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SAS9 ORAL / ORAL POSTER ABSTRACTS

MIS OUTCOMES

Abstract: 114

Conventional Posterior Lumbar Interbody Fusion versus Mini-open Posterior Lumbar Interbody Fusion Using the New Percutaneously Inserted Spinal Transpedicular Screwing System

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Conclusions: Between the group where the conventional posterior lumbar interbody fusion (PLIF) was performed using microscope and the open transpedicular screw fixation system and that where mini-open PLIF was performed using the newly-designed percutaneous transpedicular screw fixation system characterized by vertical axis and detachable screw extender system, the surgical outcome was compared. The number of cases in which the conventional PLIF was performed was 86 (Group A) and that of those in which the mini-open PLIF was performed was 145 (Group B). In the Group A, mean follow-up period was 23.7 months (6 months to 43 months) and mean age was 56.3 (34 to 73) years. In regard to the level, one level was seen in 73 cases, two levels were seen in 11 cases and three levels were seen in 4 cases. In the Group B, mean follow-up period was 25.3 months (6 months to 43 months) and mean age was 59.1 (23 to 78) years. In regard to the level, one level was seen in 117 cases, two levels were seen in 22 cases and three levels were seen in 6 cases. Clinical outcome was assessed using last clinical follow-up Low Back Outcome Score (LQOS). We also compared the operative time, intra-operative bleeding loss, postoperative surgical scar and complications.

Results: In the Group A, mean surgical time was 163.7 minutes (120-280 minutes), bleeding loss was 753 ml (350-1200ml) and average LQOS was 56.2. The levels of postoperative surgical scar were as follows: one level: 6.23 cm, two levels: 11.28 cm and three levels: 15.26 cm. Complications include five cases (5.8%) of dural tear, four cases (4.7%) of deep wound infection and four cases (4.7%) of device failure and fusion failure. In the Group B, mean surgical time was 142.6 minutes (100-240 minutes), bleeding loss was 438 ml (160-850 ml) and average LQOS was 63.8. The levels of postoperative surgical scar were as follows: one level: 3.71 cm, two levels: 6.27 cm and three levels: 8.35 cm. Complications include eight cases (5.5%) of dural tear, four cases (2.7%) of deep wound infection and five cases (3.4%) of device failure and fusion failure.

Conclusions: Vertical Axis and detachable Screw Extender System makes it easier to perform rod manipulation as well as compression and distraction. As compared with conventional PLIF, it can diminish midline skin incision. It is therefore useful in reducing operation time and intra-operative bleeding loss, thus minimizing the postoperative occurrence of back pain and complication. Accordingly, a prompt recovery and a good clinical outcome can be expected.

Keywords: Posterior lumbar interbody fusion • Vertical Axis

Abstract: 142

Tubular Microsurgery for Lumbar Discectomies and Laminectomies in Obese Patients: Operative Results and Outcome

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Introduction: Spinal surgery in obese patients is associated with increased complications, blood loss and operative times. The purpose of this study was to evaluate the potential benefits of minimally invasive spine surgery (MISS) in 115 obese and non-obese patients by operative results and patient outcomes.

Methods: All patients underwent one-level lumbar microdiscectomy (LMD) or laminectomy (LAM) using tubular retractors between the years 2004 to 2007. Data was collected on patients’ demographics, comorbidities, smoking habits, operative results and outcomes and compared for obese (BMI ≥30) and non-obese patients. Operative results included operative times, blood loss, length of stay (LOS), and perioperative complications. Clinical outcomes were assessed using pre- and postoperative Visual Analog Scale (VAS) and Macnab outcome criteria at most recent follow-up.

Results: 31% of patients were classified as obese. Obese patients tended to undergo surgery at a younger age. No significant differences were seen between obese vs. non-obese patients in terms of incision lengths, operative time, blood loss, and complication rates (Figure 1). In obese patients, operative results compared favorably to reported historical results of patients undergoing open lumbar surgery. Overall, favorable outcome was seen in 92% and 84% of obese and non-obese LMD patients, respectively, and in 75% of LAM patients (Figure 2). Obesity, comorbidities and age did not have a significant impact on perioperative complications and clinical outcome at a mean follow-up of 15.9 months.

Conclusions: This is the first study comparing operative results from tubular microsurgery between obese and non-obese patients. Operative results and complication rates, including length of stay, blood loss, and operative time in obese patients were less while performing MISS compared to open spine procedures seen in the literature. Comparison between obese and non-obese patients in operative results and complication rates for minimally invasive microdiscectomy and laminectomy procedures showed no significant difference. Obese patients improved postoperatively and had similar outcome as non-obese patients.

Figure 1: Bar graph comparing the mean operating time between procedures, with no statistically significant difference between both patient groups.
Abstract: 291
A Comparison of Traditional and Minimally Invasive Lumbar Fusion in Octogenarians
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Purpose: Spinal fusion surgery in the elderly is fraught with potential complications. In addition to the potential for bleeding, infection, or neurological injury, the comorbid health conditions in these patients often preclude operative treatment to correct spinal pathologies because anesthesia time, blood loss, and recovery are too demanding. As aging patients expect to maintain active lifestyles, the demand for spinal reconstruction will continue to increase. Traditional open approaches have proven too debilitating, but newer, less invasive approaches offer great promise.

Methods: We compared our experience treating patients\textsuperscript{\textgreater}80 yrs old with traditional fusion techniques with a similar group using MIS techniques (XLIF and AxialIF). 20 patients (13F, 7M; age 82.7, BMI 28.0) were treated with open lumbar fusion from 2003-2005. 46 patients (20M, 26F; age 82.9; BMI 27.8) were treated with MIS techniques (41 XLIF, 4 AxialIF, 1 combination Ax/XLIF) from 2006-2008.

Results: Primary diagnoses and co-morbidities were similar between the two groups. In the traditional fusion group, hemoglobin change averaged 4.13g (14/20 pts required transfusion) and LOS averaged 5.3 days. All 20 pts were discharged to a skilled nursing facility. In the MIS group, hemoglobin change was 1.47g (no patients were transfused). LOS averaged 1.3 days and only 2/46 went to SNF (all others returned to their homes). Complications occurred in 15/20 (75%) patients in the traditional group. In the MIS group, there were 2 complications (2/46; 4.3%).

Conclusion: The comparison of the two groups is striking, and demonstrative of the potential of minimally invasive techniques. None of the complications seen in the open PLIF group occurred in the MIS XLIF/AxialIF group. Prior to our adoption of MIS techniques, we had routinely refused surgical intervention to elderly patients based on our results and complications. In our opinion, frail, elderly patients require MIS techniques to avoid the severe complications seen with open fusion procedures.

Abstract: 380
Changes in the Microhemodynamics of Nerve Root Retraction in Patients with Lumbar Spinal Canal Stenosis in Minimally Invasive Surgery
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Study design: Assessment of qualitative and quantitative changes in the microcirculation of nerve roots, such as the diameter of blood vessels and the low rate of erythrocytes, was observed during lumbar interbody fusion in minimally invasive surgery.

Objective: To confirm the evidence of minimally invasive surgery with ascertaining changes in the microcirculation of nerve roots before and after retraction during lumbar interbody fusion surgery.

Summary of background data: The changes in microhemodynamics caused by nerve root retraction have not yet been elucidated.

Methods: Subjects were patients with lumbar spinal canal stenosis who underwent lumbar interbody fusion in minimally invasive spine surgery. Changes in the microcirculation of nerve roots were examined in the L5 nerve root in 29 patients and the S1 nerve root in 3 patients. Through the use of video images captured by contact endoscope and stored in a computer, erythrocytes were automatically followed to measure flow rate and the diameter of blood vessels.

Results: Plasma skimming, where blood cells and plasma flow separately, was seen in 3 of the 29 patients (10.3%) before retraction of the nerve root and in 8 of the 29 patients (27.6%) following retraction. Intravascular erythrocyte agglutination, when erythrocytes flow in clumps due to changes in the charge state of erythrocytes, was seen in blood vessels larger than 100 micron in 3 patients (10.3%)
after retraction. Following nerve root retraction, the flow rate of erythrocytes through blood vessels decreased an average of 23.9% (P< 0.005).

**Conclusions:** A contact endoscope was used to observe the microhemodynamics of nerve roots before and after retraction of the nerve root during minimally invasive lumbar interbody fusion surgery, and a decrease in the flow rate of erythrocytes was observed.

Abstract: 341

**The Location of Intra-psoas Nerve Roots when Performing Extreme Lateral Lumbar Interbody Fusion (XLIF): An Anatomical Study**


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**Background context:** Recently, the eXtreme Lateral Interbody Fusion (XLIF) procedure has been reported as a minimally invasive interbody fusion technique. With this procedure, a direct lateral, trans-psoas retroperitoneal approach is utilized to access the disc space. This trans-psoas approach carries the potential risk of nerve injury to the intra-psoas neural elements.

**Purpose:** The purpose of this study was to define the relationship of the lumbar nerve roots within the psoas muscle with reference to the XLIF approach.

**Outcome measures:** The distance from the exiting lumbar nerve root and nerve trunk to the middle of the disc space in both hip flexion and extension was measured. The L1-2, L2-3, L3-4, and L4-5 disc spaces were analyzed.

**Methods:** Ten human cadaveric specimens were analyzed. Five specimens had intact proximal femurs allowing for the effects of hip flexion and extension to be measured. A guide wire was placed in the center of the disc space under lateral fluoroscopic guidance (as is performed during the XLIF procedure). Using digital calipers, the distance from the exiting nerve root and nerve trunk to the guide wire were measured with both hip flexion and extension.

**Results:** In general, the nerve trunk was a mean of 14mm posterior to the center of the disc and was a mean of 5mm closer to the center of the disc than the exited nerve root. The nerve trunks were closer to the center of the disc caudally in the lumbar spine, with the distance ranging from a mean of 16.4mm at L2-3 to 10.6mm at the L4-5 level. The intra-psoas location of the exited nerve root was less variable and in general was greater than 15mm from the projected center of the disc at all anatomical levels. At L4-5, the nerve trunk approximated the center of the disc in 15% of specimens.

**Conclusions:** The current study suggests that although in a majority of XLIF cases the intra-psoas nerves are a safe distance from the access pathway, anatomical variations in the location of these roots place them at risk of injury in a small number of cases. These results suggest that real time neural monitoring while traversing the psoas muscle is important to enhance safety of the trans-psoas approach. Particular care is warranted at the L4-5 level where the nerve trunk lies in closer proximity to the XLIF disc access point.

Abstract: 227

**Radiographic Outcomes of the DlIF/XlIF Technique In Comparison to Other Fusion Techniques for the Treatment of Degenerative Lumbar Scoliosis**

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**Background:** The direct lateral approach to the lumbar spine (DLIF/XLIF) is a relatively new minimally invasive method for performing anterior fusion. Similar to traditional open interbody fusion, this technique can restore disc height and alignment of the disc space. Therefore, reduction of scoliotic deformity is possible with this less invasive procedure. A comparison of scoliosis correction using this less invasive procedure and other anterior and posterior fusion techniques has not been reported on to date.

**Purpose:** Assess the effectiveness of the XLIF/DLIF procedure in correcting lumbar degenerative scoliosis and compare outcomes with posterolateral fusion (PLF), anterior lumbar interbody fusion (ALIF) and transforaminal lumbar interbody fusion (TLIF).

**Patient sample:** X-ray images were collected for 39 patients treated at our institute for lumbar degenerative scoliosis with the XLIF/DLIF procedure, 18 patients treated with PLF surgery, 8 with ALIF surgery and 8 with TLIF surgery. Overall, 73 patients were reviewed with an average age of 68. Only patients with a lumbar Cobb angle of 10° or greater were included in the study.

**Methods:** In order to review scoliosis correction, various measurements were taken on pre-operative and post-operative AP and lateral X-rays of the lumbar spine. These include lumbar scoliosis using the Cobb angle measurement, focal scoliosis at each intervertebral level, lateral listhesis, global lordosis, focal lordosis/disc angle and disc height.

**Results:** Patients receiving scoliosis correction with the DLIF/ XLIF, PLF, ALIF and TLIF techniques received fusion at an average 3.0, 2.8, 2.8 and 2.4 levels respectively. Global and focal Cobb angle correction with DLIF/XLIF surgery is shown below in comparison to other fusion techniques.

**Global Cobb Angle Correction:**
- DlIF/XLIF (n=39 patients): Pre-op=20.2°±10.5°; Correction=8.5°±4.6°
- PLF(n=18 patients): Pre-op=17.0°±9.8°; Correction=2.5°±3.1°
- ALIF(n=8 patients): Pre-op=26.6°±15.0°; Correction=7.0°±6.6°
- TLIF(n=8 patients): Pre-op=17.9°±5.6°; Correction=3.0°±3.0°

**Focal Cobb Angle Correction:**
- DlIF/XLIF(n=117 levels): Pre-op=9.5°±6.4°; Correction=4.1°±4.7°
- PLF(n=47 levels): Pre-op=7.5°±5.7°; Correction=0.9±2.9°
- ALIF(n=22 levels): Pre-op=8.1°±6.4°; Correction=2.6°±4.4°
- TLIF(n=19 levels): Pre-op=6.3°±5.5°; Correction=1.4°±4.7°

The DLIF/XLIF technique is significantly more effective than PLF (p< 0.001) and TLIF (p< 0.05) in correcting global Cobb angle and is comparable to ALIF. As expected, an increase in the number of fusion levels resulted in an increase in scoliosis correction. A 2 and 3 level DLIF/XLIF fusion resulted in 6.4° and 8.6° of lumbar Cobb angle correction respectively while a 4 or 5 level fusion resulted in 11.1° of correction.

Amongst the 26 DLIF/XLIF patients with lateral radiographic images, little change in mean lumbar lordosis was noted, but focal lordosis (disc angle) at each vertebral level increased 106% from 4.1°±5.5° to 8.5°±4.7°. This also resulted in a 72% increase in anterior disc height and a 48% increase in posterior disc height.

**Conclusion:** The XLIF/DLIF procedure is comparable to ALIF and is more effective than TLIF and PLF in correcting lumbar spine deformity caused by degenerative scoliosis. It produces a greater reduction in both global Cobb angle and focal Cobb angle than these surgeries and is a less invasive procedure. It also corrects degenerative changes of the spine by significantly increasing disc height and disc angle.

Abstract: 579

**Complications in eXtreme Lateral Interbody Fusion: One Surgeon’s Experience with 566 Cases and 1550 Levels**


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**Introduction:** The eXtreme Lateral Interbody Fusion (XLIF) system continues to gain prevalence as a mini-open alternative to similar open procedures. The identification of complications...
in a large number of patients is needed to quantify the frequency of occurrence that may be expected and their relation to reported complications in the long-term follow-up of current procedures.

**Methods:** 566 patients underwent XLIF procedures by a single neurosurgeon in Las Vegas, NV between 2004 and 2008. Retrospective chart review quantified the complications.

**Results:**
- **Subsidence:** 11 cases (2%) showed post-operative subsidence, likely due to high concentration of BMP and/or endplate over-preparation. Diluting BMP with other non-inflammatory biologics and careful endplate preparation has slowed the rate of subsidence.
- **Anterior Longitudinal Ligament Rupture:** 5 cases (1%) occurred intra-operatively during implant sizing, with overly large implant. Over-distraction can cause ligamentous rupture as well as long-term implant subsidence.
- **Transient Lateral Thigh Weakness:** 79 patients (14%) experienced this complication either from direct psoas manipulation during the approach (generally at L3-4, L4-5) or from post-surgical psoas inflammation or hematoma (6 patients, 1%). 68 of these patients (86%) transiently resolved within 6-weeks post-operatively, the rest within 12-weeks. None were permanent.
- **Permanent Femoral Injury:** 1 patient (< 1%) Intra-psoas nerve damage is the most serious morbidity associated with the procedure and the approach. Close observation of the intra-operative neuromonitoring, careful blunt dissection of the psoas, and a slow dilation of the retractor system will safeguard against nerve injury or affects.
- **Dysesthesias:** Genito/Femoral: 3 cases (< 1%); Plexopathy: 2 cases (< 1%) which were treated with steroids and neurontin and bi-weekly clinical follow-up. All five dysesthesias spontaneously resolved within six months.
- **Conclusions:** These complications and their rates of occurrence, as experienced in our practice, are generally comparable to those reported in open and minimally invasive anterior, posterior, and other lateral approaches. The most significant complications observed in this series concerned nerve irritation from psoas manipulation during the approach. The majority of the nerve related complications 79/85 (93%) were transiently resolving lateral thigh weakness, which is to be considered a side-effect of the approach rather than a true complication, much as sensory back pain is a side-effect of open posterior work. Of all the nerve related injuries, only 1/85 was permanent (1.1%) and the permanent injury constituted only 1.7% of the total series. Given these lesser rates of major complications, similar or improved patient outcomes (currently following), shorter hospital stays, less intra-operative blood loss, and shorter operative times compared to open and other standard of care procedures, this system is a favorable medium between true minimally invasive (with high learning curves and difficult complication handling) and open systems (higher infection rates, vascular revision issues, and often extensive soft tissue trauma) for lumbar interbody fusion.

**CERVICAL I**

Abstract: 58

**A Prospective Randomized Comparison of Cervical Total Disc Replacement and Anterior Cervical Fusion**

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**Introduction:** Anterior cervical fusion (ACF) has been the gold standard for the treatment of cervical radiculopathy and neck pain for many years. However, fusion is designed to limit motion and may lead to adjacent segment degeneration. Cervical total disc replacement (TDR) has been developed as an alternative to ACF. The purpose of this study was to compare cervical TDR to ACF in a prospective randomized manner.

**Methods:** A total of 99 (50 males and 49 females) patients participating in one of four FDA IDE trials from a spine clinic were randomized to receive cervical TDR or ACF. The age of the patients ranged from 29 to 63 (mean = 44.32). All patients were treated for single-level symptomatic disc degeneration between C4 and C7, where the majority of cases were at C5-6. Peri-operative data were compared for the two groups. Clinical outcome was based on the Neck Disability Index (NDI), which assessed functional disability. Follow-up data were collected at baseline and 6 weeks, as well as 3, 6, and 12 months after surgery.

**Results:** The mean blood loss, operative time, and length of hospital stay were similar in the two groups. Among TDR patients the mean blood loss was 30.39cc, operative time was 81.49 minutes, and length of stay was 1.19 days, whereas for fusion the mean blood loss was 26.73cc, operative time was 81.86 minutes, and length of stay was 1.0 day. The mean functional status score, as assessed by the NDI, in the TDR group improved significantly from 50.90 pre-operatively to 14.83 at 12 months. Similarly, patients in the fusion group also improved significantly (52.58 pre-operatively to 14.39 at 12 months). There was no significant difference between TDR and fusion at any of the follow-up periods (Figure 1).

![Figure 1. Mean NDI scores](image)

**Conclusions:** There were no differences between ACF and cervical TDR in blood loss, operative time, or length of stay. Both groups showed significant improvement in NDI at 6 weeks and maintained improvement throughout the 12 month follow-up. There was no significant difference in NDI between the groups. This study demonstrated that cervical TDR improves cervical radiculopathy and or neck pain as well as the current gold standard, ACF, suggesting that TDR is a viable treatment option in such patients.

**Abstract:**

Bi-level Cervical Arthroplasty Outcomes: Compare to Single Level Arthroplasty

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**Introduction:** The concept of accelerated degeneration of adjacent disc levels as a consequence of increased stress caused by interbody fusion of the cervical spine has been widely postulated. There are many reports about the clinical success of the single level arthroplasty, alleviates neurologic symptoms and signs similar to anterior cervical discectomy and fusion, and radiological evidence supports maintenance of motion. We investigated this retrospective study to evaluate whether the outcomes and complications are acceptable with multilevel compared with single-level arthroplasty.

**Material and Methods:** Patients with symptomatic cervical radiculopathy and/or myelopathy underwent implantation
with the cervical artificial disc after a standard anterior cervical discectomy. At scheduled follow-up periods, we compared the effectiveness of the bi-level arthroplasty by evaluating each patient’s pain (VAS score, NDI), and radiographically measured range of motion at the implanted level to single level arthroplasty.

**Results:** Between the May 2005 and Dec. 2007, 125 patients underwent arthroplasty in our institute. Single level arthroplasty was done in 72 patients, and 28 patients treated with bi-level arthroplasty and 25 patients with hybrid surgery (one level artificial disc plus one anterior cervical fusion). The clinical outcomes showed significantly improvement in both group before and after surgery. The mean improvement in the VAS showed the same association: single-level mean improvement 61.4% versus the multilevel cases mean VAS improvement was 69.9%. There are significant improvements in the NDI for single and bi-level arthroplasty group. Compare with single level group, the range of movement of the whole cervical spine, the functional segmental unit, and the adjacent segments were preserved in patients treated with the bi-level artificial cervical disc group.

**Conclusion:** Evaluation of data acquired in the bi-level arthroplasty group showed that improvements in the clinical parameters were similar to those in the single level group. Additionally in the bi-level arthroplasty group, there was radiographic evidence that motion was maintained. Future studies and long term follow up will need to address the association between postoperative kyphosis, clinical outcome and adjacent segment disease in multi-level artificial disc treated group.

Abstract: 145

**A Clinical Comparison of One and Two-level Cervical Disc Arthroplasty versenvse One and Two-level Anterior Cervical Decompression and Fusion: Single Center Results from a US IDE Prospective Randomized Study**

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**Background:** Cervical disc arthroplasty is a technology that continues to evolve as a treatment alternative for radiculopathy or myelopathy at one or two levels. More studies are needed to determine the outcomes from disc arthroplasty compared to ACDF.

**Purpose:** To determine if there are differences in clinical outcomes between cervical disc arthroplasty and arthrodesis by evaluating data from a prospective randomized FDA clinical trial.

**Study design:** Patients were evaluated from one trial site operated on by the senior author who had either a cervical ADR implanted or an ACDF.

**Patient sample:** Patients with either one or two level disease were randomized to receive either treatment with ACDF (4 patients) or arthroplasty, Discover (Depuy) (16 patients). All patients were part of an FDA clinical trial.

**Outcome measures:** At baseline, post-op, 2 weeks, 3 months, 6 months and 1 year, patients were evaluated using Neck Disability Index and Visual Analog Scales. These patients also had a clinical evaluation and a chart review of surgical and hospital stay parameters. Radiographic analysis was also performed.

**Results:** Four patients were randomized to receive ACDF as treatment, two with a one-level ACDF and two with a two-level ACDF. Overall mean duration of ACDF patients was 2.4 hours. The mean for one level was 2.0 hours, the mean for two levels was 2.8 hours. Mean blood loss was 93.8 cc, with a mean of 50.0 cc for one level patients and 137.5 for two level ACDF. Mean VAS for neck pain on all patients receiving an ACDF fell from 82.5 pre-op to 44.0 at 6 months. The mean VAS fell from 78.0 at baseline for one level to a mean of 25.0 at 6 months, for two-level ACD the mean VAS fell from 87.0 to 63.0 at 6 months. NDI overall for fusion patients fell from a mean of 51.5 at baseline to 31.0 at 6 months. This mean fell from 52.0 to 28.0 for one-level and 51.0 to 34.0 for two-level ACDF. Sixteen patients were randomized to receive cervical disc arthroplasty, eight for a one level and eight for a two level arthroplasty. Mean duration of surgery was 2.2 hours with the mean for a one level procedure being 1.8 hours and 2.6 hours for two-level replacements. Overall blood loss averaged 43.3 cc, with a mean of 34.4 cc for one level arthroplasty and 53.6 cc for two level arthrolasty. The mean VAS for neck pain from all patients receiving arthroplasty fell from 79.4 at baseline to 38.9 at one year. This fell from 74.6 to 20.5 for one level replacements and 84.2 to 75.8 for two level replacements. NDI overall fell from 59.4 at baseline to 24.0 at one year. For patients receiving a one level arthroplasty, this fell from 57.3 to 18.0 at one year and for patients receiving a two level arthroplasty, this mean fell from 61.5 to 36.0.

**Conclusions:** Cervical disk arthroplasty appears to be a comparable procedure in terms of operative time and blood loss, as well as post-operative clinical course.

Abstract: 351

**Clinical and Radiographic Analysis of Cervical Arthroplasty versus Arthrodesis in Korea University Hospital**

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**Study design:** Retrospective study.

**Objective:** To compare functional and radiologic outcomes associated with cervical arthroplasty versus those of arthrodesis. The authors report the results of a retrospective single-center study to determine the role of arthroplasty for patients with symptomatic single-level cervical degenerative disc disease.

**Summary of background data:** Based on previous studies, twenty-five percent of patients undergoing cervical fusion will have new onset of symptoms within 10 years. And segments adjacent to a fusion may have an increased range of motion. Total intervertebral disc replacement (arthroplasty) is designed to preserve motion, avoid limitations of fusion, and allow patients to quickly return to routine activities.

**Methods:** We retrospectively reviewed the charts and radiographs of patients who underwent a single-level anterior cervical fusion(ACDF) or total intervertebral disc replacement(TDR) between January 1, 2004, and September 31, 2007. Disability and pain were assessed using the Neck Disability Index (NDI) and the Visual Analog Scale (VAS) of the neck and of the arm pain. Range of motion was determined by radiologic assessment of flexion-extension radiographs. Data were collected before surgery and at 6 weeks, 3, 6, 12, and 24 months after surgery.

**Results:** A total of 122 patients were identified with 59 having arthroplasty (50% Bryan, 26% Prodisc-C, 24% Mobi-C), and 63 having fusion. There were 43 males and 16 females in the arthroplasty group and 43 males and 20 females in the fusion group. The average age was 48 years (arthroplasty) and 52 years (arthrodesis). No statistically significant differences were noted in the demographics between groups. The mean NDI before surgery was not statistically different between groups: 59 (Arthroplasty) and 54(Arthrosis). Twelve-month follow-up NDI is 18 (Arthroplasty) and 30 (Arthrosis) (P = 0.00). At 2-year follow-up, NDI for the Arthroplasty group is 18 and the control group is 31 (P = 0.00). The mean neck pain VAS before surgery was 65 (Arthroplasty) and 66 (Arthrosis). One-year follow-up scores were 16 (Arthroplasty) and 20 (Arthrosis) (P < 0.001). At 2 years: 15 (Arthroplasty) and 20 (Arthrosis) (P = 0.013). The mean arm pain VAS before surgery was 64 (Arthroplasty) and 66 (Arthrosis). At 1-year follow-up, Arthroplasty arm pain VAS was 16 and arthrosis 21 (P = 0.021). At 2-year follow-up, the average arm pain VAS for the arthroplasty group was 14 and arthrosis 22 (P = 0.001).
Abstract: Cervical Hybrid Arthroplasty: Lifestyles Outcomes Analysis

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Introduction: Cervical Hybrid Arthroplasty has emerged as a means towards addressing patients with prior fusions or multilevel disc pathology. The present study evaluates our subset of patients through our Lifestyles Outcomes Scale (LOS).

Methods: A total of 50 Cervical arthroplasties in 41 patients were reviewed. Arthroplasty was performed using either the Prodisc C or Prestige ST prosthesis in concert with fusion in 41 consecutive patients. 22 Females and 19 males were evaluated with a mean age of 42 years and a mean followup of 12.64 months. Patients completed NDI, SF-36,VAS measures and completed the Lifestyles Outcomes Scale (LOS). The LOS evaluates patients perceived outcomes, length of stay, weight changes, Narcotic use, walking time and distance, return to sex, travel, driving, sport and work.

Results: The mean NDI score at baseline was 64.92 which improved to a mean of 33.28. The mean VAS Neck score at baseline was 8.48 which improved to a mean of 3.45. The mean VAS Arm pain score at baseline was 7.83 which improved to a mean of 1.95. The mean SF 36 score at baseline was 43.44 which improved to a mean of 62.25. For all outcomes measures improvement at each interval and overall was statistically significant (p< 0.05) using the Wilcoxon Rank Sum Test. The mean interval from surgery for return to work for the 36 patients in employment was 38 days. The mean interval from surgery for the 37 patients who returned to sports was 30.67 days. The mean interval from surgery for the 36 patients who returned to sexual activities was 25.3 days. The mean weight loss for the 18 patients that lost weight was 12.7 pounds. The mean weight gain for the eight patients that gained weight was 7.8 pounds. The mean interval to return to driving was 16.64 days.

Conclusions: Cervical Hybrid Arthroplasty appears to be a safe and effective treatment for painful discogenic disease and radiculopathy. The rate of improvement is rapid and sustained through 12.64 months.

Learning objectives: Cervical Hybrid Arthroplasty can be used as an adjunct towards the treatment of patients with multilevel cervical disc pathology. The arthroplasty component of the hybrid construct preserves motion and limits force concentrations at the remaining cervical segments, in patients with multiple level cervical pathology. As Spinal surgeons we must take the initiative towards defining new standards of success. This current study places the focus on lifestyle based outcomes which are important to patients and providers alike in considering short and long term expectations.
patients and additional treatment in the future. Cervical disc replacement may prove to reduce the development of adjacent level degeneration.

**Purpose:** The purpose of this study is to present preliminary clinical outcomes of the CerviCore Disc replacement with that of Fusion (ACDF) with allograft and plating for single level disease. The study is a pooled data set from 4 of the 29 sites in the US IDE prospective, randomized, controlled trial, comparing CerviCore to ACDF for treatment of cervical radicular symptoms.

**Methods:** At our sites, patients who met the inclusion criteria were randomized in a 1:1 ratio to a CerviCore artificial disc replacement (39) or ACDF (41). All the surgical treatments were between C3 and C7. Functionality was assessed using the Neck Disability Index (NDI), and pain with the Visual Analog Scale (VAS), and were documented preoperatively and at 6 weeks, 3 and 12 month follow-ups. Follow-up data is currently available for 34 CerviCore patients and 25 control patients at 12 months.

**Results:** Figure 1 presents the mean NDI scores along with the neck and worse arm pain VAS scores.

**Discussion:** Given that NDI and VAS reductions of 15 points or more are considered successful, both CerviCore and ACDF rapidly achieved success and maintained a very substantial improvement by the 12 month follow-up.

**Conclusion:** These preliminary outcomes suggest that CerviCore Intervertebral disc may be an alternative treatment for cervical radiculopathy. Full analysis of all 25 sites is needed to confirm these results and will also enable a better understanding of clinical gains from treatment with CerviCore.

### LUMBAR I

Abstract: 596

**Multiple-level Lumbar ADR with Prodisc-L: A Clinical and Radiographic Analysis of Sagittal Motion Preservation at 2-6 Years**

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**Background:** A recent FDA-sponsored randomized controlled study of the Prodisc-L (Synthes Spine, Westchester, PA) lumbar disc replacement established superior clinical outcomes with preservation of motion at both surgical and adjacent levels, as compared to lumbar fusion. However, no previous study has reported on the clinical and radiographic characteristics of adjacent multi-level lumbar disc replacements.

**Purpose:** To evaluate clinical outcomes and the sagittal range of motion of adjacent lumbar motion segments in multiple-level ProDisc-L constructs after 2-6 year follow-up.

**Patient sample:** Seventy-eight patients underwent adjacent multiple level lumbar ADR, with thirty-one patients receiving ADR at L4-L5 and L5-S1 (ADR-2) and forty-one patients receiving ADR at L3-L4, L4-L5, and L5-S1 (ADR-3).

**Study-design:** Prospective Cohort.

**Outcome measures:** Angular motion (extension and flexion measurements) on preoperative and postoperative sagittal-projection lumbar films at each operative motion segment as well as at the segment adjacent to the prosthetic construct. Oswestry Disability Index and Visual Analog Score data were also collected.

**Methods:** Patients were evaluated pre-operatively, at six weeks, three months, six months, and annually for 2-6 years postoperatively with lateral flexion-extension dynamic films and with completion of Oswestry and VAS surveys.

**Results:** There were no significant differences among the groups for age, gender, body mass index, tobacco use, or worker’s compensation status. At the motion segment adjacent to the ADR, the mean preoperative range of motion was 9.4° (SD 1.80°), compared to 10.5° postoperatively (SD 2.25, p=0.21) at last follow-up. Between the two ADR groups, there were no statistically significant differences in range of motion at a given lumbar level (p>0.05 for all comparisons of a particular level between groups) at any time point. Across both groups for all motion segments undergoing ADR, the mean preoperative range of motion was 10.15° (SD 2.71°) versus 12.30° postoperatively (SD 2.25, p=0.011) at last follow-up. At 2-6 years postoperatively, all patients had significant reductions in both ODI and VAS scores relative to preoperative levels (p<0.05). At up to six years follow-up, no patient underwent revision surgery or surgeries at adjacent levels.

**Conclusions:** The use of the multiple level ADR construct does not inhibit preservation of range of motion at the individual ADR levels. Most significantly, the nonoperative level adjacent to the construct maintains its preoperative range of motion at 2-6 years postoperatively. At up to six years of follow-up, there has been no need for revision or adjacent-segment surgery. Patients also demonstrate significant improvement in pain and disability at latest follow-up.

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Abstract: 53

**Relationship between Endplate Morphology and Clinical Outcome of Single-level Lumbar Disc Arthroplasty**


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**Introduction:** There have been several studies attempting to identify factors related to clinical outcome following total disc replacement (TDR). These include individual factors as well as biomechanical. As presented by Yue et al at SAS 2007, the shape of the vertebral endplates may be related to outcome. It was has been suggested that the shape may effect device placement, thus influencing the ability of the implant to perform optimally in producing motion. The purpose of this study was to investigate if there was a relationship between endplate shape and clinical outcome following lumbar TDR.

**Methods:** The study group included 114 patients who underwent single-level TDR at a single center. Only patients who have reached 24-month follow-up were included in the study. Endplate shape was classified as described by Oetgen, Yue, et al. (SAS J, 2008) as flat, hooked, concave, convex, or combined. The classification was made from pre-operative radiographs by a single evaluator blinded to clinical outcomes. The primary outcome measure was the percentage improvement on pre- to 24-month post-operative visual analog scales (VAS) assessing pain, and the Oswestry Disability Index (ODI).

**Results:** The mean percentage improvement on the VAS and ODI were significantly greater in the group with flat endplates than in patients with concave endplates (p<0.05; ANOVA; Figure 1). There was a trend toward the flat endplate group improving more than the group with hooked endplates (0.05<p<0.1). The convex group could not be included in the ANOVA analysis because there was only one patient in this group (VAS worsened 41% and Oswestry worsened 3%).

Within the endplate groups, there was no significant difference in outcome when comparing TDRs with spikes vs. keels for
Discussion: There was a significant difference in clinical outcome with respect to endplate shape. The group with flat endplates had significantly greater improvements than those with concave endplates and trended toward better outcomes than those seen in patients with hooked endplates. The potential impact of convex and combined endplate shapes on outcome will require much larger groups of patients to make meaningful comparisons. The reason for the differences in outcomes could not be discerned from the current study. Investigation of the relationship of endplate shape and device positioning, particularly in the anterior-posterior plane, are warranted.

Abstract: 652
Economic Outcomes in a Worker’s Compensation Cohort after Single-Level Lumbar Disc Arthroplasty vs. Anterior Lumbar Interbody Fusion
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Introduction: The estimated costs of back pain in the U.S. exceed $100 billion annually, with two-thirds related to lost wages and productivity. Most work-related back pain resolves with minimal costs, but surgery is indicated in a small percentage of workers’ compensation (WC) cases. For carefully selected patients, lumbar disc arthroplasty (LDA) is an alternative to fusion that returns patients to work more quickly and may provide improved socioeconomic outcomes.

Methods: A retrospective review of data collected prospectively on 24 WC patients with persistent low back pain secondary to single-level degenerative disc disease, for whom final settlement documentation for their disputed injury claim was available, along with clinical and functional outcomes up to the 24-month postoperative follow up. Patients were treated by a single surgeon with either LDA with the Maverick Disc (Medtronic, Memphis, TN) (n = 16) or anterior lumbar interbody fusion (ALIF) with rhBMP-2 and threaded titanium cages (Medtronic, Memphis, TN) (n = 8). Data collected from those WC settlement documents included key dates regarding employment status, injury claim, disability status and final settlement, as well as pre-injury and disability wage information, medical payments, and settlement terms. True direct cost data were obtained from the hospital for each treated patient. Work status was analyzed (Kaplan-Meier) on the basis of both a patient’s date of release by the operating surgeon to return to work (RRTW) as well as the actual return-to-work (RTW) date, and work restrictions were also recorded. A socioeconomic impact model to estimate differences in lost productivity will be presented.

Results: No significant differences in demographic or baseline characteristics were detected. Consistent with outcomes reported in the Maverick IDE trial, patients in both the LDA and ALIF groups had clinically and statistically significant improvements in Oswestry Disability Index (ODI), back and leg pain, and SF-36 versus preoperative scores up to 24 months after surgery. Hospital facility costs from index surgery to 2 years post-op were not significantly different (p=0.081). LDA patients were RRTW a median 96 days before ALIF patients (p=0.005); work restrictions were imposed on 88% of ALIF vs. 31% of LDA patients. At 2 years post-op, only 3/8 (38%) ALIF patients were working, vs. 13/16 (81%) LDA patients (p=0.037). ALIF patients were compensated for a median 109 TTD weeks vs. 67 for LDA (p=0.024). Permanent disability payments were $80K higher for ALIF patients (p=0.05).

Conclusions: WC patients receiving the Maverick Disc spent fewer days on TTD, returned to work sooner with fewer restrictions, had earlier settlement of claims, and received lower overall disability awards than ALIF patients. The societal impact in terms of productivity loss for work-related back injuries requiring surgery may be reduced significantly when arthroplasty is an option vs. lumbar fusion.

Abstract: 615
The Effect of Age on Clinical Outcomes Following Lumbar Total Disc Replacement after a Minimum 1-year Follow-up
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Introduction: Total disc replacement (TDR) has been studied extensively in younger age groups; however chronic lower back pain (LBP) commonly occurs in older patients. Treatment of chronic LBP with TDR in older age groups has been a challenging and controversial subject, with age often seen as a contraindication due to underlying comorbidities. It is appropriate that co-morbidities associated with age be taken into consideration with the underlying pathology and matched to the surgical approach used and available technology.

Purpose: • To compare the clinical outcomes of TDR for the treatment of proven degenerative disc disease (DDD) in various age groups.
• To assess the validity of chronological age as a contraindication for TDR.

Methods: 465 patients with DDD, underwent single or multilevel TDR or a simultaneous lumbar TDR and arthrodesis with a minimum one year follow-up. Patient data was analyzed based on age (18-30 years [34 patients, Group 1], 31-60 years [405 patients, Group 2] and 61-80 years [26 patients, Group 3]). Contraindications to TDR included proven osteoporosis, facet arthropathy, morbid obesity, calcific vessel disease, multiple anterior surgeries and significantly diminished cardio-respiratory function. Clinical outcomes were measured using Visual Analogue Back and Leg (VAS), Oswestry Disability Index (ODI), Roland-Morris Disability Questionnaire (RMDQ), and SF-36. Patients were assessed preoperatively and at 3, 6, and 12 months postoperatively; and annually thereafter.

Results: The average age at the time of surgery for Group 1 was 27.1yrs; Group 2 was 43.9yrs and Group 3 was 63.3yrs. Results at latest follow-up versus baseline were compared. At follow-up the VAS back scores decreased from 81.4 to 30.4 in Group 1 (-62.7%), from 77.1 to 23.8 in the Group 2 (-69.1%) and from 69.8 to 19.8 in Group 3 (-71.6%). VASL leg scores decreased from 55.8 to 22.4 in Group 1 (-59.8%), from 59.0 to 17.8 in Group 2 (-69.9%) and from 62.1 to 11.0 in Group 3 (-82.3%). ODI scores reduced from 51.5 to 17.4 in Group 1 (-66.1%), from 48.6 to 16.8 (-65.6%) in Group 2 and from 45.8 to 17.62 (-61.5%) in Group 3. For RMDQ scores, there was a...
of the anterior access for the lower lumbar levels to treat the degenerative disc disease, has been developed essentially for total disc replacement and fusion with cages. However, if the retroperitoneal left access is mostly used, it remains some questions: percentage of retrograde ejaculation, capacity to maintain a virgin access for a revision or for a surgery a level above, and risk of obstruction of the arterial axis with plates mobilization.

**Purpose of the study:** This study concerns the patients operated through a retroperitoneal right access to determines the risk of vascular injury, of intraperative arterial obstruction during the retraction (and the percentage of thrombosis) and the percentage of retrograde ejaculation.

**Methods:** 210 patients were included in the prospective study, operated from August 2003 to July 2008. They had an anterior access for implantation of a total disc replacement. 145 one level (L5-S1, L4-L5, 64 on two levels (L4-L5/L5-S1) and 1 on three levels (L3-L4/L4-L5/L5-S1). The age was 41+/9.46(from 20 to 64, Weight 75kg+/12.35 (50/107) for a height 173cm+/8.89 (150/195). The access was a medium line vertical incision, with a stable retractor. The oxymeter was set on both sides on the secon toe. The acces was below the confluent for L5, S1 and from the right of the veina cava for the level above with a systematic control of the lumbar ascending vein.

**Results:** 3 small vein injuries have been sutured (1 right iliac, 1 right hypogastric and 1 right left iliac). 1 small tear on the confluent had not requested a suture (compression). On the 72 patients who had a right access with a cava mobilisation none of them had a cava injury. Despite the use of table-held self retaining retractors with powerful blades, there were no lost of the saturation signal (SAO2) during the retraction process and no arterial thrombosis had been seen. There were no retrograde ejaculation in all the males in the study.

**Discussion:** The right retroperitoneal access is an alternative to the current left access procedure. The cava mobilisation is performed vertically for the L4-L5 level, and seem less aggressive for the vein compared to the horizontal one for the Left iliac vein in L4-L5 from the left. the thickness of the cava is also one of the major point compared to the vulnerable left iliac vein. The non obliteration of the arterial axes and the non mobilisation of the aorta and left iliac artery, seem to be a security, when coming from the right as the arterial axis is more on the left. The risk of plates mobilisation is reduced. The lack of retrograde ejaculation confirms the anatomical work on the left anastomosis of the plexus, damaged from the left access that explains this complication.

