobar) was performed in 26 and 24 of those cases. They underwent evaluated before surgery, 6 months after surgery and follow-up. The mean duration of follow-up was 18 months. Examinations included the rate of intervertebral space change (Ris), physical examination, and subjective patient evaluation using Oswestry score (ODI) and visual analog scale (VAS).

Results: Clinical symptoms, Oswestry score, and VAS improved significantly in both groups after 6 months (p=0.000). The intervertebral space in non-stabilization group decreased progressively. And in the Dynesys and Isobar groups, the intervertebral space decreased from the one week after operation to the third month after operation distinctly, but maintained a space from the third month to the last follow-up. The mean degree of flexible and extension in Dynesys and Isobar respectively were 3.49±2.04° and 1.95±0.97° at the last follow-up, and the non-stabilization group was 4.2°±1.1°. In the dynamic stabilization, there were no implant-associated complications.

Conclusions: With the treatment of nucleotomy with the fixation of dynamic stabilization system, lumbar spine function is improved and low lumbar pain is released significantly after operation. Dynamic stabilization can accomplish the postoperative lumbar intervertebral stability, satisfy the lumbar functional demand in movement, maintain the original vertebral normal anatomic structures, and reduce the risk of disc herniation recurrence. Although early postoperative following-up effects are exactly perfect, the loose and break of internal fixation implants, and adjacent segmental degeneration will be observed in a long-term follow-up.

Keywords: Dynamic stabilization, Dynesys, Isobar, lumbar spine, nucleotomy

Cervical Therapies and Outcomes

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Clinical Result and Motor Function Assessment of Artificial Cervical Disc Replacement with Prodisc-C
Q. Zhou

1Institute of Orthopaedics of Chinese PLA, Southwest Hospital, Third Military Medical University, Chongqing, China

Objective: To evaluate the clinical efficacy and effects on the motor function of the replaced level and adjacent segment after artificial cervical disc replacement (ACDR) with Prodisc-C.

Methods: There were 20 patients who received the ACDR with Prodisc-C between April 2009 and February 2011. There were 9 patients with myelopathy, 8 with radiculopathy, and the left 3 with both symptoms. There were 17 participants received single level replacement, while the other 3 got two level replaced. All the patients made computerized tomography (CT) and magnetic resonance imaging (MRI) preoperatively to get an accurate diagnosis, and the VAS scores for neck and arm pain, the Japanese Orthopedic Association (JOA) scores for neck and the cervical spine radiographs have been taken preoperatively and at the scheduled follow-up visits postoperatively.

Results: All 20 participators but one were kept follow up 6 to 18 months. The manifestations including pain of the neck, the numbness of the limbers and the weakness of muscle complained by the patients before the surgery were alleviated dramatically. The VAS and JOA scores were significantly improved after the surgery (P< 0.01). There was significant increase of the range of motion (ROM) of the replacement segment pre- and postoperatively at 1, 3, 6 months (P< 0.01), and so did the results at 12 and 18 month (P< 0.05). There is no statistic difference (P>0.05) before and after ACDR procedure with regard to the height of the intervertebral space and the ROM of the upper and lower adjacent segment. No implant migration, cinch and ectopic ossification were found either.

Conclusion: ACDR with Prodisc-C showed satisfied clinical success during the short-term follow-up visit. There were great improvements on the ROM of the replaced level. The intervertebral space height and the ROM of adjacent segment were fairly normal. While the long-term benefits still need to be followed up.

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Clinical Evaluation of Adjacent Segmental Dynamic Semi-rigid Protection of a Lumbar Fusion
Q. Zhou

1Institute of Orthopaedics of Chinese PLA, Southwest Hospital, Third Military Medical University, Chongqing, China

Objective: Adjacent segmental degeneration and unsteadiness is the frequent complication of a lumbar fusion in the middle-term and long-term. In the base to evaluate and analysis the early clinical outcome of adjacent segmental dynamic semi-rigid protection above
a lumbar fusion, the efficacy, safety and correlated complications of the elastic fixation were assessed in the mid-term. The key point of the operative procedure was summarized.

**Methods:** A group of 21 patients under the adjacent segmental dynamic semi-rigid fixation of a lumbar fusion were analyzed retrospectively. All patients were followed up for 18~36-month. The skill of the operative procedure about the dynamic semi-rigid fixation system was analyzed. The subjective symptom of low back, the motor function of lumbar, the score of therapeutic effect, the height and mobility of the intervertebral space under the elastic fixation, the disc change in MRI and the complication were observed and evaluated.

**Results:** The pedicle screws and dynamic semi-rigid rods were kept bilaterally in coincidence by implanting, and the adjacent segment was fixed in normal physio-anatomical position with the rectification of slight lateral curvature. The low back pain and lower limb symptoms were relieved in all patient. The lumbar anteflexion, extending, lateral flexion and rotation functions were approximately recovered in 70% of cases after surgery for 2~3 months. The height of the intervertebral disc space have no change (p > 0.05) with 1~3° mobility in the X-ray picture of following up, and without the loose and break of internal fixation implant. The advance of the disc degeneration was not found in MRI. **Conclusions:** Dynamic semi-rigid fixation can maintain the height of the adjacent segmental intervertebral space of a lumbar fusion, and the partial motor function of the adjacent segmental was preserved in the early clinical outcome. But long-term clinical outcome can still be unknown and evaluated in future. The more degenerative disc should be selected to be protected by the dynamic semi-rigid fixation. The axis of movement of bilateral dynamic semi-rigid fixation are kept in coincidence and parallel the frontal axis of the disc in order to diminish the complications.

**Keywords:** Lumbar degenerative disease; dynamic elastic fixation; spine nonfusion

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Arthroplasty versus Interbody Fusion in the Treatment of Cervical Disc Herniation with Myelopathy: Five Years Results Comparing Two Different Options

R. Assietti, G.J. Sciarrone

1Ospedale Fatebenefratelli e Oftalmico, Neurosurgery, Milano, Italy

The purpose of this study was to evaluate the possible advantage of arthroplasty as an alternative of the traditional cervical arthrodesis in the treatment of stenotic cervical segments. From January 2002 to January 2008 a series of 30 patients with clinical cervical myelopathy were treated with bryan cervical disc and 30 were treated treated with fusion with Cornerstone peek cages. MR scanning of the cervical spine demonstrated spinal cord compression secondary to disc/osteofyhte complex and there was a of high signal on the T2-weighted studies. The clinical examination in all of the patients showed myelopathy associated to the radicular symptoms. The prosthesis group included 30 patients, 12 male and 18 females (mean age 38, range 27-55), with degenerative disc herniation and/or degenerative osteophytosis to the following levels: 4 C3-C4, 10 C6-C7, 10 C5-C6, 3 C4-C5/C5-C6 and 3 C5-C6/C6-C7. The fusion group included 16 females and 14 males (mean age 46, range 34-59) with pathology to the following levels: 3 C4-C5, 8 C5-C6, 7 C6-C7, 5 C4-C5/C5-C6, 3 C6-C7/C7-D1, 2 C3-C4/C4-C5/C5-C6 and 2 C4-C5/C5-C6.