**Conclusion:** The right retroperitoneal access is a safe procedure to be used in male or when arterial risks and allow a virgin access from the left if the level above needs surgery in the future.

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**Abstract:**

**Cost-effectiveness-Analysis of Lumbar Disc Arthroplasty versus Lumbar Fusion from a Health-care System’s Perspective**

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**Objectives:** Chronic low back pain caused by degenerative disc disease is one of the most common causes for doctor visits in western industrial countries and presents an immense economic burden both to the individual and to society. In many cases, surgery can be a treatment option. For some indications, lumbar disc arthroplasty may be an innovative alternative to the current gold-standard (lumbar fusion) and recent clinical studies have shown at least its non-inferiority for short- and midterm follow-up. The aim of this investigation was to analyse cost-effectiveness of “lumbar disc arthroplasty” versus “lumbar fusion” from a health care system’s perspective in Austria.

**Methods:** A decision model including treatment paths and associated direct costs (surgery, inpatient stays, outpatient visits, GP and orthopaedic consultations, x-ray, medication, rehabilitation and physiotherapy) over a 12-months time horizon was developed. Main outcomes were clinical success (measured by Oswestry-Disability-Index (ODI) and SF-36 at 1 year follow-up) and costs in euros (€). Clinical input data was derived from a recently performed matched-cohort-study and a meta-analysis of trials comparing the two treatment options. Costs were derived from standard Austrian price lists and from hospital’s cost unit accounting.

**Results:** Disc arthroplasty showed comparable outcome-scores at 1 year follow-up, while at the same time caused lower costs than lumbar fusion: Costs per improved ODI-point were €918 in the fusion group and €519 in patients treated with lumbar disc arthroplasty. Costs for one gained SF36-point were €866 after disc arthroplasty.

**Conclusions:** For a period of 1 year after surgery, this study suggests that lumbar disc arthroplasty is a cost-effective treatment compared with lumbar fusion from a health care system’s perspective in Austria. Further studies, including longer follow-up and indirect-costs, are necessary for the assessment of cost-effectiveness from the societal perspective.

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**Abstract:**

**The Impact of Preoperative DEXA Scores Following Arthroplasty on Long-term Clinical and Radiographic Outcomes – A 5-Year Follow-up Study**

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**Purpose:** Osteoporosis and osteopenia are clear contraindications for arthroplasty. No data exists on the long-term impact of arthroplasty on patients with bone density scores indicative of either osteoporosis or osteopenia. The goal of this study was therefore to evaluate clinical and radiographic outcomes of patients with DEXA T scores < -1.0 and nevertheless included in the CHARITÉ IDE study. This study only analyzed patients with a mild osteopenia and provides no information on more severe osteopenia or osteoporotic patients, as they were not entered into the study.
Materials and methods: Randomized and Training CHARITÉ cases from the 5-yr CHARITE study (including CHARITÉ training cases). A total of 10 patients with DEXA T scores ≤ -1.0 were included despite the fact that osteopenia and osteoporosis were exclusion criteria in the study. The clinical and radiographic outcomes of these 10 patients (referred below as the low DEXA group (LDG)) are compared to that of the remaining 111 subjects (referred below as the normal group (NG)). Changes in VAS and ODI from baseline to 5-year postoperative were recorded.

Results: The demographics between the LDG and NG were similar except for age (mean age for LDG: 48.6±6.77; NG: 39.1±7.91, p=0.0004). There were no differences in gender, height or body mass index. Total surgery time and estimated blood loss was also similar for both groups. While not statistically significant, changes in ODI scores from preoperative to 5-year postoperative showed trend for greater improvement in the NG vs. the LDG (mean change in ODI: LDG= -19.2±28.9; NG= -25.2±22.1). VAS score improvements during the same time frame were similar for both groups (mean change in VAS: LDG= -45.6±27.5; NG= -40.8±31.2). Radiographically, ROM at the 5-year time point showed trends towards reduced motion for LDG vs. NG (average ROM for LDG= -4.8±3.42°; NG= -6.1±2.09°). Vertebra translation and disc height at 5 years was similar for both groups (average translation for LDG= -0.8±0.63mm; NG= 0.6±0.78mm; average disc height for LDG= 13.4±0.79mm; NG= 12.8±2.02mm).

Conclusions: While clinical and radiographic outcomes at the 5-year time point were not statistically different between groups, the LDG showed trends towards lower disability improvements and reduced ROM as compared to the NG. Disc height was not different between groups. It is still recommended that the DEXA < -1.0 be considered to be an exclusionary criteria until further data is accumulated.

FACET REPLACEMENT

Abstract: 112

ACADIA™ Facet Replacement US IDE Pilot Study: 6 Month Follow-up Results for 20 Patients at Four Centers

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Introduction: Patients suffering from nerve root compression and/or neurogenic claudication secondary to posterior column pathologies often undergo surgical decompressions that destabilize the segment and require fusion. Reduction in mobility and the potential for accelerated adjacent level degeneration are a two of the sub-optimal consequences associated with fusion. Facet replacement represents a new motion sparing alternative to fusion for patients with lumbar spinal stenosis. The 6 month outcome measures for the FDA IDE pilot study of the ACADIA™ Facet Replacement System (Facet Solutions, Hopkintown, MA) are reported herein.

Methods: Bilateral facet replacement procedures were performed on patients diagnosed with central, sub-articular and/or lateral stenosis at L4/5 secondary to facet hyper trophy and/or low grade spondylolysthesis. A midline approach was used to gain access to the posterior elements and decompress the central and lateral foramina. The entire L4 inferior articular process was resected along with the hypertrophic portions of the L5 superior process. Specialized instrumentation was used to prepare implant bone beds on the dorsal aspect of each pedicle. The appropriate implant sizes were determined and placed using conventional pedicle screw fixation. Perioperative data including operative time, estimated blood loss and hospital stay were collected for each patient. Outcome measures including Oswestry Disability Index (ODI) and Visual Analog Scale (VAS) pain scores for the back and legs were recorded. In addition, radiographic studies were performed to assess range of motion (ROM) and evaluate implant fixation. Patient follow-ups were conducted at 6 weeks, 3, 6, 12 and 24 months.

Results: All 20 patients have reached the 6 month time point with 3 patients out beyond one year. Mean operative time, blood loss and hospital stay were 250 minutes, 495 mL, and 4.6 days, respectively. The mean improvement in ODI was 39.0 points at 3 months and 42.2 points at 6 months which compares favorably to the 21.4 point mean improvement reported at 3 months in the SPORT stenosis trial (Weinstein 2008). The mean improvement in VAS back pain was 36.3 mm at 6 months. The VAS symptomatic leg pain scores (symptomatic leg pain > 50 pre-operative VAS) showed substantial improvement falling on average 61.1 mm at 6 months. The mean increase in flexion-extension range of motion was 2.1 degrees or 84% at 6 months. No device related adverse events have been observed to date.

Conclusions: The perioperative results are within the range reported in the literature for well established fusion techniques (Villavicencio 2006, Whitecloud 2001). Substantial improvements in functional and pain outcome measures were seen at 6 weeks, 3 months and 6 months. The large decrease in back pain is noteworthy. The indication for this study focuses on leg pain, however many of these patients experience significant pre-operative back pain. Perhaps complete resection of the inferior articular process provides relief from facetogenic back pain. The early results for this study are promising. A prospective randomized IDE pivotal trial has been initiated to obtain a statistically meaningful comparison between facet arthroplasty and fusion as treatments for lumbar spinal stenosis.

Abstract: 510

Kinematics of Facet Replacement Adjacent to Fusion

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Purpose of the study: The screw-based cementless Total Facet Arthroplasty System® (TFAS-C™), a motion restoring implant is suggested as an alternative to posterior lumbar fusion at L3-L4 and L4-L5 levels after complete bilateral facetectomy. Although previous biomechanical studies reported successful results in restoring and reproducing normal spine kinematics after facet replacement, there is no data to characterize the kinematic performance of facet replacement in conjunction with an adjacent level fusion.

Methods: Six human cadaveric lumbar spines (L2-L5, Age: 61.3±13.2) were tested in the following sequence: (1) intact, (2) after TFAS-C implantation at L3-L4 and (3) after simulated fusion at the L4-L5 level, adjacent to the TFAS-C at L3-L4. Specimens were tested in flexion (8Nm), extension (6Nm), lateral bending (LB, ±6Nm), and axial rotation (AR, ±5Nm). A 400N compressive follower preload was applied during the flexion-extension (F-E) tests.

Results: Fusion at the L4-L5 level, with TFAS-C at L3-L4, resulted in rigid stabilization, significantly reducing the segmental motion in all loading directions compared to intact (p<0.05). TFAS-C produced ROM generally similar to intact, regardless of the presence of adjacent level fusion, preserving the mobility of the spine (Figure 1). Additionally, the overall load-displacement motion profile at the L3-L4 level, with TFAS-C and adjacent fusion, was characteristic of the intact condition (Figure 2).

Conclusion: In considering its kinematics performance, the TFAS-C (L3-L4 in this study) in conjunction with an adjacent level fusion maintained the mobility and provided stability at the implanted segment. The TFAS-C maintained the ROM of the segment and the three-dimensional kinematic patterns of the spine similar to the intact spine. The results from this
characterizing facet articulation in the human cadaveric lumbar spine

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Introduction: Characterizing facet function has often been done at the expense of facet joint integrity. In order to effectively evaluate the role of the facets in a functional spinal unit (FSU), a non-invasive method utilizing CT reconstruction and applied kinematic transformation matrices was proposed. The reconstructed model based technique was used to represent both FSU motion and facet articulation.

Methods: Image segmentation software was used to generate three-dimensional (3D) models of each vertebral body in a human lumbar spine. Three 3mm diameter holes were burred into each vertebral body and filled with a doped agar preparation prior to scanning for the purpose of image registration. Flexibility tests in flexion extension, lateral bending, axial torsion and compression were then conducted on each spine segment using a six degree-of-freedom spine tester. The kinematic response of the three joint complex of the FSU has important biomechanical ramifications in understanding the three joint complex of the FSU. Index and adjacent level impactions are also important in studying facet articulation in its native non-disrupted state. Moreover, the ability to apply kinematic motion with submillimeter accuracy to CT reconstructed models provides a non-invasive means of modeling facet engagement for clinical treatment purposes and spine arthroplasty device design.
Purpose: Instrumented fusion has been a surgical standard of care for spinal stenosis. However, the fusion construct rigidity has been implicated in adjacent level degeneration. The Total Facet Arthroplasty System® (TFAS) was designed as a motion-restoring, articulating joint prosthesis to be implanted following decompression and facetectomy. It is intended to stabilize the spine while maintaining the native motion of the facet joint.

Methods: 158 patients (85 female, 73 male) were implanted with the TFAS device and followed in a prospective clinical trial. Patients were screened preoperatively and followed at 1, 3, 6, 12, 24 and 36 months postoperatively. The surgical technique involved a posterior, open approach with wide decompressive laminectomy and bilateral facetectomy at the stenotic level. Data collection included AP, lateral, flexion and extension radiographs. Zurich Claudication Questionnaire (ZCQ), visual analog scales (VAS) for back and leg pain and radiographic status were also collected.

Results: The average age is 65.1 years. Five patients have at least 36 month follow-up, ten patients have 24 month follow-up, forty six patients have 12 month follow-up, fifty five have at least 36 month follow-up, ten patients have 24 month follow-up, and four have one month follow-up. Postoperative radiographic analysis of the TFAS device demonstrates motion in all patients at the instrumented level. Clinically, 87% of these patients have significantly improved ZCQ symptom scores and 82% have significantly improved ZCQ function scores compared to preoperative scores as of their most recent post operative follow up evaluation. Of those patients having at least 36 months of follow-up, 100% have shown clinically significant improvement ZCQ symptom and function scores compared to their preoperative scores, demonstrating durability of observed clinical outcomes.

Conclusion: Early results suggest that the TFAS device successfully allows motion, provides stability, and allows for clinically significant reduction of preoperative symptoms and improvement in function that is durable in patients with follow-up beyond 36 months.

Abstract: 501

Treatment of Lumbar Spinal Stenosis with a Total Posterior Arthroplasty Prosthesis versus Posterior Lumbar Fusion: A Prospective Report on 104 Patients

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Purpose: Decompression and fusion remains the gold standard of treatment for patients with stenosis and degenerative spondylolisthesis. To avoid loss of motion at the treated segment, the TOPS system, a novel total posterior arthroplasty prosthesis, was developed to allow for an alternative dynamic, multi-axial, three-column stabilization and motion preservation. The purpose of this study is to report preliminary surgical data and clinical outcomes with the TOPS system versus traditional posterior lumbar fusion with instrumentation in patients with lumbar spinal stenosis with or without degenerative spondylolisthesis and facet arthrosis.

Methods: Thirty-eight patients were enrolled in a nonrandomized, multicenter, prospective pilot study outside the US. An additional 66 patients were enrolled in a randomized, multicenter, prospective, US IDE Study (33 patients received the TOPS device, 33 patients the fusion control). The combined average age for TOPS patients was 62 years (43-73) and for control patients was 57 years (41-71). All patients had spinal stenosis with or without spondylolisthesis at L3-4 or L4-5 due to facet arthropathy. Radiographs and outcome measures including the visual analog scale for pain, Oswestry Disability Index, Short Form-36, and Zurich Claudication Questionnaire were prospectively recorded before surgery and at 6-week, 3-month, 6-month, 12-month and 24-month intervals after surgery. Prior to instrumentation in both TOPS and fusion patients, a bilateral facetectomy and laminectomy at L3-4 or L4-5 was performed via a standard midline posterior approach. After decompression, either a
posterior lumbar fusion with instrumentation or the TOPS device was implanted. TOPS pedicle screws were inserted into four pedicles with triangulating trajectories to achieve maximal purchase. An appropriately-sized TOPS arthroplasty implant was then applied.

**Combined US/US findings:**

Oswestry

Pre-op 6week 3month 6month 12month 24months

T05s: 5.7 31.4 24.4 22.6 19.9 16.6

Fusion: 55.5 32.9 21.8 23.2 18.7 N/A

VAS Leg

Pre-op 6week 3month 6month 12month 24months

T05s: 7.3 2.3 2.5 2.2 N/A

Fusion: 7.7 2.6 2.3 3.1 4.4 N/A

VAS Leg

Pre-op 6week 3month 6month 12month 24months

T05s: 7.2 1.9 1.8 2 1.6 2

Fusion: 6.5 1.2 1.4 1 1.5 N/A

The mean surgical time for the TOPS surgery was 2.9 hours (1.3-4.7) versus 2.5 hours (1.4-4.9) for the control. Radiographic analysis showed that in the TOPS patients, lumbar motion was maintained, disc height preserved. In the TOPS group, three device-related adverse events (3/71, 4.2%) were reported which required removal of the device and subsequent fusion, one of which was due to a misplaced pedicle screw; evidence of screw loosening was found in 1/284 screws (0.35%). In the control group, two patients required revision surgery for pseudoarthrosis, and one patient required further surgery for adjacent level disease (3/33, 9%).

**Conclusions:** The TOPS surgical and outcome data indicate that the device can be safely applied via a traditional posterior approach with low surgical morbidity. And when compared to traditional posterior-instrumented fusion, the TOPS device demonstrates excellent 2-year functional and radiographic outcomes in patients with stenosis with or without degenerative spondylolisthesis and facet arthritis.

**INTERSPINOUS DISTRACTION**

Abstract: 433

**Interspinous Distraction in Conjunction with Decompressive Facetectomy: Effect on Spinal Kinematics**

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**Objectives:** Lumbar spinal stenosis (LSS) is associated with neurogenic claudication caused by compression of the lumbar nerve roots. In patients with significant stenosis at multiple levels, an interspinous spacer (ISS) may have theoretical benefits over traditional treatments when used in conjunction with decompressive procedures such as unilateral medial facetectomy (UMF) and unilateral total facetectomy (UTF) for subarticular and foraminal stenosis, respectively. The aim of the study was to investigate the biomechanical effects of the FLEXUS® Interspinous Spacer (Globus Medical, Audubon, PA), a novel radiolucent ISS, on a lumbar spine after sequential graded facetectomies.

**Methods:** Seven cadaver lumbosacral spines (L1-S1) were tested in a six degree of freedom spine tester in the following sequence: (1) Intact; (2) UMF; (3) UMF+ISS; (4) UTF and (5) UTF+ISS with L3-L4 being the surgical level. A load control protocol was used for flexibility testing with an ±8Nm moment applied in flexion-extension, lateral bending and axial rotation. Range of motion (ROM) was recorded at L3-L4. The data was normalized to intact (100%). Statistical analysis was performed with significance level of p < 0.05.

**Results:** UMF and UTF increased the ROM at L3-L4 in flexion-extension as compared to intact to 109±9% (p>0.05) and 118±19.5% (p>0.05), respectively. With the use of ISS, UMF and UTF ROM significantly reduced to 79±20% and 86±25%, respectively, when compared with intact. The ROM in lateral bending for graded facetectomies and instrumented constructs was similar to intact. The ROM for UMF and UTF increased (p>0.05) in axial rotation when compared to intact. The addition of ISS to the graded facetectomy constructs also increased the ROM in axial rotation as compared to both intact (p>0.05) and facetectomy constructs (p>0.05).

**Conclusions:** The ISS device restores the flexion-extension ROM experienced after partial or complete facetectomy to physiologic levels. This suggests that ISS may have a significant role in the treatment of LSS, particularly when the preservation of more physiologic ROM in the sagittal plane may be of benefit, as in degenerative spondylolisthesis. It may be particularly desirable when trying to preserve native structures and avoid more invasive traditional options such as lumbar fusion. A limitation of this study lies in simulating LSS. On going biomechanical studies would help to address this situation.
Abstract: 487
Clinical Outcome, Survivorship Analysis and Predictive Factors for Failure after X STOP Implantation
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Objectives: To evaluate implant survivorship and patient-oriented outcome after implantation of the X-STOP interspinous device.

Methods: A total of 45 consecutive patients who underwent X-STOP implantation were asked to complete SF-36 and Oswestry Disability Index questionnaires and some additional outcome related questions after a minimum follow-up of 3 years. The data from 31 of these patients, who did not undergo revision surgery and of whom a complete pre- and postoperative dataset was available were analyzed. All 45 cases were used to perform a Kaplan-Meier survivorship analysis.

Results: Within the 3-year follow-up period, 12 of 45 (27%) patients required further surgical intervention. At follow-up, mean improvement for lumbar pain (VAS) was 1.1 (p = 0.009) and 3.7 (p < 0.001) for radiating leg pain. SF-36 PCS improved 9.9 (p = 0.006), MCS 5.0 (p = 0.12), the Oswestry Disability Index decreased 13.7 points (p = 0.003). Mean walking distance increased from 200m to 2100m (p < 0.001). All twelve patients that required revision surgery had a reduced ROM in the treated level preoperatively compared to the "survivor-group" and showed lack of improvement at 6-week follow up compared to the other group of patients. Kaplan-Meier survivorship analysis predicted a survival probability of 62% for 54 months postoperatively.

Conclusions: The results of this study show a relatively high revision rate with two peaks. One revision peak lies within the first year after surgery, another peak occurs after 4 years. Implant survival after the first year correlates with an overall good outcome whereas reduced ROM preoperatively and lack of clinical improvement within 6 weeks postoperatively seem to be predictors for revision surgery.

Abstract: 414
X-STOP Interspinous Decompression Device in the Management of Symptomatic Lumbar Canal Stenosis. Is There a Correlation between Outcome and Change in Canal Area at Two Years?
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Aim: To assess the clinical effectiveness of X-STOP interspinous process decompression device in patients with lumbar canal stenosis in relation to its ability to maintain the increase in dural sac cross-sectional area at two years.

Methods: We have presented the clinical outcome of a Prospective Observational Study of 57 patients. Out of these 57 patients, 38 had clinical and MRI follow-up at 2 years and are the subject of this paper. Clinical outcome was assessed by Zurich Claudication Questionnaire, ODI, SF36 and pain VAS scores. The ZCQ is the most condition specific outcome measure and is used for this evaluation. There is clinically significant improvement if two of the ZCQ domains improved more than threshold set or domain of patient satisfaction present MRI scan dural sac area was measured in standing erect and sitting, neutral, flexion and extension preoperatively and at 2 years. An increase in dural sac area was taken as radiological improvement. Osiris 4.17 software program was used for the measurements.

Results: We noted a statistically significant increase in mean dural sac area in standing erect, sitting neutral, flexion and extension postures. We had 38 patients who had MRI at 2 years. Two patients were excluded. One subsequently proved to have a neurological condition unrelated to the X stop device and the other had surgery at 22 months postoperatively. There was clinical improvement in 26 and some or no improvement in 10 patients. Number with increase in canal cross sectional area at 2 years was 28 and the number with reduced area was 8. Clinical and cross sectional area improvement was seen in 20 (56%) patients and clinical improvement with reduced cross sectional area was seen in 5 (14%) patients. Some or no clinical improvement was present with cross sectional area improvement in 8 (22%) patients and some or no clinical improvement with cross sectional area deterioration occurred in 3 (8%). A further patient who had cross-sectional area improvement required decompression surgery for recurrent symptoms after two year follow up.

Conclusions:
1. The X-STOP device remains clinically effective at the end of 2 years in the majority of patients.
2. Majority of patients (56%) showed clinical and cross sectional area improvement at 2 years.
3. A small number of patients who had no significant clinical improvement (2) had subsequent decompression surgery. The rest were managing well on conservative management.
4. There is not a clear-cut correlation between clinical outcome and increase in canal cross-sectional area.

MIS

Abstract: 194
Balloon Kyphoplasty in Comparison to a Conservative Treatment in the Long Term in Osteoporotic Vertebral Fractures
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Purpose: To evaluate the long-term outcomes of 126 patients with 239 osteoporotic vertebral fractures, located in the thoracic and lumbar spine, treated with Balloon Kyphoplasty and compared with a conservatively treated control group.

Material and methods: 90 patients (37 males and 53 females) with 187 osteoporotic vertebral fractures were treated with Balloon Kyphoplasty, 36 (12 males and 24 females) with 52 vertebral fractures served as controls. We were able to have a 2 year follow up in 78 patients with 168 vertebras treated with Balloon Kyphoplasty and 32 patients with 45 vertebral fractures treated conservatively. Symptomatic levels were identified by correlating the clinical presentation with conventional radiographs, CT and / or MRI. During the 2 year follow-up reduction in pain was determined. The effects on pain symptoms were measured on a self-reported Visual analog Scale (VAS) and the Oswestry score was documented to assess disability. Radiographic scans were performed pre- and postoperatively and after 3, 6, 12 and 24 months. The vertebral height and kyphosis angle were measured to assess the restoration of the sagittal...
alignment.

Results: The median pain scores (VAS) improved significantly from pre- to post-intervention as did the Oswestry Disability Score (p < 0.001), in the conservative group no significant changes could be documented. Balloon Kyphoplasty led to a significantly vertebral height restoration and correction of kyphotic deformity in the long-term (p < 0.05), in the conservative group significant further height loss and increase of kyphosis could be documented (p < 0.001).

There were significantly fewer patients with new vertebral fractures of the thoracic and lumbar spine, after 24 months, in the kyphoplasty group (15 patients, 4 male, 11 female, 19.2%) than in the control group (13 patients, 3 male, 9 female, 40.6%).

Conclusion: Balloon Kyphoplasty as an addition to medical treatment leads to a statistically significant reduction of pain status and improvement of physical function. Further, Balloon Kyphoplasty reduces occurrence of new vertebral fractures and prevents a height loss and increase of kyphotic deformity in the long-term.

Abstract: 551 Plasma Disc Decompression Compared to Fluoroscopy-guided Transforminal Epidural Steroid Injections for Symptomatic Contained Lumbar Disc Herniation: A Randomized, Controlled Trial: Two Year Results


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Objective: Plasma disc decompression (PDD) using the COLBALT SpineWand device (Arthrex Care Corp., Austin, TX) is a minimally invasive procedure to decompress the disc in patients who present with primarily radicular pain associated with contained lumbar disc herniations, and who have failed to improve with conservative care. This study compared the effectiveness of PDD to fluoroscopy-guided transforminal epidural steroid injections (TFESI) through 6 months. Patients were monitored through 2 years to assess the stability of treatment.

Materials & methods: This was a prospective, multicenter, controlled clinical study with random assignment to PDD or a TFESI series. Ninety patients (18-75 years old) who had radicular pain (visual analogue scale (VAS) score >50) associated with a single-level lumbar contained disc herniation and who had failed >1 ESI were enrolled. Patients were randomly assigned to receive either PDD or 1-2 TFESI. Clinical outcomes included VAS scores for leg and back pain, Oswestry Disability Index (ODI), SF-36 Health Survey, and a satisfaction-with-treatment questionnaire.

Results: Age (47±12 vs 42±11 years, p = 0.1), gender (female: 52% vs 54%, p = 0.6) and pre-procedure scores for leg pain (73±13 vs 75±15, p = 0.4), back pain (44±24 vs 53±23, p = 0.09), ODI (42±15 vs 44±17, p = 0.5), and SF-36 components (all, p > 0.05) did not differ significantly between PDD and TFESI patients, respectively. Procedure-related adverse events, including injection site pain, increased leg or back pain, weakness and lightheadedness, were observed in 5 PDD (7 events) and 7 TFESI (14 events) patients. The PDD group had significantly lower leg pain scores at 6 weeks (33±4 vs 54±4), 3 months (26±4 vs 50±5), and 6 months (25±5 vs 53±5) than the TFESI group (GEE; p < 0.01). The PDD group also had significantly lower back pain (6 weeks: 30±4 vs 48±4; 3 months: 30±5 vs 54±5; 6 months: 25±5 vs 45±5; GEE; p < 0.01) and better Oswestry scores (6 weeks: 30±3 vs 39±2, 3 months: 31±3 vs 40±2, 6 months: 28±4 vs 38±3; GEE; p < 0.05) than TFESI patients. At 6 months, improvement in SF-36 physical component summary (PCS) scores was significantly greater with PDD than TFESI (8±8 vs 3±5 points; p = 0.007) and significantly more PDD patients were satisfied with treatment (93% vs 62%; p = 0.005). At the end of 2 years, 8/42 (19%) PDD and 7/40 (18%) TFESI patients were lost to follow-up. Of patients followed successfully, 21/67 patients (17/34 PDD (50%); 4/33 TFESI (12%)) were followed 2 years as treated initially and 46/67 underwent a secondary procedure (17/34 PDD (50%); 29/33 TFESI (88%)). Of the 17 patients who failed PDD, 11 had TFESI, 3 had microdiscectomy, 2 had RF ablation, and 1 had fusion. Of the 28 patients who failed TFESI, 20 had PDD, 6 had another TFESI, 2 had microdiscectomy, and 1 had RF ablation.

Conclusions: In patients with primarily radicular pain due to a contained lumbar disc herniation, PDD was associated with significantly better clinical outcomes than a continued series of epidural injections through six months. During the 2-year follow-up, 40% of PDD patients underwent a secondary procedure, compared to 70% of TFESI patients.

Abstract: 205 Nerve Injury to the Posterior Rami Medial Branch during the Insertion of Pedicle Screws: Comparison of the Mini-open vs. Percutaneous Pedicle Screw Insertion Techniques

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Background context: The multifidus muscle is innervated by the medial branch nerve (MBN) of the posterior rami. The anatomy of the MBN makes it particularly susceptible to injury during the pedicle screw insertion. The medial branch curves around the root of the superior articular process and passes between the mammillary and accessory processes where it is susceptible to injury. Due to the segmental innervation of the multifidus a transection of the medial branch could potentially denervate the muscle by injuring the MBN.

Purpose: To compare the risk of injury to the MBN, by percutaneous and mini-open pedicle screw insertion techniques.

Study design: Anatomical study using five cadaver trunk.

Methods: Following side randomization, L1-L5 pedicle screws were inserted to each of the specimens using the percutaenous technique on one side and the mini-open technique on the contra-lateral side. After the proper location of the screws was verified by fluoroscopic imaging, the screws were removed and an anatomic dissection of the posterior spine was made in order to locate and examine the integrity of the MBN.

Results: Fifty pedicle screws were inserted to the spine through either percutaneous or the mini-open approaches. The injury rate following the percutaneous insertion was 20% (5/25) compared to 84% (21/25) for the mini-open approach (p < 0.01%). The average diameter of decorticated bone around the
Introduction: Vertebral body fractures are an important source of short and mid time morbidity in younger patients experiencing trauma. Traumatic vertebral body fractures (VCF) should be distinguished from spontaneous fragility fractures due to osteoporosis or cancer. Polymethylmethacrylate cement (PMMA) is the standard in fragility fractures. In younger patients a more bio-compatible/bio-resorbable alternative is preferable. KyphOs™ FS(R), a calcium magnesium hydroxyapatite cement mimics the anorganic component of bone, matches the criterion of biological bone substitute and has been developed for use during Balloon Kyphoplasty. This single-arm multicentric clinical study evaluates the safety and effectiveness of this cement during BKp in younger patients (< 50 yrs old) with stable traumatic VB fractures.

Methods: Patients, male and female, aged 50 years or less, with up to 3 traumatic VB fractures of type A1.1, A1.2 or A3.1, according to the Magerl/AO classification were included and followed for 1 year. The primary endpoint was the change from baseline in the 24 point Roland Morris Disability Questionnaire (RMDQ) score at seven days. Secondary endpoints included the quality of life as measured by EuroQol-5 Domain questionnaire (EQ-SD), the 10 point self-rated back pain (VAS) and device quality of life as measured by euroQol-5 Domain questionnaire (eQ-5D). The minimal clinical important difference on the RMDQ is 2.85 points at 7 days. The ethical committees were informed of the highly significant results. The results on RMDQ were confirmed on all the other secondary endpoints with further improvement up to 12 mo.

Results: Overall, the most common pattern was TP type accounting for 37.4% (390/1042) of all intraosseous venogram. The incidence of others are as follows: TAP (venous-anterior-posterior) type was most common in thoracic spine (T6-T10), TP type was most common in thoracolumbar spine (T11-L2), and TAP types were most common in lumbo-sacral spine (L3-S1). Contrast leakages to soft tissue such as psoas muscle or disc was detected in 43 (4.1%) venograms. Direct venous drainage without staining of the risk of MBN injury and concomitant pedicle screw was 15 mm for the mini-open approach which accounted for the higher rate of MBN injury.

Discussion: The minimal clinical important difference on the RMDQ is 2.85 points at 7 days. The ethical committees were informed of the highly significant results. The results on RMDQ were confirmed on all the other secondary endpoints with further improvement up to 12 mo.

Conclusion: The use of KyphOs FS(R) Bone Substitute during BKp appears to be a safe and effective method to treat stable traumatic vertebral fractures in young patients. The short term clinical results are maintained up to 12 months.

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Balloon Kyphoplasty using KyphOs™ FS(R) Calcium Phosphate Bone Substitute for the treatment of Traumatic Vertebral Body Fractures: One Year Outcome

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Objectives: Bone cement (PMMA) leakage is a well-known potential complication of percutaneous vertebroplasty (PVP) in patients with osteoporotic compression fractures. Even though there has been a controversy in the efficacy of antecedent venography to prevent this complication, many authors have performed intraosseous venography before bone cement injection. The goal of this study was to classify the venous drainage patterns of spine before PVP, and compare their patterns at different vertebral levels.

Methods: The author retrospectively reviewed 1,042 intraosseous venography in 321 patients with 574 osteoporotic compression fractures during six-year period in one institution. To classify venogram patterns, we selected simple lateral X-ray of spine taken immediately after shooting of the contrast dye. We classified the venography patterns according to contrast leakage pattern and leakage direction as follows: TR(trabecular), TA(trabecular-anterior), TP(trabecular-posterior), TAP(trabecular-anterior-posterior), TL(trabecular-lateral), VA(venous-anterior), VP(venous-posterior), VAP(venous-anterior-posterior), ST(soft tissue). And we compared venogram patterns according to different spinal levels.

Results: The most common pattern was TP type accounting for 37.4% (390/1042) of all intraosseous venogram. The percentage of others are as follows: TAP 21.5%, TR 17.4%, TA 11.6%, TL 5.8%, ST 4.1%, VA 1.2%, VP 0.6%, VAP 0.4% in descending order of frequency. According to the spinal level, TR and TAP types were most common in thoracic spine (T6-T10), TP type was most common in thoracolumbar spine (T11-L2), and TAP types were most common in lumbo-sacral spine (L3-S1). Contrast leakages to soft tissue such as psoas muscle or disc was detected in 43 (4.1%) venograms. Direct venous drainage without staining of the risk of MBN injury and concomitant pedicle screw was 15 mm for the mini-open approach which accounted for the higher rate of MBN injury. The minimal clinical important difference on the RMDQ is 2.85 points at 7 days. The ethical committees were informed of the highly significant results. The results on RMDQ were confirmed on all the other secondary endpoints with further improvement up to 12 mo.

Conclusion: The authors propose a new classification system of intraosseous venography during PVP. The trabecular-posterior (TP) type was most common through all spine, and venous-filling (V) type was more frequent in thoracic spine. Further study would be necessary to elucidate the efficacy of this classification system to prevent PMMA leakage during PVP.

Keywords: Percutaneous vertebroplasty. PMMA leakage. Venography pattern. Osteoporosis. Compression fracture.

Abstract: 611

Thoracic and Lumbar Percutaneous Pedicle Screws: Safety and Accuracy

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Purpose: This is a retrospective chart review analyzing the safety and efficacy of the percutaneous placement of pedicle screws in the treatment of traumatic and degenerative conditions.

Conclusion: The authors propose a new classification system of intraosseous venography during PVP. The trabecular-posterior (TP) type was most common through all spine, and venous-filling (V) type was most frequent in thoracic spine. Further study would be necessary to elucidate the efficacy of this classification system to prevent PMMA leakage during PVP.
Methods: One hundred and twenty-six patients (744 screws) presenting with various degenerative conditions (71 patients, 371 screws) and traumatic (55 patients, 373 screws) injuries without progressive neurological injury received percutaneous pedicle screw fixation as part of their surgical treatment. Medical records and radiographic studies were reviewed for procedure related complications (infection, vascular injuries, iatrogenic neurological injuries, and accuracy of screw placement) and the ability to re-establish and maintain spinal stability and alignment.

Results: Screw placement accuracy and spinal alignment and accuracy of screw placement) and the ability to re-establish and maintain spinal stability and alignment. Medical records and radiographic studies were reviewed for procedure related complications (infection, vascular injuries, iatrogenic neurological injuries, and accuracy of screw placement) and the ability to re-establish and maintain spinal stability and alignment.

Conclusions: Our data indicate that percutaneous pedicle screw fixation is a safe, accurate, effective, and reliable alternative to traditional open surgery. Prospective randomized clinical studies are necessary to establish more definitive conclusions and to identify the most suitable candidates for minimally invasive percutaneous pedicle screw placement.

Keywords: percutaneous pedicle screws, minimally invasive surgery, spinal instability, fusion, fixation.

CERVICAL TDR: MID TERM OUTCOMES

Abstract: 587

Results from the Prospective, Randomized Multi-center IDE Trial of ProDisc®-C vs. ACDF with 4-year Follow-up and Continued Access Patients

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Introduction: Adjacent segment degeneration is a consequence of anterior cervical disc degeneration and fusion (ACDF), likely initiated by increased adjacent level stress. The 2-year ProDisc®-C total disc replacement investigational device exemption (IDE) clinical trial, and single-center European studies, have been reported previously with favorable outcomes. The purpose of this report is to present up to 4-year results of the IDE trial, and continued access (CA) ProDisc®-C patients, to assess safety and efficacy of ProDisc®-C versus ACDF for treatment of symptomatic cervical disc disease (SCDD) at 1 level between C3-C7.

Methods: A total of 209 patients were enrolled, randomized, and treated on protocol and are continuing follow-up to 7 years. After the randomized arm closed, an additional 136 CA patients had ProDisc®-C surgery. Patients were evaluated pre/post-operatively at 6 weeks, 3, 6, 12, 18, 24, 36, and 48 months. Clinical assessments included Neck Disability Index (NDI), Visual Analog Scale (VAS) intensity/frequency (neck/arm), and SF-36 questionnaires, physical and neurological examinations, and radiographic evaluations.

Results: Pre-operative NDI values of all patients were statistically similar. At 24 months, there was no difference between randomized treatments compared to baseline (p = 0.43). At 48 months, ProDisc®-C showed significant improvement from baseline compared to Fusion patients (p = 0.0258). CA patients were statistically similar to both randomized groups at all follow-up points. VAS pain scores were statistically significantly improved from baseline at all follow-up points (p < 0.0001) regardless of treatment. At 24 months, there was no difference between randomized treatments compared to baseline (neck: p = 0.20; arm: p = 0.90). At 48 months, VAS scores of ProDisc®-C patients were lower but VAS scores of Fusion patients had risen; improvement from baseline to the two treatments for VAS pain was statistically significant (neck: p = 0.0063; arm: p = 0.0267). VAS satisfaction was higher at all time points for ProDisc®-C compared to Fusion patients. At 48 months, VAS satisfaction was statistically improved (p < 0.02) for randomized ProDisc®-C versus Fusion patients. At 48 months, 97.4% of randomized ProDisc®-C, 79.0% of Fusion, and 87.0% of CA patients said they would have the same surgery again. SF-36 physical (PCS) and mental (MCS) scores improved at all follow-up points - all patients showed statistically significant improvement in PCS scores from baseline (p < 0.0001). At 24 months, 1.9% of ProDisc®-C and 8.5% of Fusion patients required a secondary surgical procedure - revision, removal, re-operation. At 48 months, 2.9% of ProDisc®-C and 11.3% of Fusion patients needed secondary surgery (p = 0.03).

Conclusions: Extended term results suggest several significant points. A 4-fold increase was seen in re-operation rates for ACDF compared to ProDisc®-C patients. From 24-48 months, satisfaction rates improved in ProDisc®-C patients; declining in ACDF patients, reaching a statistical difference at 48 months. CA patients showed consistently greater improvement in clinical outcomes than randomized ProDisc(r)-C patients; perhaps due to improved surgical technique and better patient selection.

Abstract: 153

ProDisc®-C Total Disc Replacement: 36 Month Follow-up

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Introduction: Cervical total disc replacement (TDR) is an alternative to anterior cervical discectomy and fusion (ACDF) for the treatment of symptomatic cervical disc disease (SCDD) between C3-C7. Cervical TDR has potential benefits of providing immediate stability, reducing adjacent level disc degeneration and restoring/preserving range of motion (ROM) between vertebral bodies. Long-term study results are needed to quantify these benefits. The purpose of this study was to evaluate the 36 month clinical results of ProDisc®-C TDR, comparing single level outcomes to multi-level outcomes.

Methods: A prospective, controlled, consecutive case series of 112 patients who received cervical arthroplasty with the ProDisc®-C TDR was conducted. Patients were assessed pre-operatively and post-operatively at 6 weeks, 3, 6, 12, 24, and 36 months. Patients reported outcomes using the Neck Disability Index (NDI), Visual Analog Scale (VAS) Pain Intensity and Frequency (Neck and Arm), and SF-36 standardized questionnaires. Radiographic evaluation included anteroposterior (AP) and lateral flexion-extension (F/E), and coronal right and left lateral bending films.

Results: Of the 112 patients, 73 underwent single level surgery; 39 underwent multi-level surgery. Median age was 46.4 years
with an even gender distribution in both single and multi-level groups. Of single level cases, the level treated most frequently was C5-C6 (47.9%). Of multi-level cases, two levels were most common (84.6%), with C4-C6 and C5-C7 being equally as frequent. Mean operative time totaled 81.1 minutes in single level cases and 138.9 minutes in multi-level cases; estimated blood loss for the single level group was 75.8 cc with 119.1 cc for the multi-level group. At all follow-up periods, all patients showed a statistically significant improvement in NDI scores compared to baseline (p < 0.01). At 36 months, mean scores were not significantly different between groups (baseline: single level = 51.2 ± 18.4; multi-level = 53.0 ± 16.9, p = 0.0001; 36m: single level = 32.3 ± 21.7; multi-level = 35.4 ± 23.2; p = 0.6429). Average VAS scores for neck and arm pain intensity and frequency were statistically significantly improved from baseline at all post-operative time points (p < 0.05). At 36 months there was no statistical difference between single and multi-level cases for VAS neck and arm pain intensity or frequency (neck: intensity, p = 0.7490; frequency, p = 0.5876; arm: intensity, p = 0.8622; frequency, p = 0.9921). SF-36 scores indicated improvement in physical (PCS) and mental (MCS) components at all follow-up time points. At all time points, single level patients showed a statistically significant improvement in SF-36 PCS scores from baseline (p < 0.016). F/E ROM evaluation demonstrated that patients at all levels improved functional motion out to 36 months. To date there have been no revisions, removals, or re-operations of the ProDisc®-C in any of the patients.

Conclusions: Cervical TDR using ProDisc®-C as an alternative to ACDF, for SCDD, demonstrates statistically significant clinical improvement and provides long-term patient satisfaction. This data suggests that patients who receive multi-level TDR surgery using ProDisc®-C experience similar clinical outcomes to single level ProDisc®-C TDR patients.

Abstract: 288
Long-term Follow-up Study of Patients Treated with the Prestige Artificial Cervical Disc at a Single Centre

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Purpose: Long-term function of an artificial cervical disc is essential to its clinical success, however, to date there are no reported outcomes with these devices beyond 4 years. The neurosurgical staff at Frenchay Hospital (Bristol, UK) has surgical experience with 3 generations of artificial cervical discs (Bristol Cummins, Prestige I, Prestige II) dating from 1991 to the present. In order to evaluate the long-term performance of the Prestige disc (Medtronic Sofamor Danek), a follow-up study was conducted to evaluate all patients implanted with these devices at this centre from 1998-2004.