Although the presence of the myelopathy is, in theory, a contraindication to the segmental motion preservation (also in consideration of the pathogenetic mechanism causing the medullary damage) the indication to implant of a cervical prosthetic device in these cases was young age pathology limited to the level of the disk without spread of stenosis to the vertebral body, and lack significant arthrosis of the articular facets. In all of the cases, the surgeon thought to be able to dismiss the osteophytes and perform a complete discectomy. In the Bryan group no post-operative complications were observed. In all the patients, at two years follow up evaluation, no cases of the prosthesis subsidence were observed, a mean 8° (5° - 16°) degrees of motion with the respect to flexion-extension was observed. In all the cases the patients showed a complete improvement of the radicular symptoms within a week or two from surgery. A significant improvement of the myelopathy was observed at the 2 years follow up as evaluated by a modified JOA scale (t-test p< 0,001). Similar results were obtained in the Cornerstone group except for motion at the operated levels. The comparison of the JOA score at 5 years between the arthrodesis and the prosthesis group showed no statistically significant difference and clinically none of the patients demonstrated a worsening of the clinical status.

The authors believe that when the stenosis is very focal at the level of, or around the level of the disc and when motion is preserved preoperatively, prosthetic treatment of this pathology is a viable option in young patients.

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One-stage Posterior Debridement, Interbody Graft, Rectification and Fixation for Thoracolumbar Tuberculosis

Q. Zhou

1Institute of Orthopaedics of Chinese PLA, Southwest Hospital, Third Military Medical University, Chongqing, China

**Objective:** To investigate the clinical outcome of one-stage posterior debridement, interbody graft, rectification and fixation for thoracolumbar tuberculosis.

**Method:** A total of 30 cases with thoracolumbar tuberculosis between January 2004 and March 2010 were reviewed retrospectively. All cases underwent one-stage posterior debridement, interbody graft and...
instrumentation, The operation time, intraoperative blood loss, bone fusion, intra- and post- operation complications, ASIA grade and Cobb’s angle before and after surgery were reviewed.

**Result:** All cases were followed up for 12-62 month, average time 25.2month , the average operation time was 390 min, the average blood loss was 858 ml, the average hospitalization was 26.4 d. During follow-up, 1 case was found Tuberculosis recurrence and internal fixation broken, and was cured by posterior debridement of lesion with fixation. the remains of cases had evidence of solid bony fusion without any instrument failure. Preoperative neurological function of ten cases with neurological deficit were improved significantly postoperative. The average Cobb’s angle decreased from 16.3° preoperatively to 8.1° postoperatively and final follow-up is 12°.

**Conclusion:** Posterior debridement, interbody bone graft and instrumentation can get good clinical outcome for thoracolumbar tuberculosis with the advantage of minimal invasive. The correction of angular deformity is more safe and effective with posterior instrumentation, especially with transpedicular instrumentation. The posterior approach is good alternative for the surgical treatment of thoracolumbar tuberculosis.

**Keywords:** Thoracolumbar tuberculosis, posterior spinal debridement spinal tuberculosis

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**PDN Replacement for Lumbar Disc Herniation and Analysis of Complications**

Q. Zhou

1Institute of Orthopaedics of Chinese PLA, Southwest Hospital, Third Military Medical University, Chongqing, China

**Objectives:** To evaluate the results of PDN replacement for lumbar disc herniation and explore the cause and mechanism of complication.

**Methods:** Twenty-five cases of the lumbar disc herniation received the surgery of PDN replacement, the date of which was Retrospectively analyzed. The subjective symptom of low back, motor function of lumbar, the score of therapeutic effect, the height and mobility of the intervertebral space, the disc change in MRI and the complication were observed and evaluated.

**Result:** Eighteen cases were followed up over 5 years. all the patients’ lower limb symptoms were relieved and nerve function was gradually recovered. PDN migrated into the vertebral canal in 2 cases after the surgery for one week ,which were removed by the secondary surgery. Severe low back pain emerged in two cases after operation for two months and three months respectively, with the obvious degression of intervertebral space on X-ray film and the change of severe end-plate inflammatory on MRI. The two cases received the lumbar fusion after 12 months and 15 months. Ten cases in the postoperative 5 ~ 14 days underwent a sense of mild lumbar discomfortation, which gradually relieved in short term. In the 14 cases, the motor function have kept normal situation during 5-year following up. The measurement of X-ray film show that the mobility of lumbar segment under surgery was normal or approximate normal, but intervertebral disc space became mild narrow, the migration of PDN in the intervertebral space was observed in the most of the cases. In the mean time, the different degree of end-plate inflammation was observed on MRI in all cases. The rate of excellent and good was 78%.

**Conclusion:** PDN replacement for lumbar disc herniation play a certain role in the maintain of the lumbar segment motor function. The herniation of artificial prosthesis and severe low back pain were the main complications of PDN replacement, which frequently occurred in the short term after surgery ,which may be attributed to the false of indication selection and implanting techniques, the defect of prosthetic design and immune reaction of implant materials.

**Keywords:** PDN replacement lumbar disc herniation postoperative complications

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**Lumbar Fusion by Bilateral Pedicle Approach in Posterior Median Little Incision**

Q. Zhou

1Institute of Orthopaedics of Chinese PLA, Southwest Hospital, Third Military Medical University, Chongqing, China

**Objectives:** Conventional posterior lumbar fusion has disadvantages of extensive dissection of paraspinal muscles, Severe trauma, much hemorrhage, slow recovery and complications of chronic low back pain and stiff waist. The clinical research is evaluated the clinical efficacy and skills of bilateral pedicle approach of posterior median little incision in lumbar fusion in order to explore a mini invasive and economical lumbar approach.

**Methods:** The group of 159 cases were undergone the lumbar fusion by bilateral pedicle approach in posterior median little incision, 136 cases of which were performed single-segmental fusion, 23 cases of which were performed double-segmental fusion. The lines of the bilateral pedicle axes at upper and lower segments were marked on body surface under A-P X-ray, then the posterior median incision was made between the two lines. The back fascia were cut open along bilateral supraspinail ligament, and sacrospinalis fascia were cut open along the line of 2 ~ 2.5cm lateral to spinous process. The limited exposure was performed between the upper pedicle and lower pedicle. The excision of intervertebral joint and part of laminae, the reduction of intervertebral-body, spinal canal decompression and the fixation of implant were performed. The A-P and lateral position and L-spine Lordotic Kyphotic Position X-ray film, CT and MRI of Lumbar were performed before surgery. The cases were regularly followed up with lumbar X-ray and lumbar motor function examination, some of which with three-dimensional CT and MRI.

**Results:** Operative time of single-segment fusion is 2.5 ~ 3.5 hours, operative time of double-segment fusion is 3.5 ~ 5.5 hours. Mean amount of bleeding 180ml in single-segment fusion, average amount bleeding is 350ml in double-segment fusion. Mental states were recovered
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to normal in all patients after 24 hours of surgery. The degree of pain in this group of cases is obviously less than that of the cases with conventional lumbar fusion. All patient could roll over without assisting and walk with orthosis after 48 hours of surgery, and gradually return their daily life. 126 cases of the group were followed up for 6-30 months, all of which were bony fusion, 3 cases of which were suffered with chronic low back pain and stiff waist, 123 cases of which had normal lumbar function. The results were evaluated with the criteria of Macnab, the total effective rate was 96.3%.