Methods: Under Ethics Committee approval, a long-term follow-up study was conducted to assess the clinical and radiographic outcomes of all patients treated with Prestige discs from 1998-2004. Patients were evaluated according to a standardized protocol which included neurological evaluation, patient completed outcomes measures (NDI, SF-36), Flexion/Extension x-rays, and adverse event reporting. The study comprised 2 groups of patients. Group I underwent implantation of Prestige I generation discs from 1998-2002 and group II underwent implantation of Prestige II generation discs from 2000-2004.

Results: In total, 32 patients were implanted with Prestige discs, 17 in group I and 15 in group II. Many of these patients were considered “end-stage” at time of implantation, often with multiple previous cervical levels fused. At present, 22 patient evaluations have been conducted, 12 from group I (mean follow-up 8.4 years, range 8.0-8.6 years) and 10 from group II (mean follow-up 5.0 years, range 3.7 to 6.5 years). The remainder have been lost to follow-up, or deceased. Both groups showed statistically significant improvements in mean neck disability index scores and neck pain, with arm pain also improving (not reaching statistical significance). In both groups the long-term mean angular motion was 5.8°, comparable to shorter-term results. This suggested that motion does not deteriorate over the studied time-course. Also, the few patients with reduced motion were linked with either failure of placement of the ball in the posterior one-third of the disc space, or with insertion of the disc with the neck positioned in extension at surgery resulting in its subsequent almost flexed state in the neutral position.

In group I, 5 of the patients required second surgeries at the treated level following device implantation in order to treat unresolved symptoms. These events all occurred within 1.5 years of the initial surgery, and were generally performed for persistent neck or arm pain. No patients in group II required revision surgery.

Conclusion: This study of a series of patients treated with the Prestige disc at a single centre provides insight into the viability of the device at long-term post-operative intervals (5-9+ years). Reduced motion was associated with improper surgical placement of the disc, and provided proper placement was initially achieved, long-term mobility of the joint was observed. Clinical evaluation showed long-term improvements in neck pain, arm pain and NDI scores from preoperative assessments.

CERVICAL TDR AND MYELOPATHY

Abstract: 499

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Introduction: Postoperative recurrence of myelopathy following cervical arthroplasty or ACDF may occur because of inadequate decompression or adjacent-segment disease. This in-vitro biomechanical study was undertaken to define the multi-directional flexibility properties of laminoplasty and laminectomy following cervical arthroplasty, and determine if posterior decompressive surgery is contraindicated with an existing arthroplasty device.

Methods: Seven fresh frozen cadaveric cervical spines were used for the multi-directional flexibility testing and evaluated under the following reconstruction conditions: 1) Intact, 2) Diskectomy (C5-6), 3) PCM Device, 4) PCM + three-level laminoplasty (C3-5), 5) PCM + four-level laminoplasty (C3-6), 6) PCM + five-level laminoplasty (C3-7), 7) PCM + laminoplasty without hydroxyapatite spacers, 8) PCM + laminectomy (C3-7). Multi-directional flexibility testing utilized unconstrained, pure moments of ±2Nm for axial rotation, flexion-extension and lateral bending. The centers of intervertebral rotation (COR) were calculated for the operative C5-C6 level. Quantification of the operative and adjacent level range of motion (ROM) and neutral zone (NZ) were normalized to the intact spine (100%).

Results: Flexion-extension loading of the diskectomy condition demonstrated a significant increase in operative level range of motion compared to intact spine and PCM constructs (p< 0.05). With the insertion of the PCM device, flexibility of the operative motion segment was restored near to the intact condition for both range of motion (92.2±36.6°) and neutral zone (120.8±35.0°) (p > 0.05).
Laminoplasty combined with disc arthroplasty exhibited greater motion at the operative C5-C6 level than the PCM alone (p<0.05). Although there were no statistically significant differences between three-level (121.2±49.7%), four-level (134.1±49.9%) and five-level (147.6±55.6%) laminoplasties, inclusion of additional levels in the laminoplasty procedure demonstrated a trend toward increased segmental C5-C6 motion. Subsequent laminoplasty without spacers (162.8%) and laminectomy (170.6%) combined with disc arthroplasty indicated even greater segmental motion (p<0.05). Lateral bending testing and axial rotation testing also indicated trends similar to that observed for flexion-extension loading (Figure 1). The discectomy procedure resulted in posterior movement of the COR, which was effectively restored following PCM reconstruction to within the posterior one-third of the inferior C6 vertebral element. Subsequent laminoplasty and laminectomy procedures did not significantly alter the COR.

Conclusions: Multidirectional flexibility analysis demonstrated increased range of motion and neutral zone in all loading planes - flexion/extension, lateral bending and axial rotation - following posterior decompressive surgery versus that produced by disc arthroplasty alone. The data also indicated that laminoplasty markedly reduces segmental motion compared to laminectomy. In addition, extending the laminoplasty to adjacent levels increased overall segmental flexibility of the cervical spine. Therefore, minimizing the extent of the laminoplasty is more favorable from a biomechanical standpoint in revision procedures. Moreover, the current findings suggest that immobilization of cervical spine may be necessary after multilevel posterior decompressive surgery following disc arthroplasty in early postoperative term.

### Table 1: Clinical Outcome Scores

<table>
<thead>
<tr>
<th>Group</th>
<th>Pre-op</th>
<th>6 wk</th>
<th>12 wk</th>
<th>26 wk</th>
<th>52 week</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDI</td>
<td>38/36</td>
<td>36/28</td>
<td>35/26</td>
<td>31/28</td>
<td>29/20</td>
</tr>
<tr>
<td>PCM/ACDF</td>
<td>55/56</td>
<td>31/36</td>
<td>23/27</td>
<td>20/25</td>
<td>18/29</td>
</tr>
<tr>
<td>Neck VAS</td>
<td>67/75</td>
<td>29/35</td>
<td>25/30</td>
<td>21/25</td>
<td>18/27</td>
</tr>
<tr>
<td>Arm VAS</td>
<td>54/57</td>
<td>19/18</td>
<td>20/24</td>
<td>18/21</td>
<td>15/21</td>
</tr>
<tr>
<td>PCM/ACDF</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

### Abstract: 349

**Results of Bryan Disc Replacement for Severe Cervical Spondylotic Disorder**

**Introduction:** Contemporary surgical management of severe cervical spondylotic disorder is evolving towards anterior cervical surgery, including discectomy or laminectomy and fusion procedures, as considered as the gold standard in surgical management of cervical spondylotic radiculopathy and myelopathy. Cervical disc replacement is a newer concept and rapidly developing surgical procedure. Our retrospective study was conducted to determine, if accurately implanted Bryan’s cervical disc prostheses can provide relief from objective neurological symptoms and signs; stability and restore motion in cases of severe cervical spondylotic disorders.

**Methods:** 84 patients underwent Bryan cervical disc replacement from April 2006 to May 2007. 30 patients between age groups 37 to 70 years with severe cervical spondylotic disorder (greater than 40% narrowing and marked spur) with myeloradiculopathy were included in this study. Patients with significant facet joint arthropathy, unstable spine, trauma, tumor, osteoporosis and active infection were excluded from this study. Patients were operated by anterior cervical approach using a specially designed Bryan’s cervical artificial disc system. Japanese Orthopedics Association Score (JOA), VAS outcome and flex-extension radiological follow-up was assessed pre- and post-operatively.

**Results:** The patients were in the age group of 37 to 70 years. There were 19 (63.33%) male and 11 (36.67%) female in this study. All the patients were observed up from 12 months to 26 months (average 24 months). According to JOA and VAS scale, all of 30 patients (48 levels) had excellent to good outcome. The range of movement recovered during the follow up, average range of motion was 10.05° ±3.6° (4.1°~18.0°). The treated segment showed restore good movement when compared with preoperative levels. No prosthesis subsidence or excursion Babinski reflex or positive Hoffman’s sign. Neck Disability Index (NDI), neck and arm VAS scores, Nurick Grading, complications and adverse events were recorded at 6, 12, 26, and 52 weeks postoperatively and compared via one-way ANOVA.

**Conclusions:** The treatment of carefully selected patients with radiculopathy and mild myelopathic symptoms with CTD R can result in similar short-term clinical outcomes to ACDF. However, further study and more long-term follow up is needed. Treatment of patients with signs of myelopathy and congenital stenosis may be uniquely contraindicated for CTD R.
was identified.

**Conclusions:** Cervical disc replacement for severe cervical spondylotic disorder with myeloradiculopathy represents an exciting result. 100% patients (30/30) maintenance of good motion was found during follow up. More patients with longer follow up and postoperative MRI to find out the protection to adjacent discs from abnormal stress will be required.

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**CERVICAL TDR BASIC SCIENCE**

Abstract: 635

**Does Implant Design Impact Cervical TDR Performance - A Finite Element Investigation**

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**Introduction:** Artificial discs preserve motion at the index level and lessen effects on the adjacent segments. Existing devices provide motion, but may not actively preserve or correct sagittal balance. We compare a new disc design with existing devices, analyzing the effects of design variables on kinematics and sagittal balance in neutral posture (NP), using a finite element model (FEM).

**Materials and methods:** An experimentally validated ligamentous intact C3-C7 FEM [1] was modified to simulate four disc designs at C5-C6 level: Synergy 0°(S0), Synergy 6°(S6), a ball & socket (BS) and a ball & trough (BT). S0 has parallel metal endplates whereas S6 has 6° built-in lordosis between the endplates and both have a polymer core. BS has an inferior polymeric ball and a superior metal socket. BT has a metal ball on superior endplate with an elongated inferior trough. Appropriate material properties, contacts and boundary conditions were defined for all the models. A compressive follower load of 73.5N and incremental moments up to 1.5 Nm were applied to define the neutral posture and to simulate physiologic motions respectively.

**Results:**

![Graphs for qualitative & quantitative motion results](image)

The NP loading resulted in: less than 1° of extension for intact, S0 and S6, extension around 3° for BS and flexion over 1° for BT. BS had excessive extension, lateral bending and axial rotation as compared to intact; also in extension, the endplates contacted and the ball and socket dislocated, limiting the range of motion. S0 and S6 had comparable motions with the intact (≈15% increase). In all of the cases, the motions increased as compared to intact, except in extension for BT design. The adjacent segment motions were not significantly affected in all cases. The S0, S6 and BT appear to have index level angular-response curves similar to intact. The built-in lordosis of S6 appears to shift the response curve accordingly near the neutral zone (+/-0.5 Nm). BS appears to have excessive and rapid motion compared to intact in the NP zone. Flexion-extension COR was close to intact for all the discs except for BT, where it was significantly superior. COR in lateral bending for BS is furthest from intact. The inherent device COR and device placement according to anatomical COR seems to affect the device behavior under NP loading.

**Conclusions:** Based on the FEM data, the Synergy disc design had kinematics closer to the intact condition and imparts a relatively stable neutral posture in the sagittal plane. Further investigations are warranted to understand the effects of design variables on sagittal balance and range of motion.


**Acknowledgements:** Study funded in part by a grant from OrthoKinetic Technologies, NC.

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Abstract: 569

**Variability of Range of Motion For 3-lobe versus Ball and trough TDR Designs**

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**Introduction:** A new non-congruent, self-centering, cervical disc replacement (TDR) was tested in a cadaveric kinematic model to evaluate the variability in its ROM compared to a conventional ball and trough design. The test TDR consists of 3 hemispherical lobes arranged in a tripod configuration on the superior component, articulating against mating non-congruent hemispherical pockets on the inferior component. The 3-lobe device maintained a more predictable range of ROM across all specimens compared to the range observed with the more conventional ball-in-trough TDR design. This suggests that the 3-Lobe device is a more forgiving design, thus less prone to problems associated with too much motion or too little motion.

**Materials and methods:** Six human cervical spines (C2-C7) were studied utilizing a 7-Axis spinal testing system. A hybrid load/position control protocol was used to test the specimen. The intact spine was tested first in flexion/extension, lateral bending, and axial rotation to 1.5Nm. Then the C4-C5 segment was implanted with the test and control TDRs utilizing an implant placement fixture that provided accurate placement of the device in the spine. Data collected included applied moments, forces, and rotations at C2 and C7, and 3D vertebral movements via an optical tracking system (Optotrak). Statistical analysis of kinematic data was performed with paired-ANOVA followed by a Tukey-Kramer HSD post hoc test.

**Results:** No statistically significant difference was observed between the Average ROM for the intact, 3-lobe, or ball and trough design (p= .96) (Table 1). However, when observing the minima and maxima, the ball and trough had values that were significantly outside the intact values (Table 2); while, the 3-Lobe had values close to that of the intact. It is observed that the ball and trough exhibited...
1.95, 1.84, and 1.51 times the ROM Range compared to the 3-Lobe in flexion/extension, lateral bend, and axial rotation respectively.

### Table 1

<table>
<thead>
<tr>
<th></th>
<th>FE-ROM (deg)</th>
<th>LB-ROM (deg)</th>
<th>AR-ROM (deg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact</td>
<td>4.6±1.0</td>
<td>1.6±0.6</td>
<td>9.3±0.8</td>
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<tr>
<td>3-Lobe</td>
<td>4.7±0.7</td>
<td>1.9±0.3</td>
<td>10.7±1.0</td>
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<tr>
<td>Ball &amp; Trough</td>
<td>4.9±1.6</td>
<td>2.1±0.5</td>
<td>11.0±1.3</td>
</tr>
</tbody>
</table>

### Table 2

<table>
<thead>
<tr>
<th></th>
<th>Minimum</th>
<th>Maximum</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flex/Ext</td>
<td>Intact</td>
<td>2.6</td>
<td>7.5</td>
</tr>
<tr>
<td>3-Lobe</td>
<td>2.5</td>
<td>7.0</td>
<td>4.5</td>
</tr>
<tr>
<td>Ball &amp; Trough</td>
<td>1.5</td>
<td>9.3</td>
<td>7.8</td>
</tr>
<tr>
<td>Lat Bend</td>
<td>Intact</td>
<td>1.3</td>
<td>2.5</td>
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<tr>
<td>3-Lobe</td>
<td>1.2</td>
<td>2.5</td>
<td>1.3</td>
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<tr>
<td>Ball &amp; Trough</td>
<td>0.7</td>
<td>3.1</td>
<td>2.4</td>
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<tr>
<td>Axial Rot</td>
<td>Intact</td>
<td>6.8</td>
<td>11.7</td>
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<tr>
<td>3-Lobe</td>
<td>8.4</td>
<td>11.9</td>
<td>3.5</td>
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<tr>
<td>Ball &amp; Trough</td>
<td>8.3</td>
<td>13.6</td>
<td>5.3</td>
</tr>
</tbody>
</table>

Discussion: It is known that too much motion, or too little motion, can cause facet degeneration or auto-fusion and that the ROM of conventional devices is affected by a variety of factors. The position of a TDR device within the disc space as well as variations in normal anatomy and errors in device placement can adversely affect reconstructed ROM. The 3-lobe cervical TDR studied in this experiment was able to accommodate variations in anatomy and placement and maintain its reconstructed ROM.

Abstract: 94

**Biotribology Assessment of NUNEC, a PEEK on PEEK Cervical Total Disc Replacement, According to ISO and ASTM Recommendations**

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**Introduction:** The current state of the art for devices in the cervical arthroplasty clinical arena consists of various material combinations which may have significant implications on their biotribological performance. ASTM and ISO have developed a guide and standard, respectively, detailing the methodology for evaluating the wear properties of cervical arthroplasty devices. However, in the absence of clinical retrievals, the appropriate model is yet to be defined, and for this reason, the methodologies employed to assess the wear characteristics of these devices has been diverse. The purpose of this study was to perform an *in vitro* biotribological assessment of NUNEC, a PEEK-on-PEEK cervical arthroplasty device in clinical use, using ASTM and ISO recommendations along with a comparative wear particle analysis.

**Methods:** Six NUNEC devices were tested on a spine wear simulator (MTS, USA). The test parameters consisted of ASTM F2423-05 recommended multidirectional motion and static load profiles from 0-10 million cycles (Mc) followed by ISO 18192-1 recommended motion and dynamic load profiles from 10-20 Mc. The average wear rates were determined using linear regression analysis with significant differences determined (ANOVA, p< 0.05). Analysis of the testing fluids after enzyme and mild acid digestion was performed using Low Angle Laser Light Scattering (LALLS: mn=average size based on number analysis and mv=average size based on volume distributions) and SEM for quantitative analysis.

**Results:** The results showed that the wear rates were not significantly different between these two methodologies. The wear rate for the ASTM method was 0.26±0.02 mm³/Mc and for the ISO method 0.31±0.02 mm³/Mc. These wear rates compare well with other cervical arthroplasty devices in clinical use (Figure 1). The particle analysis revealed that the size (ECD) of the particulate was significantly larger for the ISO testing methodology as compared to the ASTM methodology, with consistent morphology (Figure 1).

**Conclusion:** PEEK-OPTIMA is commonly used for spinal fusion and non-fusion applications due to its strength, biocompatibility and radiolucency. However it represents a unique material combination for use as a bearing material in cervical disc arthroplasty. The results showed that the wear rates were consistent to 20 Mc, suggesting long-term durability, with the particle size sensitive to the test method. However the particle morphology, an equally important parameter influencing biological activity, was similar for both methods. In addition, it is unlikely that static compressive loading occurs during rotational excursions, since the literature suggests that *in vivo*, dynamic compressive loading occurs due to muscle contraction during kinematic activities [8]. Overall, these results suggest that self-mating PEEK in the form of NUNEC could be a viable material combination for cervical disc arthroplasty.

**References:**

1. Laureysen, et al. SAS6;
2. Kim, et al. SAS6;
3. Dooris, et al. SAS7;
4. PMA data;
5. Reah, et al. SAS7;
7. PMA data;

CERVICAL TDR: RADIOGRAPHIC/OUTCOMES

Abstract: 343

**Comparison of Index and Adjacent Level Kinematics Following Cervical Disc Replacement versus Fusion: A Radiographic Analysis**

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**Objective:** To assess the *in vivo* motion of the cervical spine following cervical fusion and arthroplasty.

**Background:** Spinal arthroplasty theoretically can impede the development of adjacent segment disease by maintaining...
spinal motion. Rigorous in vivo study however needs to be performed to ensure that new arthroplasty devices maintain preoperative spinal motion and reduces the risk of adjacent level disease compared to cervical fusion.

**Methods:** As part of a multi-center, prospective, randomized FDA IDE clinical evaluation of the Porous Coated Motion Device Intervertebral Dynamic Disc Spacer (PCM), patients underwent either a single-level total disc replacement (TDR) (83 patients) or anterior cervical disectomy and fusion (ACDF) (183 patients) for treatment of cervical radiculopathy or myelopathy. Neutral, flexion and extension radiographs of the cervical spine were obtained pre-operatively, and at three, six, and twelve months post-operatively. Quantitative assessments and comparisons of motion patterns were produced using validated computer-assisted methods (QMA, Medical Metrics Inc., Houston, TX). Kinematic parameters such as segmental rotation, translation, and center of rotation were calculated.

**Results:** Mean angular rotation at the index level following TDR decreased from 8.2° preoperatively to 6.1° at 12 months post-operatively (p < .0001). The extent of change in rotation at the superior and inferior adjacent levels was similar between the groups. Intervertebral translation at the level of surgery, superior, and inferior to the treated level had not changed at 12 months for both groups. For the TDR group, center of rotation (COR)-X and COR-Y were 1.5 mm anterior and 0.3 mm at 12 months (p = 0.016). COR-Y averaged 2.5 mm below the endplate preoperatively and 4.4 mm below the endplate at 12 months (p = 0.002). Superior adjacent level center of rotation (COR)-X showed a significant difference with ACDF having a relatively more anterior COR at 3 months (p = 0.004). Inferior level COR-X also showed significant differences between groups with ACDF having a more anterior position at 3 and 6 months (p = 0.05, p = 0.04). Values of COR-Y between groups revealed no significant differences at either levels at any time points.

**Conclusions:** TDR is able to maintain angular motion while allowing for similar translation to that seen preoperatively. Both TDR and ACDF slightly increased sagittal rotation at superior and inferior levels. At the adjacent levels the sagittal center of rotation remains unchanged with TDR, but shifts anterior at the adjacent levels in the postoperative period with ACDF. This study provides in vivo data regarding the functioning of TDR and ACDF and their impact on adjacent level kinematics.

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**Abstract: 192**

**Difference in Occurrence of Heterotopic Ossification According to Prosthesis Type in the Cervical Artificial Disc Replacement**

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**Purpose:** Heterotopic ossification is a well-known phenomenon in the field of joint replacement but heterotopic ossification in cervical artificial disc replacement has not been elucidated well. The purpose of this study was to investigate the incidence and characteristics of heterotopic ossification, especially this study focused on difference of heterotopic ossification occurrence according to different type of prosthesis. The prosthesis related factors for making difference of heterotopic ossification occurrence were also discussed.

**Material and methods:** The total of 170 patients undergoing cervical arthroplasty with the Bryan Cervical Disc Prosthesis (Medtronic Sofamor Danek, Minneapolis, TN, USA), Mobi-C disc prosthesis (LDR medical, Troyes, France) and ProDisc-C (Synthes, Inc., West Chester, PA, USA) in our institute since December 2003 with follow-up duration longer than 12 months were included. Patient group included concurrent cervical fusion surgery. Cervical lateral radiographs obtained at scheduled time points before and after surgery were used to identify heterotopic ossification. Classification of heterotopic ossifications was made according to the McAfee’s classifications and consensus on heterotopic ossification determination for equivocal findings was made in the beginning of study. Occurrence rate, occurrence free period, location and grade of heterotopic ossifications were investigated according to the different prosthesis.

**Results:** In the patient population, male to female ratio was 105:65. Mean age and follow up duration were 43.5 years (14-66), 19.9 months (12.0-55.1) respectively. Each prosthesis group included patients as follows; Bryan disc 81 patients, Mobi-C 61 patients, and ProDisc-C 28 patients. Among all of the 170 patients, heterotopic ossification was found in 69 patients (40.6%). Heterotopic ossification occurrence rate was 21.0% (17 patients) at 17.6 months after surgery in the Bryan disc group, 52.5% (32 patients) at 11.9 months in the Mobi-C group and 71.4% (20 patients) at 13.8 months in the ProDisc-C group. Most of patients over 80% were classified as grade I or 2 of heterotopic ossification and 2 patients with grade 4 were found only in the Bryan disc group. Anterior located ossification was more frequent than posterior location but difficulty in detection of posterior ossification using plain radiographs should be considered. In the survival analysis of heterotopic ossification occurrence, all patients showed 27.1±3.7 months as median survival. The Bryan disc group showed statistically longer survival (48.4±7.4 months) rather than the other groups.

**Conclusion:** Occurrence of heterotopic ossification is inevitable postoperative complication after cervical artificial disc replacement, contrary to the fundamental goal of artificial disc. The occurrence rate of heterotopic ossification was higher than our expectation. Moreover, definite differences in occurrence rate according to the prosthesis type were identified by this study. Differences in the design, biomechanical property, prosthesis specific endplate articulation component, surgical procedure would be contributing factors for making difference in heterotopic ossification. Various kinds of prosthesis more than this study should be included in the future study to elucidate prosthesis specific complication. Computed tomography would be helpful for increasing sensitivity of detection. Factors not predisposing ossification would be important in the future study.

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**Abstract: 659**

**Predicting Relief of Radiculopathy in Patients Receiving ACDF or TDR: Factors Associated with Response**

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**Introduction:** Although both cervical TDR and ACDF have been reported to be successful procedures in the relief of cervical radiculopathy refractory to non-operative care, there are subsets of patients with a less than optimal response to the surgery. The purpose of this study is to determine which specific clinical and radiographic factors correlate with success as measured by relief of radiculopathy in a similar cohort of patients randomly assigned to receive TDR or ACDF. These factors may be critical to patient selection for either procedure and contribute to favorable clinical outcomes.

**Methods:** As part of a multi-center, prospective, randomized FDA IDE clinical evaluation of the PCM cervical artificial disc, patients were treated with a single-level PCM artificial disc or ACDF with allograft and cervical plating for treatment of cervical radiculopathy or myelopathy. Patients reporting at least 50/100 Arm VAS score preoperatively were included in the analysis. Patients were determined to be “responsive” if their arm VAS declined by 50% or more and “unresponsive” if their arm VAS declined by less than 50% at 1 year follow up. Fifteen independent preoperative or postoperative,
LUMBAR TDR OUTCOMES

Abstract: 65
Sexual Function in Men and Women Before and after Total Disc Replacement Compared to Posterior Lumbar Fusion
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Study design: A randomised, controlled trial (RCT) comparing total disc replacement (TDR) and fusion, either performed as an instrumented posterior lumbar fusion (PLF), or as a posterior lumbar interbody fusion (PLIF).

Objective: To investigate how chronic low back pain (CLBP) of assumed discogenic origin affected sexual function in patients considered for surgical treatment, and whether sexual function was affected by the surgical treatment, and if so, whether there were differences in this respect between the surgical procedures; TDR and PLF/PLIF.

Summary of background data: Sexual function may be affected by CLBP, but few studies have addressed this issue. Sexual dysfunction after anterior lumbar fusion has mainly been focused on impaired male biological function (retrograde ejaculation). This has led to concerns on whether sexual function was affected by the surgical treatment, and if so, whether there were differences in this respect between the surgical procedures; TDR and PLF/PLIF.

Methods: 152 patients were included in a RCT in order to compare the effect on LBP of either TDR or instrumented posterior lumbar fusion, either as a PLF or as a PLIF. Patients received a gender specific preoperative questionnaire, and an additional questionnaire at the two-year follow-up. Clinical outcome was recorded through the Swedish Spine Registry (“SweSpine”) preoperatively, and after two years. Clinical data included the Oswestry disability index (ODI), were ODIB, the question reflecting the impact of pain on sexual function, was analysed separately. TDR was implemented through an anterior retroperitoneal approach.

Results: A majority of the patients had impaired sexual function before surgery. In all 31% reported that their sex life was severely restricted or prevented by pain. Sex life, as monitored with ODIB, improved in both groups after surgery, with a strong correlation to reduction of CLBP. The gender specific questionnaire used at the two years follow-up revealed some changes after surgery: there was no negative effect of TDR, compared to fusion, upon erection, orgasm or retrograde ejaculation, but 26% in the fusion group reported postoperative deterioration in ability to achieve orgasm compared to 3% for TDR patients.

Conclusion: Sexual function seems to be negatively affected by CLBP, and improvement after lumbar surgery, either performed as total disc replacement or posterior fusion, was in this study positively correlated to reduction of pain. Anterior retroperitoneal approach, as used for TDR in this study, was not associated with more sexual dysfunctions compared with instrumented posterolateral- or interbody fusion. The males in the fusion-group reported in higher frequency deterioration in ability to achieve erection and orgasm postoperatively, compared with the male TDR-patients.

Purpose: In patients with degenerative disc disease (DDD), preoperative disc height at the diseased level is one of many indicators of degeneration. The impact of preoperative disc height on long-term success is poorly documented. The purpose of this study was therefore to valuate pain and disability improvements in the CHARITÉ IDE patient population, treated either with CHARITÉ or BAK with autograft, based on preoperative disc height.

Materials and methods: All CHARITÉ and BAK patients from the 5-yr CHARITÉ IDE study (including CHARITÉ training cases) with available preoperative disc height measurements were included in this study. At the 5-year follow-up time point, all patients were divided by treatment type (BAK vs. CHARITÉ), implanted level (L4-L5 vs. L5-S1) and preoperative disc height. For this subdivision, preoperative disc height for all patients was analyzed and subjects within the lowest 25 percentile of all disc heights (LDH) were compared to those in the higher 75 percentile (HDH). The subgroups were compared for pain (VAS), disability (ODI) as well as ROM and disc height, at the 5-year time point. A receiver operating characteristic (ROC) curve was constructed to evaluate if preoperative disc height was predictive of successful outcome. The AUC (area under the curve) and associated statistical test were calculated for the ROC curve.

Results: Preoperative disc heights and corresponding VAS and ODI changes from preoperative to 5 year post-operative are shown in Table 1 below. At L4-L5, changes in ODI for CHARITÉ or BAK patients with LDH vs. HDH were not statistically significant. At L5-S1, changes in ODI for CHARITÉ patients, but not BAK patients, were greater for LDH cases vs. HDH cases (p=0.0335). At L4-L5, changes in VAS for CHARITÉ and BAK patients with LDH vs. HDH were not statistically significant. At L5-S1, changes in VAS for CHARITÉ patients, but not BAK patients, were slightly greater in the LDH group than in the HDH group (p=0.0520). No significant differences in 5-year disc height, ROM and translation were observed between groups. The ROC analyses indicated however that preoperative disc height might not be a strong predictor for clinical success.
Introduction: Previously published TDR studies reported on the pooled data averages collected from various cohort sizes. The individual patient’s prognosis as well as prognostic factors of postoperative improvement remain unestablished. The objectives of this study were to examine whether baseline variables VAS (Visual Analogue Scale) and ODI (Oswestry Disability Index) correspond with late and final parameters (≤6 months) revealed significant and strong associations with the final results following TDR. Whilst the vast majority of patients with an early highly satisfactory outcome maintained satisfactory results at later FU stages, any significant improvement considered as ‘highly satisfied’ is unlikely in a group of patients which reported early unsatisfactory results. In summary, any clinically relevant changes are unlikely to occur after the early postoperative period.

The current findings offer a foundation for weighing both the patients and the spine surgeons expectations against possible realistic achievements. Whilst the data show that the mid-term outcome is predictable following TDR, the long-term results of lumbar disc replacements still need to be established.

### Abstract: 178

**Is the Final Outcome Predictable Following Total Lumbar Disc Replacement?**

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**Results:** The overall results from 161 patients with an average overall results from 161 patients with an average Fu of 4 years (mean 45.5 months, range 24.1 - 94.4 months) revealed a significant and maintained improvement of VAS and ODI scores (p< 0.0001). The most pronounced changes occurred within the early postoperative period (p< 0.0001) with no significant changes thereafter (p>0.05). Baseline ODI levels were significantly correlated with VAS / ODI scores and patient satisfaction rates at the final FU (p< 0.0001).

Postoperatively, early and late ODI levels were highly significantly correlated with each other (r=0.84, p< 0.0001). Similar associations were observed between early and late VAS scores and patient satisfaction rates (p< 0.006).

The individual patients subjective outcome evaluation revealed stable postoperative results. An improvement or a deterioration by 2 classes on a 3-scale grading system was only observed in 3.1% (n=5/161) of all cases overall. Patients with an early ‘highly satisfactory’ result (n=83) maintained either a satisfactory (15.7%, n=13/83) or a highly satisfactory outcome (79.5%, n=66/83) in 95.2% of all cases (n=79/83). Conversely, the probability that patients with an ‘unsatisfactory’ outcome would still achieve a ‘highly satisfactory’ result after the early postoperative period was 5.0%.

**Conclusion:** Baseline ODI and early postoperative outcome parameters (≤6 months) revealed significant and strong associations with the final results following TDR. Whilst the vast majority of patients with an early highly satisfactory outcome maintained satisfactory results at later FU stages, any significant improvement considered as ‘highly satisfied’ is unlikely in a group of patients which reported early unsatisfactory results. In summary, any clinically relevant changes are unlikely to occur after the early postoperative period.

The current findings offer a foundation for weighing both the patients and the spine surgeons expectations against possible realistic achievements. Whilst the data show that the mid-term outcome is predictable following TDR, the long-term results of lumbar disc replacements still need to be established.

### LUMBAR TDR BIOMECHANICS

**Abstract: 75**

**Explanation of Unequal Wear Patterns in the Charité Polyethylene Core: A Quantitative Analysis of Intra-prosthesis Motion Distribution**

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**Background:** In Charité lumbar disc prostheses, with mobile core design, angular motion within the prosthesis can occur between the superior endplate and the core and between the inferior endplate and the core. A recent study showed one-sided wear in 43% of explanted Charité cores retrieved from 32 patients after 7.3yrs average implantation, suggesting unequal motion distribution between the two bearings. However, there is no quantitative data to assess the extent of asymmetric intra-prosthesis motion distribution.

**Purpose:** To test the hypothesis that distribution of total prosthesis motion between the two bearings of an implanted Charité disc would not be equal.

**Methods:** 13 human cadaveric spines (L1-S1, 48±8.6yr, 20 Charité implants) were tested. Specimens were tested in flexion (8Nm) and extension (6Nm) under 400N follower preload. After intact tests, the PLL was resected and a Charité disc was implanted at L3-4 (n=6), L4-5 (n=4) or L5-S1 (n=10), centered in the frontal plane and centered on or slightly posterior to sagittal midline. Fluoroscopic images acquired during flexion-extension (FE) were analyzed using validated, radiographic measurement techniques to calculate intervertebral motion in implanted segments, total prosthesis motion and its distribution between the two bearings (superior endplate-core and inferior endplate-core).

**Results:** The ratio of motion at the superior bearing to the motion at the inferior bearing was 3.02±1.95 (95% CI: 2.11-3.94). This ratio was significantly larger than 1.0 (p< 0.001), signifying unequal motion distribution in the two bearings. 18/20 implants showed larger motion at the superior bearing than at the inferior (Fig. 1), and in 12 of these, motion at the superior bearing was more than double that at the inferior (Fig. 2).
Conclusions: Unequal motion at the two bearings is necessary to preserve normal kinematics of the lumbar spine with the center of rotation located at or below the inferior endplate of the lumbar disc. The quantitative results of unequal motion distribution between the two bearings of the implanted Charité disc prosthesis may explain the one-sided wear observed in explanted cores. This data will be useful in further improving in vitro wear test protocols to better replicate in vivo wear-producing conditions.

Abstract: 335

Influence of a TDR Device on Facet Joint Biomechanics
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Introduction: Severe cases of degenerative disc disease sometimes require extreme surgical treatment. Total disc replacement (TDR) devices restore vertebral segmental motion and disc height. However, the effect of TDR on the facet joint has not been clarified yet. The objectives of this study were to measure the facet loads and investigate the effect of the TDR device on spinal kinematics on intact and instrumented motion segments under physiological loading conditions and motions.

Materials and methods: A metal-on-metal total disc replacement device (MaverickTM, Medtronic, Memphis, TN) was used in this study. Fourteen (12F/2M, mean age 80.4 yrs), L4-L5 human, fresh-frozen, cadaveric functional spine units, were divided into 2 groups. The first group (n=7) served as a control group for kinematics with intact facets and was tested with and without the TDR device. The second group (n=7) was used for facet load measurement, again with and without the artificial disc. Facet loads were measured with thin-film piezoresistive load transducers inserted in-between the zygapophyseal joints. Care was taken to preserve the intervening disc, facet joints and all ligaments.

Biomechanical testing involved application of ±7.5N·m moments in smooth continuous flexion-extension, lateral bending, and axial rotation motion, with and without a compressive load of 400N. The angular range of motion (ROM) was recorded using an optoelectronic motion tracking system. Specimens were kept moist throughout the test by wrapping the disc in saline-soaked gauze. Statistical differences among groups were sought using paired t-tests with p < 0.05.

Results: For the axially loaded specimens, there were no significant differences in the ROM mean values for extension (0.91° vs. 1.23°) and axial rotation (2.62° vs. 2.68°), intact vs. TDR, respectively. However, the TDR produced larger ROMs (p< 0.05) for the flexion (3.44° vs. 8.11°) and lateral bending (2.93° vs. 5.13°) cases. In all intact specimens, the axially loaded ROMs were significantly smaller than unloaded cases (p< 0.05). To determine the effect of the TDR on the facet loads, this was only measured in extension and torsion. Facet loads in the fully extended position (26.2±9.1N, Mean±S.E.) did not show significant differences after TDR. In flexion, the facet load reached only an average of 44% of the extension value. There were no significant differences between intact and TDR facet loads when the axial load was applied. The two cases where only one facet sustained most of the load were lateral bending and axial torsion. In lateral bending, a maximum of 41.4N (for both intact and TDR) was recorded for the ipsilateral side against a contralateral facet experiencing only an average of 7.3N. There were no differences with respect to the intact specimens. In torsion, the loaded facet reached an average of 121.3N contact force with no significant differences between all four cases (intact/TDR and axially loaded/unloaded).

Conclusions: Increased angular ROMs in lateral bending and flexion were the only significant changes produced by the TDR device. Overall, this study found that the TDR did not alter facet loads considerably when subjected to physiological motions and loads.

Abstract: 212

First Generation TDR Devices Do Not Adequately Resist Shear in the Lumbosacral Spine
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Purpose: Several clinical studies have reported accelerated facet degeneration following TDR. To date, there are no biomechanical studies available to clarify whether this is related to increased facet loads or a consequence of a change in loading conditions.

During physiological daily activities, the lower lumbar spine experiences large anteriorly-directed shear forces, particularly in the lumbosacral joint. Therefore, loading conditions that approximate this effect are necessary to accurately determine the biomechanical effects of lumbosacral TDR. Previous studies evaluating TDR kinematics primarily utilize pure moment protocol that imposes no shear force on the specimen. Thus, it remains unclear whether current ball-and-socket designs are capable of resisting the shear imposed on the lumbosacrum. The facet joints assist the disc in resisting shear and preventing forward translation of the superior vertebral. It is logical to assume that if the disc is altered such that its ability to resist shear is compromised, a greater burden will be placed on the facets. The aim of this study is to investigate changes in LS/S1 facet loading post-TDR with respect to sagittal placement of the device.

Methods: Six human lumbosacral motion segments were tested under shear and axial compressive force designed to mimic the average loads experienced in the upright standing position. Flexion, extension, and lateral bending postures were imposed. Each specimen was first tested intact, followed by surgical placement of the Prodisc-L artificial disc in 3 positions:
Comparison of Two Lumbar Total Disc Replacements

Abstract: 55

24-month Follow-up of a Prospective Randomized Comparison of Two Lumbar Total Disc Replacements

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Introduction: Lumbar total disc replacement (TDR) has been available for several years. In earlier randomized studies, TDR was compared to various types of lumbar fusion. The purpose of this study was to compare two lumbar TDRs.

Methods: A total of 85 patients, all treated for symptomatic disc degeneration unresponsive to non-operative care, from two centers participating in the FDA-regulated trial were randomized in a 1:1 ratio to receive Kineflex or Charité total disc replacement. All procedures were single-level performed at either the L4-5 or L5-S1 level, with the majority of cases at the lower level. Data collection included peri-operative data, clinical outcome, adverse events, and radiographic results, the two discs produced similar results. This study reinforces that when employing well-defined selection criteria, outcomes are consistent between TDR devices.

Discussion: This study provides 24-month follow-up data from two sites participating in the FDA-regulated trial evaluating the Kineflex artificial disc by comparing it to the Charitez disc. This prospective randomized study found that with respect to peri-operative data, clinical outcome, adverse events, and radiographic results, the two discs produced similar results. This study reinforces that when employing well-defined selection criteria, outcomes are consistent between TDR devices.

Abstract: 144

Volumetric Analysis of Foraminal Parameters Following Lumbar Total Disc Replacement: A Radiographic and Clinical Comparison of 3 Biomechanical Types of Lumbar Disc Replacements: A Semi-constrained Device, a Controlled Translation Device (CTD) and an Unconstrained Device

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Background: Total disc prostheses created for motion may have different mechanisms and levels of constraint. These inherent properties of the implant may have biomechanical significance on the motion segment, adjacent segments and surrounding structures and may alter the patient’s clinical course.

Purpose: To determine if there are differences in motion and foraminal dimensions based on type of ADR implant by evaluating data from a prospective randomized FDA clinical trial.

Study design/setting: Patients were evaluated from two different sites by two separate surgeons who had one of three different types of ADR implanted with a minimum
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12-month and maximum 24 month follow-up.

**Patient sample:** One of three ADRs was implanted into each patient as part of a FDA clinical trial. Charité (14), Prodisc (12) and Activ-L (49) were randomly selected for implantation into a group of people with similar demographics and inclusion/exclusion criteria.

**Outcome measures:** At baseline, 3, 6, 12, and 24 months follow-up, patients were evaluated radiographically and clinically.

**Methods:** Patients undergoing a single-level ADR were randomized to receive either a Charité, Prodisc or Activ-L implant. Radiographs taken at baseline, 3, 6, 12, and 24 months post-operatively were evaluated. Comparison of foraminal height and change in foraminal height were compared.

**Results:** The average change in foraminal height for Charité was 2.45 mm, the average change for Prodisc was 3.26 mm and the average change in foraminal height for Activ-L was 4.14.

Overall mean ODI across all groups decreased from 59.9 to 24.1. Individually, the mean ODI for the Activ-L patients decreased from average 59.6 at baseline to 23.0 at 24 month follow up, Prodisc fell from 63.0 to 29.6 and Charité from 57.0 to 25.4. The VAS score for back pain across all groups decreased from a mean of 81.6 to 25.0 at 24 months post-operatively. For the Activ-L patients the mean baseline VAS for back pain was 83.1 and fell to 23.0 at 24 months. Prodisc fell from 85.0 to 30.7 and the Charité patients fell from 73.5 to 30.5.

**Conclusions:**
1. All three types of prosthesis induced an increase in foraminal height at the operative level.
2. Although the height of the controlled translation device was the smallest (avg 8.5mm), the CTD resulted in the greatest increase in foraminal height. There was no clinical difference in patient outcomes among the three devices.

**Abstract: S24**

**Biomechanical Comparison of the Prodisc-L, Charité, and Maverick Lumbar Disc Prostheses**

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**Introduction:** Interest in lumbar disc arthroplasty as an alternative to fusion surgery continues to grow. The goal of disc arthroplasty is to replace the diseased disc while preserving and/or restoring motion at the operated spinal level. Different paradigms exist in the design of total disc arthroplasty devices. The purpose of this study was to compare the in vitro biomechanics of a constrained ball-and-socket design (Prodisc-L, Synthes Spine and Maverick, Medtronic) and a less constrained mobile-bearing design (Charité, DePuy). The biomechanical performance of the disc prostheses was compared to a fused spine condition.