Conclusions: The bilateral pedicle approach in posterior median little incision is fit for one or two segmental lumbar fusion. By the approach with limited exposure, all of the procedure in lumbar fusion surgery not only can be performed but also the implanting of pedicle screw is made easy and the injury of the adjacent anatomy structure is avoided with better protection of the nerve and muscle and less bleeding than by the lumbar posterior median approach. This lumbar operative approach has less trauma, less hemorrhage, faster recovery, less complications than the lumbar posterior median approach, and its skills is easy to be grasped and applied in surgery.

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Survivorship Analysis of Posterior Dynamic Instrumentation - Two Year Follow up of 409 Patients from Two Medical Centers
P.C. McAfee¹, J. Lindley²
¹St. Joseph’s Hospital, Spine and Scoliosis Center, Towson, MD, USA; ²Neurosurgery Institute of Savannah, Savannah, GA, USA

Purpose: Posterior dynamic instrumentation has been one of the most challenging areas of motion preservation engineering due to high failure rates, recalls, and screw loosening. The authors wished to study the survivorship and revision incidence on a cohort of patients.

Methods: 409 patients were treated with TRANSITION posterior dynamic instrumentation in the thoracolumbar spine at two medical centers, Savannah, GA and Baltimore, MD. The application of this modular system has the advantages of
a) improved load sharing with a cushioning of the anterior column as the pedicle-to-pedicle distance can gradually shorten with time.
b) the pedicle screw attachments can be placed in one of several lordotic positions.
c) the instrumentation system contains an end bumper which increases the amount of elastomeric material available for dynamic force transmission.

The three main applications of the novel system were
1) anterior load sharing with an anterior and middle column spacer (TLIF or ALIF);
2) hybrid application adjacent to conventional static 5.5 mm rods; and
3) topping off longer static scoliosis constructs of up to 300 mm in length.

Results: The indications for surgery in these 409 cases were—spinal stenosis, 56%; spondylolisthesis, 24%; junctional instability, 34%; HNP, 33%; and scoliosis, 21% (overlap within same patient). The follow up was a minimum of 24 months. Complications included epidural hematoma (1), infections (2), CSF leakage (1); screw repositioning (1) screw breakage (17 screws); malrotation of a TLIF spacer (1); and death in 3 patients in which the indications were overextended into patients with extreme co-morbidities.

Survivorship raw data was analyzed with Kaplan-Meier estimates and the lower bound of a two-sided 95% CI for the survival rates are illustrated on the graph below. This was time to first event, so it ignored the 2nd procedure information—3 patients required two revision procedures. Peto’s method was used to estimate the survival rate. At two year’s follow up the survivorship for TRANSITION was 95.8% (lower bound at 92%).

Conclusions: The survivorship and longevity of TRANSITION was favorable compared to reported series of Dynesys, Agile, N-Hance, and ScientX. The TRANSITION system used porous ingrowth screws which virtually eliminated the incidence of screw loosening. The revision procedures were straightforward and usually involved replacement of a screw and conversion to conventional static 5.5 mm instrumentation.

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Epidural Lipomatosis as a Cause for High Impedance Values during a Neuromodulation Trial
T. Davis¹, C. Schulz²
¹Director of Physical Medicine and Interventional Pain, The Spine Institute, Santa Monica, Santa Monica, CA, USA; ²UCLA, Physical Medicine and Rehabilitation Residency, Los Angeles, CA, USA

Introduction: Spinal cord stimulators have been used to treat a variety of pain conditions including chronic neuropathic limb pain. A neuromodulation trial typically involves lead placement and stimulation in the lower thoracic levels without major complication or drastic changes in impedance values. However, cases have demonstrated abnormally high impedance readings due to epidural fibrosis, abnormally large canal diameters or burrowing into the ligamentum flavum. Spinal epidural lipomatosis is a rare pathological overgrowth of adipose tissue in the extradural space that has been linked to excess exogenous cortisol use or endogenous cortisol production. To date, there is limited published literature on how spinal epidural lipomatosis may affect impedance values during a neuromodulation trial.

Case report: We present a case of a patient with a thoracic epidural lipomatosis who failed a neuromodulation trial. During lead placement, significantly higher impedance values were noted in an area dorsal to the T8 vertebral body compared to adjacent levels. Leads were then successfully placed at the level above, but the intraoperative and patient trial failed to relieve her neuropathic pain between the waist and popliteal fossa. The leads were then removed without complications. A subsequent MRI of the thoracic spine revealed T8 dorsal epidural lipomatosis that...
Directly correlated to the high impedance levels during the neuromodulation trial. 

**Conclusions:** Spinal epidural lipomatosis causes a dramatic increase in epidural impedance values, which may, in turn, lead to neuromodulation trial failure. Epidural lipomatosis should be considered as a possible cause of abnormally high impedance during a neuromodulation trial.

### Lumbar Therapies and Outcomes

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Safety and Efficacy of the Minimally Invasive Lateral Transpsoas Interbody Fusion vs. Posterior Lumbar Interbody Fusion in Overweight and Obese Patients

*K.T. Huntsman*, M.A. Berdugo

1Salt Lake Orthopaedic Clinic, Salt Lake City, UT, USA

**Background:** The long-term complications of lumbar surgery in overweight and obese patients have been well documented; however, a comparative review of the surgical complications of Extreme Lateral Interbody Fusion (XLIF) versus posterior lumbar interbody fusion (PLIF) in overweight, obese, and morbidly obese have not been documented.

**Methods:** Retrospective analysis of 57 obese patients (33 female and 24 male) who have undergone one to multilevel XLIF procedure between 2006 - 2010 with a literature analysis and comparison of obese patients who have undergone PLIF. Fifty-seven patients with one to multilevel XLIF procedures performed were retrospectively analyzed. Outcomes from several published articles on PLIF procedures on obese patients were compiled, analyzed, and finally compared to the outcomes of the XLIF procedures. Obesity scale used was the CDC scale, where: 25-29.9 is Overweight and 30 or higher is obese.

**Results:** Average age of XLIF patients was 64.50 ± 11.36, average BMI was 30.71 ± 4.61, average levels fused were 2 ± 0.8, and average estimated blood loss (EBL) during surgery was 75.65 ± 106.85, LOS in hospital was 2.57 days. Short-term side effects: Transient Psoas weakness (54%), Transient Anterior thigh dysthesia (12%), Resolution of side effects within an average of 3 weeks. Diagnoses include DDD (32), Radiculopathy (30), LSS (26), Foraminal Stenosis (7), Spondylolysis (4). Associated underlying pathologies reported were Diabetes Mellitus (14), smokers (7), thyroid disease (3). Patient reported outcomes were compiled, analyzed, and finally compared to the outcomes of the XLIF procedures. Obesity scale used was the CDC scale, where: 25-29.9 is Overweight and 30 or higher is obese.

**Conclusion:** The XLIF procedure is a safer and a more effective option than PLIF for lumbar fusion in patients who are overweight, obese, and morbidly obese. These results indicate that this procedure can minimize the risk of developing complications, therefore minimizing the possibility of re-intervention. Furthermore, long-term clinical and radiologic data demonstrate successful fusion in this demographic. Many of the complications noted in this review were a consequence of a combination of a high BMI and underlying co-morbidities, which regardless of the procedure, are expected in this demographic.