**Methods:** Twenty human cadaveric lumbar spines (L1-sacrum) were tested in flexion, extension, lateral bending, and axial rotation under displacement control. Five spine conditions were tested in flexion, extension, lateral bending, and axial rotation at L1-L2 for all disc conditions and at L3-L4 for the Charité and during right-left lateral bending at L1-L2 for all disc conditions and at L3-L4 for the Charité. Issues pertaining to adjacent segment disease (ASD) with PSF were supported by the increase motion at multiple adjacent segments. However, disc arthroplasty eliminated any significant increase and may prevent ASD.

**Conclusions:** Issues pertaining to adjacent segment disease (ASD) with PSF were supported by the increase motion at multiple adjacent segments. However, disc arthroplasty eliminated any significant increase and may prevent ASD. Compared to pedicle screw fixation, the three differently designed disc prostheses (Prodisc-L, Maverick, and Charité) remained stable and provided improved lumbar mobility. The only notable difference between the disc designs was the increased flexion-extension motion at the operative level of the semi-constrained Charité disc compared to the more constrained ProDisc-L disc.

**LUMBAR TDR BASIC SCIENCE**

**Abstract: 634**

**FlexiCore® Lumbar Arthroplasty: Blood Metal Ion Levels**

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**Background:** Lumbar Arthroplasty with metal-on-metal devices is emerging as an alternative to fusion for the treatment of degenerative disc disease. One of the main concerns about these devices is the generation of metal ions, either as wear debris or surface decomposition. Wear debris may elicit acute neural or inflammatory responses and has been implicated in osteolysis and device loosening. Metal ions may also have long-term toxicity.

**Purpose:** The purpose of this study is to report on blood metal ion levels after lumbar arthroplasty with FlexiCore®. FlexiCore® is composed of a Cobalt Chromium Molybdenum (CoCrMo) alloy, consisting of 58.65% - 68.85% cobalt, 26.0% - 30.0% chromium, 5.0% - 7.0% molybdenum, and less than 1.0% of each carbon, nickel, iron, silicon, manganese, and nitrogen.

**Methods:** Whole blood samples were taken from patients who received the FlexiCore implant as part of a US FDA IDE study and analyzed with spectroscopy and spectrometry by an independent laboratory. Data is available for 37 patients at pre-op, 30 patients at 6 months, 31 patients at 1 year, and 29 patients at 2 years.
Discussion: The median levels of cobalt and chromium did not change at any follow-up, and the median level of molybdenum remained nearly constant. In analyzing the maximum values, cobalt levels rose in some patients at all follow-ups, chromium levels rose in some patients at 6 months but declined at 1 and 2 years compared to pre-op, and molybdenum levels rose in some patients at 6 month but was similar to pre-op at 1 and 2 years. The maximum levels of cobalt and chromium were always well below the dose/body-weight levels shown in animal studies to elicit acute neural or systemic responses (Spine J, 2007; 7: 2S-3S). The possible effects of molybdenum have not been well studied, but the levels found here did not show much increase over pre-op. Interestingly, the changes of the levels of the three ions did not mirror their proportions in the FlexiCore® device composition, suggesting either that the body eliminates them from the blood at different rates or that the three elements are exuded from the device surface at different rates (Basic Clin Pharmacol Toxicol, 2007; 101: 441-6). None of the three elements appeared to be continually increasing, suggesting that metal ions do not simply accumulate in the blood over time.

Conclusion: This report suggests that in the FlexiCore® patients studied, metal ion levels do not increase and are not sufficient to cause acute reactions. The long-term safety should still be monitored.

Abstract: 107
Total Disc Arthroplasty Using a Compressible Disc Prosthesis: Effect of Compressive Preload Magnitude on the Kinematics of Lumbar Spine
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Introduction: The lumbar spine experiences compressive preloads up to 800N during activities of daily living (ADL). However, kinematics of lumbar disc prostheses under large preloads have not been reported. In our experience, disc prostheses with articulating bearings tend to “bind” under large preloads, resulting in degradation of motion quantity and quality.

Purpose: To test the hypothesis that quantity and quality of motion of lumbar segments implanted with compressible non-articulating disc prostheses will not be significantly affected by compressive preload magnitude.

Methods: Six human cadaveric human lumbar spines (L1-S1, 44±6.5 yr) were tested in flexion (8Nm) and extension (6Nm) under 0N, 400N and 800N compressive follower preloads. Following intact tests, the PLL was resected and a disc prosthesis, composed of a compressible polymer core and fiber matrix between two metal endplates (Spinal Kinetics, Sunnyvale, CA), was implanted in the L3-L4 or L4-L5 disc space, centered in the frontal plane and centered on or slightly posterior to the sagittal midline. Range of motion (ROM) was calculated in all conditions. Quality of motion was assessed by calculating stiffness in flexion and extension, and center of rotation (COR) in flexion-extension (FE).

Results: More than 90% of total intervertebral motion occurred within the implant under physiologic preloads; prosthetic-bone interface motion was less than 0.5deg. The prosthesis maintained segmental FE ROM to intact levels at all preloads (p>0.05, Fig. 1). The kinematic signature of implanted segments approximated intact controls (Fig. 2). The flexion and extension stiffness values were not different between implanted and intact conditions at all preloads (p>0.05). The FE COR of implanted segments was 1.6±1.3mm posterior to midline and was similar to intact at each preload (p>0.05).

Conclusions: The compressible disc prosthesis maintained physiologic quantity and quality of motion in FE under compressive preloads up to 800N. Maintenance of physiologic motion under preloads experienced during ADL may be one of the main benefits of compressible non-articulating disc prostheses.

Abstract: 155
Comparison of GUR 1020 Ultra High Molecular Weight Polyethylene Wear Debris from Simulation Studies on Prodisc-L Total Disc Replacements, Total Hip Replacements and Total Knee Replacements
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Introduction: It is well recognised that macrophage responses to ultra high molecular weight polyethylene (UHMWPE) wear particles generated at articulating interfaces of hip and knee replacements are the key factor in osteolysis leading to late failure. Particles ranging from 0.1-1.0µm have been shown to be most reactive [1]. Current designs of lumbar total disc replacements (TDR) utilise UHMWPE and the long term consequences of wear and wear particles have not been adequately investigated.

Aims: The aim of this investigation was to determine the wear and characterise UHMWPE wear particles generated by Prodisc-L TDRs (Synthesis, Philadelphia, USA) during 5
CERVICAL II

Abstract: 574

Kinematic Response of 3-lobe Cervical Disc Replacement Device as a Function of AP Placement

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Introduction: A new non-congruent, self-centering, hard-on-hard cervical disc replacement (TDR) was tested in a cadaveric kinematic model to evaluate the device’s tolerance to variations in AP placement. The TDR consists of 3 hemispherical lobes oriented in a tripod configuration on the superior component, articulating against mating non-congruent hemispherical pockets on the inferior component. The device was implanted at the C4-CS level, positioned at varying AP depths, and tested in flexion/extension, lateral bending, and axial rotation. Range of motion for the implanted segment had nearly the same motion range independent of AP placement. This suggests that the new 3-locale device could be placed centrally and is tolerant of substantial variations in positioning.

Materials and methods: Six human cervical spines (C2-C7) were studied utilizing a 7-Axis spinal testing system. A hybrid load/position control protocol was used to test the specimen. The intact spine was tested first in flexion/extension, lateral bending, and axial rotation at 1.5Nm. Then C4-CS level was then implanted with the TDR in the center of the endplate, as well as 2mm posterior and 2mm anterior positions utilizing implant placement fixtures that provided precise positioning of the device. Data collected included applied moments, forces, and rotations at C2 and C7, and 3D vertebral movements via an optical tracking system (Optrak). Statistical analysis of kinematic data was performed with paired-ANOVA followed by a Tukey-Kramer HSD post hoc test.

Results: The flexion/extension range of motion and the distribution of this motion between flexion and extension is shown in Table 1. Statistical difference was not detected in the Range of Motion between the intact and varying placements depths (p=.96). However, there is a shift to greater amounts of extension when the TDR is placed in the anterior position.

Discussion: Total range of motion was remarkably similar for the implanted segment regardless of anterior, central, or posterior position. The central and posterior placement positions provided the best distribution of motion as compared to the intact spine. For most articulating cervical TDRs, the position of the implant in the AP direction has a significant impact on reconstructed range-of-motion. A more posterior position is recommended for most devices. Deviation from this position may reduce motion substantially and the axes of rotation for the facets may be misaligned with the mechanical axis of the TDR, thus potentially increase stress on facet joints. This noncongruent 3-lobe design appears to be tolerant of variations in positioning, preserving excellent ROM across the placement domain, and may be more forgiving to surgical variability and potentially decreasing stress to facet joints.

Abstract: 498

Effects of a Saddle Joint Prosthesis on Cervical Facet Joint Loading

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Purpose: The combination of both Fuji film and thin film load cells has resulted in a sensor applicable to elucidate the effects of a saddle shaped cervical disc replacement upon the facet joints under various loading modes.

Methods: Thin film load cell sensors were preconditioned and calibrated. Fuji film was mounted to the thin film cell by a topaq contact pressure analysis system was utilized to extract contact Fuji film data. Six...
cervical ovine spine specimens were embedded and tested to 3Nm in flexion, extension and lateral bending and to 2.5Nm in torsion using a materials testing. In order to expose the Fuji film, the respective loads were sustained for 30s at the termination of the loading ramp. Specimens were evaluated in the intact state and again following insertion of a saddle shaped cervical total disc replacement (TDR) (Stryker Spine, CerviCore® Intervertebral Disc®, Allendale, NJ) at C3-C4. Fuji film exposure was analyzed for motion and 8 points of laminar surface strain were recorded. Fuji film exposure was analyzed for motion and 8 points of laminar surface strain were recorded.

Methods:

9-N follower load. Optical markers measured 3D vertebral height thereby reducing facet joint loading.

Findings:

 Fuji Film: Three dimensional contour mapping did not elucidate regions of high pressure for either the intact or TDR condition (Figure 1). No statistically significant differences were detected between the intact disc and the TDR for maximum pressure regardless of loading mode. (P>0.05). With respect to average force and pressure, no statistical differences were detected regardless of loading mode. Although no differences in contact area were detected for flexion, lateral bending and torsion, a significant difference (P< 0.02) was observed in extension. Thin Film Ink Sensor: The residual contact forces did not differ significantly during the intact and TDR state regardless of loading mode (P>0.2 for all). When the increase in contact pressure was computed during loading prior to and following TDR insertion, all loading modes displayed a decrease in contact force with a significant difference occurring in flexion.

Conclusions:

Pressure mapping did not show regions of elevated contact pressure over the respective loading modes. Further, continuous measurement of forces within the facet joint, resulted in an overall trend toward reduced force values with a significant decrease observed in flexion. Insertion of a TDR not only permits motion, but in doing so increases intervertebral disc height thereby reducing facet joint loading.

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Biomechanics of the CerviCore® Intervertebral Disc

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Introduction: In vitro nondestructive flexibility testing of the CerviCore® total disc replacement (TDR) was performed. It was hypothesized that TDR would not significantly alter biomechanics relative to normal, whereas rigid fixation would cause significant changes. Biomechanical assessment included a wider array of parameters than is typically studied.

Methods: Nine human cadaveric C3-T1 specimens (8 male, 1 female; mean age 55 years) were tested normal, after TDR, and after anterior plating. Flexion, extension, lateral bending and axial rotation were induced by pure moments; flexion-extension was then induced by a simplified muscle force model with 70-N follower load. Optical markers measured 3D vertebral motion and 8 points of laminar surface strain were recorded for assessing C5-C6 facet loads. Biomechanical parameters studied included Range of Motion (ROM), Lax Zone (LZ), angular coupling pattern, sagittal Instantaneous Axis of Rotation (IAR), and facet loads normal to the facet joint plane. Mean values of parameters were compared statistically using RM-ANOVA/Holm-Sidak tests.

Results: TDR caused significant reduction in ROM during flexion (p=0.004) and significant reduction in LZ during lateral bending (p=0.01, Figure 1). However, plating significantly reduced both ROM and LZ during flexion, extension, and lateral bending (p<0.006). Sagittal IAR shifted relative to normal by 1.9 mm after TDR (Figure 2, p>0.05) and 4.1 mm after plating (p>0.05). Coupled axial rotation per degree lateral bending was 99% of normal after TDR, but 76% of normal after plating (p=0.15). Coupled lateral bending per degree axial rotation was 95% of normal after TDR, but 85% of normal after plating (p=0.43). Facet loads after TDR and after plating were significantly increased relative to normal during extension with follower load (p<0.05); neither construct altered facet loads from normal during other loading.

![Figure 1](image1.png)

Mean ROM (full bars) and LZ (angle to horizontal dividing bars) in each configuration studied. Error bars show standard deviation of the ROM. *Represents significant difference from normal in ROM; †represents significant difference from normal in LZ.

![Figure 2](image2.png)

Mean shift from normal in the position of the sagittal axis of rotation. Error bars show standard deviations. With regard to ROM, LZ, IAR, and coupling, deviations from normal biomechanics were less substantial after TDR than after plating. Facet load alterations were minimal with either construct. Our results show that this particular TDR permits range of motion and kinematics in a cadaver model.
Background context: Although, the primary objective of cervical disc replacement is to preserve segmental motion, the reports of postoperative sagittal kyphosis after Bryan disc implantation have raised concerns, as it has been shown that segmental kyphosis can accelerate the adjacent disc degeneration in the long term. The impact of the ProDisc-C on these radiographic parameters has been inadequately reported.

Purpose: The aims of this study were to evaluate the in-vivo kinematics and sagittal alignment at operated level, adjacent levels and overall cervical spine in patients with implanted artificial cervical disc.

Methods: Twenty one patients who underwent anterior cervical disc replacement and Prodisc-C replacement surgery at 23 levels for degenerative cervical spine with median follow up of 30 months (Range 13 to 39 months) formed the study sample. Sagittal alignment and range of motion (ROM) at C2-C7, implanted levels and adjacent levels; and shell angle were measured using Cobb’s method from digitized cervical radiographs using Centricity Radiology Web v1.0 (2002 General Electric Medical Systems) software. Statistical analysis of collected data was performed using Wilcoxon signed rank test and Pearson’s correlation coefficient.

Results: The preoperative lordosis at the implanted level of 3.7 degrees (Range -12.1 to 14.7) increased to 4.3 degrees (Range -7.5 to 15.6) after implantation of Prodisc C in early postoperative period and the increase was statistically significant (p=0.039). At the final follow up, this further increased to 4.6 degrees (Range -10.4 to 15.4) but the difference did not remain statistically significant (p=0.267). The ROM at implanted level preoperatively was 8.7 degrees (Range 1.5 to 25) and at final follow up, it was 8.1 degrees (range 1.5 to 19.2) without any statistically significant difference from preoperative value (p=0.62). The ROM at the implanted level at final follow-up showed a statistically positive correlation with preoperative ROM (r=0.583; p=0.004), while it showed no correlation with postoperative shell angle (r=0.074) and change in sagittal profile at implanted level (r=0.082). The heterotrophic ossification at the implanted level was assessed using the grading of Mehren et al. There was no heterotopic ossification at final follow-up in 15 patients (65%) while in remaining 8 patients heterotopic ossification was noted (Grade 1: n=2(9%), Grade 2: n=4 (17%), Grade 3: n=2(9%), Grade 4: n=0).

Conclusions: The Prodisc-C preserves motion at the implanted level and do not exhibit kyphosing effect, as noted with unconstrained devices. Moreover, it does not alter the sagittal alignment and motion of overall cervical spine and adjacent levels significantly. The range of motion achieved at the implanted level depends upon preoperative range at the same level, while postoperative shell angle or change of segmental sagittal alignment does not have any bearing on it.

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Sagittal Alignment and Ranges of Motion 1 Year after Cervical Disc Replacement with the DISCOVER® Cervical Prosthesis

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Purpose: The purpose of this study was to evaluate ROM in flexion and extension as well as left-right bending at index- and adjacent levels, following cervical total disc replacement. Complete motion from C2 to C7 was also evaluated, to determine whether shifts of motion were observed at other levels, beyond those immediately adjacent to the index level. Increased ROM adjacent to an anterior cervical disc degeneration and fusion (ACDF) has been identified as a potential trigger for adjacent-level disc degeneration. ACDF has been shown to increase motion at non-operated levels adjacent to a fusion, and adjacent segment disease has been reported to occur at a rate of 2.9% in the first decade following fusion. New cervical arthroplasty devices that preserve normal range of motion at the index and adjacent levels may potentially alter this occurrence. In this study, range of motion (ROM) analyses were conducted to evaluate the effect of a novel, ball-and-socket implant (the DISCOVER® cervical artificial disc) on motion at the index and adjacent levels. Motion was analyzed in all one-level subjects enrolled in the DISCOVER® IDE clinical trial.

Materials and methods: Complete radiographic data including flexion/extension and A/P left/right bending views were available and readable at pre-operative and 6 months post-operative time points for 60 of the 77 IDE subjects. Radiographic analyses were performed by an independent core lab using validated, computer-assisted methods (QMA™). Analyses included intervertebral rotation in flexion/extension and left-right bending at the index and immediate adjacent levels, and overall flexion/extension rotation from C2 to C7.

Results: Preoperatively, flexion/extension ROM at the lower adjacent, index and upper adjacent levels was 10.1±5.0°, 7.6±4.1° and 7.8±4.4°, respectively. At the 6-month post-operative time point, the lower and upper adjacent levels remained unchanged (lower adjacent level: 10.6±4.3°; upper adjacent level: 7.2±4.3°), while there was a non-statistically significant trend for increased motion at the index level (9.0±4.4°; p=0.0740). Left/right bending ROM at index level was also unchanged from preoperative to 6 months post-operative (preoperative: 4.9±3.1°; 6 months postoperative: 4.9±2.6°). C2-C7 ROM was 42.8±15.1° preoperatively, and remained statistically similar at 45.2±12.7° by 6 months.

Conclusions: From preoperative to 6 months post-operative, there was a non-statistically significant trend for increased ROM at levels implanted with the DISCOVER Artificial Disc, which was associated with a non-statistically significant increase in overall C2-C7 motion. No changes in ROM were observed at the lower and upper adjacent levels, a finding that may be relevant to the prevention of adjacent level degeneration.

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Radiological Analysis of the Cervical Spine Following Implantation of Prodisc-C

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Purpose: The purpose of this study was to evaluate ROM in flexion and extension as well as left-right bending at index- and adjacent levels, following cervical total disc replacement. Complete motion from C2 to C7 was also evaluated, to determine whether shifts of motion were observed at other levels, beyond those immediately adjacent to the index level. Increased ROM adjacent to an anterior cervical disc degeneration and fusion (ACDF) has been identified as a potential trigger for adjacent-level disc degeneration. ACDF has been shown to increase motion at non-operated levels adjacent to a fusion, and adjacent segment disease has been reported to occur at a rate of 2.9% in the first decade following fusion. New cervical arthroplasty devices that preserve normal range of motion at the index and adjacent levels may potentially alter this occurrence. In this study, range of motion (ROM) analyses were conducted to evaluate the effect of a novel, ball-and-socket implant (the DISCOVER® cervical artificial disc) on motion at the index and adjacent levels. Motion was analyzed in all one-level subjects enrolled in the DISCOVER® IDE clinical trial.

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Results: Preoperatively, flexion/extension ROM at the lower adjacent, index and upper adjacent levels was 10.1±5.0°, 7.6±4.1° and 7.8±4.4°, respectively. At the 6-month post-operative time point, the lower and upper adjacent levels remained unchanged (lower adjacent level: 10.6±4.3°; upper adjacent level: 7.2±4.3°), while there was a non-statistically significant trend for increased motion at the index level (9.0±4.4°; p=0.0740). Left/right bending ROM at index level was also unchanged from preoperative to 6 months post-operative (preoperative: 4.9±3.1°; 6 months postoperative: 4.9±2.6°). C2-C7 ROM was 42.8±15.1° preoperatively, and remained statistically similar at 45.2±12.7° by 6 months.

Conclusions: From preoperative to 6 months post-operative, there was a non-statistically significant trend for increased ROM at levels implanted with the DISCOVER Artificial Disc, which was associated with a non-statistically significant increase in overall C2-C7 motion. No changes in ROM were observed at the lower and upper adjacent levels, a finding that may be relevant to the prevention of adjacent level degeneration.

Abstract: 475
Radiographic Analysis of Rotation at Index and Adjacent Levels Following Total Disc Replacement - Clinical Experience from IDE Subjects

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Purpose: The purpose of this study was to evaluate ROM in flexion and extension as well as left-right bending at index- and adjacent levels, following cervical total disc replacement. Complete motion from C2 to C7 was also evaluated, to determine whether shifts of motion were observed at other levels, beyond those immediately adjacent to the index level. Increased ROM adjacent to an anterior cervical disc degeneration and fusion (ACDF) has been identified as a potential trigger for adjacent-level disc degeneration. ACDF has been shown to increase motion at non-operated levels adjacent to a fusion, and adjacent segment disease has been reported to occur at a rate of 2.9% in the first decade following fusion. New cervical arthroplasty devices that preserve normal range of motion at the index and adjacent levels may potentially alter this occurrence. In this study, range of motion (ROM) analyses were conducted to evaluate the effect of a novel, ball-and-socket implant (the DISCOVER® cervical artificial disc) on motion at the index and adjacent levels. Motion was analyzed in all one-level subjects enrolled in the DISCOVER® IDE clinical trial.

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Results: Preoperatively, flexion/extension ROM at the lower adjacent, index and upper adjacent levels was 10.1±5.0°, 7.6±4.1° and 7.8±4.4°, respectively. At the 6-month post-operative time point, the lower and upper adjacent levels remained unchanged (lower adjacent level: 10.6±4.3°; upper adjacent level: 7.2±4.3°), while there was a non-statistically significant trend for increased motion at the index level (9.0±4.4°; p=0.0740). Left/right bending ROM at index level was also unchanged from preoperative to 6 months post-operative (preoperative: 4.9±3.1°; 6 months postoperative: 4.9±2.6°). C2-C7 ROM was 42.8±15.1° preoperatively, and remained statistically similar at 45.2±12.7° by 6 months.

Conclusions: From preoperative to 6 months post-operative, there was a non-statistically significant trend for increased ROM at levels implanted with the DISCOVER Artificial Disc, which was associated with a non-statistically significant increase in overall C2-C7 motion. No changes in ROM were observed at the lower and upper adjacent levels, a finding that may be relevant to the prevention of adjacent level degeneration.
and sagittal alignment + ranges of motion.

**Purpose:** To evaluate the intermediate clinical and radiological results in patients treated by TDR with Discovex® semi-constrained cervical mobile prosthesis.

**Methods:** 31 consecutive patients (18m/13w: mean age 47.2 ± 9 yrs [33-65]) with single-level cervical arthroplasty (for degenerative disc diseases) and a minimum follow-up of 12 months (for both clinical and radiological data) were included in this prospective observational study.

**Outcome measures:** Clinical criteria: VAS (1-100) self-reported cervical and radicular pain, Neck Disability Index (1-50 scale) and symptoms evolution (ODOM score). Radiographic evaluation: flexion-extension mobility, mean centers of rotation (MCR) and disc/vertebra height ratio for treated and adjacent levels and cervical (C1/C7) and local lordosis.

**Results:** Clinical outcomes highlighted symptoms relief: pre- and postoperative cervical and radicular pain decreased from an average of 65.9±5-95 and of 66.8±0-100 (before surgery) to 19.3±0-70 and 13.4±0-80 at 1 year follow-up. ND1 improved from 26/50 to 7/50 and results as per ODOM criteria were good (20%) or excellent (80%) at 12 months follow-up. Quantitative radiographic analysis showed an average cervical mobility at the treated levels of 6.7±4° (4-15°) at 3-6 months follow-up and of 8.3±4° (4-19°) at 12 months follow-up, except for 3 patients for whom ranges of motion were inferior to 3°. MCRs had a normal location in 56% of patients at 12 months, most of the abnormal locations being projected on the upper plate of the prosthesis. The adjacent level mobility was found within normal ranges post-operatively: i.e. 12.7 ± 5° [3-23] in early exams (3-6 months) and 14.3 ± 5° [6-29] at 12 months follow-up. For the last follow-up, MCRs were normal for the superjacent in 90% of cases and for the subjacent ones in all cases presenting ranges of motion > 3°.

Ten patients presented a regional kyphosis before surgery (average 4°) which significantly decreased after surgery. After a statistically significant postoperative increase (from an average of 2° before surgery to 9° one day after), local lordosis was stable postoperatively and a similar evolution was observed for the disc/vertebra height ratios. Moreover, C1/C7 lordosis marked a progressive increase from 48±10° before surgery to 55±10° at last follow-up.

**Conclusions:** Intermediate clinical and radiological results in TDR with Discovex® prosthesis highlight a satisfying level of symptoms relief associated to preserved mobility and postoperatively stable normal sagittal alignment.

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**LUMBAR II**

**Abstract:** 439

**The Impact of Postoperative Disc Height Following Arthroplasty on Long-term Clinical and Radiographic Outcomes - A 5-year Follow-up Study**

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**Purpose:** Preoperatively, patients with degenerative disc disease (DDD) may present with decreased disc heights at the diseased levels. Restoring disc height is achieved with arthrodesis or arthroplasty. However, no evidence exists on the impact of post-operative disc height restoration on clinical and radiographic outcomes. The purpose of this study was therefore to evaluate pain and disability improvements and well as range of motion in the CHARITÉ IDE patient population as a function of post-operative disc height.

**Materials and methods:** Randomized and Training CHARITÉ patients from the 5-yr CHARITÉ IDE study with complete preoperative and 5-year postoperative radiographic data were included herein. To determine whether the index-level disc height was optimally restored, the post-operative disc height at the index level was compared to that of the adjacent superior level (i.e., for L4-L5 index-level, the L4-L5 disc height was compared to the height of the L3-L4 disc space. For L5-S1 index-level, the L5-S1 disc height was compared to the height of the L4-L5 disc space). Two groups were generated: 1) the Large Disc Group (LDG) (≥ 5mm difference between index- and superior-level disc space) and 2) anatomically-sized group (ASG). Both groups were compared for pain (VAS), disability (ODI) as well as ROM and translation, at the 5-year time point. In addition, a receiver operating characteristic (ROC) curve was constructed to evaluate if post-operative disc height was predictive of successful outcome. The AUC (area under the curve) and associated statistical test were calculated for the ROC curve.

**Results:** There were 81 subjects in the ASG group vs. 31 in the LDG group. Using the parameters defined above, the average disc height decreased from 12.4±1.79mm in the ASG group vs. 14.2±2.37mm in the LDG. Demographics between groups were similar for gender, race, age, weight and body mass index. In the ASG, 23 subjects were implanted at L4-L5 and 58 at L5-S1. In the LDG, 6 were implanted at the L4-L5 and 25 at L5-S1. Total surgery time was comparable for both (ASG: 116.6±44.38min; LDG: 111.8±54.17min, p=0.6339), however there was a statistically significant difference in blood loss between groups (ASG 179.9±157.0cc; LDG 371.0±410.5cc, p=0.0005). Duration of hospitalization also showed a trend towards shorter times for the ASG vs. the LDG (ASG=3.8±0.94 days; LDG=3.5±0.68 days, p=0.0717). ODI scores were very similar between groups (Change in ODI scores: ASG=−25.2±25.2 points vs LDG=−25.4±25.2 points). VAS pain scores and translation were also similar (Change in VAS scores: ASG=−40.6±30.2 vs. LDG=−43.5±34.4; Translation: ASG=0.6±0.85mm; LDG=0.5±0.42mm). Mean ROM showed trends towards reduced motion in the LDG vs. ASG (L4-L5: Mean ROM for ASG: 5.9°±5.58°; Mean ROM for LDG: 5.1°±4.35°; L5-S1: Mean ROM for ASG: 6.5°±5.24°; Mean ROM for LDG: 4.8°±4.16°). The non-parametric assessment of correlation between postoperative disc height and clinical success did not indicate a strong correlation (rho=−0.034, p=0.6935).

**Conclusions:** Large disc implantation resulted in increased blood loss and hospital stay but did not affect the long-term pain and disability outcomes.

**Abstract:** 663

**Magnetic Resonance Imaging of Artificial Lumbar Disks: Safety and Metal Artifacts**

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**Objective:** To investigate the safety of two types of commercially available lumbar artificial discs (CHARITÉ and PRODISC®) procedure in a 1.5-Tesla MR system, and to evaluate the size of metal artifacts on the MR image for different sequences.

**Methods:** A 1.5-Tesla clinical MR imaging system was used. The degree of deflection of the endplates of two artificial discs was evaluated by an angle-measurement instrument at the portals of the MRI scanner. The heating effect of the radio frequency (RF) magnetic field was evaluated by using “worst-case” imaging sequences on a human cadaver implanted with an artificial lumbar disc at the L5/S1 intervertebral disc location. The temperatures of the tissue adjacent to the implant, and of the L4/L5 intervertebral disc (used as a control) were measured, respectively, using a digital probe.
Controversy Compared to Fusion Cages

Total Disc Arthroplasty in Lumbar Spine: Contemporary or Controversy Compared to Fusion Cages

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Introduction: The beginning of degenerative changing in spine mostly occurs in anterior column, which consequently transmits the degenerative damage to the posterior column that includes facet joints over times. In back pain patients, the therapeutic strategy for anterior column should be considered foremost since the anterior column is the original source of pain. Total disc arthroplasty with restoration of disc height results in decreased abnormal loading of other spinal structures, such as the apophyseal joint. TDR has been introduced as an alternative procedure that replaced spine fusion, which was formerly accepted in degenerative disc disease. TDR was given much attention when it was first introduced. However, the device is failing to live up to the expectations, and the usage of this device continues to decrease. In order to find the reason, an analysis of whether or not the fault lies within the device itself or within the surgical procedure is imperative. In our spine institute, TDR has been used through anterior approach since 1999.

Method: Analysis of the clinical outcome and radiological evaluation is based on 1500 case studies for TDR and 450 cases for fusion.

VAS score, Oswestry Disability Index and radiological measurement were assessed both groups at baseline, 6-week, 3-month, 6 month 1 year and 2-years. On radiological measurement, segmental angle and inter-midbody distance was checked to evaluate the disc height at operation level. Intervertebral disc height (IVD) and intervertebral foramen (IVF) on the adjacent levels was measured. The frequency of transfusion was also compared.

Result: In clinical outcome of TDR, VAS was markedly reduced (4.47) and ODI was improved (46.3) compared to fusion group (4.42/34.3 P< 0.5). Decrease in IVD was maintained to be less 2 mm in 89.3% of TDR group, while in the fusion group, all cases resulted in more than 2 mm disc height decrease within a year. Both IVD and IVF at the adjacent level are maintained in TDR (P>0.5). The frequency of transfusion was markedly reduced in TDR. No feral vessel injury was noted. There was no evidence of complication related to the prosthesis.

Conclusion: The IVD and IVF in TDR as a disc spacer was maintained stably both at the op level and adjacent levels.

TDR has been a reasonable strategy for mending pain source in tandem with spine fusion. However, because surgical anatomy of anterior approach is unfamiliar to a spine surgeon, learning curve is a mandatory. TDR can be an attractive procedure in anterior column spine diseases such as degenerative disease, recurrent prolapsed, and intervertebral stenosis. Combination strategy with anterior TDR and posterior decompression can be considered for deteriorating disc space with narrowing spinal canal. This strategy offers a greater opportunity for gaining the neuronal compliance. TDR has been one of the most innovative prosthesis close to biomechanical function of disc and less chance to deteriorate the adjacent levels. If the subsequent surgical learning curve is improved, TDR can be utilized in a very functional way to substitute the spine fusion devices in degenerative disc diseases.

Abstract: 641

Radiographic Range of Motion Is Related to Clinical Outcomes in Lumbar Artificial Disc Replacement Patients: One Site Analysis of 219 Patients with Minimum 2 Year Follow-up, USA-FDA IDE Study

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Few studies have reported on the associations among range of segmental motion (ROM) and outcomes after lumbar ADR. Maintenance of ROM has been reported at 5 to 10 degrees for ProDisc-L patients. Data on how ROM relates to self-reported outcomes have not yet been reported yet are important considerations for efficacy in evidence based medicine. Since ProDisc-L is intended to allow motion, there is interest in relationships ROM and self-reported outcomes.

Purpose: To evaluate relationships among ROM and self-reported clinical outcomes in single or multilevel ProDisc-L patients.

Methods: Analysis of ROM with clinical outcomes was performed using data from single and multilevel patients at one site participating in the multicenter USA-FDA IDE trial [Randomized (RCT, n=59), Pilot (Pn=6), Continued Access (CA, n=147) and Compassionate Use (CU, n=37)]. Patients were followed at 6 weeks, 3, 6, 12, 24 months. Self-assessments included Oswestry Disability Index (ODI), Visual Analogue Scale for pain (VAS). Physical exams were completed; radiographs were analyzed. Degree of ROM was determined from disc angle on extension - flexion. ROM average was calculated over lumbar levels. Relationships between ROM and self-assessments were evaluated.

Results: There were a total of 219 ProDisc-L treated patients (89%) with 24-month data. The average ROM was 8.5° ± 2.8 preoperatively and slightly lower at 6.6° ± 2.4 at 6 weeks, while steadily recovering with 7.1° ± 2.4 at 3 months, 7.8° ± 2.7 at 6 months, 8.4° ± 2.6 at 12 months, and 8.7° ± 2.6 at 24 months postoperatively. There was 29% to 52% range of average improvement in ODI and 44% to 56% improvement in VAS pain from 6 weeks to 24 months. There was a significant negative correlation between ODI and ROM (r=-0.41, p<0.0001) with 18% common variability, indicating that the greater the average lumbar ROM, the less the reported functional disability (ODI); associations were similar for ROM and ODI at 3 months (r=-0.27, p<0.0002), 6 months (r=-0.19, p<0.006), 12 months (r=-0.26, p<0.0003), and 24 months (r=-0.31, p<0.0001). Greater average ROM was significantly correlated with less VAS pain at 6 weeks (r=-0.29, p<0.0001), 3 months (r=-0.12, p=0.09), 12 months (r=-0.15, p<0.04), and 24 months (r=-0.22, p<0.002). Greater body mass index (BMI) was related to less ROM preoperatively (r=-0.16, p<0.01), and postoperatively at 12 months (r=-0.16, p<0.02) and 24 months (r=-0.18, p<0.007). BMI was marginally
related to VAS pain preoperatively (r=0.12, p=06) yet not postoperatively, while BMI was not related to ODI (all NS). Multiple regressions yielded powerful associations of greater ODI with lower ROM at 12 months (β=1.07, p<0.0003) and 24 months (β=1.41, p<0.0001), and similarly, the associations held when controlling for BMI and age. A relationship was found for higher VAS pain and lower ROM at 12 months (p<0.04) and 24 months (p<0.002). Further, higher satisfaction was associated with greater ROM at 12 months (β=0.14, p<0.04) and 24 months (β=0.40, p<0.002).

Conclusions: ROM was maintained throughout follow-up in ProDisc-l patients. Importantly, greater ROM was strongly associated with greater functional ability, less pain, and greater satisfaction. This is the first report of these associations.

Abstract: 298

Sagittal Profile Modification after Lumbar Fusion, Posterior Dynamic Stabilization, and Lumbar Total Disc Replacement - A Comparative Radiographic Analysis

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Purpose: Iatrogenic alteration of the sagittal spinal profile is a main source of pain and a potential cause for adjacent segment degeneration following lumbar fusion; non-fusion technology is believed to allow for a better restoration of spinal balance. Therefore, a comparative radiographic evaluation of lumbar fusion, posterior dynamic stabilization, and total disc replacement (TDR) was conducted in order to analyze their influence on the sagittal profile of the lumbar spine.

Methods: Inclusion criteria were mono-segmental instrumentations at the level L4/5 due to degenerative changes with a minimum follow-up of more than two years. 15 patients received instrumented 270° fusion, 11 patients Dynesys, and 12 patients ProDisc-L TDR. Segmental angulation of the level L4/5, the adjacent levels L3/4 and L5/S1 and lumbar lordosis (L) from L2 to S1 were measured using the Cobb method. Intra-observer variability was assessed using the 95%-confidence interval (95%-CI).

Results: Concerning mean absolute values for index and adjacent level angulation and LL, fusion did not alter significantly any of these. In contrast, Dynesys significantly decreased L4/5 and significantly increased L5/S1 angulation. TDR led to a significant increase of L4/5 angulation and LL. Regarding mean relative segmental angulation (percentage of LL), fused patients showed non-significant changes only. Contrary, Dynesys significantly decreased L4/5 and significantly increased L5/S1 angulation. ProDisc-L TDR resulted in a significant decrease of the angulation of both adjacent levels. Data categorization according to the measurement error (95%-CI:±2.5°) showed the relative majority of fused patients being unchanged with regard to all levels and LL. Following Dynesys, a relative majority had a decrease of LL and the absolute majority a decrease of L4/5 angulation. The absolute majority of patients with ProDisc-L TDR showed an increase of LL and L4/5 angulation.

Conclusion: Iatrogenic alterations of spinal balance were seen more frequently following non-fusion technology compared to fusion. With regard to potential consequences like pain and adjacent segment degeneration, further trials are needed to investigate the influence of radiographic alterations on the clinical outcome.

Abstract: 130

Motion Track Variations in Alternative Wear Testing Protocols for Total Disc Replacements

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Introduction: Wear is a potential concern for metal-on-polyethylene lumbar total disc replacements (TDRs) [1]. Polyethylene acquires preferential molecular orientation (PMO), and experiences higher wear for crossing motions transverse to the PMO [2]. TDR wear test interpretations therefore need to take prominent account of cross-shear. This study compares articulation kinematics for Prodisc and Charité, under four contemporary wear testing protocols.

Methods: Finite element models of ProDisc and Charité were created in ABAQUS software. Inputs considered were: (1) ISO standard 18192-1 for lumbar TDR wear, (2) alternative loading conditions for lumbar TDRs from 18192-1 (axial rotation and lateral bending inputs at higher frequency than flexion-extension), (3) ASTM standard F2423 for lumbar TDRs, with flexion-extension input out of phase from axial rotation and lateral bending, and (4) ASTM standard F2423 with all rotations in phase. ProDisc Euler angle inputs for flex-extension (FE), axial rotation (AR), and lateral bending (LB) were confirmed independently in Matlab and Excel, for the ISO Standard and Alternative waveforms, for alternative Euler orderings (LB-AR-Fe, AR-LB-Fe, AR-Fe-LB), with the duty cycle discretized into 200 increments. Additionally, ISO Standard and Alternative motions for Charité were simulated using Cosmos Motion software for peak axial loads of 600, 1300, and 2000 N.

Results: Distinctly different motion tracks ensued from these respective simulations (Figure 1). Closed motion tracks with a long elliptical axes, (e.g., from the ISO standard) suggest strong PMO. More circular tracks, (e.g., from the out-of-phase ASTM standard) have less tendency for strong PMO and cross-shearing wear. The motion track produced by the in-phase ASTM standard suggest a strong PMO but low wear, since the motion is essentially linear reciprocation, involving little cross-shear.

Figure 1: Motion tracks of polyethylene on endplate for each bearing couple, under all four input conditions. All views are oriented the same with anterior (A), posterior (P), trocinal (M), and lateral (L) as indicated in the upper left.

Discussion: Clearly, these four different input protocols...
result in dramatically different local bearing surface kinematics, each with seemingly very different implications for polyethylene wear. In the case of Charité, the predominance of motion at the upper bearing surface is intriguing, given identical friction at upper versus lower surfaces in both simulations.

References:

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POSTERIOR DYNAMIC STABILIZATION

Abstract: 616
The Effect of ‘Pedicle-to-Pedicle Distance Excursion’ after Posterior Dynamic Stabilization - A Biomechanical Study on Cadaver Spine
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Introduction: Most of the posterior dynamic stabilization devices have limited capability of pedicle-to-pedicle distance excursion. This appears to be the key limiting factor in biomechanical effect on kinematics and survival against fatigue failure. The purpose of this study is to assess the effect of posterior dynamic stabilization with variable and adjustable pedicle-to-pedicle distance excursion, on kinematics of cadaver lumbar spine.

Method: Five cadaver lumbar spines were tested in a six-degrees-of-freedom spine tester with continuous cyclical motion using a continuous motion tracking system. Pedicle-to-pedicle distance (PtP), load-deformation (L-D) curves, instant axis of rotation (IAR), and Disc pressure were analyzed from the intact spine, following destabilization, and following stabilization using a novel posterior dynamic stabilization system (PDS) with varying degree of PtP excursion. Only flexion-extension motion was tested.

Results: The PtP distance in normal cadaver spine were 9.5 mm at L5-S1, 14 mm at L4-S and 15.5 mm at L3-S level. With the novel PDS system used as Dynesys, the PtP distance was grossly limited in extension, but permitted 40% of normal PtP excursion in flexion. The disc pressure was negative in extension, and minimized in flexion. With the novel PDS system was set to permit normal PtP excursion, it permitted a normal upward rise of the disc pressure, and also produced a uniform rise of the disc pressure both in flexion and extension.

Conclusion: This study established the importance of pedicle-to-pedicle distance travel following posterior dynamic stabilization, to ensure an uniform load-sharing by the device and motion segment. This indirectly ensures resistance to fatigue failure.