### Biomechanics/Basic Science

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Design, Fabrication and in vitro Test of a Dynamometric Interspinous Distractor for the Study of Lumbar Instability at the Interspinous Space

*L. Perez-Orribo*, V. Garcia-Marin*, S. Kalb*, N. Theodore*, N.R. Crawford*

1Hospital Universitario de Canarias, Santa Cruz de Tenerife, Spain, 2Barrow Neurological Institute, Spinal Biomechanics, Phoenix, AZ, USA

**Purpose of study:** Currently, numerous lumbar spine arthrodesis and dynamic stabilization systems are being used to treat lumbar degeneration without an objective quantification of instability during surgery. With this study, we present an innovative method that measures instability at the lumbar segment in situ.

**Methods:** We performed sequential anatomical dissection of four cadaveric lumbar spines. Using a dynamometric distractor designed by the authors placed at the interspinous space, measurements of the static distraction force needed to separate the spinous processes by 5 mm were performed. Measurements were obtained before and after the dissection of paraspinal musculature and the removal of the supraspinous ligament, removal of the interspinous ligament, unil and bilateral flavectomy, and unil and bilateral discectomy. All motion segments from L2-L3 through L5-S1 were analyzed in each specimen. The amount of separation obtained after a distraction force of 100 N was also analyzed in all segments and specimens.

![Fig. 1. Instrumented spinous process distractor.](image)

**Results:** The resistance of the motion segment to distraction forces dropped 37.9% after the resection of the supraspinous ligament. After adding unilateral discectomy, resistance of the motion segment further
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dropped to 47% in total (p < 0.001, ANOVA on Ranks, typical error < 1N).

[Fig. 2: Drop in force with sequential resection.]

Conclusions: We have developed a new, accurate, and reproducible method for measuring lumbar instability that is useful during surgical procedures without changing the surgical strategies or adding risk. Our preliminary results highlight the stabilizing roles of the different anatomical structures of the motion segment, awarding a real and objective value to each structure. These results demonstrate the importance of the supraspinous ligament and annulus as the main structures resisting sagittal flexion of the lumbar motion segment.

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A Novel Approach to a Challenging Clinical Scenario - Revision Surgery for L5-S1 Pseudoarthrosis
D.R. Lebl1, F. Taher1, A.A. Sama1, F.P. Cammisa1, F.P. Girardi1
1Hospital for Special Surgery, Spinal Surgery, New York, NY, USA

Background: Pseudoarthrosis at L5-S1 is a relatively common problem following long fusion to the sacrum. Revision approach to L5-S1 for cage or graft removal by ALIF, PLIF, or TLIF is challenging and potentially dangerous which makes salvage by a posterior reamed transacral technique appealing. Here we present the technique, radiographic and clinical outcomes of a series of patients that underwent a novel method for revision L5-S1 interbody fusion.

Methods: Consecutive patients with symptomatic pseudoarthrosis at L5-S1 who underwent a novel posterior reamed (utilizing an ACL reamer) fluoroscopically-guided technique were identified over a 3-year period. Operative notes, medical records, pre- and postoperative plain radiographs, CT scans, Visual Analog Scores (lower extremity and low back) preoperatively and at most recent follow-up were studied.

Results: Ten patients age 53±2.8 yrs with prior lumbar spinal operations (mean 3.5±0.6) met inclusion criteria. Prior procedures at L5-S1 were ALIF(n=4), PLIF(n=3), and PLF(n=3). Mean Meyerding grade was 1.41(range 0-4). Reaming was performed between the S1&S2(n=9) or S2&S3(n=1) nerve roots and allowed fragmentation/removal of PEEK interbody grafts (n=3) or femoral ring allografts (n=3).

Transacral Harms cage (n=8) or autograft (n=1) was passed through the reamed channel or a carbon fiber reinforced PEEK directly into the interspace (n=1).

Conclusions: We report a series of patients that underwent a revision novel technique for symptomatic lumbosacral pseudoarthrosis. Despite the small numbers in this cohort, a salvage technique is presented that permitted fusion as confirmed by CT scan and improved VAS scores in the majority of patients. The data suggest that this technique should be considered as an alternative to revision anterior or posterior approaches to L5-S1 and merits further investigation.

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Can Non-fusion Fixation Work in the Lumbar Spine? A 4 Year Outcome Study Using Cosmic Fixation
P.F. de Muelenaere1,2
1University Manitoba (at Brandon), Orthopaedics, Brandon, MB, Canada, 2Brandon Medical Arts Clinic, Brandon, MB, Canada

Purpose: The purpose of this prospective study was to evaluate the late outcome and safety of fixation of the lumbar spine, without fusion, using the Cosmic fixation system. This pedicle based system has hinged screws allowing motion in flexion and extension only, giving non rigid fixation.

Method: A prospective study of 107 patients who underwent one or 2 levels fixation without fusion was undertaken from January 2006 to August 2008. Completely non fused fixation was done in 40 patients while 67 underwent hybrid fusions. During the same time 299 standard fusions were performed at the same
in order to fix the endplates of artificial disc to the adjacent vertebrae. The metals have a strong radiolucency. Most other cervical artificial discs either are made of all metals or contain two metal plates which are radiolucent. NuNec is made of PEEK OPTIMA, which is patient with radiculopathy and/or myelopathy caused by disc degeneration disease at C3-C7 levels. 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. There was no major intra-op and post-op complication occurred in this series. In the follow-ups ranged from 3 to 6 months, patients experienced significant pain reduction and functional improvement 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. In 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.

Cervical Therapies and Outcomes

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Early Clinical Experience of NuNec Artificial Cervical Disc
D. Zou

306 Hospital of PLA, Beijing, China

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. 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 radioluency. 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.

Lumbar Therapies and Outcomes

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Use of MIRDC® Chitosan-enveloped Titanium Cage to Minimize Soft Tissue Infiltration Following Lumbar Spinal Fusion Surgery

1Chimei Medical Center, Tainan, Taiwan, Republic of China, 2I-Shou University, Department of Orthopedics, E-DA Hospital, Kaohsiung, Taiwan, Republic of China, 3Metal Industries Research and Development Center, Kaohsiung, Taiwan, Republic of China

Introduction: Minimizing soft tissue infiltration is a key challenge in spinal fusion surgery. Recently, considerable attention has been given to chitosan-based materials in the field of orthopedic tissue engineering. This study investigated whether use of MIRDC® chitosan-enveloped titanium cage in lumbar spinal fusion surgery results in better minimization of tissue infiltration.