Abstract: 390
Posterior Motion Preserving Implants Evaluated by Means of Intervertebral Disc Bulging and Annular Fiber Strains
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Introduction: The aims of motion preserving implants are to stabilize the spine by also maintaining a physiological loading. A limitation in the disc deformation can negatively influence the biological environment leading to accelerated disc degeneration. Dynamic spine stabilization might keep active nutrition transport, also stimulating cells. Standard biomechanical testing does not provide sufficient data to evaluate whether the load transmission through the disc has changed from the physiological condition. The aim of this in-vitro study was to investigate disc bulging and annular fiber associated strains evaluating different posterior stabilization concepts.

Methods: The investigation was performed on 6 human spinal specimens (L2-3). A 3-d laser scanner was developed to measure the disc bulging and annular fiber associated strains while the specimens were loaded with axial compression of 500N, or with pure moments of 7.5Nm in flexion, extension, lateral bending and axial rotation. Range of motion (ROM), disc bulging and fiber strain distribution were measured from three different disc preserving implants: flexible internal fixator (DSS™, Paradigm Spine), an interspinous implant (Coflex™, Paradigm Spine) and facet joint replacement (TOPS™, Implant). These data were compared to measurements of the intact condition and to specimens with a rigid internal fixator (AMT).

Results: In the intact condition, flexion produced the hypermobility. Therefore it is imperative to provide evidence for the allegation that dynamic stabilization devices would avoid hypermobility at the adjacent segments as this would substantiate a potential beneficial effect on the adjacent segments.
implanting an interbody fusion cage, IDPs for two-level Niti rods tend to decrease and more so with one-level rods. Upon primary destabilization, adjacent level moments for Niti than Ti and for one-level versus two-level constructs. Primary fixation, with and without an intervertebral body spacer. Following the Hybrid testing Protocol of Panjabi, Seven fresh-frozen human lumbar spinal units were utilized. The study evaluates one- and two-level pedicle screw and rod constructs based on range of motion (ROM) and intradiscal pressure (IDP) using identical rod geometry but different material thereby providing either “rigid” or “non-rigid” fixation, with and without an intervertebral body spacer.

Methods: Seven fresh-frozen human lumbar spinal units were utilized. Following the Hybrid Testing Protocol of Panjabi, non-destructive analysis of the intact spine and two levels of destabilization were performed. For each condition, one- and two-level constructs were created using either Ø5.5mm Ti-6Al-4V (Ti) or Ø5.5mm Nitinol (Niti) rods. For each motion, Flexion/Extension, Lateral Bending and Axial Rotation, ROM and IDP were measured at the operated and adjacent levels.

Results: F/E, Axial Rotation, and Lateral Bending - ROM and Moment Force: ROM decreases with instrumentation while peak moments increase and both are more notable with two-level Ti rods. When destabilized, one-level Ti and two-level Niti rods show greater ROM than their comparative. Overall, two-level rods resulted in less ROM and higher peak moments than one-level rods. Interbody cages show increases in ROMs and lower peak moments for Niti than Ti and for one-level versus two-level constructs. Flexion - IDP: Niti rods typically result in lower IDPs than Ti rods and more so with two-level constructs. Primary destabilization causes a reduction in IDPs. Upon implantation of an interbody fusion cage, one-level construct IDPs remain low and two-level construct pressures increase at the adjacent level. Extension - IDP: IDPs during extension are generally lower than in flexion. Upon primary destabilization, adjacent level IDPs tend to decrease and more so with one-level rods. Upon implanting an interbody fusion cage, IDPs for two-level Niti rods are greater than Ti rods.

Discussion: The results, while not statistically significant, show Niti rods maintain greater ROM and lower peak moments at instrumented levels and have less compensatory effect at uninstrumented levels. IDP in flexion is greater and less in extension due to disc loading and unloading, respectively. When instrumented, IDPs typically remain lower than the intact spine suggesting stress shielding. Interbody cages result in lower IDPs at adjacent levels suggesting a cage with supporting instrumentation may not adversely affect the adjacent level disc. All ROMs and moments show similar trends suggesting rod material affects the cadaveric spine similarly for all motion types. In summary, rotational motion for one-level and NiTi constructs show a trend toward greater ROM and lower peak moment forces than two-level and Ti constructs.

Conclusions: A growing trend in spine surgery is to implant less rigid rod constructs to dynamically stabilize the spine. Though there is a small but consistent difference in ROM and peak moment data for NiTi vs. Ti, there is no statistical difference in the biomechanical performance of these rods in the cadaveric spine model. While NiTi rods are three times more flexible than Ti rods of the same dimensions, these differences may not translate significantly to the cadaveric spine model. Therefore, NiTi rods are mechanically acceptable and possibly biologically favorable as a fusion device but further study is needed.

Abstract: 607

Are Flexible Rods Truly Dynamic? Biomechanical Testing of Semi-rigid Rods

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Introduction: The use of posterior dynamic stabilization is becoming increasingly popular. In an attempt to quickly enter the growing dynamic stabilization market, several companies have released elastic rods with a low bending stiffness to be used with standard pedicle screw systems. The major design requirement of posterior dynamic stabilization systems is that they allow physiologic range of motion of the treated segment while controlling abnormal or unstable states. There is little published data on the biomechanical requirements and behavior of posterior dynamic stabilization systems.

Objective: The objective of this study was to determine the effect of several flexible posterior constructs on spine kinematics and their usefulness in satisfying the goals of dynamic stabilization.

Methods: Mechanical testing of various “dynamic” systems (Cosmic, Isobar, PEEK rod, Agile, Dynesys) was conducted on a spine simulator. The biomechanical behavior of these systems was compared to that of a solid rod system (Aesculap S4). An independently developed flexible rod (Morpheus) was similarly tested and the results were compared to those found within our own testing and in literature.

Results: The flexion/extension ROM in degrees was: 1.47 for solid rod S4, 1.54 for Cosmic, 1.36 for Isobar, 1.48 for the PEEK rod, 1.48 for Agile, 1.71 for Dynesys, and 1.51 for Morpheus. The lateral bending in degrees was: 1.30 for S4, 1.13 for Cosmic, 1.58 for Isobar, 2.20 for the PEEK rod, 1.54 for Agile, 1.71 for Dynesys, and 1.51 for Morpheus. The axial rotation in degrees was: 2.02 for S4, 3.52 for Cosmic, 1.50 for Isobar, 4.24 for PEEK, 6.85 for Agile, 9.75 for Dynesys, and 6.62 for Morpheus.

Conclusions: The pedicle screw constructs tested in this study with elastically bendable rods do not allow physiologic flexion/extension due to their inability to
elongate or due to their intrinsic rigidity. Furthermore, these elastic or semi-rigid rods do not have a significantly lower rotational stiffness as compared to constructs with standard solid Titanium rods when an anterior support is present. These results indicate that systems using elastically bendable rods are too stiff for adequate dynamic stabilization and may be more effectively used as adjunct-to-fusion devices. In summary, flexible rods are semi-rigid but not necessarily dynamic.

Abstract: S16
Assessment of Normal Interpedicular Motion in Flexion-extension X-rays of the Lumbar Spine
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Purpose: To provide normative reference data to help design and evaluate pedicle screw-based motion preserving devices.

Methods: Lumbar, flexion-extension radiographs were previously obtained for volunteers with no prior history of surgery or treatment for back pain. Subjects were coached to maximally flex and extend during the imaging. A standardized protocol was used to minimize out of plane effects and to ensure that all levels of the lumbar spine were fully mobilized. A calibration marker was used to obtain measurements in real-world units of millimeters. Cases with radiographic abnormalities, including osteophytes, disc space narrowing, spondylolisthesis and instability were excluded from this analysis. Cases with significant parallax effects, poor contrast or poor visualization of the posterior elements were similarly excluded.

Interpedicular motion measurements were produced using validated, computer-assisted methods accurate to better than 1 degree and 1 millimeter. Interpedicular distance was measured between the mid-pedicular axes of adjacent vertebrae using points slightly posterior to the superior articular process of each vertebra, representing the typical location of the junction between posterior rod and pedicle screw in dynamic systems. The change in angle between the mid-pedicular axes from extension to flexion was used to measure interpedicular rotation (which is equal to intervertebral rotation). Interpedicular translation was measured parallel to the mid-pedicular axis of the inferior vertebra. The measurements were produced at L3-L4, L4-L5 and L5-S1. A modified version of the measurement technique was applied at L5-S1.

Results: A total of 42 subjects (24 females and 18 males) were included in the analysis. The average age was 40 ± 11 years. Change in interpedicular distance from extension to flexion ranged from 4.7 to 14 mm, with an average change of 9.2 ± 2.3 mm. Gender-based differences were not found (P=0.07). Interpedicular translation was significantly (P<0.001) less at L5-S1 (2.2 ± 1.1 mm) than at L3-L4 and L4-L5 (5.9 ± 1.3 mm and 6.0 ± 1.2 mm, respectively). Intervertebral rotation averaged 13.6 ± 3.5 degrees and was greatest at L4-L5. There was a strong (R²=0.84, P < 0.0001) linear relationship between the amount of interpedicular rotation and the change in interpedicular distance from extension to flexion. This interpedicular excursion was also linearly (R²=0.86, P<0.0001) dependent on how far posterior the excursion was measured, based on the correlation between changes in posterior disc height and interpedicular distance.

Conclusions: Based on a 95% confidence interval, these data suggest that between 7 and 20 degrees of interpedicular rotation, up to 9 mm of interpedicular translation, and between 5 and 14 mm of distraction can be expected in the mid-to-lower lumbar spine during maximum flexion and extension. These normative reference data on interpedicular motion may assist in evaluating motion patterns as they may relate to the design of dynamic, pedicle screw-based implants.

Abstract: 209
A Prospective Randomized Evaluation of DyneSys vs. Isobar Posterior Pedicle Based Dynamic Stabilization for the Treatment of Axial Back Pain
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Purpose: To evaluate the safety and efficacy of 2 posterior pedicle screw based dynamic stabilization systems in the treatment of axial back pain.

Methods: 61 patients (age 26-53 average 48.2 yrs) with 1 or 2 level discographic proven internal disc disruption and axial back were prospectively randomized to operative treatment with DyneSys or Isobar posterior pedicle screw based dynamic stabilization. Entrance criteria required predominance of back pain, greater than 1 year of symptoms, greater than 6 months of conservative treatment, maintenance of 50% or more of disc height, MRI findings of disc dessication, and provocative discography identification of symptomatic levels with non-painful control. Surgeries were all performed via modified Wiltse exposure with no direct decompression. Key outcome parameters followed included visual analog pain scale (VAS), Oswestry Disability Index (ODI), plain radiographic evaluation of flexion/extension motion, screw loosening, MRI pre and followup evaluation, and presence or absence of further surgery. 58/61 were available for 2 year or greater followup with average current followup 38 months. Randomization yielded 22 1 level DyneSys procedures and 9 2 level procedures for 31 total patients in the DyneSys group. There were 23 1 level Isobar procedures and 7 2 level procedures for a total of 30 in the Isobar group.

Results: 58 of 61 patients were available for follow up at 2 years or greater with average followup 38 months. In the DyneSys group back pain VAS decreased from 8.2 to 3.3 (p<0.05) across the sample and 26/31 (83%) had a drop of 2 points or greater on a 10 point scale. In the Isobar group back pain VAS decreased from 8.6 to 3.4 (p<0.05) and 24/30 (80%) had a 2 point or greater drop. ODI scores improved by 15 points or greater in 23/31 (74%) DyneSys patients and 22/30 (73%) of Isobar patients. Stratification by 1 and 2 level cases is presented. No statistically significant difference between instrumentation group is demonstrated in clinical outcomes. Flexion/extension radiographic analysis by independent radiologists showed motion in both groups less than accepted measurement error. Screw loosening was evaluated by independent radiologists and found in 21/142 (14%) of the DyneSys screws and 8/134 (6%) of Isobar screws (p<0.05). Representative MRI findings from 2 years post op are presented. Re-operation has occurred in 3/31 (9%) DyneSys patients and 2/30 (7%) Isobar patients. 1 late deep infection has been encountered in the DyneSys group. No patient had neurologic deterioration.

Conclusions: Posterior pedicle screw based dynamic stabilization via muscle splitting approach does appear to be a safe and effective treatment for axial back pain recalcitrant to conservative treatment in a younger patient population. Although no statistically significant differences could be shown in outcomes of the DyneSys vs Isobar groups, the entire cohort demonstrated clinical improvements consistent with published IDE data for fusion or total disc replacement. There is a statistically significant lower rate of screw halo formation using Isobar instrumentation than DyneSys for this application.
Abstract: 203
Morphometric Analysis of the Ventral Nerve Roots and Retroperitoneal Vessels with Respect to DLIF/XLIF Technique in Normal and Deformed Spines
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Study design: A morphometric analysis, using MRI studies of the lumbar spine.

Objective: To identify the anatomic position of the ventral root and the retroperitoneal vessels in relation to the vertebral body in normally aligned and deformed spines.

Summary of background data: The lateral approach to the lumbar spine is a relatively new method for performing interbody fusions. In contrast to the standard open anterior approach with direct vision of the operative field, the lateral approach uses expandable retractors that are positioned under fluoroscopic guidance. Risks of this technique include injury to the exiting nerve root and retroperitoneal vessels.

Methods: One hundred lumbar spine MRI studies were reviewed from patients that treated for various spinal pathologies. The measured intervertebral segments were divided into 3 groups: Group 1 (n=247) normally aligned vertebrae and disc spaces, Group 2 (n=19) degenerative spondylolisthetic segments, Group 3 (n=19) segments from the apex of degenerative lumbar scoliosis. Axial MR images were used to measure: the vertebral endplate anterior-posterior (AP) diameter, the overlap between the ventral root and the posterior margin of the vertebra, and the overlap between the retroperitoneal large vessels and the anterior edge of the vertebra.

Results: The overlap between the adjacent neuro-vascular structures and the vertebral body endplate gradually increased from L1-2 to L4-5. The maximal overlap, at the L4-5 level reached 50.3% and 36.5% resulting in a relatively narrow corridor for performing the operative procedure. Alteration in the anatomic location of the nerve root and the retroperitoneal vessels at the concavity compared to the convexity side in the scoliosis group further decreased the safe corridor.

Conclusion: The safe corridor for performing the discectomy and inserting the intervertebral cage narrows from L1-2 to the L4-5 level. This corridor is further narrowed with rotation deformity of the spine. Using the preoperative MRI to assess the relative position of the adjacent neuro-vascular structures in relation to the lower vertebra’s endplate at each level is recommended.

Abstract: 592
A Comparison of the Operative Efficacy of Alif and Xlif L4-5 Fusion Procedures with Bilateral Posterior Fixation
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Introduction: Utilizing a minimally invasive approach, specifically XLIF, in place of similar open procedures is gaining in prevalence as preference for many surgeons. The purpose of this experiment was to directly compare operative variables associated with minimally invasive vs. open procedures.

Hypothesis: Our hypothesis is that patients who underwent L4-5 interbody fusion with posterior fixation via the XLIF approach will have shorter OR times (ORT) and length of post-operative hospital stay (LOS) as well as less blood loss (EBL) than patients who received the procedure via the ALIF approach.

Methods: 95 patients were identified as having undergone isolated L4-5 interbody fusion procedures with posterior fixation. 45 received the procedure via an anterior/posterior approach (ALIF), and 50 via a lateral/posterior approach (XLIF). No intra-operative complications were reported. ORT, EBL, and LOS were compiled through retrospective chart review and analyzed via a 1-way MANOVA.

Results: The two cohorts were matched in all demographics except the XLIF group had a significantly greater mean age than did the ALIF group. The significant multivariate effect of approach (λ = 0.488) was associated with univariate effects on ORT, EBL, and LOS. ORT was significantly longer for the ALIF approach (M_ALIF = 150.84mins, SE_ALIF = 4.75mins) than for the XLIF approach (M_XLIF = 99.08mins, SE_XLIF = 4.50mins) F(1,91) = 62.57, p < .001. EBL was significantly greater for the ALIF approach (M_ALIF = 228cc, SE_ALIF = 18.55cc) than for the XLIF approach (M_XLIF = 64.72cc, SE_XLIF = 17.59) F(1,91) = 64.77, p < .001. LOS was significantly greater for the ALIF approach (M_ALIF = 70.4hrs, SE_ALIF = 4.08hrs) than for the XLIF approach (M_XLIF = 40.68hrs, SE_XLIF = 3.87hrs) F(1,91) = 28.26, p < .001.

Discussion: The results confirm our hypothesis. Our findings suggest that the minimally invasive XLIF procedure significantly decreases surgery time, intra-operative blood loss, and length of post-operative hospital stay when compared to the same procedure being pursued via an open approach, despite the XLIF cohort’s greater mean age. This is consistent with the widely held notion that minimally invasive procedures are less traumatic than open procedures, however the decreased operative time suggests less technical difficulty, which is atypical of minimally invasive procedures, namely endoscopic techniques.

Long-term follow-up will be required to determine if the approaches are comparable in patient outcomes.

Abstract: 289
Single Level Lumbar Fusion at L5-S1: A Comparison of MIS TLIF and AxiaLIF
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Purpose: Minimally invasive fusion techniques are becoming more accepted as viable alternatives without the morbidity associated with traditional open techniques. The lumbo-sacral junction remains a challenging fusion site due to the shear forces across the segment and the anatomic difficulties imposed by the posterior iliac crest which can make transfemoral access impossible. In this report, we compare our experience using two alternatives to fusion at the LS junctions: MIS T/PLIF and AxiaLIF.

Methods: A retrospective review of prospectively collected data on the first 50 patients (25 MIS T/PLIF, 25 AxiaLIF) treated by a single surgeon for single level fusion at the LS junction using two alternative MIS techniques. The two cohorts were treated sequentially - the first 25 patients (11M, 14F, age 48.7 yrs, BMI 30.8) were treated with MIS T/PLIF and the second 25 (13M, 12 F; age 51.4 yrs, BMIA 31.4) with AxiaLIF. Early clinical and radiographic results and complications are reported.

Results: In the MIS T/PLIF group, OR time averaged 102.8 min, hemoglobin change 2.0 g, and length of stay 1.69 days. Disk height increased 2.9 mm from preop to postop with 0.6 mm settling at 6 mos; llisthesis (10 pts) decreased only 1.2 mm from preop to postop with maintenance of reduction at 6 mos; Lenke scores measured 2.2 at 3 mos and 1.6 at 6 mos. VAS improved from 8.1 preop to 3.1 postop
Objective: The aim of the study was to compare pedicle screw fixation for lumbar fusion procedures using Iso-C / 3D neuronavigation versus standard AP/lateral fluoroscopy.

Summary of background data: Minimally invasive spinal surgery (MISS) has evolved over the past years due to the combination of microsurgical techniques, minimal access strategies and neuronavigation. Percutaneous pedicle screw fixation demands accurate real-time imaging for safe and effective placement of instrumentation. We postulated that stereotactic navigation would be superior to conventional AP/lateral fluoroscopy during the initial learning phase of MISS.

Methods: 42 patients underwent one- or two-level lumbar or lumbosacral fusion procedures for degenerative lumbar pathology including stenosis, spondylolisthesis, and degenerative disc disease. Either 3D Siemens Iso-C / BrainLAB neuronavigation (3DNAV, n=29) or standard fluoroscopy (n=13) was used to aid screw placement. Demographics, operative time, blood loss, and screw placement accuracy were evaluated. Screw placement was evaluated postoperatively using lumbar CT scanning. Accuracy of 3DNAV was evaluated by comparing intraoperative BrainLAB planning screenshots to postoperative CT placement of screws.

Results: There were no significant differences between groups for mean age, gender or intraoperative blood loss. The median operative times for one and two level procedures were 226.5 ±70.3 and 277.3 ±32.1 minutes, respectively, for 3DNAV, and 313.2 ±143.8 and 362.5 ±74.2 minutes for conventional fluoroscopy. 90.9% of Iso-C/3D screws and 73.7% of fluoroscopy screws had no pedicle perforation (p=0.04). Intraoperative screenshots accurately predicted pedicle screw placement in 90.9% of cases. There was a positive correlation between 3D navigation accuracy and better screw grade (rs 0.45, p=0.036).

Conclusions: Utilization of Iso-C/3D neuronavigation for percutaneous lumbar screw placement was associated with significant reduction in operative time, and significant reduction in pedicle perforations. This study demonstrates that the use of 3D neuronavigation is an important factor in facilitating MISS, especially during the initial learning phase.

Abstract: 257
Iso-C/3D Neuronavigation versus Conventional Fluoroscopy for Minimally Invasive Pedicle Screw Placement in Lumbar Fusion: Prospective Comparison of Screw Placement
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Background context: Symptomatic adult scoliosis deformity presents as a difficult problem to solve. Traditional treatments include anterior and posterior open approaches. The purpose of this paper is to present a lateral retroperitoneal minimally invasive approach (eXtreme Lateral Interbody Fusion - XLIF) for the treatment of adult scoliosis requiring more than four levels of arthrodesis without the morbidity of an open procedure.

Methods: A prospective, non-randomized, single center study with 14 patients, mean age 69.64 (51-87 years) with two years follow up. Lateral, A-P, flexion-extension X-rays, neurological examination and clinical outcome assessments using Oswestry and VAS scores were performed at the preoperative, 1, 6 week, 3, 6, 12 and 24 months postoperative intervals. The extreme lateral approach was done through the retroperitoneal space and through psoas muscle avoiding vascular lesions. A partial discectomy was done and the end-plate cleaned preserving ALL, keeping the spine more stable than the traditional anterior surgery. The operated levels ranged from four to seven levels, including T10-T11 to L5-S1.

Results: The procedures were performed without complication in an average 121 minutes and with less than 50cc blood loss. Ten patients had four levels of fusion; two patients had five levels and two patients with seven levels of arthrodesis. VAS pain scores improved from an average 8.33 at pre-op to 3.16 at 2 years, standard deviation 1.49 and 1.06 respectively. Oswestry scores improved from an average 51.2 at pre-op to 27.33 at 2 years with standard deviation of 13.42 and 13.09 respectively. Coronal and sagittal alignments improved from average Cobb angles of 16.4 degrees at pre-op and 7.8 degrees at 2 years, and average lordosis angles of 35.7 degrees at pre-op to 46.5 degrees at 2 years.

Conclusions: Using the XLIF approach we were able to treat long thoracolumbar deformities 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 in long thoracolumbar reconstructions.

Abstract: 581
Can Minimally Invasive Adult Spinal Deformity Correction Maintain Lordosis and Global Sagittal Balance?
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Introduction: Traditional surgical approaches for adult deformity are associated with significant blood loss and significant morbidity. A combination of 3 MIS technologies allow correction of spinal deformity with considerably less blood loss than historical controls. Nevertheless little data exists regarding maintainence of lordosis or sagittal balance using these procedures. We present radiologic data on patients undergoing long segment deformity correction and fusion using MIS technologies.

Methods: 24 patients underwent circumferential deformity correction and fusion over 3 or more levels using 3 minimally invasive spine (MIS) surgical techniques: transpsoas discectomy and interbody fusion, Trans1 AxialIF transsacral minimally invasive lumbosacral interbody fusion
and percutaneous pedicle screw fixation using the Medtronic CD Horizon longitude system. All interbody fusions were performed with local autograft and bone morphogenetic protein (rh-BMP2). Indications included lumbar degenerative scoliosis, adult idiopathic scoliosis and post laminectomy deformity. 36° standing films were obtained pre and postop. Cobb angles were measured on AP radiographs. Lumbar lordosis was measured from T12 to S1 on lateral views as per STSG guidelines. Global sagittal balance was measured dropping a plumb line from the center of the C7 vertebral body and measuring the distance of this to the posterior superior portion of the sacral endplate.

**Results:** Mean patient age was 67.25 (SD 12.03) with mean number of levels operated on being 4.92 (SD 1.67). 16 patients underwent fusion to the sacrum. Mean preoperative Cobb angle was 42.33° (SD 12.89); postop was 6.51 (SD 6.60). Mean preoperative sagittal lordosis was 42.33° (SD 15.24); postop was 44.87° (SD 11.71). Mean preop global sagittal balance was 1.89 cm (SD 5.54 cm); postop was 1.66 cm (SD 3.74 cm).

**Conclusions:** MIS deformity correction maintains and recreates lumbar lordosis. Global sagittal balance was not appreciably changed in this population. Performed in the manner described here, MIS deformity correction and fusion is not associated, at least in the short term, with iatrogenic flatback deformity.

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**Clinical Results of Percutaneous Rigid Endoscopic Discectomy for Various Types of the Lumbar Disc Herniations**

**Abstract:**

**Introduction:** The purpose of this study was to evaluate the efficacy of percutaneous endoscopic discectomy for all radiculopathic pain from various non-contained lumbar disc herniations.

**Methods:** The study was performed on 456 cases of all 458 disc herniation between August 2004 and October 2007. All endoscopic procedures were performed by endoscopic postero lateral and interlaminar approach without foraminoplasty techniques or other bony resection techniques for visualization of nerve root and ruptured disc material. Therefore, all procedures were operated with only Suprapedicular approach and semirigid flexible curved probe. Suprapedicular approach was used to remove the disc materials in the cases of far down inferior migration, high canal compromised, stenosis combined type. The levels of improvement were evaluated with VAS and Macnab’s criteria.

**Results:** There were 252 male and 204 female average age of 48.95 ± 12.71 (Range: 15-79 years). The age distribution of patients is as follows: adolescence (6), 20s (24), 30s (76), 40s (125), 50s (98), 60s (109), and 70s (18). According to level, L2-3 (5), L3-4 (64), L4-5 (236), L5-S1 (142), L3-4-5 (5), L4-5-S1 (4). According to the herniation types, 103 cases of central types (L2-3 (2), L3-4 (19), L3-4-5 (2), L4-5 (75), L5-S1 (5) ); high canal compromise type(63, non-high canal compromise type(40 ), 295cases of paracentral types (L2-3 (2), L3-4 (29), L3-4-5 (3), L4-5 (134), L5-S1 (123), L4-5-S1 (4) ), 32cases of foraminal type(L2-3 (1), L3-4 (10), L4-5 (16), L5-S1 (5) ), 26cases of far lateral type (L3-4 (6), L4-5 (11), L5-S1 (9)). Among the patients, 46 cases were disc herniation combined with stenosis (central stenosis (43), foraminal stenosis(33)). The mean preoperative VAS for the leg pain was 8.58 ± 0.43 points (range, 7-10), the mean postoperative VAS for the leg pain at 1 month later follow up was 1.84 ± 0.71 points (range 1-3). According to Macnab’s criteria, excellent results in 242 cases(53.1%), good in 176 cases(38.6%), fair in 22 cases(4.8%), poor in 17cases(3.7%).

**Conclusions:** Compared to traditional microdiscectomy, a percutaneous endoscopic lumbar discectomy is regarded as difficult, not good outcome, high recurrence rate. But the results of percutaneous endoscopic lumbar discectomy for all discogenic radiculopathy patients were satisfactory and recurrence rate is not high.

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**Surgically Relevant in vitro Testing of Injectable PVA Nucleus Replacement Hydrogels**

**Abstract:**

**Aims:** Replacing the compromised nucleus percutaneously in a moderately degenerated intervertebral disc may afford relief of painful symptoms and prevent or delay the degenerative cascade. Current approaches include implantation of devices or injection of gelling materials. Here we report further progress on testing of an poly(vinyl alcohol) (PVA) based injectable hydrogel system[1], with poly(ethylene glycol) as gellant. PVA is biocompatible and hydrophilic and is frequently used biomedically. The surgically-relevant validation of this hydrogel for nucleus replacement is described using in vitro tests and a delivery mechanism is proposed for an out-patient setting.

**Methods:** Biocompatibility was tested in vitro using agarose overlay (cytotoxicity) and LAL (endotoxicity) tests. A subcutaneous rat model (Wister) was used to validate safety at four weeks. A previously designed silicone annulus[2] fatigue model with permeable endplates[3] was used to compare hydrogel-filled and non-filled annulus properties over time. In addition flexion/extension fatigue and diurnal loading were also examined. Two approaches for delivery of the pre-gel solution were developed. In both scenarios, the pre-gel is injected through a 16G needle to cure, conforming to the annulus. In one, the solid gel is melted and subsequently cooled to body temperature before injection. In the other, a dual-chamber dynamic mixer is used to combine the hydrogel components and inject pre-gel solution into the disc.

**Results:** The gamma sterilized PVA hydrogel exhibited excellent potential for a minimally invasive nucleus replacement. The formulation was injectable by hand after melting, and the dynamic mixing device is showing promise. The formulation met basic ISO standards for biocompatibility. There was no indication of mechanical deterioration after 500kc at 40°C in cyclic fatigue at loads up to 3kN, and no evidence of debris. In addition, the hydrogel-filled annulus exhibited less disc height collapse than the annulus alone. Creep testing indicated that the hydrogel recovered following rest similar to natural disc behavior. The material did not extrude through a 5mm orifice at 3kN in confined compression, relieving concerns about device extrusion from annular tears.

**Conclusions:** These in vitro data prove that these PVA-based hydrogels are suitable for injection filling of a nucleated disc. The highly biocompatible nature of the materials used, and the ease of use and manufacture of the PVA hydrogels, make these materials candidates for nucleus augmentation. Rapid gelation and extrusion resistance in fatigue overcome the disadvantages of many currently available materials.
Furthermore, the simple delivery mechanisms provide a useful model for application of the system in a minimally invasive out-patient setting.

**References:**

Abstract: 29
**Comparing the Effect of Leading Nucleus Replacement Technologies on Bone Remodeling and Subsidence**

M.C. Dahl

Abstract: 562
**Wear and Fatigue of a Nucleus Pulposus Replacement Using a Surrogate Annulus and the ISO 18192 Duty Cycle**

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A method has previously been developed and validated for testing nucleus pulposus replacement (NPR) materials in a surrogate annulus fibrosus model (SAFM). Previous testing of the DiscCell™ (Gentis, Wayne, PA) nucleus pulposus material has consisted of cyclic axial compression and cyclic torsion. To characterize the wear and fatigue properties of the material under combined six degree of freedom loading, the validated method was used. ISO 18192 was used as a guide to combine axial loading, axial rotation (AR), lateral bending (LB) and flexion/extension (F/E) into a single test cycle. Rate dependency of the viscoelastic material was explored before conducting the 10 million cycle test. The objective of this study was to evaluate the effect of multi-axial cyclic loading on the wear and stiffness properties of the DiscCell™ nucleus pulposus material. Using a SAFM and a six degree-of-freedom MTS Spine Wear Simulator (MTS, Eden Prairie, MN) 10 million cycles of testing was conducted. Specifically, a total of eight DiscCell™ NPR samples were molded; six were used for wear/fatigue and the remaining two served as load soak controls. First, compressive stiffness characterization was performed in a 37±2°C PBS bath on the unfilled SAFMs and the filled SAFM constructs. The NPRs were soaked for 48 hours in PBS and weighed prior to the filled stiffness characterization. The filled SAFMs were then tested on the wear tester in accordance with the lumbar specifications in ISO 18192-1. Specifically, the samples were loaded sinusoidally between 600 and 2000N while F/E, LB and AR were performed at +6.0°/−3.0°, ±2.0°, and ±2.0°, respectively. Motions were performed at 2.0 Hz and the axial loading was performed at 4.0 Hz with the peak compressive force coincident with the maximum F/E peaks. The x-y translation table inferior to the SAFM was free to translate in both the medial-lateral and anterior-posterior directions. Constructs were submerged in PBS and maintained at 37±2°C. The simulator was stopped at 1.0, 2.0, 2.5, 5.0, 5.7, 7.5 and 10.0 MC, PBS was exchanged, stiffnesses were evaluated and the surrogate NPR was weighed. Additionally, the SAFM was replaced with a freshly molded SAFM at 2.5, 5.0 and 7.5 MC. The rate of mass loss for the wear samples was initially (0-1.0MC) 1.01 ± 0.181 g/MC but decreased to 0.04 ± 0.015 by the 7.5 to 10 MC interval. The percent difference between the filled and unfilled compressive stiffness was 35.8% initially and decreased to 29.1% by the end of the test. A marginally
Objective: The nucleus replacement device aims not only to restore spinal biomechanics, but also to establish proper load sharing in disc tissues. In order to mimic the effect of normal hydrostatic pressure inside the disc, the implant has to be able to deform under the applied load and maintain constant contact with the surrounding tissues. This FEA study evaluates how the hardness of the nucleus implant affects the biomechanics and load sharing in an L5-S1 spinal segment.

Methods: A previously developed and validated nonlinear FE model of the L5-S1 spinal segment [SAS 2008] was used to simulate implantation of the nucleus device. This model includes all critical components of the spinal segment with the material properties collected from literature. The nucleus in the healthy segment was simulated with a fluid-filled cavity. The implant was modeled by filling the nucleus space with an elastomer. Frictionless contact was assumed between the implant and disc tissues. The elastomer hardness (Shore A) was varied from 10A to 100A and modeled using the Mooney-Rivlin approach. All segments were subjected to ±7.5 Nm flexion/extension with a 400N preload. Segmental biomechanics and endplate stresses over implant and annulus were analyzed and compared to the healthy segment.

Results: Compared to the healthy segment, axial stiffness slightly decreased in the softer materials (-6% for 10A, -2% for 20A), and substantially increased in the harder materials (15% for 40A, 59% for 60A, 150% for 80A and 410% for 100A). For material with hardness less than 60A no significant difference in ROM (< 5%) compared to the healthy segment was predicted. With harder materials, such as 80A and 100A, ROM decreases by 15% and 36%, respectively.

As shown in Fig.1, the increase in material hardness transfers stresses to the implant and unloads the annulus. FEA results also indicate that hard materials do not conform to the disc space under some loading (i.e. flexion) and separate from the endplates (Fig.2). No separation from the endplate was observed in materials with hardness less than or equal to 40A.

Conclusions: FEA results indicate that the material hardness affects the ability of the implant to accommodate spinal loading. Softer materials maintain segmental biomechanics and constant contact with the surrounding disc tissues, which results in proper load sharing in the disc tissues. Harder materials cannot deform to fill disc space under spinal loading, which results in increased segmental stiffness and concentration of the endplate stresses over the implant.

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FEA Investigation of the Influence of Nucleus Replacement Hardness on Spinal Biomechanics

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Abstract: 198

Intra-operative Analysis of Anular Competence as Related to Anular Repair in Primary Lumbar Discectomy Patients

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Abstract: 654

Discographic Disc Healing with Posterior Dynamic Stabilisation of the Lumbar Spine

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Aim: To demonstrate healing of painful lumbar disc tears, managed by posterior dynamic stabilisation, with subsequent
LUMBAR TDR: NOVEL APPROACHES

Abstract: 328
TSMS, a Novel Posterior Disc and Dynamic Stabilization System, Restores the Kinematics of Lumbar Spine to Normal: In vitro & FEM Study

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Introduction: Total lumbar disc replacements are used to restore spinal alignment and kinematics of a degenerated segment. Posterior disc design concepts are proposed to address the present deficiencies of anterior lumbar arthroplasty such as the difficulty in surgical approach, difficulty in revision and post-operative facet pain while preserving the kinematics of the spine. In this study we used in vitro testing and Finite Element (FE) modeling to compare the biomechanical behavior of the intact lumbar spine after single level replacement of TSMS™ (Total Spinal Motion Segment), a novel 360 motion preservation system (DMT Inc., FL, USA).

Methods: A cadaveric experiment using six healthy L1-S1 spine segments was conducted, with methodology according to our previous in vitro studies (Goel et al, 2005), to analyze spine biomechanics following placement of TSMS 360 system at L4-L5 versus intact. TSMS included a pair of Disc which was placed following a posterior surgical approach (total nucleotomy and bi-lateral facetectomy plus partial removal of posterior annulus and posterior longitudinal ligaments) along with a pedicle screw–based posterior dynamic stabilizer (PDS) system. Each specimen was subjected to 10Nm moment (applied incrementally) to simulate flexion, extension, right and left/right lateral bending, and left/right axial rotation. The angular motion at the implanted and adjacent levels and the extension-to-flexion center of rotation (COR) of the operative level were computed in each case.

A FE analysis using a 3D experimentally validated FE model of L3-S1 spine (Goel et al, 2006) was followed to simulate in vitro experiment by simulating similar surgical procedure, implant setting and loading/boundary conditions.

Results: Placement of TSMS didn’t alter the motion of the adjacent segment in both in vitro experiment (P>0.27) and FE simulation (motions within 1SD of the in vitro data) in all loading cases. All patients had improvement in their discographic pressures and pain levels at one year. All but one had full resolution of their pain with discographic “healing” of the discal tears by two years. The system was then removed in eight, these patients remaining well. One patient refused implant removal. One patient is due three year discography, having shown improvement but not yet full healing up to two years.

Discussion: Disc healing is the holy grail of many spinal interventions, but seldom seen, as the process is slow and repeated injury is likely. This study suggests that discographic healing can occur in torn and painful lumbar discs, by the use of a temporary prosthesis’ to off-load the tear. Once healing is confirmed, the system may be removed, leaving the patient with a normal back.

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Acknowledgments: Grant from Disc Motion Technologies (DMT) Inc., Boca Raton, FL.

Abstract: 196
Preliminary Clinical Evaluation of Posterior Disc Arthroplasty

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Purpose: This ongoing multicenter study was designed to evaluate clinical results obtained with the NuBac disc arthroplasty system when implanted with a posterior approach. This abstract will discuss the obtained results.

Methods: Patients with discogenic LBP who did not respond to conservative treatment are included to investigate the effects of NUBAC on pain and function. A minimally invasive posterior approach is used. With a partial unilateral laminectomy and facetectomy, the nucleus is removed and the NUBAC is placed. Correct implant positioning is checked with fluoroscopic images. Intra-operative complications, EBL, and operation time are monitored to evaluate posterior approach.

Pain and function are evaluated by VAS and ODI questionnaires completed pre-operatively and 6 weeks, 3, 6 and 12 months.

Results: 45 patients suffering from discogenic LBP are included. 43 cases are single-level treatments mainly performed at level L5-S1 (73.8%), double-levels were on L4-S1. Mean age is 36.8 years (22-58 years) and 52.6% of the patients are male.

No major intra-operative and postoperative neurological complications occurred. Mean operating time is 98 minutes (45 - 210 minutes). The EBL is 85 ml (10 - 150 ml). VAS score shows a decrease from the pre-operative score of 84 to respectively 30, 24, 15 and 18 at 6 weeks, 3, 6 and 12 months indicating pain relief at all time points.

ODI score shows improvement at all time points with ODI scores of 62 pre-operatively and 23, 18, 14 and 14 at 6 weeks,
**Discussion:** In literature ODI and VAS scores are reported for this device. The ODI score decreased from 51 pre-operatively to 31, 27, 24 and 23 at 6 weeks, 3, 6 and 12 months postoperative (figure 1) and the VAS score decreased from 76 pre-operative to 31, 27, 24 and 23 at 6 weeks, 3, 6 and 12 months (figure 2). This study confirms the reported improvement of function and pain after implantation of the NuBac. Also, this study indicates that posterior approach is safe and able to relieve pain and improve function.

**Results:** Patients included 16 males and 20 females, average age 43 yrs (24-60). Surgeries included 14 1-level, 3 2-level, and 19 hybrid TDR/ALIF cases. The surgery is performed through a 4cm lateral incision in an average of 134 minutes (90-300) and with an average 58cc blood loss (30-150). There have been no intra-op or post-op complications. Postoperative x-rays show good device placement, with restoration of disc height, foraminal volume, and sagittal balance. All patients were up and walking within 12 hours of surgery and all but 9 were discharged the next day (7/9 were hybrid TDR/ALIF cases). 5/36 patients (13.8%) had psoas weakness and 3/36 (8.3%) had anterior thigh numbness postoperatively, both resolving within 2 wks. 4/36 (11%) had postoperative facet joint pain, all in hybrid cases. VAS pain scores improved from an average of 9.3 at pre-op to 2.4 immediately post-op, 3.2 at 6 wks, 1.9 at 3 mos, 2.6 at 6 mos, 2.4 at 1 yr and 2.45 after 2 years. Oswestry Disability Index improved from an average of 57 at pre-op to 31 at 6 wks, 23 at 3 mos, 21 at 6 mos, 15 at 1 yr and 19.2 after 2 years. Average postoperative ROM remains steady, not significantly different from preoperative values.

**Conclusion:** Our results of a laterally placed TDR device demonstrate maintenance of pain relief and functional improvement. The benefits of this technique -- minimal morbidity, avoiding mobilization of the great vessels, preserving the anterior longitudinal ligament, biomechanically stable orientation, and broader revision options - suggest a promising new direction for TDR procedures.

**Abstract:**

**Observations from Retrieved ProDisc® Total Disc Replacements and Their Implications for Interpreting Spine Wear Testing Conditions**

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**Purpose:** Wear and osteolysis are major concerns in all joint replacements, including disc replacement. Long term clinical results are the true measure of wear performance, but simulator tests and analyses of retrieved implants provide important evidence. Correlation of findings from wear simulations with damage observed on retrievals provides confidence in laboratory predictions and a link between in vivo wear and its causes. The purposes of the study were to describe wear observed on retrieved components and to compare in vivo damage to that observed on components tested in a simulator.

**Methods:** 24 Prodisc® devices were collected at revision surgery: 13 cervical (12 patients) and 11 lumbar (10 patients). Partial clinical data were available for 19 patients; most were female, age from 31 to 52 years, and length of implantation from 2 days to 5.8 years. Revision diagnoses included pain, trauma, infection, subluxation, dislocation, and impingement. Implants were cleaned and catalogued as part of an IRB-approved retrieval program. Polyethylene inserts and metallic endplates were examined using light stereomicroscopy at magnifications up to 32X. Wear modes were identified based on previously developed techniques. Similar observations were made on bearing surfaces of 6 cervical and 6 lumbar ProDisc® polyethylene inserts that had been wear tested a minimum of 5 million cycles under ISO 18192-1 conditions.

**Findings:** The wear pattern on the polyethylene bearing surfaces was typically asymmetrical, covering most of the available surface, but skewed anteriorly or posteriorly with...
deformation along the edge of the wear area. Burnishing was the dominant mode, observed on 11/13 cervical and 9/10 lumbar bearing surfaces (one lumbar surface was too damaged for assessment). Scratching was also common, occurring on 8/13 cervical and 7/10 lumbar surfaces. In 5 implants (3 cervical; 2 lumbar), scratching was associated with embedded titanium debris from the plasma-sprayed fixation surfaces.

Burnishing of the metallic endplates near the rim of the bearing surface was routine (10/13 cervical; 7/11 lumbar retrievals), consistent with metal-on-metal impingement. Bone ingrowth to the fixation surfaces was present on 10/13 cervical and 7/11 lumbar retrievals, though < 30% of the surface was covered with bone.

The bearing surfaces of the simulator specimens were highly burnished with little evidence of other wear modes. Wear of the cervical specimens was symmetrical in half the cases, but in the other half, asymmetry with edge deformation, similar to that observed in the retrieved components, was observed. For lumbar specimens, the asymmetry and deformation were more pronounced.

Conclusions: In vivo wear was mild, though multiple modes were present including 3rd body debris, which can contribute to wear of the opposing metallic bearing surface. The wear pattern demonstrates the restoration of motion, though the large portion of cases with impingement shows that patients often exceeded the motion allowed by the device. The similar asymmetry in wear patterns between retrievals and simulator specimens demonstrates that the motions and alignment prescribed by the ISO standard successfully mimic the in vivo situation. However, lack of damage modes beyond burnishing suggests the simulator does not capture all in vivo conditions.

Abstract: 476

Intervertebral Disc Kinematics Following Implantation of an Elasticum Artificial Lumbar Disc

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Aim: Abnormal centers of rotation and range of motion following total disc arthroplasty may result in new or increased facet joint and adjacent level degeneration. A device that restores or maintains the kinematics of the lumbar spine may help avoid these problems. The objective of the present study was to determine whether an elasticum lumbar artificial disc (Physio-L) is capable of restoring and maintaining the normal range of motion and center of rotation at the index and adjacent levels post-operatively up to one year follow-up.

Methods: The center of rotation at the index level (L5-S1) and adjacent level (L4-L5), together with overall intervertebral rotation between L1 and S1, was measured from neutral, flexion, and extension x-rays for 18 patients implanted with the Physio-L. The radiographic analysis was performed at the pre-operative, 6 weeks, 3, 6, and 12 month time points using validated, computer-assisted methods (QMA)1, Medical Metrics, Inc., Houston, TX). Center of rotation data was reported for all 18 patients at the L5-S1 index level, while adjacent level results at L4-L5 were reported for the 12 patients who were treated at a single L5-S1 level only. All data were compared to the 95% confidence interval (CI) established for a population of 63 asymptomatic (normal) volunteers analyzed using identical methodology.

Results: The analysis indicated that the patients receiving the Physio-L disc demonstrated a similar overall range of motion between L1 and S1 and center of rotation at the index level to the normal, asymptomatic group. Specifically:

1. The center of rotation was restored or maintained to normal following implantation at the L5-S1 index level. This center of rotation at the index level was within the 95% CI of normal at all post-op time points. Further, none of the patients (0%) had a center of rotation located outside the 95% CI of normal.
2. The center of rotation at the L4-L5 adjacent level did not change significantly between the pre-op and the post-op time points, indicating that the use of an elasticum disc at the L5-S1 index level did not adversely affect the kinematics of the adjacent level.
3. Intervertebral rotation between L1 and S1 increased from 46º ± 19º pre-operatively to 51º ± 23º at 12 months. This change was not statistically significant (p=0.56). Calculated as a proportion of L1-to-S1 motion, intervertebral rotation at the index level did not change from pre-op to 12 months (21% ± 12% vs. 22% ± 7%, p=0.7).

Conclusions: Normal kinematics and range of motion of the lumbar spine was demonstrated at the index and adjacent level following the implantation of the Physio-L at each follow-up time point studied. Patients suffering from low back pain symptoms tend to have reduced overall motion, so the observed increase in overall motion would be consistent with a reduction in symptoms.


Abstract: 404

Effects of Lumbar Artificial Disc Design on Intervertebral Mobility - In vivo Comparison between Mobile-core and Fixed-core

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Purpose: Lumbar disc prosthesis is thought to restore segmental motion. However it is reported that disc prosthesis increase the intervertebral translation (VT) and consequently may increase load on the facet joint. The concept of the mobile-core prosthesis is to mimic the kinematic effects of the migration of the natural nucleus and therefore core mobility should minimize the VT. The goal of this study was to assess in vivo this concept that core translation should influence VT and may facilitate physiological intervertebral mobility replication. In vivo intervertebral motion characteristics of levels implanted with mobile-core prosthesis were compared to levels treated by fixed-core prosthesis, to untreated levels and to normative data from literature.

Methods: VT, core translation, range of motion (ROM) and distribution of flexion-extension were measured on flexion-extension and on neutral standing films in 77 patients who received a mobile-core prosthesis (Mobidisc) and in 25 patients who received a fixed-core prosthesis (ProDisc-L). A new method of VT measurement was developed to optimize the accuracy of the measures. VT was expressed in mm adjusted to 10º of ROM.

Results: At implanted L4L5 levels the VT with a mobile-core was significantly lower than with a fixed-core (respectively -1.1mm versus -1.74mm) and similar to the VT of untreated levels (-1.2 mm) and normal levels (-1.03mm). At implanted LSS1 levels the VT with a mobile-core (-0.74 mm) was still...
significantly lower than with a fixed core (-1.58mm) but was significantly different to untreated levels (+1.07mm) and to normal levels (+0.03mm). At levels implanted with a mobile-core prosthesis no correlation was found between VT and ROM but a strong correlation was found between VT and core translation: the VT decreases as the core translation increases (p<0.0001). At levels implanted with a fixed-core prosthesis the VT increases as the ROM increases (p<0.05). Mean ROM at levels implanted with a mobile-core prosthesis were significantly higher at both L4L5 and L5S1 levels compared to levels implanted with a fixed-core prosthesis: respectively 10.3° ±5 and 6.9° ±3.5 at L4L5 levels and 8.9° ±3.9 and 6.4° ±3.8 at L5S1 levels. No significant difference was found between the ROM of untreated levels and levels implanted with a mobile-core prosthesis. Regarding the mobility distribution at L5S1 implanted levels compared to normal distribution we observed a tendency of deficit in extension for the mobile-core prosthesis and in opposition a deficit in flexion for the fixed-core prosthesis.

Conclusion: This study revealed that intervertebral mobility was different between levels implanted with a mobile-core or a fixed-core prosthesis. Our results validate in vivo the concept that the core translation minimizes the VT. Mobile-core prosthesis at L4L5 levels succeeded to replicate physiological mobility including VT, ROM and mobility distribution but failed at L5S1 levels regarding VT and mobility distribution. Nevertheless core mobility minimized VT even at L5S1 levels. Fixed-core prosthesis increased VT at both L4L5 and L5S1 levels and generated a deficit in ROM and in flexion. The long-term clinical consequences of this VT increase concerning arthritic progression of the facet joints remain questionable.

**LUMBAR TDR: OUTCOMES**

Abstract: 590

**SF-36 Quality of Life Results: ProDisc-L® versus Circumferential Fusion - Results from a Prospective, Multi-center Randomized Clinical Study**

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**Purpose:** Randomized clinical trials have provided evidence that lumbar disc arthroplasty with the ProDisc-L (Synthes Spine) or Charité (DePuy Spine, Inc.) is as safe and effective as fusion for treatment of single level degenerative disc disease (DDD). However, to date, a critical look at the Short Form 36 (SF-36) Health Survey outcomes (eight health scales and two summary measures) has not been undertaken. The Physical Component Summary measure is useful in assessing impairment of patients with DDD compared to U.S. normal population. As a result of surgery, the patients’ physical and mental health, as measured by mean SF-36 scores, improved at two years. The ProDisc-L® patients experienced a greater improvement in the Physical Component Summary measure. The improvement was statistically and clinically significant.

Abstract: 233

**A Prospective Outcome Analysis of Artificial Disc Replacement versus Anterior Interbody Fusion in Single Level Symptomatic L5/S1 Degenerative Disc Disease**

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**Study design:** Seventy patients with a minimum of two year follow-up were included in this single centre prospective non-randomized study of degenerative disc disease (DDD) at L5/S1 treated with either Artificial total disc replacement (TDR) device (Prodisc, Synthes) or Anterior lumbar interbody fusion (STALIF, Surgicraft or SYNFIX, Synthes ) device.

**Aim of the study:** To compare the outcomes achieved with the Prodisc disc replacement (TDR) device versus stand alone anterior interbody fusion (ALIF) for a single level symptomatic DDD at L5/S1.

**Methodology:** 47 patients were treated with Prodisc disc replacement device (TDR) and 23 patients were treated with Anterior interbody fusion with STALIF/SYNFIX device (ALIF). TDR consisted of 33F:14M patients with a mean age of 39 years and a mean BMI of 26.2. The ALIF group consisted of 12F:11M with a mean age of 43 years and mean BMI of 28.5. All patients had clinical evaluation followed by plain X-rays, MRI scans and Discography. All patients had undergone a minimum of one year of conservative treatment. Patients with previous lumbar surgery and more than one level of DDD were excluded from the study. Implant choice was determined by the surgeon and patient preference. All patients completed standard questionnaires for assessment of disability i.e. VAS, ODI, and LBOS preoperatively and at two years post-operatively.

**Results:** The two groups were well matched for age, sex, duration of symptoms and preoperative scores. The mean preoperative and two year post-operative ODI scores were 53.5 (SD±16) (TDR) & 58 (SD±12) (ALIF) and 26 (SD±18) (TDR) & 38(SD±14) (ALIF) respectively (p<0.05). The mean preoperative VAS scores were 8 (SD±2) for both groups and the mean two-year post-operative scores were 3.5 (SD±2) (TDR) & 5.5 (SD±2.5) (ALIF) <0.05). The mean preoperative LBOS were 22(SD±14) (TDR) and 20 (SD±12) (ALIF). The mean two-year post-operative LBOS were 45 (SD±22) (TDR) & 30 (SD±
LUMBAR TDR: MULTI-LEVEL

Abstract: 536

Hybrid Surgery: Fusion and Disc Arthroplasty Is Superior to Two Disc Arthroplasties in the Lumbar Spine

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Two-level fusion constructs have been implicated in accelerating adjacent disc disease in lumbar spine. Two-level TDA s and fusion/TDA hybrids attempt to preserve motion while minimizing the risk for adjacent disc disease.

Purpose: To prospectively evaluate clinical outcome of two-level TDA s and fusion/TDA.

Study design setting: Patients surgically treated for 2-level degenerative disc disease were divided into two groups: fusion/TDA (group A) and double TDA (group B). Their clinical outcomes were compared. Group A: ALIF at L5S1 and TDA at L4-5. ALIF was performed using an anterior impacted cage (Union cage or Perimeter cage, Medtronic, Memphis, USA) The disc arthroplasty at the level L4L5 was performed using a maverick implant (Medtronic, Memphis, USA). Group B: The disc arthroplasty at L5S1 and L4L5 was performed using a maverick implant (AMav and OMAV) through an anterior retroperitoneal approach.

Patient sample: 70 patients were prospectively randomized with a ratio of 1:2 (one double-disc (DD): two fusion-disc (FD)). Group A: 50 patients Group B: 20 patients.

Outcome measure: Clinical examination including Oswestry, VAS for back and leg pain, SF 36, X rays with dynamic examination and full standing radiographs were performed and at each follow up interval with a minimum two years follow up. CT scan and MRI were performed pre operatively.

Complications were noted. Student t-test was used to compare the results of both groups.

Results: 45 patients have completed the 3 years follow up in group A and 19 in group B. Mean follow up is 38 months (23 to 46 months).

In group A: Oswestry score improved by 29.6% (p<0.05), VAS for back pain improved significantly (39.1%; p<0.05) and SF 36 showed significant improvement for mental (3 pts) and physical scores (6,4pts). No evidence of non-union was noted at the level of L5S1 at the latest follow up. One patient had peripheral calcification at level L4L5 but the prosthesis remained mobile. One patient had subsidence of the prosthesis into the L5 vertebral plate. Twelve patients had facet syndrome and were all treated successfully with steroid injection.

In group B: Oswestry score improved by 25.6% (p<0.05), VAS for back pain improved significantly (37.1%; p<0.05) and SF 36 showed significant improvement for mental (3 pts) and physical scores (5,3pts). One patient has peripheral calcification at level L4L5 but was still mobile on dynamic x Rays. Two patients had a subsidence of the prosthesis in the L5 vertebral plate and aren’t mobile. 10 patients had facet syndrome and were all treated successfully with steroid injection.

Comparison between the two groups: VAS back and Oswestry scores were significantly better in group A when compared to group B.

Two-level lumbar artificial disk replacement in previous publications have been shown to be equivalent or inferior to the clinical outcome of one-level TDA. This study suggests that 2-level TDA confers no advantages when compared to hybrid constructs.

Abstract: 585

Multiple-level Lumbar Artificial Disk Replacement Adjacent to Concurrent Anterior Lumbar Interbody Fusion: A Clinical and Radiographic Analysis of Sagittal Motion
Preservation at 2-6 Years
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Background: A recent FDA-sponsored randomized controlled study of the Prodisc-L (Synthes Spine, Westchester, PA) lumbar disc replacement established superior clinical outcomes with preservation of motion at both surgical and adjacent levels, as compared to lumbar fusion. However, no previous study has reported on the radiographic characteristics of single or multiple level lumbar disc replacements adjacent to a concurrent fusion construct.

Purpose: To evaluate clinical outcomes and the sagittal range of motion of one, two, or three level ProDisc-L lumbar replacements adjacent to a concurrently-performed anterior lumbar interbody fusion (ALIF) construct using InFix (Abbott Spine, Austin, TX) stand-alone cage. Patient sample: Forty-six patients underwent simultaneous lumbar ADR at one or more levels and ALIF at L5-S1. Twenty-three patients had one-level ADR at L4-L5 with an L5-S1 ALIF (ADR-1 + ALIF), nineteen patients had a two-level ADR (at L3-L4 and L4-L5) with adjacent fusion (ADR-2 + ALIF), and four patients had a three-level ADR (L2-L3, L3-L4, L4-L5) with adjacent fusion (ADR-3 + ALIF).

Study-design: Prospective Cohort.
Outcome measures: Angular motion (extension and flexion measurements) on preoperative and postoperative sagittal-projection lumbar films at each operative motion segment as well as at the segment adjacent to the ADR+ALIF construct. Oswestry Disability Index (ODI), Visual Analog Score Pain (VAS-P), and Visual Analog Score Satisfaction (VAS-S) data were also collected.

Methods: Patients were evaluated pre-operatively, at six weeks, three months, six months, and annually for 2-6 years postoperatively with lateral flexion-extension films and with completion of Oswestry and VAS surveys.

Results: There were no significant differences among the groups for age, gender, body mass index, tobacco use, or worker’s compensation status. At the motion segment adjacent to the ADR+ALIF constructs, the mean preoperative range of motion was 5.40° (SD 1.80°), compared to 10.50° postoperatively (SD 2.25, p=0.21). The mean preoperative range of motion at levels undergoing ADR was 10.15° (SD 2.71°) versus 12.30° postoperatively (SD 2.25, p=0.011). There was no statistically significant difference in range of motion at each prosthetic motion segment between patients receiving one-, two-, or three-level ADR (p<0.05 for all comparisons between groups). The mean preoperative range of motion at the L5-S1 segment to undergo fusion was 1.90° (SD 2.44°), with all patients having a postoperative range of motion of 0.00° (p>0.05). At 2-6 years postoperatively, all patients had significant reductions in both ODI and VAS scores relative to preoperative levels (p<0.05). At up to six years follow-up, no patient underwent revision surgery or surgeries at adjacent levels.

Conclusions: The use of the hybrid ADR+ALIF construct, with either single or multiple level ADR, does not inhibit the efficacy of fusion at the ALIF level nor does it inhibit preservation of range of motion at any of the ADR levels. Most significantly, the nonoperative level adjacent to the hybrid construct maintains its preoperative range of motion at 2-6 years postoperatively. At up to six years of follow-up, there has been no need for revision or adjacent-segment surgery. Patients also demonstrate significant improvement in pain and disability at latest follow-up.

Abstract: 141
Does an Adjacent Abnormal Non-concordant Discogram

Impact the Clinical Results of Lumbar Artificial Disc Replacement (ADR)?
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Background context: This is the only study performed to specifically evaluate the question of whether ADR can be successfully performed above or below disc’s that are abnormal on MRI and non-concordant in pain response based on discography.

Study design/setting: Every patient involved in FDA IDE studies with three different ADRs were evaluated at two-year follow-up for clinical success and divided into two groups. Group A had a single abnormal disc based on MRI and discograms with a normal disc above and/or below. Group A included 28 patients. Group B had a single abnormal disc with an adjacent abnormal, non-concordant disc above and/or below based on discography. Group B included 18 patients.

Patient sample: Demographics between the groups in terms of gender, BMI, levels operated upon, and type of ADR were similar. Specific data will be discussed. The average age of Group A was 34.3 vs. the average age of Group B at 44.5. This difference was significant.

Outcome measures: Clinical success was based on the FDA IDE study criteria and specifics will be discussed.

Methods: Every patient in the study underwent pre-operative MRI and discograms at L3-4, L4-5, and L5-S1. Discogram results were based on the Dallas discogram classification. All patients underwent a single level ADR based on abnormal MRI and abnormal concordant discogram. All patients were then followed prospectively with a minimum two-year follow-up.

Results: Group A had a pre-op average Oswestry of 60.8 and VAS of 76.4. Two-year follow-up Oswestry averaged 29.4 and VAS of 41.8. Group B had a pre-op average Oswestry of 61.2 and VAS of 78.7. Two-year follow-up Oswestry averaged 16.9 and VAS of 17.8. IDE clinical success averaged 86% in Group A and 88% in Group B. There was no difference in complications or recovery time between the groups.

Conclusions: Group A and B were similar in all demographics except age. The average age in group B was 10 years older than group A. This group appears to demonstrate the natural aging process of non-concordant annular tears. Their clinical results in terms of improvement was actually better than Group A, but not statistically significant. These results indicate it is safe and effective to perform ADR above or below an abnormal non-concordant disc. Clinical results can be expected to be similar to the more ideal patient with a totally normal disc adjacent to ADR.

COMPLICATIONS TDR

Abstract: 50
Early Failure of Metal-on-Metal Artificial Discs due to Metal Hypersensitivity: The Diagnostic and Treatment Approach in 4 Collected Cases
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Introduction: Metal-on-metal designs in hip arthroplasty have gained popularity due to decreased volumetric wear rates and theoretically increased implant longevity. Systemic metal ions produced have not been associated with adverse clinical sequelae, although there have been reports of local soft-tissue reactions leading to early prosthetic wear.
failure. Histological evaluation in these cases suggested a cell-mediated delayed-type hypersensitivity reaction. Metal-on-metal bearings have also emerged in lumbar and cervical total disc replacement (TDR) prostheses, but to our knowledge, this complication has not been reported. The purpose of this study is to report the collective diagnostic and treatment approach undertaken in patients with failed spinal arthroplasty due to presumptive metal allergy.

Methods: This report is on four patients, from three centers, who underwent TDR using a metal-on-metal implant and later presented with symptoms that were determined to be due to metal hypersensitivity. Details of their symptoms, diagnostic work up, treatment and outcomes were compiled.

Results: All patients initially had a good surgical outcome, followed by onset and worsening of axial pain and/or radicular symptoms. A description of the cases is provided in Table 1. All patients had imaging findings of a mass lesion with neurologic impingement. Infection was suspected, but was later ruled out in all cases. In two patients (cases 2 and 4), an audible squeaking and/or grinding sound was produced by the prosthesis during motion.

Discussion: To our knowledge, this is the first report of presumptive metal allergy causing subsequent failure of metal-on-metal lumbar and cervical disc arthroplasties. This phenomenon has previously been recognized with metal bearings in hip arthroplasty, with a reported prevalence of 1%. Our findings from one of the prostheses in this report suggest that a similar prevalence could exist in metal-on-metal TDR and should be considered prior to using this bearing alternative.

Abstract: 51

Re-operations in Lumbar Total Disc Replacement: Experience with Our First Consecutive 800 Cases

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Introduction: As with any surgery, there will inevitably be some patients requiring revision following lumbar total disc replacement (TDR). The incidence of re-operation cannot be investigated well in small case series. The purpose of this study was to review the re-operations encountered in the consecutive series of the first 800 patients undergoing lumbar TDR at a single center.

Methods: A database of all TDRs performed since the first case in 2000 was created from logs from the FDA IDE trials and an ongoing surgery log. Re-operations were identified from adverse event records and surgery logs in which repeat surgery could be identified for TDR patients. A total of 982 TDRs were implanted in 800 patients (583 one-level, 165 two-level, 7 three-level, 41 single-level as part of a TDR/fusion hybrid and 4 two-level TDR as part of a hybrid). There were five different TDRs used in the series. The mean length of time since the TDR surgery was 44 months. Re-operations were classified based on the level of the spine operated with respect to the index procedure and the reason for re-operation.

Results: Among the 800 patients, 46 (5.75%) underwent a total of 70 interventions. Twenty-seven of these involved the use of a spinal cord simulator and its trial, implantation, explantation, and/or revision. The reasons for index level revision procedures included: malpositioned polyethylene core (n=1), facet arthropathy (n=2), wound infection of posterior incision (n=1 hybrid patient), painful posterior instrumentation (n=1 hybrid patient), vertebral body fracture (n=1), pars fracture (n=1 at TDR level, n=1 at 2 levels above TDR level), synovial cyst (n=1), metal sensitivity (n=2), spinal cord tumor (n=1), or ongoing pain or onset of new back and/or leg pain (n=34). A description of the re-operations is presented in Table 1 (if a patient had a procedure in addition to spinal cord stimulation, they are counted as the non-SCS stimulator procedure). The mean length of time between the index and re-operation surgery was 26.7 months, ranging from 2 days to 85 months. When considering the 982 TDRs, only 18 re-operations (1.8%) were performed at the TDR level.

Conclusion: The results of this study found that the re-operation rate for lumbar TDR was relatively low. In only a small percentage of cases, must the disc be approached anteriorly for removal. In several cases, posterior fusion at the TDR level was successfully performed to stabilize the segment to treat painful conditions. The revision rates compare well with the rates experienced in more commonly-performed spinal procedures.

Abstract: 62

Retrospective Analysis of the Etiology and the Salvage Procedure in Cases of Failed Lumbar Arthroplasty

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Objective: 1. Analyze and discuss the etiology of complications of lumbar arthroplasty in order to minimize the incidence of such complications in the future.
2. Present a strategy that can be applied to lumbar intervertebral disc prosthesis in the event that the salvage procedure needs to be performed.

Materials & methods:
Between October 2002 and July 2008, we performed revision for 47 patients who presented severe back pain or radicular pain with complications following lumbar total disc replacement (TDR). The indication for the initial lumbar disc arthroplasty procedure and technical aspects of the initial implantation were analyzed to determine the etiology implant failure. We also analyzed data from salvage procedures with respect to the surgical technique and patient outcome.

Results: Technical error during the initial arthroplasty were thought to be most common cause of implant dislocation or failure (misplacement, oversize or undersize, inappropriate preparation in end plate or posterior longitudinal ligament, and end plate fracture during implant insertion), and there were cases which was suboptimal indication for implant procedure on the basis of end stage facet disease with previous wide laminectomy.

In 14 of 47 cases, primary revision of artificial disc was performed for the reposition. In 10 cases, fusion surgery was done followed by removal of inadequate position of prosthesis. We just fixed the failed segment by posterior screws in 10 cases. In 6 cases, we performed the vertebroplasty for the subsidence. Decompressive laminectomy in 6 cases and endoscopic foramenotomy in one case was performed. There was no irreversible complication and favorable clinical outcome was shown in most cases. No vescic injury and fetal vascular damage was noted due to the failed mobile prosthesis even though in explosion of prosthesis.

Conclusion: While the majority of lumbar TDRs are successful, a small number of cases will require salvage procedure. TDR implant reoperation occurred largely as a result of technical errors in positioning and sizing of the implant. In addition, adherence to strict patient selection criteria will eliminate many cases of implant failure.

Conclusion: After careful selection of patients, lumbar XlIF can be a safe, effective treatment for multiple thoracolumbar degenerative conditions. XlIF surgery can be performed in many conditions with a low complication rate.

Abstract: 529
A Comprehensive Analysis of 80 Cases of Failed Cervical Instrumentation. Comparison of Revision to instruments versus Revision with Arthroplasty - Total of 142 Operative Levels
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Introduction: This analysis of 80 cases of failed cervical instrumentation and revision procedures was undertaken to compare the incidence and outcomes from single versus multilevel cervical instrumentation failures, with comparison to historical controls for primary ACDF.

Methods: A consecutive series of 80 patients presenting with failed cervical instrumentation procedures from April 1996 to Oct 2008 comprised the basis for this analysis and included 40 single level, 34 bivertebral and 6 trilevel index procedures (126 operative levels—largest series in world’s literature to date). All 80 patients (42 female, 38 male; avg. age 50±9.5) had either structural allograft/autograft or PEEK cages augmented with anterior cervical plates in 52% of the single level, 61% of the bivertebral and 83% of the trilevel cases.

A total number of 142 levels were revised. The primary indication for return to the OR and revision was adjacent disease - single level (20/40, 50%), bivertebral (15/34, 44%) and trilevel (1/6, 17%), followed by pseudoarthrosis - single level (18/40, 45%), bivertebral (18/34, 53%) and trilevel (2/6 33%) and spinal instrumentation failures single level, (2/40 5%) bivertebral (0%) and trilevel (1/6, 17%).

Results: Revision procedures for the cases presenting with adjacent level disease were managed using a motion preserving arthroplasty procedure in 7/20 (35%) of the single level cases, 1/5 (6.6%) of the two level and 1/1 (100%) of the three level cases, while the remaining cases were revised using interbody structural graft and anterior plates. The operative demographics between the surgical revision groups indicated multilevel cases are more technically difficult than single level or the allograft control group. The mean EBL ranged from 95.3±119.7cc to 142.3±222cc for the revision cases and was statistically different from the allograft control 58.6±29.5cc (p<0.05). The length of surgery ranged from 95.7±49.1 minutes to 134.7±66 minutes and was greater than the control (65.9±9.5 minutes) (p<0.05). The length of stay ranged from 2.2 days to 4.3 days and was higher than the control group 1.84 days (p<0.05). There were no significant differences in complications. Total rate was 10 (12%). This included 5% infection rate with a single, double and triple level incidence of 3, 6, and 17%, respectively.

Conclusion: Results of this study show that these revisions are within the parameters and demographics of historical
primary ACDF Procedures. This is in complete contradiction to revisions of anterior lumbar procedures which have a dramatically higher complication rate than primary anterior lumbar procedures. For the majority of patients presenting with adjacent level disease, arthroplasty remains a viable option for revision. All revision parameters were improved with use of the arthroplasty but not significant with decreased blood loss (p=0.09), operative time (p=0.23), and hospital stay (0.31). As expected, complication rates for these revisions are slightly higher than index procedures with increasing complication incidence correlating with an increasing number of vertebral levels. The use of arthroplasty for revision of failed anterior cervical instrumentation resulted in fewer levels of surgery compared to revisions using fusion, which tended to increase the number of additional surgery levels.

Abstract: 621
Minimally Invasive Decompression for Lumbar Spinal Stenosis (LSS) - An Analysis of Failed Cases
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Purpose: LSS remains the leading preoperative diagnosis for adults over 65 who undergo spine surgery. The cost of over 30,000 LSS surgeries in 1994 exceeds $1 billion. Surgery is associated with increased morbidity in elderly populations; yet systematic reviews defining preoperative factors predicting undesirable outcomes are limited. Aalto (2006) found depression, cardiovascular comorbidity, poor ambulation, scoliosis predicted poorer outcome; central stenosis, male gender and youth predicted better outcome. Outcome measures often lack patient satisfaction. Further, it remains undetermined whether imaging characteristics identify patients likely to fail surgery. Little evidence correlates degree of stenosis with failure. While some evidence indicates patients with severe stenotic symptoms benefit more from surgery than conservative means, it remains unstudied whether this group is more likely to fail surgery versus those with mild stenosis. Some studies implicate lateral recess stenosis as pain generator for most failed back surgery patients; this has not been explored fully. Reported poor outcomes/failure rates have ranged from 10-37%. Axial back pain is felt to respond more poorly to decompression than radiculopathy; explanatory factors have not been delineated. Given these unresolved issues, the purpose of this study is to analyze factors prevalent amongst patients failing decompressive surgery for LSS.

Methods: Retrospective analysis of 170 consecutive patients undergoing minimally invasive decompression for LSS (hemi laminotomy, foraminotomy, medial facetectomy, lateral recess decompression, partial laminectomy, microdiscectomies) by the senior author at two institutions between 2004-2008 was performed using chart and radiologic review via the Thalgott classification for lumbar DDD; questionnaires surveying subjective symptoms; SF-36 and ZCQ. “Failure” was defined as patient-rated “fair” or “poor” outcome, or requirement for further lumbar surgery.

Results: OF 170 total patients undergoing minimally invasive decompression for LSS, 17 (10%) were considered failures. Nine patients underwent two-level decompression; four patients single-level decompression; three patients triple-level decompression, and one patient underwent four levels of decompression, a total of 35 levels decompressed. With regard to the index level(s), central stenosis was identified at 34 levels; lateral stenosis at 20 levels, foraminal stenosis at 19 levels. Nine levels demonstrated coronal deformity; nine others demonstrated total collapse of disc space with loss of endplate anatomy plus anterior osteophytes; seven levels exhibited spondylolisthesis. All but one level exhibited severe facet joint degeneration with stenosis. Age range was 45-87 (median 69); ten were male (59%) and seven female (41%). Nine (53%) patients reported fair outcomes; five (29%) required additional surgery and 3 (18%) reported poor outcomes. Only 12% comprised workmen’s comp cases; 29% smoked; 24% had radiculopathy without axial back pain.

Conclusion: Minimally invasive decompression for LSS can be highly successful in reducing pain symptoms, improving neurologic deficit and maintaining physiologic motion and stability. Patients likely to fail share several characteristics. Future efforts will investigate clinical factors influencing outcome and identify radiographic features predicting success with conservative or surgical (minimally invasive or more aggressive) treatment. Delineation of preoperative variables predicting success will enable better application of treatment course, conservative or surgical, for LSS patients. Well-designed clinical trials are required to test the validity of these variable prospectively.

Abstract: 258
The Vertebral Artery and the Cervical Pedicle: Morphometrical Analysis of a Critical Neighborhood

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Objectives: Measurement for the distance between the vertebral artery (VA) and the cervical pedicle and its surrounding structures. Second objective is to provide valuable data delineating a “safety zone” and its application for the use of upper cervical spine screw fixation. No previous study in Western populations has offered evidence of VA’s proximity to the cervical pedicle and the percentage of occupancy in the transverse foramen.

Methods: 127 consecutive patients that received CTA of the neck were enrolled in this study. Bilateral measurements were performed on axial CT-scans at the levels C2-C7 using a digital caliper (0.01 mm increments). The measurements included: sagittal diameter of the transverse foramen (DTFS=A), coronal diameter of the transverse foramen (DTFC=B), pedicle diameter (PD/ID=C), sagittal diameter of the vertebral artery (DVAS=D), coronal diameter of the vertebral artery (DVAC=E), lateral pedicle border to vertebral artery (LPVA=F), and medial pedicle border to vertebral artery (MPVA=G). The cross sections of the VA and the transverse foramen were measured in order to determine the occupation ratio (OR) of the VA. Finally, a “safety zone” was determined by measuring the distance that the VA, theoretically, can be pushed aside while a misplaced pedicle screw breaches through the lateral pedicle border. Statistical analysis was employed to determine significance.

[Illustration of Morphological Measurements]
Results: The study shows that there is a meaningful “safety zone” between the cervical pedicle and the VA. A dominance of the VA on the left side was seen in 69.3% of the patients. The mean VA diameter was 3.24 mm on the right side and 3.55 mm on the left side. 12.6% of the patients presented with hypoplastic arteries, with three incidences found bilaterally. Mean PD increased from 4.9 mm to 6.5 mm from C3 to C7. Statistically significant differences were seen in pedicle diameter between males and females (p < 0.0001). C2 was seen to be different with regards to PD/ID with a mean of 5.6 mm. Mean LPVA increased from 1.1 mm to 6.5 mm from C2 to C7 on both sides with no significant difference between males and females. Level of VA entry at C6 was seen in approximately 80% of the patients. The occupation ratio of the VA with respect to the transverse foramen was found to be the greatest in C4 and C7 (37.1% and 74.2% respectively). The “safety zone” respectively is increasing from C3 to C6, with C2 seen to be greatest. We detected in 23.6% of the patients an abnormal pathway of the VA, with the highest incidence found in C2.

Conclusions: We found there is abundant space beside the lateral pedicle with a relatively high “safety zone.” Because of the high percentage of irregular VA pathways, we highly recommend performing and reviewing a CTA of the neck before instrumented cervical spine procedures.

**Abstract: 609**

**Non Fusion Surgery for Unstable Thoracolumbar Fractures**

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Purpose: This study aims to evaluate the results of Closed Reduction and Percutaneous Fixation (CRPF) without fusion for unstable burst fractures, without deteriorating neurological exam, in a level I trauma center.

Methods: Thirty-eight consecutive patients (271 screws) with unstable burst fractures without progressive neurological injury were treated with short segment CRPF without fusion. Medical records and radiographic studies were reviewed for procedure related complications (infection, vascular injuries, iatrogenic neurological injuries, and accuracy of screw placement) and the ability to re-establish and maintain spinal stability and alignment following vertebral fracture. Twenty-four patients (191 screws) had postoperative CT scan available for review and assessment of screw placement accuracy. Twenty-nine patients underwent planned removal of hardware and manipulation of spine under anesthesia. Of the remaining 9 patients, mostly with thoracic injuries, 4 decided to keep the hardware unless it becomes symptomatic and 2 patients moved back out of state and were lost to follow up. Three patients are not yet due for hardware removal.

Results: None of the patients experienced (treatment related) neurological deterioration. All but 6 screws were well confined within the pedicle walls in the CT scan group (191 screws) and no suspicious misplacement was noted in the plain X-ray group (80 screws). The average (thoracic and lumbar) local kyphosis measured 16.1° preoperatively and negative 2° at the final follow-up of 15 months (3–28). After removal of the hardware, no patient lost more than 4° with an average loss of 1.6° (within measurement error).

Conclusions: Our data suggest that closed reduction and internal stabilization is a very appealing option for unstable burst fractures without progressing neurological injury. It is safe and effective in re-establishing spinal stability. In this particular group of patients (who presented with multiple injuries and vulnerabilities) CRPF without fusion was the sensible middle course between unpredictable bracing and the more extensive (and invasive) spinal fusion. Prospective randomized clinical studies are necessary to establish more definitive conclusions (and to identify the injuries and pathological processes most amenable to CRPF without fusion).

**Keywords:** Closed Reduction and Percutaneous Fixation (CRPF), unstable spinal burst fracture, Spinal burst fracture reduction, temporary internal stabilization without fusion.

**Purpose:** The US FDA has recently made a decision that instrumentation of unfused motion segments is off label use of an FDA approved spine implant. The purpose of this study is to evaluate surgical outcomes for use of percutaneous Instrumentation and Selective Fusion.

**Background context:** Instrumentation of unstable thoracic and lumbar fractures has traditionally been conducted by open techniques that include instrumenting and fusion of exposed segments. Rod Long Fuse Short techniques have also been applied to open instrumentation to attempt to reduce number of fused levels. Percutaneous techniques have further potential to limit number of segments fused and morbidity related to surgical exposure. Prior Percutaneous techniques have been limited by constrained rod passage and number of levels accessible. This series reports the initial multicenter experience with unconstrained percutaneous instrumentation of unstable thoracic and lumbar fractures.

**Study design/setting:** Prospective data collection following IRB approval reviewed for indications, complications, safety and outcome.

**Patient sample:** Multicenter study of trained surgeons and select fracture patients.

**Outcome measures:** Surgical indications, technique, complications and outcome are reported.

**Methods:** Prospective case series with retrospective radiographic review.

**Results:** Fifty six patients underwent percutaneous stabilization of unstable thoracic and lumbar fractures over the interval October 2005 to October 2006. Fracture Pattern was Magerl A 18, B 26 and C 12. One to eleven motion segments were spanned (m 3.6) Selective fusion was added anteriorly in 12 or posteriorly in 17 Patients. Twenty seven patients were not fused for osseous fractures (Chance, Burst, non braceable polytrauma patients and AnKspond).All patients were instrumented without complication and no neurologic deficits occurred. A single early screw head dissasemble occurred at 6 week followup in a fixation T12 to L5 for a patient with three level lumbar fractures a a pelvis fracture.

**Hardware removal for instrumented but unfused segments has been conducted or is planned in 38 of the patients.**

**Conclusions:** Unconstrained Percutaneous instrumentation of unstable thoracic and lumbar fractures is safe, feasible and can be conducted for select fracture patterns wherein selective fusion of unstable segments can be combined with longer instrumentation.

**FDA Device/Drug status:** Medtronic Longitude Horizon - Fixation without fusion is an off label use of an FDA approved implant: Not approved for this indication.; No Second Device: Approved for this indication.; No Third Device: Approved for this indication.
The C1-C2 joint is affected by multiple entities that may produce biomechanical instability. Optimal management for atlanto-axial instability has been searched by ways of different surgical techniques with different results, generating discussion between second effects of a particular treatment. In the following study, we propose a minimally invasive (MIS) C1-C2 fusion technique through the anatomical corridor between the posterior major rectus capitis and the inferior obliquus capitis. We performed a C1 lateral-mass screws and C2 pedicular screws instrumentation. The use of a MIS technique to perform posterior C1-C2 fixation, reducing muscle devascularization and denervation would preserve the medial tension band. This means less intraoperative blood loss, less postoperative pain and shorter hospital stay, also better postoperative cervical spine stability.

**Methods:** Prospective study, 9 patients with C1-C2 instability do to dens fracture and/or reumatoid arthritis atlanto axial subluxation were enrolled. Operative time, blood loss and hospitalization time were recorded. Subjects were evaluated preoperatively and postoperatively at 1, 3, 6, 12 and 24 months.

**Analysis** consists of clinical outcomes and radiological assessment.

**Results:** We performed in all cases a minimally invasive transmuscular approach through a 25mm bilateral paramedian skin incision, using the access MIS platform Maxcess II™; and subsequent placing screws according to the modified Harms technique. This approach uses a progressive tubular dilators system through the superficial nucal musculature (trapezius and semispinalis capitis) and then through the anatomical corridor. A 4.0 mm diameter poliialaxial screws are inserted using Harm’s technique. The articular surfaces of C1 and C2 are decorticated using curettes and demineralized bone matrix mixed with bone marrow aspirated is placed inside the joint. The same procedure is made in the contra lateral side in the same way. There were no intra-operative and postoperative complications. All patients (100%) recovered uneventfully and recovery of the preoperative symptoms. Patients experienced minimal post-operative pain and were discharged before 46,8 hours mean time.

**Conclusions:** As our experience in minimally invasive techniques improves, we can offer our patients less morbid treatment options with similar or better results to those achieved with conventional procedures.

**PERCUTANEOUS TECHNIQUES**

**Abstract:** 440
**Minimally Invasive Posterior Trans Muscular C1-C2 Screw Fixation through an Anatomical Corridor to Preserve Occipital-cervical Tension Band - Prospective 24 Months Clinical and Radiological Study**

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The C1-C2 joint is affected by multiple entities that may produce biomechanical instability. Optimal management for atlanto-axial instability has been searched by ways of different surgical techniques with different results, generating discussion between second effects of a particular treatment. In the following study, we propose a minimally invasive (MIS) C1-C2 fusion technique through the anatomical corridor between the posterior major rectus capitis and the inferior obliquus capitis. We performed a C1 lateral-mass screws and C2 pedicular screws instrumentation. The use of a MIS technique to perform posterior C1-C2 fixation, reducing muscle devascularization and denervation would preserve the medial tension band. This means less intraoperative blood loss, less postoperative pain and shorter hospital stay, also better postoperative cervical spine stability.

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**Conclusions:** As our experience in minimally invasive techniques improves, we can offer our patients less morbid treatment options with similar or better results to those achieved with conventional procedures.

**Abstract:** 398
**Guided Oblique Lumbar Interbody Fixation: A Surgical Anatomic Study**

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**Study design:** A new endoscopic procedure, the “Transforaminal Endoscopic Stenosis Surgery” (TESS), is presented. This technique uses a posterolateral transforaminal approach and allows widening the foramen in a collapsed lumbar disc by undercutting the superior facet under direct endoscopic control. A new endoscopic small reamer is used for this purpose that allows minimizing the aggression to the surrounding tissues.

This study of 216 cases of lumbar foraminal stenosis compares the results of one group, in which the new endoscopic bone reamers were used for the foraminoplasty, with another group, in which only classical foraminoplasty was performed with a standard Holmium-YAG laser.

**Methods:** 216 patients with lumbar foraminal stenosis underwent endoscopic spine surgery from 2003 to 2008 at Centro Médico Teknon in Barcelona (Spain).
- 125 patients underwent classical endoscopic surgery, thus, only a Ho-YAG laser was used for the foraminoplasty (Group A)
- 91 patients underwent TES surgery, hence, the new endoscopic bone reamers were used for the foraminoplasty (Group B)

The inclusion criteria were:
- a) Unilateral or bilateral radicular leg pain associated to image evidence of foraminal or lateral stenosis.
- b) Inadequate response to conservative treatment for > 6 months.