Methods: One titanium cage with collagen and one chitosan-enveloped titanium cage were both surgically implanted in vertebral wings L3-4 in six pigs (Lanyu 300, Taitung, Taiwan). Minimizing effect on soft tissue...
infiltration between both sets of cages was determined by radiology one, three and six months after surgery. **Results and discussions:** Although there were no significant differences between the two conditions one and three months after surgery, the data showed MIRDC® chitosan-enveloped titanium cage was more effective when compared with titanium cage with collagen in minimizing soft tissue infiltration six months after surgery. **Conclusions:** MIRDC® chitosan-enveloped titanium cage was not only more beneficial than titanium cage with collagen in promoting spinal fusion, but also proved more effective in minimizing soft tissue infiltration. **Acknowledgements:** This grant was wholly supported by Metal Industries Research and Development Center (MIRDC), Kaohsiung, Taiwan. **References:**
1. Di, M. A., Sittinger, M., and Risbud, M. V., Biomaterials 26, 5983-5990, 2005
2. Xue, Q., Li, H., Zou, X., Dalstra, M., Lind, M., Christensen, F. B., and Bunger, C., Int. Orthop. 34, 447-451, 2010

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**Lumbar Therapies and Outcomes**

487 Clinical Application of Posterior Paramedian Approach in Low Back Surgeries

D. Zou

³06 Hospital of PLA, Beijing, China

**Objective:** Though traditional posterior median approach is widely used in spine surgery, reports of its application in low back surgery and its advantages/disadvantages in laminectomy decompression are seldom seen. Common clinical complications due to the defects of this traditional approach are misplacement of pedicle screws or other implantations, incomplete relief of original symptoms after laminectomy and decompression, triggering of new nerve root irritating symptoms and post-op intractable low back pain due to long period of para-spinal muscle traction. retracting the canal space after laminectomy and decompression are seldom seen. Common clinical complications due to the defects of this traditional approach are misplacement of pedicle screws or other implantations, incomplete relief of original symptoms after laminectomy and decompression, triggering of new nerve root irritating symptoms and post-op intractable low back pain due to long period of para-spinal muscle traction. Retracting the canal space after laminectomy to perform intervertebral fusion could also cause nerve damage.

**Material and methods:** Study group includes 30 cases, DDD 8 cases, Spondylolisthesis 6 cases, LDH 11 cases, Low back surgery failure re-operation 5 cases. Based on the comprehensive understanding of modern spine anatomy, "the Spinal canal" does not display a complete hermetic bony appearance. Vertebral body, the basic bony functional component of the spine, are complete independent segments. The connection in between is the intervertebral joint, a triangular matrix complex composed of the anterior disc and posterior facets with no corresponding bony structure in order to provide 3 dimensional movement in 6 different directions. Hence, for a segmental structure like the spinal canal, excluding conditions such as lamina congenital dysplasia and OPLL, there will be no such thing as continuous bony structured spinal stenosis. The spinal canal is formed by alternating “soft” and “hard” elements, the hard bony structure of the canal will not become narrow after maturity, but the soft structure - intervertebral joint which provides movement, will accumulated the load from everyday activities and develop degenerative changes such as loss of disc height, LDH, facet cohesion, causing the stenosis in the “soft” part of the spinal canal. According to the evidence above, laminectomy is not an effective procedure to free the compressed nerve running through the degenerated soft spinal canal, on the other hand might even destroy the stabilization of the posterior column. We applied a mid-waist skin incision, dissect to the paraspinous muscles where you could easily reach the facets by separating between the multifidus and longissimus, enlarge the canal by performing resection along ligamentum flavum and the inner broader of the articular process, remove enough tissue till you could expose the traversing root and the disc space. Once the anatomy mark of the pedicle is located (usually would be at the central area of the incision), pedicle screws placement would be precise and easy without struggling with muscle traction. The following procedures would be Spondylolisthesis reduction, discectomy and interbody fusion.

**Result:** Post-op patients of study group all showed significant improvement of pain symptoms, VAS reduced from 7.5 pre-op to 1.5 post-op, narrowed disc space regained height, spondylolisthesis reached anatomic reduction, no complications such as pedicle screw misplacement and nerve root damage were found. Significant difference is discovered (P< 0.001) in statistic study concerning the rate of intractable low back pain between para-median approach to traditional median approach.

**Conclusion:** Applying low back surgery through posterior para-median approach has the advantage of lowering the surgical difficulty of implantation, reducing the risk of nerve damage and is also a minimum invasive procedure. In many cases, laminectomy is unnecessary, leaving the lamina intact could preserve the physiological anatomy of the spine.

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**MIS Technique and Results**

489 Additional Pain Block Procedures Combined with Kyphoplasty for the Patients with Osteoporotic Vertebral Compression Fractures

M.-S. Kim¹, D.-H. Lee², N.H. Kim²

¹Incheon Medical Center, Dept. of Orthopaedic Surgery, Incheon, Korea, Republic of, ²Asan Medical Center, Univ. of Ulsan, College of Medicine, Dept. of Orthopaedic Surgery, Seoul, Korea, Republic of

**Introduction:** Vertebroplasty and kyphoplasty have gained wide acceptance in treatment of painful osteoporotic vertebral compression fractures (OVCF). However, we could observe some patients continuously suffered with disability due to remaining back pain even after these procedures. The remaining back pain
might come from the accompanying pathologies of nearby muscles, fascias, and facet joints. We performed additional pain block procedures in conjunction with kyphoplasty (KP) for the patients who had acute OVCF and analyzed their effectiveness. 

Materials and methods: This is a retrospective, single institution, matched-pair study with minimum 1-year follow-up. Thirty five consecutive patients simultaneously underwent pain block (PB) at the time of KP due to painful single-level OVCF in thoracolumbar junction area (T10-L2). For pain block, 2:1 mixture (8 cc) of bupivacaine and triamcinolone was injected into the fascias and facet joints on which the patients complained tenderness. Among them, twenty eight patients (male:female = 9:19) were followed up longer than 1 year. Based on age, gender, preoperative bone mineral density (BMD), and vertebral height loss, they were matched with other 28 patients who previously underwent KP alone without any pain block procedures with same indications. Visual analog scale (VAS) of back pain and Oswestry Disability Index (ODI) score were evaluated preoperatively and at postoperative 2 day, 6 week, 6 month, and 1 year. Short Form - 36 (SF-36) questionnaire was also assessed at postoperative 6 weeks, 6 month and 1 year. The independent samples t-test and chi-square test were used for statistics analysis (SPSS v18.0).

Results: There were no significant differences between PB (+) and PB (-) groups with regard to age, gender, preoperative BMD, and vertebral height loss (p>0.05). Preoperative back pain was similar in both groups (6.1±1.2 vs 6.1±1.4, P>0.05), however, the mean VAS scores in PB (+) group were significantly lower than those in PB (-) group until postoperative 6 week (2.3±0.8 vs. 3.9±0.9 at 2 day, P< 0.001; 2.4±1.0 vs. 3.7±1.1 at 6 week, P< 0.001). The mean ODI scores in PB (+) group were also significantly lower than those in PB (-) group at both 2 day (35.3±13.9 vs. 46.4±12.9, P=0.003), and 6 week (31.5±13.7 vs. 40.0±11.3, P=0.014) postoperatively. These differences in VAS and ODI decreased with time. At 6 month and 1 year after KP, PB (+) group still demonstrated less back pain and disability than PB (-) group, however, the differences were not statistically significant. The mean SF-36 scores were significantly greater in PB (+) group than PB (-) group until 6 week and became similar to each other at 6 month and 1 year postoperatively. There was no complication associated with PB procedures.

Conclusion: Additional pain block procedures were effective for the control of remaining back pain and disability following kyphoplasty. It further relieved back pain and consequently improved patients’ function and quality of life for at least 6 weeks, which could contribute to patients’ early rehabilitation and satisfaction after kyphoplasty.
MIS Technique and Results

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Minimally Invasive Transforaminal Lumbar Interbody Fusion: The Surgical Learning Curve
K. Singh1, M. Pelton1
1Rush University Medical Center, Orthopaedic Surgery, Chicago, IL, USA

Background context: Recent studies have demonstrated that Minimally Invasive (MIS) Transforaminal Lumbar Interbody Fusion (TLIF) may have significant short and long-term clinical benefits. Very few studies have characterized a surgeon’s learning curve with this technically demanding technique.

Purpose: The purpose of this study is to characterize based upon intra- and peri-operative parameters, the learning curve for one practicing spine surgeon during his initial phases of performing an MIS TLIF.

Study design: This study was a non-randomized, non-blinded prospective review.

Patient sample: 75 consecutive patients with at least one year follow-up that underwent a single-level MIS TLIF by one spinal surgeon were evaluated. Only those patients that were single level, primary surgeries were included (Table 1). Every patient had a diagnosis of either degenerative disc disease or spondylolisthesis and stenosis. Patients underwent a laminectomy with bilateral facetectomy and foraminotomy using a 21mm non-expandable tube with unilateral pedicle screw fixation and a single intervertebral cage.

Outcomes measures: Surgical time (Skin-Skin, minutes), anesthesia time (Induction-Extubation, minutes), estimated blood loss (cc), IV fluids during surgery (cc), intraoperative complications (durotomy) and post-operative complications (pseudarthrosis, hardware failure, malpositioned instrumentation).

Methods: Patients were analyzed chronologically from the date of surgery. A total of 75 patients were identified with at least one year follow-up and CT scan analysis. The study cohort was split in half based upon the initial date of surgery. A two-tailed, unpaired T-test was performed. Pearson’s correlation coefficient was used to characterize the relationship. Statistical analysis was conducted by SPSS Version 17.0.

Results: Average surgical time was significantly longer in the first cohort (130 mins versus 104; p = 0.001) (Table 2). Estimated blood loss was also significantly greater in the first group. (201 cc versus 98 cc; p < 0.001). Intraoperative IV fluids and duration of anesthesia were greater in the first group than the second (p < 0.05). There were no significant differences in intraoperative complications (two durotomies in both groups). Additionally, there was no significant difference in the rate of pseudarthrosis at final follow-up based upon CT analysis (1 versus 1). There was one case of graft migration identified in the second group. No post-operative infections or persistent dural leaks were identified in either group. Pearson’s correlation coefficient demonstrated that the date of surgery is related to decreased IV fluids (r = -0.356; p = 0.002), decreased EBL (r = -0.430; p < 0.001), decreased surgical time (r = -0.361; p = 0.001) and decreased duration of anesthesia (r = -0.316; p = 0.006).

Conclusions: The MIS TLIF procedure presents a significant learning curve to the practicing spine surgeon with regards to intra- and peri-operative parameters of surgical time, EBL, IV fluids and duration of anesthesia. Limitations of the study are clear in that only a single surgeon’s experience is evaluated. Nevertheless, it is apparent that operative time and proficiency does rapidly improve in adapting to a minimally invasive technique. Close attention to detail can minimize complications that may be associated with the learning curve.

Cervical Therapies and Outcomes

493
Bow-string Principle or Traction Mechanism? Posterior Shifting Pattern of Spinal Cord Following Cervical Open-door Laminoplasty
Y.Z. Diao1, Y. Sun1, F.S. Zhang1, S.F. Pan1, X.G. Liu1, Z.J. Liu1, G.T. Dang1
1Peking University Third Hospital, Beijing, China

Objectives: To investigate influencing factors and the pattern of posterior movement of spinal cord after cervical laminoplasty, and to offer evidence to more reasonable surgical strategy.

Methods: Forty-three patients with compressive cervical myelopathy were performed open door laminoplasty from C3 to C7, whose pre- and postoperative imaging data were studied. Parameters indicating shift distance of cord and dura, local curvature at each level, and the overall curvature of cervical spine were determined.

Table 1 and 2

[Table 1 and 2]
Then correlation analyses of the parameters above were performed with SPSS 15.0.

**Results:** The anterior margin of dura rarely changed its location after surgery, however SCA (shift of cord anterior margin), SCP (shift of cord posterior margin) and SDP (shift of dura posterior margin) changed significantly and synchronously. At the level of C5/6, SCP was the maximum, but not correlated to the overall curvature (P=0.197). Actually, SCP was correlated to the local curvature (r=0.392, P< 0.001) and highly correlated to SDP (r=0.927, P< 0.001) at the same level.

**Conclusion:** Not the overall curvature but local factors such as the degree of dura expansion and local curvature affected the shift of spinal cord. The finding that SDP was the most influencing factor suggested the cord is probably influenced mainly by the traction conducted from dura to migrate passively to balanced location following laminoplasty. According to this mechanism, decompression range for laminoplasty can be selected according to compression segments; although the cervical curvature is straight or slight kyphosis, the cord may still shift significantly.

**Biomechanics/Basic Science**

**497**

**Growing Spine Profiler - A New Device in the Treatment of Progressive Spinal Deformities, Early Results**

D. Zarzycki1, T. Potaczek1

1Jagiellonian University, Faculty of Medicine, Department of Orthopedic Surgery and Rehabilitation, Zakopane, Poland

**Introduction:** Treatment of progressive spinal deformities in “growing” population is a challenge. Available solutions include classic growing rods, expandable prosthetic rib and techniques not requiring staged surgery, e.g. Shilla. Growing Spine Profiler (GSP) is a new distractible rib-vertebra construct designed for pediatric population.

**Material, methods:** Study group consists of 27 patients; 13 with congenital defects (gr.A), 8-syndromic deformity (gr.B), 6-idiopathic scoliosis (gr.C), treated in a single center. Mean age at surgery was 7.1 (3-13).2 patients were previously treated with different “growing” constructs. Lengthening procedures were performed every 6 months, no external support was used. Mean curve preoperatively was 87.8°. We evaluated course of surgery, number of additional interventions, obtained direct correction, loss of correction, spine length, space available for lungs (SAL) ratio. Minimal follow-up period was 6 months, mean 8.3 (6-22).

**Results:** The implantation procedure was uneventful in all cases, mean blood loss 55ml, surgery time 82 minutes. Three cases of early complications were noted: one screw pull-out, two cases of hook dislodgement, complication rate was 10.7%. No cases of instrumentation failure were noted. 18 lengthening procedures were performed, all uneventful. Direct correction after implantation procedure was 38.6%; at final follow-up 32.9%. T1-T12 and T1-S1 length increased by 11% and 12.5% respectively. SAL ratio increased by 8.9%. The coronal and sagittal balance were within 20mm.

**Conclusions:** The new rib cage-spine distraction system offers decent direct curve correction with a low complication rate compared to other “growing” systems. The lengthening procedures are simple. In this series good correction was obtained in all groups, lowest in gr.A (31.3% vs. 35.3% vs. 35.3%). The increase of SAL ratio is stable over this early follow-up period.