All 216 procedures were performed in prone position and under local anesthesia. Pain was scored for every patient, pre- and post-operatively, with a Visual Analogic scale and the disability with the Oswestry Disability Index. The post-operative scores were updated every 3 months. The mean follow-up period was 2.8 years (with a range of 6 - 61 months).

**Results:** 216 patients who met the inclusion criteria underwent TES surgery. This 216 patients comprised 143 men and 73 women with ages ranging from 17 to 82 years (mean age 45.8 years). The overall results, evaluated according to Macnab criteria, for the 216 cases were: 151 excellent (69.9%), 45 good (20.8%), 16 fair (7.4%), 4 poor (1.9 %)

Results for group A (125 cases):
- 90 excellent (72%), 20 good (16%), 14 fair (11.2%), 1 poor (0.8%) (see table 3)

Results for group B (91 cases):
- 61 excellent (67%), 25 good (27.5%), 2 fair (2.2%), 3 poor (3.3%) (see table 3)

The surgical time average was of approx. 50 min. for group A, while the surgical time average was of approx. 30 min. for group B.

**Conclusions:** This study demonstrates the efficacy and efficiency of a new surgical technique for foraminal stenosis that uses bone reaming under direct endoscopic control to widen the foramen in cases of foraminal or lateral stenosis. This technique appears to be more accurate than other reaming techniques that only use X-ray C-arm control and have no direct endoscopic vision.

Similar outcome and scoring results were achieved for the laser foraminoplasty and the reamed foraminoplasty but the latter was more efficient, as it presented a lower average surgical time (approx. 20 min less) and lower material costs.

This new endoscopic reaming technique opens the way for surgeons to primarily avoid more aggressive methods of decompression and minimize the surgical costs.
inserting a pair of screws with robotic guidance through the pedicles of the inferior body that passes diagonally through both endplates to end at the anterior cortical rim of the superior body. However, there have been no detailed anatomic studies to assess the relevant surgical anatomy and document the inherent risks of this technique. This study defines the surgical anatomy, outlined the appropriate trajectory, and determined the inherent risks of GOLIF in human cadavers.

**Methods:** GOLIF fixation was carried out on two cadavers using SpineAssist®, a robotic guidance system. The procedure was carried out bilaterally across all levels from T12-sacrum and a total of 12 levels were instrumented. Post-procedure CT scans were obtained and analyzed to verify the accuracy of GOLIF screws positioning against preoperative plan in three planes. The spines were explanted for further dissection and visually inspected in order to analyze, document and confirm placement of the screws at the desired location.

**Results:** Twenty-three of 24 screws were inserted with average deviation of 1.3 mm +/- 0.2 mm from the preoperative plan. One K-wire was inserted 3 mm anterolaterally and extra pedicular when compared to the preoperative plan. No violation of the foraminal or epidural space and no encroachment on the exiting or traversing nerve roots were observed.

**Conclusions:** The current study confirmed that GOLIF screw trajectory is reproducibly safe and is attainable with robotic guidance. A generous corridor to accommodate the GOLIF screw exists from the insertion point at the junction of the pedicle, facet and transverse process, across the pedicle, into the disc space and then into the cephalad vertebral body.

**Summary sentence:** GOLIF involves inserting a pair of screws diametrically across a lumbar spine motion segment. The anatomy study described here demonstrated that the procedure is safely attainable and reproducible with robotic guidance.

Abstract: 619

**An Economical Analysis of the Inpatient Treatment Costs after Primary Balloon Kyphoplasty versus Conservative Treatment for Osteoporotic Vertebral Fractures**

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Operative treatment of osteoporotic vertebral fractures seems to result in higher primary costs compared to conservative treatment. However, it is still unclear whether the inpatient related follow-up costs don’t result in a different outcome.

**The aim of this analysis** was a nationwide comparison of spine related inpatient treatments after balloon kyphoplasty versus conservative treatment of balloon kyphoplasty patients.

**Materials and methods:** 110 patients after conservative treatment and 141 patients after balloon kyphoplasty treated primarily between 2002 and 2005 in one center were followed up via a nationwide analysis of spine related inpatient treatment.

Data from the Austrian DRG-system, which includes all inpatients treated in Austria have been used to identify admission of the target population between 2002 and 2006. Because no unique patient identifier is available in the data set, a matching according to data of birth, gender and postal code was used. Outpatient visits are not included. From these data the number of admissions, the length of stay and the scores can be determined. Furthermore each admission was classified as spine related or not.

To calculate the exact follow up times the data were matched against the Austrian death registry. If a patient has died this data was used to calculate the follow up time otherwise December 31st 2006 was used.

The mean age of the conservative group was 75.49 and of the kyphoplasty group 71.16 years.

The total follow up time was 324.55 years (mean + standard deviation 2.92 +/- 1.40) for the conservative and 354.25 (2.53 +/- 0.96) for the kyphoplasty group. The shorter mean follow up interval for the kyphoplasty group is due to the fact that in the years 2004 and 2005 more patients have been treated by kyphoplasty.

**Results:** The mean number of admissions in the kyphoplasty group is 0.779 or 0.308 per follow up year whereas in the conservative group these figures are approximately twice, namely 1.757 and 0.601. Considering the average length of stay the kyphoplasty group shows less inhospital days (9.2 per patient or 3.6 per follow up year), whereas in the conservative group this is 14.4 and 4.6 inpatient days. Finally the scores per admission in the follow up period are lower in the kyphoplasty group (3146 and 1243 DRG related treatment points) whereas in the conservative group these values are 3824 and 1308. The final financial analysis implementing day care and treatment costs shows a significant difference in the total per year per patient costs with conservative treatment being 919 € more expensive.

**Conclusion:** These data show a strong superiority of kyphoplasty compared to conservative treatment of spine problems based on the data of one big hospital in Austria where 251 patients have been treated between 2002 and 2005.

We demonstrate a long term superiority of balloon kyphoplasty compared to non-surgical treatment regarding inpatient treatments.

**BIOLOGICS I**

Abstract: 640

**Human Chondrocyte Transplants for Damaged Intervertebral Disc**

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**Background:** Human chondrocytes are a cellular candidate for repair of a degenerating intervertebral disc. Chondrocytes are phenotypically similar to adult nucleus pulposus cells, readily proliferate with rapid divide times. Polydactyly derived human chondrocyts provide a unique cell line that has been established and which provides limitless supply of donor cells (hCs). hC line does not express the MHC Class II molecule and can be transplanted like an allograft without eliciting a graft vs. host mediated rejection response. Unlike stem cells, hCs are fully differentiated, having the capability to integrate functionally from the onset of transplantation. hCs have a greater safety profile (oncogenic potential) than stem cells and eliminate the uncertainty that the host environment will transform the stem cell into the appropriate target cell.

**Purpose:** To determine the feasibility of using transplants of a unique human chondrocyte cell line to prevent degeneration and repair damaged intervertebral disc in a rabbit pucture disc degeneration model.

**Study design/setting:** hCs were introduced into an experimentally punctured intervertebral disc in rabbits (n=16 rabbits). L2-3, L4-5 were experimentally treated and L3-4 was observed (control). Treatments of hCs+DMEM vs DMEM alone were assigned to levels in a balanced manner after initial puncate injury. Comparisons were of pre-post surgery and treatment vs. control.

**Patient sample:** Rabbits (n=16)

**Outcome measures:** Segmental radiographs, MRIs, and histology were done. Percent disc height change was computed from 3 height measurements adjusted for vertebral body height from radiographs at 4 and 8 weeks and divided by the pre injury heights. Cell counts and characterization of newly differentiated chondrocytes of various phnyotypes,
3. Group C, Experimental, punctured disc followed by implantation of ESCs (n = 16 discs, level L3, 4).

Methods: A right retroperitoneal approach was used to expose the right anterior aspect of the disc from L2-5. An 18 gauge needle puncture injury was produced in the intervertebral discs. During the same procedure, at a second virgin site, treatments were administered using a 26 gauge needle. Immediately prior to surgery, hCs were concentrated to 5x10^5 cells. During surgery, treatments were transplanted in one of two experimental disc levels L2-3, L4-5.

Results: At 4 and 8 weeks after puncture injury, there was greater disc height radiographically in sites with hC+DMEM (87.1% of pre-op) vs. sites with DMEM (average disc height of 77.2% of pre-op). At 8 weeks, greater signal intensity on MRI (brighter appearance) was observed in 60% (5/8) sites treated with hC+DMEM compared ‘no signal’ observed for sites treated with DMEM alone (0/4). No evidence of immunologic rejection was detected.

Conclusions: Fetal human chondrocyte transplants may offer biological protection against degeneration of the intervertebral disc after puncture injury in the rabbit. Herein a hC line was transplanted into rabbits without evidence of immunologic rejection. This hC cell line has limitless donor capacity, does not require harvest from a recipient host, can be transplanted via allograft into damaged recipient without immunologic rejection. hCs offer an avenue of biologic disc repair and regeneration.

Abstract: 339 Human Mesenchymal Stem Cells Differentiate into NP-like Cells when Cultured on Allograft Nucleus Pulposus Scaffolds

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“Smart Scaffolds” impart crucial spatial and regulatory information to cells for selected gene expression and contain biomolecules, such as growth factors, that promote cell infiltration, proliferation, and differentiation. The goals of this in vitro study were to measure human mesenchymal stem cell (hMSC) proliferation, differentiation, and glycosaminoglycan (GAG) production after seeding the hMSCs on two different injectable human allograft nucleus pulposus (NP) derived smart scaffolds. Allograft NP tissue was frozen to -80°C, particulated into 1mm x 1mm pieces and used to create two different scaffolds. A proteoglycan depleted scaffold (PGDNP) was manufactured by enzymatic digestion of the tissue with C-ABC and Keratanase. NP particles, without enzymatic digestion, were used as a second scaffold (NP). 50,000 hMSCs per well were added to culture medium, 10% or 25% platelet rich plasma (PRP), and one of three scaffold conditions: with PGDNP, with NP or without scaffold (hMSC+PGDNP, hMSC+NP, & hMSC groups, respectively) and cultured for 4 weeks. hMSC proliferation was measured between 1 and 2 weeks of culture by CytoTox 96 assay. GAG content was measured by Alcian blue assay. GAG production was calculated by subtracting preculture GAG content of each group from the GAG content of the medium and pellets following four weeks of cell culture. Cell seeded scaffolds were injected through a 16 gauge needle to determine cell viability following injection. Lastly, pellets from all groups underwent histological examination. hMSCs proliferated 10% slower on NP than in medium alone or on PGDNP (p < 0.05). Comparison of GAG content before and after 4 weeks of culture treatment with 10% PRP showed GAG production of 13 mg, 16 mg, & 132 mg of GAG in the hMSC, hMSC+PGDNP, and hMSC+NP groups, respectively. The use of NP as a scaffolding produced a significant increase in GAG production (p < 0.0001). hMSCs in all three groups produced more GAGs when cultured in 10% PRP.
PRP than in 25% PRP (p < 0.05). Less than 10% of hMSCs died following passage of the cell seeded scaffolds through a 16 gauge needle. hMSCs grew into and revitalized both scaffolds. hMSCs differentiated into large oval proteoglycan (PG) rich NP-like cells when seeded on PGDNP and NP scaffolds. However, the cells in hMSC group, without NP derived scaffold, contained little PGs, were spindle shaped with cytoplasmic processes similar to fibroblasts. Human MScs differentiated into NP-like cells when cultured on Allograft human NP particles. The MScs proliferated faster but differentiated less when cultured on PGDNP compared to NP. Injectable allograft NP scaffold, hMSCs, and PRP may conceivably be used to regenerate NP tissue to treat early degenerative disc disease. However, limited diffusion across degenerative vertebral endplates could adversely affect hMSC viability within the degenerative disc.

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Abstract: 447

Analysis of PH, Hygrometry, and Relaxation Pressure in Lumbar Degenerative Disc Disease: Study for the Tools Validation and Comparison between Normal and Pathologic Discs

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Background: In lumbar degenerative disc disease, the diagnosis tests after the analysis of the clinical signs is principally based on Xrays, MRI and Discogram results. The real difficulty is the attempt of correlation between those parameters but this does not include biochemical and physical changes from the degradation of the proteoglycans. Those chemical and physical changes are the reflect of the evolution of the disc disease and their measures could be included in the diagnosis tool.

Goal of the study: This study demonstrates the capacity to measure through sensors the Ph, the percentage of hydration and the relaxation pressure. Comparing the results between normal discs (normal signal on MRI) and pathologic discs (Black disc with collapsus and eventually Modic 1), it is possible to confirm the difference of results between the two groups.

Methods: The equipment utilizes sensors integrated in a needle probe (20 gauge) that has been introduced in the discs during a surgical procedure, in the pathologic disc operated on and on the normal disc just above. The sensor needle device was connected to a PC with a proprietary software. Ph, humidity percentage and relaxarion pressure were measured. 5 patients have been included in the study, each one had a measurement on one pathologic and one normal disc.

Results: For the normal discs, two L4-L5, two L3-L4 and one L2-L3 were measured. For the pathologic group, Two L5-S1, two L3-L4 and one L2-L3. The age of the patient was from 42 to 60 years old. The normal disc had a Ph of 6.4 (from 6.5 to 6.2), humidity 90% (87-91) and a pressure 2030 mmmhg (2187-1781). For the pathologic disc, Ph was 5.3(5.4-5.2), humidity 48% (54-43) and a pressure 2030 mmmhg (2187-1781). The results confirmed the capacity to use a sensor device to record te parameters chosen and confirmed the calibration process. The repetition of the same measurement on the same area confirmed the repeatability of the process. The correlation of the parameters measures with the evolution of the disc allow the use of those parameters and this method as a diagnosis tool. There is no before this study, real measures in vivo of those parameters despite the fact that some treatment use rehydration of the disc space through nucleus introduction without knowing the value of humidity, and those measures (Ph essentially) are the prerequisite for any cells or RNA therapy in this disc. More tha that the evolution in the direction of more acidity of the pathologic disc content when degenerates will open the comprehension of the cartilage damages. More research is performed with larger groups of patients with the use of the tool during the discogram and with additional parameters (PO2 e.g.)

Conclusion: This study confirms the capacity of measurement through sensors, of chemical and physical parameters in the disc space and demonstrates as early results the evolution of the measures in case degenerative disc disease.

BIOLLOGICS II

Abstract: 572

The Anabolic Effect of Plasma-mediated Ablation on the Intervertebral Disc: Stimulation of Proteoglycan and IL-8 Production


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Purpose: Utilizing techniques which encourage disc repair after surgical intervention for chronic pain and disability may help reduce the incidence of recurrent disc herniation. Plasma-mediated radiofrequency-based ablation (Coblation) is an electrosurgical technique currently used for tissue removal across a wide range of surgical applications, including lumbar microdiscectomy. In vitro and in vivo studies have shown the technique to alter the expression of inflammatory cytokines in the disc, increasing levels of IL-8, which promotes maturation and remodeling of the disc matrix. This may mitigate chronic disc degeneration and help prevent recurrent herniation after surgery. To better understand Coblation’s treatment effect, this study characterizes the temporal and spatial pattern of healing following stab injury to the rabbit intervertebral disc with and without plasma-mediated radiofrequency treatment.

Materials & methods: Twenty-three New Zealand white rabbits underwent annular/nuclear stab injury on 3 consecutive lumbar discs (L2-L3 to L4-L5). The three levels were randomly assigned into one of three groups for treatment with a plasma-mediated radiofrequency ablation device (TOPAZ, ArthroCare Corp., Austin, TX): 1) active treatment of nucleus only (SN); 2) active treatment of both nucleus and annulus (SNA); 3) sham treatment. Unstabbed/untreated discs from L5-L6 (n=5) served as controls. Animals were euthanized at 4, 8, and 28 days post-surgery.

Sandwich ELISA immunoassay evaluated concentrations of cytokines TNFα, IL-1β, and IL-8. Histopathologic evaluations were performed on whole discs and endplates. Tissue sections were stained with Safranin-O to evaluate nucleus pulposus and annulus fibrosus proteoglycan content, and Alcian blue for extracellular proteoglycan content. Intradiscal leakage pressure was evaluated by injecting methylene blue dye into the nucleus.

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Results: IL-8 was detected in sham discs at 4 and 8 days, but not in Coblation groups (SN or SNA); IL-1β was below detection in all three treatment groups. IL-8 levels increased in all treatment groups at 4 and 8 days compared to control, peaking at 4 days for sham and SN groups and 8 days (p < 0.03) for the SNA group (a 2.5-fold increase). Pressure measurements revealed higher leakage in the SN group, but no statistically significant differences.

Histopathology showed higher proteoglycan production by 28 days in the SNA and SN groups compared to sham. All 3 treatment groups maintained overall annular architecture. Remnants of notochordal tissue within the nucleus were evident in all treatment groups at 4 and 8 days, but only found in sham group by 28 days. At this time, unlike the normal or sham controls, the nucleus of SN and SNA discs...
had fibrocartilaginous tissue with chondrocyte-like cells. Significant differences in disc architecture grade were only noted when comparing controls to other groups by 28 days (p< 0.001).

Conclusion: Plasma-mediated radiofrequency ablation appears to have an anabolic effect on disc cells, stimulating proteoglycan and IL-8 production and maintaining annulus architecture. Coblation treatment appears to reduce cellular response to pro-inflammatory stimuli and to restore overall disc architecture, which may prove beneficial in a number of degenerative disc paradigms. Further studies are encouraged to investigate the technique’s therapeutic effect.

Abstract: 281

Intervertebral Disc Repair Using Adipose Tissue-derived Stem and Regenerative Cells: Experiments in a Canine Model
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Purpose of the study: Intervertebral disc tissue engineering holds the promise of a minimally-invasive degenerative disc disease treatment, but many of the necessary biological processes remain unclear. Our goal is to optimize stem cell-based tissue engineering strategies in the context of the intervertebral disc environment. To enhance the ability of mesenchymal stem cells (MSCs) to perform in the demanding disc environment, we explored the benefits of co-culturing nucleus-pulposus cells (NPCs) and adult mesenchymal stem cells (MSCs) using a novel spherical bi-layer pellet culture system where one cell type is enclosed in a sphere of the other cell type. Our 3D system provides a structural organization that exploits embryonic processes such as tissue induction and condensation. We have shown that signaling interactions between MSCs and NPCs regulate matrix production. Our experiments showed that a bi-layer pellet with MSCs inside and NPCs outside produced up to 48% more proteoglycan than other structures and over using MSCs or NPCs alone. Here we describe a novel feature of this system that has important implications for disc nucleus regeneration: the co-culture pellets spawn offspring “satellite-pellets” that mimic their composition and structural organization.

Methods: Human MSCs and bovine NPCs were cultured using a bi-layer pellet. Pellets were formed with three different structural organizations: with random organization, with MSCs inside & NPCs outside, and with NPCs inside & MSCs outside. The ratio of cell numbers was also varied from 25%/75%, 50%/50%, and 75%/25% for each organization. Before the pellets were formed, MSC were stained with DIO and NPC were not stained. Throughout the culture time, we used fluorescent microscopy to view the main pellet and the satellite-pellets as they formed. After three weeks, the satellite-pellets were paraffin embedded and sectioned. We used immunohistology techniques with a species-specific antibody to analyze the structure and composition of the satellite-pellets that were generated from the main pellets.

Findings: After 14 days, all co-culture pellets had spontaneously generated satellite-pellets. The satellite-pellets were composed of both cell types and surprisingly all had the same structural organization with MSC on the inside and NPC on the outside. This organization was independent of the structure and ratio of the main pellet that they stemmed from.

Conclusion: We have previously shown that co-culture bi-layer pellets offer a clear advantage over using MSCs or NPCs alone in terms of matrix synthesis and cell proliferation. Interestingly, the bi-layer pellets generate satellite-pellets that spontaneously organized into the same structure that created the most proteoglycan. This implies that structural organization occurs naturally in this cell culture system and may be inherently favorable for cell-based tissue engineering strategies. We anticipate that these satellite-pellets will enhance the ability of this technique to repopulate and regenerate the disc nucleus.
Abstract: 374
A Finite Element Parametric Study of the Disc Nutrition

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Introduction: It is well known that a nutritional deficiency or a mechanical overloading can alter the normal functioning of disc cells and hence accelerating IVD degeneration. The IVD being an avascular tissue, nutritional process occurs mainly by diffusion through the aqueous phase of the disc and then is highly dependent of the tissue fluid content. Hence, as the porosity of the media is related to the osmotic pressure and thus to the amount of proteoglycans synthesized by the IVD’s cells, a feedback loop appears between load, porosity, osmotic pressure and nutrient concentration levels into the IVD.

Materials and methods: A 2-D finite element model for the intervertebral disc in which quadriphasic theory is coupled to the transport of solutes involved in cellular nutrition was developed for investigating these settings. The disc is modelled as a porous media which consists of a solid phase representing its extracellular matrix, an aqueous phase and two ionic phases. Proteoglycans are represented by a charge density fixed to the solid phase. The solute transport is solved considering a diffusion coefficient (Fick’s law). A 2D intervertebral disc is modelled using a plane strain formulation at the equilibrium state under physiological conditions after a long rest period (called unloaded state).

Results: The correlations between solute distribution and various properties of healthy and degenerated discs are investigated. The numerical simulation shows that solute distribution in the disc depends slightly on the elastic modulus or on the proteoglycan concentration but greatly on the porosity, diffusion coefficient and endplate diffusion area. A mechanical loading has opposing effects on the disc nutrition, it reduces the porosity (i.e. the fluid content) and hence decreases the diffusion coefficient of solutes but on the other hand it decreases the disc height which facilitated the transport of nutrients. Critical concentrations, where the minimum glucose and oxygen concentrations and the maximum lactate concentration are observed, are found in the middle of the disc, near the interface between inner and outer anterior annulus in both healthy cases and at the top of the endplate in the degenerated case.

Conclusion: The model predicts higher lactate levels, and thus lower pH levels, in the degenerated disc than in the healthy disc, in agreement with experimental data. As the disc degenerates, the porosity and endplate diffusion area decrease, obstructing lactate evacuation. The changes in these two parameters occurring during degeneration greatly override changes in other parameters, such as the stiffness increase and the loss of proteoglycan and living cells. Low pH levels are problematic because they reduce cell viability and slow the renewal of the extracellular matrix.

Background: A recent FDA-sponsored randomized controlled study of the Prodisc-C (Synthes Spine, Westchester, PA) cervical artificial disc replacement (ADR) established superior clinical outcomes with preservation of motion at both surgical and adjacent levels, as compared to anterior cervical discectomy and fusion (ACDF). However, no previous study has reported on the clinical and radiographic outcomes of adjacent multiple-level cervical ADR.

Purpose: To evaluate the clinical outcomes and sagittal range of motion of adjacent three-level ProDisc-C disc replacements.

Patient sample: Seventy patients receiving consecutive multiple-level cervical ADR between C3 and C7, with thirty-eight patients receiving a two-level ADR (ADR-2), twenty-four patients receiving a three-level ADR (ADR-3), and four patients receiving a four-level ADR (ADR-4).

Study design: Prospective Cohort.

Outcome measures: Angular motion (extension and flexion measurements) on preoperative and postoperative sagittal-projection cervical films at each operative motion segment as well as at the segments adjacent to the prosthesis construct. Neck Disability Index (NDI), Visual Analog Score Pain (VAS-P), and Visual Analog Score Satisfaction (VAS-S) data were also collected.

Methods: Patients were evaluated pre-operatively, at six weeks, three months, six months, and annually for 2-5 years postoperatively with lateral flexion-extension dynamic films and with completion of NDI and VAS surveys.

Results: There were no significant differences among the groups for age, gender, body mass index, tobacco use, or worker’s compensation status. At the rostral and caudal motion segments adjacent to the ADR construct, the mean preoperative range of motion was 10.53° (SD 2.59°), compared to 12.32° postoperatively (SD 1.92°, p<0.05). Between the three cervical ADR groups, there were no statistically significant differences in range of motion at a given cervical level (p>0.05 for all comparisons of a particular level between groups) at any time point. Across the groups for all motion segments undergoing ADR, the mean preoperative range of motion was 9.27° (SD 1.98°) versus 9.80° postoperatively (SD 2.05, p>0.05), indicating no significant difference at last follow-up. At 2-5 years postoperatively, all patients had significant reductions in both NDI andVAS scores relative to preoperative levels (p<0.05). At up to five years follow-up, no patient underwent revision surgery or surgeries at adjacent levels.

Conclusions: The use of the multiple-level cervical ADR construct does not inhibit preservation of range of motion at the individual ADR levels. Most significantly, the nonoperative levels adjacent to the construct maintain their preoperative range of motion at 2-5 years postoperatively. At up to five years follow-up, there has been no need for revision or adjacent-segment surgery. Patients also demonstrate significant improvement in pain and disability at latest follow-up.

Abstract: 103
2-Level Cervical Disc Arthroplasty: One-year Clinical Results from 6 Centers in a Prospective Randomized IDE Trial

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Introduction: With the introduction of cervical arthroplasty in the United States, appropriate indications for these devices must be carefully studied. We report early clinical outcomes from six centers participating in the ongoing prospective randomized Prestige LP investigational device
examination with anterior fusion in patients with two-level cervical disc disease.

**Methods:** To date at these six sites, 180 patients with two adjacent levels of cervical disc disease have undergone surgery and received either the Prestige LP devices (n = 97) or a two-level anterior cervical discectomy and fusion utilizing allograft spacers and the Atlantis anterior cervical plate (n = 83). At the time of this report, 47% of patients have been evaluated at the one-year follow up interval. Entrance criteria included symptomatic two-level cervical disc disease documented neurologic deficit and confirmatory preoperative imaging studies. Demographic variables including age, sex, race, and work status are similar between the two study groups. Operative variables including operative time, blood loss and levels treated were also similar. All patients were evaluated according to the standardized IDE protocol preoperatively and at defined postoperative intervals: 6 weeks and 3, 6, 12, and 24 months. Outcomes measures include neck and arm pain visual analog scales (VAS), neck disability index (NDI), and the Short-Form 36 (SF-36). Cervical flexion/extension and right/left lateral bending X-rays were obtained at all data points. Additionally, all adverse events are recorded.

**Results:** Preoperative values for the VAS, NDI and SF-36 scores were similar. There is a statistically significant postoperative improvement for both groups at the 6 month follow-up interval. At 12 months, there was a 39.0 point mean improvement in the NDI in the Prestige group as compared to a 31.7 point improvement in the fusion group. In the SF-36 PCS, an 18.1 point mean improvement is seen in the Prestige group as compared to a 13.3 point improvement in the fusion group. The Neck and arm pain VAS also showed greater mean improvement in the Prestige group at 12 months compared to the fusion group. These one-year differences are encouraging for multi-level cervical disc arthroplasty. Radiographic analysis shows the Prestige device to maintain segmental motion. Rates of adverse events are similar in both groups; however there have been four secondary surgical procedures in the fusion group and none in the Prestige group.

**Conclusion:** Analysis of one-year data from 6 sites participating in the Prestige LP 2-level IDE study suggest that cervical disc arthroplasty appears to achieve favorable outcomes at one-year postoperative for patients with 2-level cervical disc disease. Longer term follow-up is required.

**Abstract:**

**Cervical Total Disc Arthroplasty: The Effect of Preoperative MRI Modic Changes on the Clinical and Functional Outcome**

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**Introduction:** The objective of this study is to investigate the correlation between the pre-operative MRI Modic I and Modic II changes on the clinical and functional (TDA range of movement, ROM) outcome. To our knowledge this is the first such study.

**Material and methods:** We prospectively investigated 122 protheses in 86 consecutive patients who have undergone a Prestige LP cervical disc replacement. All the patients had pre-operative, immediate post-operative, then 6 months interverval cervical spine Xrays. The pre-operative MRI was reviewed to assess Modic changes I and II. The pre and post-operative Neck Disability Index (NDI), SF-36, Visual Analogue Score (VAS), Hospital Depression score (HDS) and Hospital Anxiety Score (HAS) were recorded.

**Results:** There were 62 males and 60 females, with a mean age at surgery of 50.09+/-0.99 (32.3-75.5). Fifty patients had one level disc replacement, and 36 had 2 levels. The mean follow up was 2.23±0.23 years.

**Outcome in Modic I:**

There was significant improvement in all scores between pre and postoperatively, NDI (45.03+/-2.66 versus 18.91+/-2.83, p<0.012), HDS (9.88+/-0.98 Versus 3.48+/-0.54, p<0.001), HAS (7.79+/-0.83 versus 3.85+/-0.57, p< 0.001), SF-36 bodily pain (27.55+/-2.98 versus 60.45+/-3.082, p< 0.001), SF-36 Mental health (55.91+/-3.79 versus 74.09+/-2.87 p=0.033), VAS neck pain (7.42+/-0.31 versus 1.88+/-0.31, p< 0.001) and VAS arm pain (7.09+/-0.3 versus 2.03+/-0.44, p=0.003)

**Outcome in Modic II:**

There was significant improvement in all scores between pre and postoperatively, NDI (44.38+/-3.36 versus 26.46+/-4.47, p<0.012), HDS (8.15+/-0.91 Versus 4.81+/-0.9, p< 0.001), HAS (8.92+/-1.01 versus 5.27+/-1.0), SF-36 bodily pain (34.77+/-4.127 versus 54.38+/-5.47, p<0.001), SF-36 Mental health (61.54+/-3.07 versus 71.92+/-4.12, p=0.02), VAS neck pain (6.77+/-0.39 versus 3.54+/-0.57, p< 0.001) and VAS arm pain (6.73+/-0.33 versus 3.19+/-0.62, p=0.003)

**Comparing the outcome between patients with Modic I and Modic II:**

There was statistical significant difference in the improvement in functional out come between Modic I and Modic II patients in the following:

VAS neck pain (5.55+/-0.47 versus 3.23+/-0.52, p=0.002)
SF-36 bodily pain (32.91+/-4.296 versus 19.62+/-4.823, p=0.044)
HDS (6.39+/-0.816 versus 3.35+/-0.863, p=0.014)

There was no statistical difference in the improvement in functional out come between Modic I and Modic II patients in the following:

NDI between (26.12+/-3.72 versus 17.92+/-4.26, p=0.152). HAS (3.65+/-0.764 versus 3.94+/-0.877, p=0.813)
SF-36 mental health (18.18+/-4.046 versus 10.38+/-2.093, p=0.119)
VAS Arm pain (5.06+/-0.52 versus 3.54+/-0.582, p=0.055)

**Conclusion:** Although there was significantly better clinical outcomes after TDA for those with M1 changes relative to those with M2 in some scores, this was not the case across all scores, whilst functional outcome (i.e. in terms of ROM) proved variable. In conclusion, significant improvements can be made in patients with both M1 and M2 lesions after cervical TDA.

**CERVICAL TDR: MISCELLANEOUS**

**Abstract:**

**Facet Degeneration and Axial Pain in a Late Cervical Total Disc Replacement**

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**Introduction:** Many information and classifications about lumbar facet joint degeneration after lumbar total disc replacement are available, but in the cervical spine this concept is unknown and there isn’t a radiological classification for cervical facet degeneration. Here we show our experience and propose a CT scan classification to evaluate a degenerative facet join disease after cervical
Methods: After four years follow-up for total disc replacement in a consecutive series of 158 patients with a total of 272 Porous Coated Motion total cervical disc replacement from C3-4 to C7-T1, we analyzed the facet degeneration in four grades at the index levels using CT scan, and compared with preoperative images. CT scan, X-rays (AP, lateral and dynamics images) and clinical outcomes were collected preoperatively, 1, 3, 6, 12, 24, 36 and 48 months postoperatively. The Neck Disability Index (NDI) and Visual Analog Scale (VAS) were used to assess pain and functional outcomes.

Results: From all operated levels, we found 8.09% (22 levels) of degenerated facets. Analyzing the CT scan images, we found four different stages of facet degeneration. For this purpose, we propose a CT scan classification for facet degeneration, using this four degeneration grades. Based on this classification, 54.55% (12 levels) of all degenerated levels had grade I, 31.82% (7 levels) with grade II, 9.09% (2 levels) with grade III and 4.54% (1 level) had grade IV of facet degeneration. All patients with grade III and IV had a worsening in NDI and VAS outcomes assessment.

Conclusion: The degenerative facet joint disease in the cervical spine after cervical arthroplasty exists. In our proposed 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. A CT scan classification to evaluate a degenerative facet joint disease is essential to better understand this spinal physiologic and anatomic unit.

Abstract: 166

Radiological Observations in the Cervical Spine Following Cervical Arthroplasty in Minimum 24-month Follow-up: Bryan versus ProDisc-C

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Objectives: The purpose of this predesigned non-randomized retrospective study is to determine the radiological changes at the index and adjacent levels after cervical arthroplasty in a minimum 2-year follow-up, and to demonstrate the possible clinical factors related with these changes.

Methods: Between April 2004 and March 2006, 53 consecutive patients with degenerative cervical disc diseases underwent cervical arthroplasty. Among 53 patients, 40 patients, who could be followed up for more than 2 years were enrolled: 21 patients (23 levels) using Bryan, and 19 patients (21 levels) using ProDisc-C. The clinical outcome was assessed. Average follow-up period was 27.3±4.9 months.

Pre- and postoperative changes of the disc height, segmental static angle and range of motion (ROM) were measured. Facet arthrosis was examined pre- and postoperatively by using the Weishaupt’s system and heterotrophic ossification (HO) at the index level was assessed by using the McAfee’s system. The postoperative degenerative changes at the adjacent segments were also determined. Various potential peri-operative and prosthesis factors for facet degeneration and occurrence of HO were evaluated.

Results: At the final follow-up, mean VAS and NDI scores decreased from 7.05±2.31 to 1.62±1.72 (p<0.000) and from 42.10±22.83% to 9.75±13.65% (p<0.000), respectively. In the Bryan, mean functional segment unit (FSU) angle and height rather decreased at the last follow up. The average FSU ROM increased from 5.88±3.03° to 7.78±4.37° (p=0.887). In ProDisc-C, mean FSU angle significantly increased from 1.09±2.00° to 2.53±1.79° (p=0.037). The average FSU ROM significantly decreased from 5.89±2.98° to 4.17±2.30° (p=0.017). But mean FSU height did not change. At the index level, the progression of facets degenerations (PFA) was observed in 9 of 44 levels (20.5%), more frequently in the ProDisc-C (P=0.007): 1 in the Bryan, and 8 in ProDisc-C. At the adjacent levels, PFA was minimally observed. HO was observed at 22 levels (50%): 13 (56.9%) in Bryan (grade1: 6, grade2: 4, grade3: 3), and 9 (42.9%) in ProDisc-C (grade1: 6, grade2: 3). There was no difference of HO occurrence between two groups.

Among the variables examined in ProDisc-C, prostheses’ sagittal position and the postoperative FSU ROM appeared to be related to the occurrence of PFA at the index level. The more frequently PFA was observed, the more anteriorly the prosthesis was placed (p=0.034), and the less degree of FSU ROM was observed (p=0.049). The degenerative changes of disc morphology and uncinate process at the adjacent segments were observed in 8 levels (11.1%). Between the clinical outcome and occurrence of PFA or HO there was not any significant relationship.

Conclusions: The present study demonstrates that PFA at index level is observed more frequently in ProDisc-C in minimum 2-year follow-up. The results herald that the occurrence of PFA is technically-related and the semi-constrained type of cervical artificial disc may be technically less forgiving. The occurrence rate of HO is higher in Bryan without significance, and the degenerative changes at the adjacent segments are minimal regardless of the type of prosthesis. The postoperative radiological changes observed are not related with the clinical outcome.
in comparing the Ti levels in the total disc cohort with the reported values [1, 2] due to differences in methodologies, analytical instruments, and detection limits. **Conclusions:** This is a unique study presenting results of trace metal levels in a prospective series of titanium ceramic composite metal-on-metal cervical disc replacements. These results indicated that short-term metal levels are lower than those observed in posterior spinal instrumentation and metal-on-UHMWPE hips with titanium femoral and acetabular components using different analytical methods. Continued surveillance of this patient cohort is ongoing and will provide longer-term follow-up data for this cervical disc replacement system.

**References:**
1. Kasai et al, Spine, 28(12); 1320-1326, 2003;

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**CERVICAL TDR: OUTCOME PREDICTORS**

**Abstract:**

**Impact of Adverse Events on Outcome in Cervical Total Disc Replacement Trials**

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**Introduction:** The results reported for cervical total disc replacement (TDR) have generally been favorable. However, there are patients who do not do as well as others. Adverse events (AEs) are recorded during the course of a clinical trial to monitor safety. All complications are AEs, but many AEs are not complications and include events such as injuries from car accidents, onset of new illnesses, ankle injuries, etc. While many AEs are not directly related to the study intervention, the onset of these new medical problems may impact the patient’s overall well being, including responses to self-reported outcome questionnaires, following surgery. It was reported that AEs were related to clinical outcome in patients participating in clinical trials evaluating lumbar TDR (Ohnmeiss et al. SAS 2008). The purpose of this study was to determine if AEs were related to outcome in patients enrolled in cervical TDR trials.

**Methods:** AEs recorded for all patients enrolled in cervical TDR IDE trials at a single site were reviewed. For each AE, the onset and resolution dates, severity (mild, moderate, severe) and the relationship to study procedure (unrelated, inconclusive, related) were recorded. The number of active AEs (not resolved) at the 12-month follow-up were also recorded. The study group included 72 patients undergoing one-level (n=55) or two-level (n=17) cervical TDR between C4 and C7. ANOVA analysis was used to determine if AE severity, number of active AEs, and/or the relationship of AEs to the study procedure were related to the percentage of change in the pre- to 12-month post-operative scores on the Neck Disability Index (NDI).

**Results:** AE severity was significantly related to clinical outcome. Patients with moderate AEs had significantly less improvement on NDI scores that did patients with mild or no AEs (Figure 1; ANOVA, p< 0.05). The number of active AEs was also significantly related to the mean percentage improvement on the NDI from pre- to post-op. There were only three patients with AEs classified as related to the surgery and thus no meaningful comparison could be made with respect to the relationship of AEs to surgery and clinical outcome.

**Abstract:**

**CerviCore® Disc Replacement vs. Fusion for Single-level Cervical Radiculopathy: Changes in Unemployment and Worker’s Compensation**

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**Background:** Anterior cervical discectomy and fusion (ACDF) procedures have high rates of success, however, some patients do not improve. Arthroplasty is an emerging alternative, aiming to restore motion at the operated level. In order to achieve higher success rates - for either ACDF or arthroplasty - more scientific knowledge is needed about the small subgroup of patients who do not improve. The relation between their clinical condition and their work status is one possible area of explanation.

**Purpose:** The purpose of this abstract is to analyze the correlation between VAS and ODI with unemployment or worker’s compensation.

**Methods:** Patients with single-level cervical radiculopathy were blindly randomized to receive either CerviCore® arthroplasty or ACDF. Functionality was assessed with the Neck Disability Index (NDI). Neck pain was measured with a Visual Analogue Scale (VAS). Pearson’s correlation coefficient was used to assess the correlation between level of less improvement of NDI or VAS and unemployment or worker’s compensation at 1-year follow-up. Data was available at 1 year for 37 CerviCore® subjects vs. 38 ACDF subjects.

**Results:** The correlation between NDI and unemployment at 1-year follow-up was r=0.27 p=0.11 for CerviCore® and r=0.24 p=0.15 for ACDF. The correlation between VAS and unemployment was r=0.09 p=0.61 for CerviCore® and r=0.27 p=0.11 for ACDF. The correlation between NDI and worker’s compensation at 1-year follow-up was r=0.51 p< 0.01 for CerviCore® and r=0.27 p=0.10 for ACDF. The correlation between VAS and worker’s compensation was r=0.46 p< 0.01 for CerviCore® and r=0.14 p=0.40 for ACDF.

**Discussion:** There was a moderately strong and statistically significant correlation both between NDI and VAS with worker’s compensation for CerviCore® patients, however, there was no correlation to unemployment for CerviCore®, worker’s compensation for ACDF or unemployment for ACDF patients.

**Conclusion:** This analysis suggests that CerviCore® patients with improvements in NDI and VAS have a decreased dependence on worker’s compensation after 1 year. There is no such correlation for ACDF. By contrast, less improvement in VAS scores does not appear to correlate with

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**Figure 1. Mean NDI improvement by severity group.**

**Conclusion:** This study found that AEs were significantly related to outcome in cervical TDR clinical trials. While AEs are recorded to assess safety, they appear to be one factor that may help to explain variation in results even among rigorously selected patients enrolled in FDA IDE trials.
with unemployment for CerviCore® patients, or unemployment and worker’s compensation for ACDF patients. Further analysis of all 23 sites is needed to verify if these findings continue to the 2 year follow-up.

Abstract: 90
Cervical Total Disc Arthroplasty: The Correlation between Centre Placement and Clinical and Functional Outcome
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Introduction: We set out to investigate the potential correlation between the accuracy of centre placement of a cervical total disc arthroplasty (TDA) device upon clinical and functional outcome. To our knowledge, this is the first such study within the cervical spine.

Material and methods: We prospectively investigated 80 consecutive patients in whom a total of 110 Prestige LP TDAs were implanted. The pre and post-operative Neck Disability Index (NDI), SF-36, Visual Analogue Score (VAS), Hospital Depression score (HDS) and Hospital Anxiety Score (HAS) were recorded. All patients had pre-operative, immediate post-operative, as well as one and two year flexion-extension cervical spine x-rays. Coronal (i.e. inter-pedicular) and sagittal (mid-vertebral body) off-centre placement were measured, (x-rays have previously been shown to correlate strongly with high resolution CT regarding midline placement in the lumbar spine).

Results: Results were obtained in n=60 males and n=50 females, with mean age of 50.09 +/- 0.99yrs. N=50 patients had 1-level TDA, whilst n=30 had 2-level TDA. The mean follow up was 24.02 +/- 0.11 months.