**Lumbar Therapies and Outcomes**

**502**

Direct Neurologic Decompression Improves Functional Neurologic Outcomes in Spinal Stenosis and Low-grade Spondylolisthesis: A Comparison of Coflex® Interlaminar Stabilization, Laminectomy and Spinal Fusion, and X STOP

J.D. Auerbach1, C. Lauryssen2, R.J. Davis3

1Bronx-Lebanon Hospital Center, Bronx, NY, USA, 2Department of Neurological Surgery, Los Angeles, CA, USA, 3Greater Baltimore Neurosurgical Associates, Baltimore, MD, USA

**Introduction:** Interspinous process device technologies have been developed to complement conservative care, laminectomy, and laminectomy with or without spinal fusion as treatment options for spinal stenosis and low grade degenerative spondylolisthesis. While the X STOP interspinous implant relies upon indirect decompression and fixation to the spinous processes, the coflex® interlaminar stabilization device is implanted following a direct neurologic decompression, and is fixated to the stronger laminar bone. The purpose of this study is to compare 2-year functional outcomes in patients treated with X STOP, coflex® interlaminar stabilization device, or spinal fusion in the treatment of spinal stenosis with up to Grade 1 spondylolisthesis.

**Methods:** Comparative analysis of the results of two separate, independent, randomized, prospective, multicenter Food and Drug Administration Investigational Device Exemption trials comparing:
1) conservative care with X STOP, and
2) direct decompression and coflex® interlaminar stabilization with decompression and fusion.

In the coflex® IDE trial, a total of 219 patients (146 coflex® and 73 fusion controls) were randomized and treated from 21 US sites to receive direct decompression and coflex® interlaminar stabilization or laminectomy and posterolateral spinal fusion with spinal instrumentation in a 2:1 ratio. In the X STOP IDE trial, a total of 191 patients (100 X STOP and 91 controls) were randomized and treated from 9 US sites to receive X STOP or to continue with conservative treatment.

The primary outcome measure was Zurich Claudication Questionnaire, a patient-reported validated functional outcomes instrument for spinal stenosis and neurogenic claudication. Composite success criteria required a 0.5 point improvement in ZCQ-Functional Physical and ZCQ-Symptom Severity, and < 2.5 in ZCQ-Patient Satisfaction.
Results: At 2 years, Composite ZCQ success was achieved in 75.7% of coflex® patients, compared with 68.3% of fusion controls, and 48.4% of X STOP patients. The proportion of patients achieving success was significantly higher in the coflex® cohort than in the X STOP cohort (p<0.001). Similarly, fusions also significantly outperformed the X STOP cohort (p=0.019). There were no significant differences between the coflex® and fusion cohorts (p=0.37).

Conclusions: Coflex® interlaminar stabilization following direct decompression facilitated superior ZCQ composite success at 2 years compared with X STOP to treat spinal stenosis and degenerative spondylolisthesis, and nonsignificant improvements over laminectomy with spinal fusion. Similarly, laminectomy with spinal fusion led to significant improvements over X STOP. Our data highlights the fact coflex® and X STOP are intended for different patient populations, and also suggests that there are clear benefits of direct neurologic decompression that is facilitated with either coflex® interlaminar stabilization or with laminectomy and fusion over indirect decompression alone with the X STOP interspinous implant.

Lumbar Therapies and Outcomes

506 Comparative Cost-effectiveness Analysis of Coflex Interlaminar Stabilization versus Posterolateral Fusion for Lumbar Stenosis and Low-grade Spondylolisthesis

J.D. Auerbach1, J.D. Zigler2, R.J. Davis3, K. Pettine4, A. Yeung5
1Bronx-Lebanon Hospital Center, Bronx, NY, USA, 2Musculoskeletal Clinical Regulatory Advisers, LLC, Washington, DC, USA, 3Greater Baltimore Neurosurgical Associates, Baltimore, MD, USA, 4The Spine Institute, Loveland, CO, USA, 5Desert Institute for Spine Care, Phoenix, AZ, USA

Introduction: While lumbar spinal fusion remains the standard of care surgical treatment for recalcitrant spinal stenosis with back pain and spondylolisthesis, the potential for perioperative morbidity, adjacent segment degeneration, and increased costs have led to the investigation into less-invasive, and perhaps less costly, alternative treatments. Two-year interim analysis results from the IDE trial comparing coflex® interlaminar stabilization with posterolateral spinal fusion (PLF) for stenosis with spondylolisthesis have demonstrated clinical equivalence or superiority with coflex®, and have shown clear superiority with respect to perioperative outcomes including shorter hospital length of stay, less blood loss, and shorter surgical times (data reported separately), resulting in significantly decreased healthcare resource utilization. Consequently, we hypothesize that the actual costs associated with coflex® interlaminar stabilization are favorable compared with PLF.

Methods: Actual cost of care data was available for 3 of the 20 sites that participated in the randomized, prospective, IDE trial comparing coflex® with PLF for stenosis and spondylolisthesis. For each study enrollee, the costs-per-case data were calculated, which included OR costs, recovery room costs, and non-recurring costs such as implant costs, supplies, drugs, and durable medical equipment. Although the data was captured for surgeries performed between 2006 and 2010, conversions were made to 2011 US dollars in order to create a common, relative cost value. Since the coflex® device is not commercially available, the following implant assumptions were made for the current analysis: 1) coflex® device cost range: $4-8000/device; 2) PLF implant costs range: $7-11000 for 1-level, and $10-14,000 for 2-level.

Results: Actual cost data was available for 62 patients. Table 1 depicts the baseline demographics, perioperative data, and costs. The average blood loss, hospital stay, and OR time were substantially lower with coflex®. Using the national average for cost-per-minute of $30/minute for OR time and $10/minute for recovery time in the inpatient setting, as well as other cost-per-minute values provided by facility administrators, a 1-level coflex® procedure saved on average $8,776 peri-operatively, compared with 1-level PLF. Similarly, a 2-level coflex® procedure saved $4,702 compared with 2-level PLF. Most savings were in implant costs (in 1-level procedures), drugs/supply, and OR costs. For this cohort of 62 patients, %ODI improvement was similar among the 4 cohorts at 2 years: 1-level coflex® (59.5%), 1-level fusion (38.0%), 2-level coflex® (63.3%), 2-level fusion (64.1%).

<table>
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<th>1-level coflex®</th>
<th>1-level PLF</th>
<th>2-level coflex®</th>
<th>2-level PLF</th>
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<tr>
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<tr>
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</table>

Table 1. Patient Demographics, Perioperative Outcomes

Discussion: While prior data has shown clinical equivalence or superiority with coflex® when compared with PLF at 2 years, the current study is the first to quantify the actual cost savings associated with coflex® interlaminar stabilization. On average, 1-level coflex® procedures saved $8,776 per case, while 2-level coflex® procedures saved on average $4,702 compared with fusion, while producing similar or improved clinical outcomes for patients.
outcomes at 2 years. Our data suggest the potential for substantial cost-savings, without compromising clinical outcomes, with coflex® interlaminar stabilization compared with fusion in the treatment of spinal stenosis and spondylolisthesis.

Sports and Spine

510 Does Applying Normal Saline Significantly Change the Waiting Time for Dressing Application to Dermabond?

G. Gendy1, M. Wongworawat1, R. Eggers2
1Loma Linda University Medical Center, Orthopedic Surgery, Loma Linda, CA, USA, 2Loma Linda University School of Medicine, Loma Linda, CA, USA

Background and purpose: Several topical adhesives have been on the market. Many of these have been used in spine surgery as a topical dressings. The base of the adhesives is cyanoacrylate. Cyanoacrylate rapidly polymerizes in the presence of water or hydroxide ions to bond surfaces together. In the surgical setting, moisture on the skin surface starts the polymerization. The application of water or saline has been used anecdotally to speed the curing time, however no studies to date have looked at whether this is true.

Hypothesis: Null-Hypothesis- The addition of Normal Saline to cyanoacrylates during curing does not change the waiting time for dressing application to Dermabond.

Test-Hypothesis- The addition of Normal Saline to cyanoacrylates during curing does change the waiting time for dressing application to Dermabond.

Materials and methods: Dermabond was applied to 1.5 x 12 cm strips of full thickness porcine skin. Specimens were randomized into two groups: Control or Saline. Both groups had Dermabond applied as instructed by industry in two layers at 30 second intervals. The Saline group had 5 cc of normal saline applied in drip fashion from a syringe after the second layer of Dermabond was applied, the Control group had no saline applied. Strips of gauze were then applied to the Dermabond at 30 second intervals. Seven strips of Dermabond were tested for each group. Each Dermabond had 24 strips of gauze for a total of 168 strips of gauze for each group.

After final cure of 120 minutes, we attempted to peel off the gauze from the Dermabond. The goal is to compare at which time of application gauze stops incorporating itself into the Dermabond. The times, which gauze stops incorporating, were compared with a Kaplan-Meier Plot and a Log Rank Test.

Results: Application of saline resulted in faster cure times. For the control group, mean time for gauze to no longer incorporate to the Dermabond was 8:47 ± 2:29 minutes, whereas that of the Saline group was 4:38 ± 1:04 minutes (p=0.001).

Discussion and conclusion: The hydroxyl group is needed to activate curing of Dermabond. Adding normal saline significantly decreases the waiting time for dressing application to Dermabond.
Discussion and conclusion: Although the hydroxyl group is needed to activate curing of Dermabond, adding saline does so at a detriment to the strength of the final cured compound.

Cervical Therapies and Outcomes

517
Prodisc® - C Total Disc Replacement - 3-8 Years
Follow up
R. Bertagnoli

Introduction: Cervical TDR is used between C3-C7 with potential benefits of providing immediate stability, reducing adjacent level disc degeneration and restoring/preserving range of motion between segments. The purpose of this study was to evaluate the 3 - 8 year clinical results of ProDisc®-C TDR.

Material and methods: A case series of 348 patients between 2002 and 2008 with a total number of 558 implants. Patients were assessed pre- and post-operatively up to 96 months using VAS; NDI, and SF-36.

Results: From the total of 164 male mean age 48,7 yrs. ± 8,8 (30 - 72) / 184 females mean age 48,3 yrs. ± 9,2 (18 - 73) 168 underwent single level, 180 multi-level surgery. The most frequent single level was C5-C6 (43.4%) followed by C6/C7 (34.5%), C4/C5 (14.8%), C3/C4 (5.9%) and C7/Th1 (1.2%). Of multi-level cases, 2 levels were most common (83.3%), with C4-C6 (33%) C5-C7 (46.8%) being most frequent, 3 level (15.5%) and 4 levels (1.1%). The scores decreased at 3 months postoperative and were then maintained.

VAS decreased from a mean of 7.3 ± 7.0 baseline to 3.8 ± 2.4 at 3 months; 3.8 ± 2.5 at 6 months; 4.0 ± 2.7 at 1 yr ; 4.1 ± 2.9 at 2 yrs.; 4.0 ± 2.7 at 3 yrs; 4.0 ± 2.8 at 4 yrs; 5.1 ± 2.9 at 5 yrs; 4.6 ± 2.6 at 6 yrs; 3.9 ± 4.8 at 7 years and 3.0 ± 2.9 at 8 years. NDI in % reduced from 50 ± 18.2 baseline to 33,7 ± 19.0 at 3 months, 33,5 ± 18.9 at 6 months; 33,7 ± 20.9 at 1 yr; 34.0 ± 20.7 at 2yrs; 33.8 ± 19.9 at 3 yrs. 34,0 ± 19.0 at 4 yrs; 40,6 ± 22,8 at 5 yrs; 32,7 ± 19.1 at 6 yrs; 31,1 ± 24,1; 34,8 ± 23,5 at 7 yrs and 32,5 ± 29.5 at 8 yrs. The SF 36 physical / mental component and total was baseline P 34,0 ± 11.0 M 27,2 ± 11.9 T 75,8 ± 16.4 and improved at 3 month P 39,9 ± 9.0 M 28,7 ± 9.3 T 84,4 ± 16.9; 6 month P 40,5 ± 9.9 M 28,3 ± 9.8 T 85,1 ± 18.8; 1 yr P 40,9 ± 10,8 M 29,3 ± 9.2 T 86,7 ± 18.8; 2 yrs P 41,5 ± 11,5 M 27,3 ± 9.0 T 84,7 ± 19.5; 3 yrs P 39,7 ± 11.0 M 29,2 ± 9,4 T 82,8 ± 22,3; 4 yrs P 41,0 ± 10,8 M 28,4 ± 7,5 T 86,0 ± 19.5; 5 yrs P 38,0 ± 9.1 M 28,1 ± 9.9 T 80,9 ± 19.6; 6 yrs P 38,9 ± 9.8 M 31,4 ± 9.6 T 86,7 ± 18.6; 7 yrs P 39,3 ± 13.7 M 25,5 ± 8.6 T 79,6 ± 21,2 and 8 yrs P 42,8 ± 16,4 M 22,2 ± 13.2 T 82,8 ± 18.6.

Conclusions: Cervical TDR using ProDisc®-C demonstrates significant clinical improvement and provides long-term patient satisfaction in single and multilevel patients.
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EDUCATIONAL OBJECTIVES

Upon completion of the CME-accredited portions of this program, participants should be better able to:

• Identify and describe the results of new research in spinal arthroplasty/surgical approach and clinical results for the management of conditions requiring treatment.

• Discuss practical clinical information aimed at improving diagnostic skills.

• Identify key aspects of the latest devices available for preserving the motion of the spine.

• Evaluate and determine a wider range of treatment and surgical options for patients with degenerative disc disease.

• Describe, compare and contrast innovative methods in both assessment and treatment options in spinal arthroplasty.

MEETING PURPOSE

The purpose of the Twelveth Annual Conference is to provide continuing medical education for practicing neurosurgeons and orthopedic spine surgeons, residents in training, postgraduate fellows as well as allied health professionals including nurses and physician assistants.

This education will be provided in many forms:

• Lectures

• Symposia

• Panel discussions to provide in-depth coverage of selected topics

• Exhibits demonstrating the newest devices and technologies

• Industry Workshops

• Paper and Poster abstracts to provide the most current information regarding clinical and basic science advances in spine surgery

PHYSICIAN ACCREDITATION FOR GENERAL SESSIONS

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Tuschel, Alexander - available onsite

V
Van Meirhaeghe, Jan - (e,f) Medtronic; (e) Synthes
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Volcan, Ildemaro - (a) Globus Medical, NuVasive; (c) Globus Medical; (f) NuVasive, Boston Scientific

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Zhou, Qiang - available onsite
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Zou, Dewei - (g) nothing to disclose
Zou, Li - (g) nothing to disclose
Zigler, Jack - (c) Zimmer Spine; (d) Flexspine, Expanding Orthopedics; (e) Synthes Spine, SpineArt, Flexspine, Expanding Orthopedics
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