Clinical outcome
There was statistically significant improvement in the outcome between pre- and post operative scores for: NDI (47.60 +/- 1.99 versus 23.09 +/- 2.32, p < 0.001), HDS (9.50 +/- 0.62 versus 4.40 +/- 0.46, p = 0.013), HAS (8.59 +/- 0.58 versus 4.71 +/- 0.48, p = 0.008), SF-36 bodily pain (29.01 +/- 2.20 versus 55.87 +/- 2.77, p < 0.001), SF-36 mental health (57.71 +/- 2.17 versus 72.71 +/- 2.14, p < 0.001) VASneck pain (7.23 +/- 0.21 versus 2.77 +/- 0.31, p < 0.001) VASarm pain (6.97 +/- 0.20 versus 2.69 +/- 0.33, p < 0.001).

Radiological analysis
The mean coronal off-centre placement was 1.71 +/- 0.13 mm, whilst the mean sagittal off-centre coronal placement was 1.09 +/- 0.66 mm. The mean ROM was 9.04° +/- 0.35.

Coronal off-centre placement
There was a significant negative correlation between the coronal off-centre placement and the NDI (r = -0.260, p = 0.031), HDS (r = -0.486, p < 0.001), SF-36 bodily pain (r = -0.354, p = 0.003), SF-36 mental health (r = -0.301, p = 0.012), VASneck pain (r = -0.481, p < 0.001) and VASarm pain (r = -0.388, p = 0.001). There was significant negative correlation between coronal off-centre placement with total ROM (r = -0.362, p = 0.001) and the NDI (r = 0.168, p = 0.186), HDS (r = 0.146, p = 0.232), HAS (r = 0.150, p = 0.219), SF-36 bodily pain (r = -0.164, p = 0.179) and HAS (r = 0.178, p = 0.144). There was no significant correlation between the posterior segment translation and the total ROM (r = -0.01, p = 0.92)

Conclusion: Coronal off-centre placement correlated uniformly negatively with post-operative ROM, and uniformly negatively with all clinical outcome scores. By contrast, sagittal off-centre placement did not correlate at all with post-operative ROM, and correlated inconsistently with clinical outcome scores. We conclude that coronal centre-placement is a critical factor in determining clinical and functional outcomes after cervical TDA.

CERVICAL TDR MOTION

Abstract: 232
Effect of Preoperative Degeneration, Segmental Alignment and Surgical Technique on Postoperative Segmental Alignment with the Bryan Cervical Disc Prosthesis
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Introduction: Various short and intermediate follow-up studies have reported promising clinical results after treatment of degenerative disc disease with the Bryan Cervical Disc Prosthesis. However, several research groups reported adverse outcomes, e.g. postoperative segmental kyphosis. The question raised whether this phenomenon is device related or if other actuators exist. The aim of this study is to investigate the influence of preoperative degeneration, preoperative segmental kyphosis and surgical technique on the postoperative segmental alignment after surgery with a Bryan Cervical Disc Prosthesis.

Methods: In a retrospective study, postoperative segmental alignment of 20 consecutive patients, operated by one surgeon with a Bryan Cervical Disc Prosthesis in 2000-2001 (Group 1), was compared with postoperative segmental alignment of 20 consecutive patients, operated by the same surgeon with a modified surgical technique, i.e. changing the angle of approach, in 2005-2006 (Group 2). In both groups, postoperative segmental alignment was correlated with preoperative degeneration, preoperative segmental kyphosis and surgical technique. Preoperative degeneration of the treatment level was scored using an objective scoring system. Based on lateral radiographs, the intervertebral range of motion (ROM); the disc insertion angle (aDI), which is a measure for the angle of approach; the angle of the functional spinal unit (afSU); and the angle between the shells of the prosthesis (aSfH) were calculated. The disc insertion angle is described as the angle between the bisector of the prosthesis shells and the line connecting the posterior superior corner of the superior vertebra with the posterior inferior corner of the inferior vertebra. The angle of the functional spinal unit together with the angle between the shells of the prosthesis are used to quantify postoperative segmental alignment. Lordosis is represented by a negative value, kyphosis by a positive value. A Student t-test was used to compare continuous and normally distributed variables between age groups. A nonparametric Mann-Whitney U-test was used when these criteria were not met. To investigate correlations, the Spearman r was used. A p-value of 5% was considered significant.

Results: ROM was maintained postoperatively in both groups (8.9+/-5.4° versus 10.6+/-3.8°; p>0.05). A significant difference in degeneration score (6.0+/-1.4 versus 4.0+/-1.8;
Comparison of Finite Element Analysis Results with Early Clinical Experience

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Introduction: Finite element analyses (FEA) are commonly used to evaluate spinal medical implants, in terms of mechanical loading and overall motion. However, little evidence has been created to confirm FEA findings with clinical outcomes. In this study, the quality of the motion obtained using the DISCOVER Artificial Cervical Disc - a new fixed ball and socket cervical arthroplasty device - was evaluated using a FEA model as well as using early radiographic data from the ongoing DISCOVER IDE study. Specifically, the center of rotation (COR) of the device was evaluated to determine possible long-term impact on facets and other spinal structures.

Methods: A validated FEA model of the C5-C6 motion segment was used to evaluate the theoretical COR of the device, as compared to that expected based on the natural motion of the spine and the facet morphology. The model simulated the 10.5mm radii of curvature of the DISCOVER artificial disc. In addition, radiographic data for subjects implanted with the DISCOVER Artificial Disc were reviewed. Flexion and Extension radiographs taken preoperatively and 6-months postoperatively were scanned, digitized and analyzed. Complete and analyzable radiographs at both time points were available for 57 levels implanted discs from C3 to C7. The location of the COR after implantation of the device was compared to that observed preoperatively and the distance between the preoperative and post-operative CORs was measured for all cases. For clinical purposes, the preoperative COR was used as an indicator of the unaltered, "optimal" motion, required to minimize stress on the facets. Both theoretical (from the FEA) and clinical data were compared.

Results: The FEA analysis confirmed that the device, at C5-C6 and with its specific 10.5mm radii, resulted in a kinematics agreement between prosthesis and facets, due to the fact that the COR of the implanted device and that of the facet joints were at the exact same location. Clinically, the average distance between the preoperative and postoperative CORs was 2.24±1.07mm. There was no difference in the distance between CORs at different levels (C4-C5: Distance in CORs=2.15±0.81mm; C5-C6: 2.32±1.17mm and C6-C7: 2.07±1.03mm).

Conclusions: The results of this study show that postoperative segmental malalignment associated with the Bryan Cervical Disc Prosthesis can be avoided, and is therefore device unrelated. Preoperative degeneration, preoperative segmental alignment as well as surgical technique were (significantly) different between both groups and might act as possible actuators for postoperative Kyphosis.

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Center of Rotation Analysis for DISCOVER Artificial Disc - Comparison of Finite Element Analysis Results with Early Clinical Experience

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Introduction: To date, few details have been published on the effects of implant height (i.e., distraction) on spine kinematics for cervical total disc replacement (TDR using Discover™, DePuySpine). We investigated the effects of distraction on instantaneous axis of rotation (IAR) and hypothesized that disc space over-distraction would alter IAR distribution. Further, we assessed the effects of inferior adjacent segment TDR or fusion (C6-7) on the primary disc replacement under investigation (C5-6).

Methods: Seven spines (C2-T1) were each mounted to a custom 6-DOF pure moment spine tester with a 66N follower load. Segmental motion was tracked using iLED markers. Unconstrained pure moments (±2Nm) were cycled in flexion-extension (FLX-EXT), lateral bending (LAT) and axial rotation (ROT). Table 1 lists test conditions.

Results: IAR calculations resulted in approximately 150 data points for each mode of loading after Butterworth filtering. Figure 1 shows representative plots for all loading modes for intact and TDR conditions. For all specimens and conditions the IAR was found to shift during loading. This sometimes resulted in a broad locus, and sometimes a general movement pattern during cycling. Flexion generally moved the intact IAR forward and extension backward. The range of the IAR locations with TDR was similar to intact, but it was closer to the TDR’s center over a greater portion of the loading cycle. IAR distributions were neither substantially affected by TDR height changes, nor by adjacent procedures. Intact LAT IAR demonstrated some variability. While consistently near midline, IAR resided within the disc in 5 specimens and above the disc in 2. Intact IAR movement was generally toward the ipsilateral side. Implantation shifted the IAR again to the approximate TDR center with few differences following implant over- or under-sizing, or adjacent procedures. The intact ROT IAR resided about the center to the posterior aspect of the vertebral endplate without a distinct pattern during loading. Following TDR, IAR was centered about the middle of the vertebral endplates. IAR was again maintained with over- or under-sized TDR, and with adjacent procedures.

Discussion: A study was undertaken to assess the kinematics of the Discover™ TDR. Discrete IAR calculations were performed over entire segment movements to identify IAR locations and shift patterns. The data suggest that while IAR locations for intact and TDR segments were similar, the fixed-bearing tended to co-locate the segment’s IAR. Although somewhat expected by the TDR design, no substantial
change was found with over- or under-distraction.

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<td>Intact</td>
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<td>Nominal Disc</td>
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<td>Small Disc</td>
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<td>Large Disc</td>
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<td>Adjacent Disc</td>
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Abstract: 494
PDN Nucleus Replacement: 9 Year Follow-up Experiences
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Introduction: The PDN prosthetic disc nucleus has been developed for treating moderate forms of degenerative disc disease, trying to fill the gap between discectomy and fusion. The surgical goals are pain relief, maintaining the disc height and allowing the flexibility at the index and adjacent levels. Here we show our experience after 9 years using PDN prosthesis.

Material and methods: 80 patients with moderate forms of degenerative disc disease were enrolled in this study. Radiographic (AP, lateral and dynamic) and clinical outcomes were collected preoperatively, 1 week and 1, 3, 6, 9, and annually through 9 years postoperatively. The VAS and ODI questionnaires were used to assess pain and functional outcomes.

Results: After 9 years follow up, the retrieval incidence was 47.5% (38 patients). From these patients, 23 (60.53%) had PDN expulsion and 15 (39.47%) had subsidence, with significant loosening of the disc height at the operated level. All patients underwent fusion as a retrieval surgery. The mean VAS was 8.1 and decreased to 3.8 nine years after surgery. Mean ODI was 4.471 at preop and decreased to 2.258 at nine years follow up.

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 the literature.

Abstract: 279
Restoration of Motion and Disc Height Following Cadaveric Implantation of a Novel Allograft-filled Conformable Nucleus Replacement
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Purpose: The primary objective of nucleus pulposus (NP) replacement is pain relief at the affected level while preserving motion and maintaining disc height. An innovative concept for a biologic NP implant has been proposed comprising a conformable mesh container that is percutaneously deployed into the nucleus cavity and filled with a novel flowable, spongy allograft formulation. The purpose of this study was to evaluate the ability of this device to restore flexibility and disc height following cadaveric implantation.

Methods: Twelve fresh-frozen human cadaveric lumbar motion segments were acquired (n=6 L2-L3 & n=6 L4-L5) and potted. Tests were performed in the intact, denucleated, acutely implanted, and post-cyclic loading states. A lateral approach was used for surgical access and nucleotomies were performed through a small annulotomy. An OptiMesh device (Spineology, St. Paul, MN) was deployed within the disc space and filled in situ by delivering the uniquely formulated allograft material (MTF, Edison, NJ) through a small tube. Flexibility tests applied unconstrained moments of ±7.5Nm with a 50N axial preload in flexion-extension, lateral bending and axial torsion using a hydraulically-actuated spinal loading fixture (MTS, Eden Prairie, MN). Motion was tracked using a 4-camera motion measurement system (Vicon, Hauppauge, NY). Cyclic loads to ±5Nm at 0.5Hz for 500 cycles were applied in each direction under constant 50N axial preload. Fluoroscopic disc height measurements were obtained under axial compressive loads of 0, 200, and 800N. Range of motion (ROM) data were analyzed statistically using repeated measures ANOVA.

Results: No significant differences were detected in ROM between the intact and implanted conditions after cyclic loading in any test direction (P≥0.46). Cyclic loading post-implantation resulted in non-significant ROM increases of less than 1.3º in each direction. Device implantation significantly re-stabilized the denucleated motion segment (P<0.002). Unloaded intact disc height averaged (±SD) 11.1±1.6mm and was reduced by 1.3mm following denucleation. Device implantation significantly increased disc height versus the denucleated condition (P=0.002) by 1.8mm whereas there were no statistical differences between intact and implanted disc heights (P=0.262).

Conclusions: A unique NP implant has been developed featuring a deployable mesh container filled with a novel allograft formulation that is conformable to specific patient
Anatomy. In this cadaveric investigation, the device effectively restored disc height and motion to that of the intact segment in both the acutely implanted condition and after cyclic loading. These data are encouraging and support further investigation into the clinical effectiveness of this device.

Abstract: 154
A New Polymerizing Gel for Injection in the Nucleus Pulposus - Evaluation of the Biomechanical Behavior and the Extrusion Risk
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Introduction / purpose of the study: Recently, successful therapeutic approaches have been designed and clinically tested to utilize autologous intervertebral disc cells as a source for regenerative cell populations to be re-injected into the damaged nucleus pulposus of patients. The drawback of the current method is the fact that cells are injected as a liquid suspension, creating the risk of leakage of cells from the injection site at mechanical loading of the freshly injected disk. To overcome this technical problem, an in situ polymerizing gel based on chemically crosslinking albumin as a cell carrier and hyaluronic acid as a hydrodynamic additive was designed. The suspension is delivered via a two-chamber syringe and a mixing device, with one chamber containing the unpolymerized cell/albumin/HA mixture and the second chamber the crosslinker. The gel polymerizes within a few minutes after injection and is supposed to anchor the „implant“ within the nucleus pulposus. In order to evaluate the biomechanical changes of a spinal segment after injection of the gel and to evaluate the risk of extrusion a biomechanical in-vitro test was performed.

Methods: The in-vitro test was conducted on 12 lumbar motion segments of 5-6 month old calves. 6 specimens were treated with the in situ polymerizing gel, 6 were used for an untreated control group. Biomechanical evaluation was obtained from flexibility measurements in the three principal motion planes. Subsequently, for evaluation of the extrusion risk specimens were stepwise exposed to cyclic fatigue loading of 100,000 load cycles caused a successive increase of the flexibility in all motion planes beyond the initial ROM. The disc height showed an initial increase of about 0.25 mm after the gel injection and then a decrease of -1.4 mm due to cyclic testing with 100,000 load cycles. These changes in flexibility as well as in height were the same as in control-group with untreated intact specimens. Most importantly, however, no extrusion of the polymerizing gel could be noticed over the 100,000 cycles. Finally, macroscopic sections exhibited a decrease of the volume of the implanted gel, probably due to loss of water.

Discussion: The results suggested that injection of the new polymerizing gel might be suitable to anchor re-injected autologous intervertebral disc cells or mesenchymal stem cells as a source for regenerative cell populations into the damaged nucleus pulposus. The gel will polymerize within the center of the nucleus thus reducing the risk of leakage of cells from the refilled defect.

Acknowledgment: This work was supported by Braun-Aesculap, Tuttingen

Abstract: 535
Multi-directional Flexibility Properties and Abrasion Assessment of an in situ Cured Polyurethane for Nucleoplasty Reconstruction: An in-vitro Human Cadaveric Model
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Introduction: The current study was designed to evaluate the multi-directional flexibility and biodurability of an in situ curable polyurethane nucleus pulposus replacement following implantation in a cadaveric model. Analyses were based on static and dynamic fatigue testing parameters.

Methods: Eight human cadaveric lumbar sacral spines (L2 to Sacrum) were biomechanically evaluated under the following L4-L5 reconstruction conditions: 1) Intact Spine; 2) Unilateral facetectomy and nucleotomy; 3) Polyurethane device (NuDisc) pre-fatigue and 4) Polyurethane device post-fatigue. Multi-directional flexibility testing utilized the Panjabi hybrid testing protocol, with intact moments of ±10Nm for axial rotation, flexion-extension and lateral bending. Fatigue testing of 40,000 cycles (∓2.5Nm) was performed following device implantation to assess construct wear and changes in range of motion (ROM). The center of intervertebral rotation (COR) was calculated for the operative and adjacent levels, and intradiscal pressures (psi) at the superior L3-L4 and inferior L5-S1 levels. Operative level intervertebral disc height (mm) changes were compared. Quantification of the operative and adjacent level range of motion (ROM) and neutral zone (NZ) were normalized to the intact spine (100%). Based on gross examination, the polyurethane area (mm²) / nucleotomy area (mm²) was computed to determine the extent of filling and wear response assessed using photography.

Results: Multidirectional flexibility testing demonstrated no significant changes in the operative or adjacent level motions for any loading modality - axial rotation, flexion-extension or lateral bending - for the four treatment conditions (p>0.05) (Figure 1). The polyurethane nucleoplasty preserved segmental kinematics in both overall ROM and NZ pre- and post 40,000 cycles fatigue (p>0.05). Intradiscal pressures at the adjacent levels indicated marked decreases in flexion following nucleotomy (L3-L4: Intact 14.5±11.2, Nucleotomy 6.25±4.4, Nucleoplasty 14.5±13.1) (L5-S1: Intact 28.5±16.3, Nucleotomy 20.5±20.9, Nucleoplasty 25±26.2) which were restored following implantations (p>0.05). No significant differences were observed for the operative or adjacent level COR's when comparing the intact spine or nucleoplasty reconstructions - pre- or post fatigue. Intervertebral disc height changes were not significantly different when compared to the intact condition (100%): nucleotomy (94.5±11.2%), and nucleoplasty pre-fatigue (96.2±13.7%) and post-fatigue (90.45±15.79%) (p=0.456). The nucleoplasty procedure effectively reconstructed 83.79±11.98% of the nucleotomy area with significant evidence of polyurethane adherence to the vertebral endplates and remnant annulus. There was no evidence of disc fragmentation or polyurethane device extravasation during the fatigue cycles.

Discussion: The current study evaluated the biomechanical properties of the in situ curable polyurethane nucleus...
Biomechanical Evaluation of the Lumbar Spine after Anular Repair

Abstract: 450

Biomechanical Evaluation of the Lumbar Spine after Anular Repair

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Introduction: Disc degeneration with or without herniation is one of the major causes of low back pain and sciatica and is believed to be associated with segmental instability of the spine. Instability, which can be simulated in cadaveric discs by creating anular disruptions, was repaired in this biomechanical study using an advanced closure method. The objective was to assess the effect of anular incisions and repair on the lumbar kinematics, disc pressure, and facet loads.

Materials and methods: Two different types of anular incisions (4mm and 8mm) were made obliquely on the right postero-lateral side of human lumbar (L2-L3) motion segments (n=7) and each was followed by anular repair using Xclose™ Tissue Repair System (Anulex Technologies Inc., Minnetonka MN). This repair technique involves placing soft tissue T-anchors behind the anulus and tensioning attached suture lines resulting in a snug tension band. Each specimen was tested in five different conditions: intact, 4mm incision, 4mm incision repaired with one tension band, 8mm incision and 8mm incision repaired with two tension bands. Pure moments (+7.5N-m) were applied to create flexion/extension, lateral bending, and axial rotation. Kinematics, disc pressure and facet loads after anular incisions and repair were compared with the intact spines. Differences among groups were sought using ANOVA with p < 0.05 as significance level.

Results: Results indicated that a 4mm incision or 4mm with repair resulted in negligibly small changes in the motion range under various loading conditions. Lateral bending (p=0.003) and flexion/extension (p=0.038) were strongly affected by the 8mm anular incision, while no significant differences were observed during axial rotation. Most notably, the 8mm anular incision produced a significant increase (17.2%) in the range of motion accompanied by a corresponding decrease in stiffness during lateral bending. Furthermore, there was a significant increase (18.3%) in flexion/extension range of motion after the 8mm incision. Anular repair of the 8mm incision was effective in restoring the biomechanics back to near normal state in terms of range of motion. The repair of the 8mm incision showed a significant increase (p=0.03) in stiffness during left lateral bending compared to the 8mm incision without repair condition. There were no statistically significant differences in disc pressure with either of the anular incisions and subsequent repair. However, facet loads increased after both anular incisions and repairs during all physiological motions with the left facet being significantly affected (opposite the incision side, p ≤ 0.03 in all cases).

Conclusions: This study successfully showed that anular tears or defects can disrupt the normal biomechanics of the lumbar spine by altering kinematics and facet loads. It also proved the feasibility of anular repair as a treatment for degenerated lumbar disc with anular defects by reducing the abnormal motion and thus potentially preventing further degeneration of the anulus fibrosus and the intervertebral disc.

References:

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Abstract: 467

Acute Pull-out Resistance of Bone Anchor Elements Used for Anular Repair

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Introduction: Lumbar discectomy includes removal of disc material through an anular defect or incision. Anular repair after discectomy can be challenged by the location of the defect since this pathway for herniation can be close to bony endplates. Anular repair techniques to close defects can include bone anchor fixation elements. Resistance to pull-out of bone anchorage elements, in comparison to expected in situ loads determined experimentally, was evaluated in this cadaveric study.

Materials & methods:

A) Expected in situ load requirements for bone anchors in the posterior vertebral body were estimated using cadaveric lumbar motion segments. Soft tissue anchors (n=11) were placed into intervertebral discs and a transducer was attached by a perpendicular tension pull-line positioned through the spinal canal. Maximum angular flexion motion (avg= 13 degrees) was applied three times and the resultant tensile load was measured on the third cycle.

B) Linear pull-out loading until failure (0.5 in/min) was applied to 5 mm titanium toggle anchors (n=25) placed approximately 4 mm away from the endplate in cadaveric posterior vertebral bodies. Two different size screws (n=10 each) were subsequently placed in holes left after toggle anchor pull-out and maximum pull-out load was determined.

Results: Average load requirement for a bone anchor element in the posterior vertebral body was 16.5 +/- 7.0 N. In comparison, the pull-out load for titanium toggle anchors was 34.75 +/- 14.1 N. Smaller screws placed in holes vacated by toggle anchors pulled out at 32.9 +/- 13.4 N and larger screws at 44.5 +/- 24.3 N.

Conclusion: Repair of the anulus fibrosus after lumbar discectomy can impact the post-surgical outcome of discectomy patients. Placement of suture-tethered soft tissue anchors has been used to close the pathway suspected for reherniation. An option to anchor the repair into lumbar vertebrae would enable repair of defects closer to the endplate. Requirements for resistance to pull-out were determined in this study and the average pull-out load for a toggle anchor was demonstrated to be more than two times the average estimated load required. If a toggle bone anchor fails intra-operatively, a screw could be used in its place to continue the repair technique since the average resistance to pull-out was more than 25% greater than the toggle anchor.
Abstract: 546
Multidirectional Flexibility and Fatigue Assessment of the Anular RimClose System Using an in-vitro Human Cadaveric Model

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Introduction: The complexity in spinal kinematics presents a challenging biomechanical environment for devices implanted within the intervertebral disc. Technologies to repair a compromised anulus fibrosus have been proposed to improve outcomes following symptomatic disc hernia excision, yet placement of anular repair devices is not without concern of migration or failure. Anular tears or defects near the endplate represent a particularly challenging repair.

Objective: Using an in-vitro cadaveric model, static and dynamic multidirectional flexibility testing examined the operative level kinematics and assessed the efficacy of Rimclose Tissue to Bone Repair System (Anulex Technologies, Inc, Minnetonka MN) for repairing the anular-endplate margin based on static and cyclic fatigue testing parameters following discectomy.

Methods: A total of four human cadaveric lumbosacral spines (L2 to Sacrum) were biomechanically evaluated under the following L4-L5 and L5-S1 reconstruction conditions:
1) Intact spine,
2) Subtotal discectomy alone,
3) Rimclose reconstruction and
4) Post-Fatigue reconstruction.

Subtotal discectomies were performed using a standard laminotomy. Anular defects created within 2mm of the superior endplates of L4 and L5 were repaired using Rimclose Tissue to Bone Repair System. Static multidirectional flexibility range of motion properties were compared between the intact condition and after placement of the device, both before and after cyclic loading. Multi-directional flexibility testing included pure, unconstrained moments (±8Nm) in axial rotation, flexion-extension and lateral bending. Fatigue testing of 40,000 cycle’s flexion-extension (±2.0Nm), lateral bending (±2.0Nm) and axial rotation (±2.0Nm) was performed following device implantation to assess construct wear and changes in range of motion (ROM). Direct visualization of the repair was performed at the conclusion of the testing to examine the post-fatigue condition of the repair system and the closure of the anulus.

Results: Each Rimclose device was accurately placed within the margin of the endplate and anular wall. There was no evidence of Rimclose failure in any of the experimental cases. Furthermore the repaired anular defect remained closed after cyclic loading. The static and cyclic multidirectional flexibility properties - axial rotation, flexion-extension and lateral bending - of the operative motion segment was not affected by implantation of the implant when compared to the intact condition (p=0.05).

Discussion: The ability of an anular repair device to remain intact and in its intended intervertebral disc position, thus constraining the contents of the intervertebral disc, are important attributes to its utility. The acute stability characterized of this implant suggests an increased potential for constraining intradiscal material, without significant affect on the spinal kinematics. In vivo corroboration of these findings is warranted and anular repair devices may ultimately offer a method to improve clinical outcomes after discectomy.

Treatment of Lumbar Disc Herniations: A Prospective Study

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Object: The purpose of this multi-center study is to evaluate the safety and performance of the BARRICAID ARD device in the treatment of single and multi-level lumbar disc herniations. This evaluation involved a comparison to prospective, surgically treated (no implant) patient population (108) with the same condition. The BARRICAID ARD is an implant that is anchored to an adjacent vertebral body (either cephalad or caudal) and deploys a mesh to mechanically block the anular defect.

Methods: A prospective clinical study is being conducted at two study sites in Europe. A total of 20 patients have been recruited based on a study protocol consistent with FDA guidance for spinal implant studies. In addition, 108 patients treated surgically for lumbar disc herniations are being followed under the same prospective protocol design. Clinical and radiographic data is collected pre-operatively and at 6 week, 3 month, 6 month, one and two year time intervals following surgery. Oswestry Disability Index (ODI) and the Visual Analogue Scale (VAS) are the primary outcome measurements. The SF-36, neurological status and the radiographic assessment of degree of spondylolisthesis, disc height, and device condition were secondary outcomes measured. All radiographic data was independently measured. The data generated in this prospective study meets the definition of class II level research data.

Results: The patients’ clinical status improved significantly following treatment with the BARRICAID ARD device. The mean ODI score improved versus baseline by 76% at 3 months, while the VAS Back, and ipsilateral VAS leg scores improved by 91% and 83%, respectively, over the same time period. No reherniations have occurred in the implanted population while a 10% reherniation rate has occurred in the nonimplanted population. Radiographic analysis showed that disc height was preserved in the implanted group, and no evidence of bone anchor loosening was observed. There were no device malfunctions or migrations and no device-related adverse events reported during the study.

Conclusion: Follow-up is now available for the first time for any anular reconstruction device. The results demonstrate that BARRICAID ARD patients’ experienced significant improvement in clinical outcomes at all time points, postoperatively. Preliminary results demonstrate that this bone anchored, anular reconstruction device can reduce reherniation rates when compared to surgical treatment alone. Coupled with the fact that independent radiographic analysis has demonstrated stabilization of the implant and maintenance of disc height, this study indicates that the BARRICAID ARD can safely and effectively close anular defects.

FACE Replacement: Kinematics

Abstract: 247
ACADIA™ Facet Replacement System Lumbar Kinematics: A Comparison of Finite Element, in vitro and in vivo Investigations

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Introduction: Some posterior lumbar motion sparing devices have demonstrated maintenance of segmental range of motion (ROM) through in vitro cadaveric studies and finite element simulations. However, data regarding in vivo kinematics for these devices is sparse. The aim of this study was to investigate the kinematics of the ACADIA™ Facet Replacement System (Facet Solutions, Hopkinton, MA) comparing the results from a finite element model (FEM), an in vitro cadaveric study and an in vivo radiographic study.

Methods: Pre-operative, 3 month and 6 month standing flexion-extension x-rays were taken for 20 patients with lumbar spinal stenosis implanted at L4/5 with the facet replacement device in an FDA IDE pilot study. Vertebral motion was analyzed using a validated image analysis software package (Medical Metrics, Houston, TX). Flexion-extension pure bending moments of 10 Nm and a preload of 400 N were applied to 6 human cadaver lumber spines. Intact and implanted ROMs were recorded using a 3D optical tracking system (Northern Digital, Waterloo, Ontario). Identical loading was applied to a validated three-dimensional osteo-ligamentous FEM. Predicted flexion-extension values were calculated for intact and implanted models using a finite element analysis software package (ABAQUS, Providence, RI). The student’s t-test was used to make statistical comparisons between groups. The paired student’s t-test was used to make comparisons within groups.

Results: Pre-operative (intact) FEM, in vitro and in vivo flexion-extension ROMs were 7.7°, 9.4°±3.1 and 4.9°±3.7, respectively. Implanted FEM, in vitro and in vivo 6 month flexion-extension ROMs were 9.2°, 8.4°±2.9 and 7.0°±3.8, respectively. The 3 month in vivo flexion-extension ROM was 7.1°±3.8. The difference between the in vitro and in vivo pre-operative (intact) flexion-extension means was statistically significant (p = 0.0056). The difference between the in vivo pre-operative and in vivo 3 month flexion-extension means was statistically significant (p = 0.0066). The difference between the in vivo pre-operative and in vivo 6 month flexion-extension means was also statistically significant (p = 0.0084). No other comparisons yielded statistical significance.

Conclusions: The pre-operative in vitro and intact in vivo results were statistically significantly different. This may reflect the random nature of cadaveric specimen selection and the clinical study inclusion criteria. The facets in the in vivo group have moderate to severe hypertrophy while no such criteria was imposed on the in vitro cadaver specimens. The notable result is that once the facets were removed and the facet replacement device was implanted, the FEM and in vitro data closely predicted the post-operative in vivo flexion-extension ROM. Further, the in vivo group demonstrated a statistically significant increase in flexion-extension ROM from pre-op at both the 3 and 6 month time points. These data support the theory that stenosis patients with incompetent facet joints may experience restored ROM with the ACADIA™ facet replacement system.
Purpose of the study: Nucleus arthroplasty is indicated for the treatment of patients with degenerative disc disease. However, it is contraindicated in cases of stenosis or facet disease. Utilization of a total facet replacement (TFR) in conjunction with a nucleus replacement (NR) would allow for complete motion-preserving treatment of the three-joint complex in the lumbar spine and may mitigate the concomitant degeneration of the posterior and anterior elements and preclude accelerated degeneration of adjacent levels. This study utilized a six-degree-of-freedom spine simulator testing machine to evaluate the intersegmental kinematic response of a TFR (TFAS-TL™, Archus Orthopedics’) in conjunction with a NR (HydraFlex™, Raymedica).

Methods: Simulated physiologic loads were applied to six human L2–L5 lumbar spines in multiple test conditions under Flexion/Extension (FE, ±8Nm/-6Nm) with and without 400N follower load, and both lateral bending (LB, ±6Nm) and axial rotation (AR, ±5Nm) without follower load. Each specimen was tested (a) intact, (b) after HydarFlex implantation at L3-L4 and, with HydarFlex in place: (c) after L3-L4 facetectomy, (d) after TFAS-TL implantation and (e) after posterior fusion.

Results: Range of motion (ROM) for the Intact, HydraFlex and HydraFlex+TFAS-TL conditions were similar (Fig 1). Facetectomy significantly increased the motion of the implanted level (p<0.05). Fusion reduced the motion of the implanted level in comparison to all other conditions. All motion preserving implant conditions maintained a sigmoidal characteristic to the kinematic signature, suggesting that the spine moved in a manner that will not overstress the maintained tissues.

Conclusion: The TFAS-TL when used in conjunction with the HydraFlex reproduced the function of the natural facets and maintained the ROM of the segment and three-dimensional kinematic patterns of the spine. This synergistic performance of the two devices to provide total lumbar joint replacement may ensure long-term mobility of the segment and prevent the overloading of the remaining soft tissues. The concurrent implantation of the TFAS-TL and TNR is a viable option to maintain the mobility and stability of the lumbar spine segment while treating the patient in a 360-degree tissue sparing approach. This positive functionality will advance motion preserving treatment of the degenerative cascade and permit progressive surgical intervention without requiring retrieval of existing implants.

DYNAMIC STABILIZATION: OUTCOMES

Abstract: 489

X-STOP - Different Outcomes for Different Indications

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Objectives: To evaluate the influence of different indications, especially the presence of low-back-pain on patient-oriented outcome after implantation of the X-STOP interspinous device.

Methods: A total of 45 consecutive patients who underwent X-STOP implantation were asked to complete SF-36 and Oswestry Disability Index questionnaires and to indicate their pain-level on a VAS separately for low-back and leg-pain after a follow-up of 3 years. The same data has been assessed prospectively prior to surgery. Outcome was dichotomised as “good” or “bad”, dependent on subsequent revision surgeries and the improvement of scores and pain. A multivariate logistic regression model was developed to clarify the influence the presence and intensity of preoperative low-back pain on the overall outcome.

Results: Within the 3-year follow-up period, a good outcome was achieved in 62% of the cases. Logistic regression showed a good overall fit of the model (p=0.006) with a statistically significant influence of the presence of low-back pain in the outcome (p=0.013). The odds-ratio for a bad outcome was 8.9 if low-back pain was at least as intense as leg pain prior to surgery.

Conclusions: The results of this study show that preoperative low-back pain has a high influence on the overall outcome after X STOP implantation. The risk for a bad outcome was almost nine times higher if significant low-back pain was present preoperatively. Therefore, the indication for X STOPT implantation should be critically questioned in cases with lumbar spinal stenosis where low-back pain seems to be a significant part of the patient’s symptoms.

The Total Facet Arthroplasty System (TFAS®) in the Treatment of Degenerative Lumbar Spinal Stenosis: Midterm Results of US IDE Trial with Longest Follow-up of 24 Months

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Abstract: 278

The Total Facet Arthroplasty System (TFAS®) in the Treatment of Degenerative Lumbar Spinal Stenosis: Midterm Results of US IDE Trial with Longest Follow-up of 24 Months

1Texas Back Institute, Plano, TX, USA, 2Florida Spine Institute, Clearwater, FL, USA, 3East Tennessee Brain and Spine Center, Johnson City, TN, USA, 4Florida Orthopedic Institute, Tampa, FL, USA, 5The Disc Replacement Center of North Florida, Tallahassee, FL, USA, 6Norwich Orthopedic Group, North Franklin, CT, USA, 7Southern NY Neurosurgical Group, Johnson City, NY, USA, 8Panorama Orthopedics, Golden, CO, USA
Background context: Instrumented fusion has been established as the surgical standard of care for spinal stenosis. However, the elimination of motion at the fusion level has often been implicated in further degeneration of the spine at adjacent levels.

Purpose: The Total Facet Arthroplasty System® (TFAS®, Archux Orthopedics, Redmond, WA) was designed as a motion-restoring, articulating joint prosthesis to be implanted following removal of the facets and ligamentous structures during wide neural decompression and facetectomy. It is intended to stabilize the spine while maintaining some degree of the natural motion characteristics of the facet joint at the affected spinal segment. The intended benefits of facet arthroplasty using the TFAS device include the elimination of lumbar fusion and reconstruction of the motion segment and the preservation of segmental biomechanics, thus reducing the long term potential for degeneration of spinal levels adjacent to the involved spinal segment.

Study design/setting: This multicenter, prospective, randomized clinical trial with concurrent control was comprised of patients treated in the United States under an approved IDE. Patient sample: 145 patients (126 TFAS and 19 fusion control) undergoing lumbar decompression and facetectomy were implanted. The average age is 65.1 years (range 50-85 years).

Outcome measures: Clinical evaluation included the Zurich Claudication Questionnaire (ZCQ), visual analog scales (VAS) for back and leg pain, and neurologic status preoperatively and at 1, 3, 6, 12, and 24 months postoperatively. Range of Motion (ROM) via flexion-extension radiographs and freedom from complications was also assessed.

Methods: Only patients meeting strict inclusion criteria were enrolled. A regime of 1 non-randomized TFAS patient followed by a 2:1 randomization TFAS: Control was employed. The surgical technique involved a posterior, open approach with wide decompressive laminectomy and bilateral facetectomy at the stenotic level.

Results: TFAS/Control follow-up is: 9/0 with 24 month follow up, 39/0 patients with 12 month follow-up, 46/2 with six months follow-up, 10/2 with three months follow-up, and 11/4 with one month follow-up. For TFAS patients, radiographic analysis shows all devices to be intact and functioning, with post-op ROM evident in all patients. Clinically, 66 of 79 patients (84%) have significantly improved ZCQ symptom scores (mean improvement 1.4 with 0.5 being considered clinically significant) and 64 of 79 patients (81%) have significantly improved ZCQ function scores compared to preoperative scores (mean improvement 1.0 with 0.5 considered clinically significant). Leg Pain VAS scores improved in 75 of 79 patients (95%, with an average 5.5 point improvement) and back pain VAS scores improved in 73 of 79 patients (85% with an average 4.6 point improvement) compared to preoperative scores. Analysis of control data is not included due to small sample size.

Conclusion: The TFAS is a novel facet arthroplasty device designed as an alternative to spinal fusion with instrumentation for spinal stenosis. Early data suggests that the device successfully restores motion, provides stability, and allows for clinically significant reduction of preoperative symptoms. Also noteworthy is the reduction in back pain which may be attributed to the motion preservation properties of the TFAS device.

Introduction: The uni- or bilateral undercutting decompression is a well established procedure in the operative treatment of symptomatic Lumbar Spinal Stenosis (LSS). A number of interspinous process devices have recently been introduced to the lumbar spinal market as an alternative to conventional surgical procedures in the operative treatment of LSS. Published information is limited, and there are so far no data of comparison between the implant and traditional surgical approaches such as laminectomy.

Methods: A prospective analysis was performed on 60 patients treated for a one or two level symptomatic LSS with decompressive surgery. Two groups were built. In Group one (UD) we treated 30 patients with decompression surgery alone and group two (CO) in 30 patients an interspinous device (COFLEX™) was additional implanted. Pre- and postoperatively disability and pain scores were measured using the Oswestry Disability Index (ODI), the Rowland Morris Score (RMS), the Visual Analogue Scale (VAS) and the pain free walking distance (WD). The ROM (flexion-extension) of the operated levels was analysed pre- and postoperatively. The patients underwent postoperative assessments 3, 6, 12 and 24 month including the above mentioned scores as well as patient satisfaction.

Results: After decompressive surgery all measured parameters improved significantly (p < 0.001) in both groups compared to base line. In the UD-Group the ODI improved from 39.4% to 19.9%, the RMS from 13.4 to 5.3, the VAS from 6.0 to 2.7, the WD raised from 550m to 2400m. Within the CO Group the ODI improved from 47.8% to 19.2%, the RMS from 13.2 to 5.1, the VAS from 6.4 to 2.6, and the WD raised from 276m to 2800m. We couldn’t find any statistic significant differences within both groups. In the CO group two cases had to be re-operated due to Implant dislocation and two patients had to be fused. In the UD group also two patients had to be fused.

Conclusion: In our trial the additional placement of a Coflex interspinous device did not improve the clinical outcome at the 24-month follow up interval within the two groups. This study has a limitation in the missing randomisation and the number of patients being included.

Because there is no current evidence of the efficacy of the Coflex Device we need further data from randomized controlled studies for defining the indications for theses procedures. Therefore in Germany a multicenter randomized controlled study was started in 2008.

DYNAMIC STABILIZATION: PEDICLE BASED

Abstract: 504
Evaluation of Hybrid Posterior Dynamic Stabilization (ISOBAR TTL): A Two Year Follow-up
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Background: Instrumented fusion has been established as the gold standard in the care of degenerative disc disease because of its effectiveness in stabilizing the spine and resolving pain. However the elimination of motion at the index levels has been implicated in the development of adjacent level degeneration.

Purpose: The dynamic rod allows for stabilization of a pathological motion segment above a fused segment. This creates a transitional zone and decreases the loads applied to the adjacent normal segment.

Methods: This is an IRB approved, prospective, consecutive, non-randomized clinical trial. 27 patients underwent a L5-S1 posterior lateral spinal fusion with transforaminal

Does an Interspinous Device (COFLEX™) Improve the Outcome of Decompressive Surgery in Lumbar Spinal Stenosis? 2-year Follow up of a Prospective Case Control Study of 60 Patients
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lumbar interbody fusion using a cage, with a L4-L5 posterior dynamic instrumentation (ISOBAR TTL Scient’s USA). All 27 patients had discography: all presented with a L4-L5 and L5-S1 fully concordant pain response and abnormal architecture on the CT scan. The superior adjacent level (L3-L4) presented no pain response with a normal “cottonball” architecture on CT/discography. Functional clinical outcomes were measured with a 100 point visual analog scale (VAS), Oswestry disability index (ODI) and SF-36 questionnaire. Radiographic measurements of disc height intervertebral angle, lumbar lordosis and motion were performed with flexion, extension and plain x rays. Fusion evaluation was performed at one year with CT scans and 3D reconstructions. MRI scans were also performed at one year. Complication and screw loosening was also assessed.

**Results:** Follow-up ranges from 39months to 60 months. Radiograph analysis shows all devices to be intact and functioning. No device failure or screw breakage was identified. Post operative range of motion (ROM) averaged 4.14 degrees at the index level and the superior adjacent level ROM remained unchanged. No pseudarthrosis were identified at L5-S1. Disc height was preserved at all levels. Radiographic screw loosening presented as an incidence of 7%; none of which has required surgical revision to date. Two revisions were performed; one for iatrogenic synovial cyst at L3-L4 and one for persistent low back pain. Functional outcomes were assessed. Evidence showed significant improvement in VAS (61 to 42) of 19 points and ODI (51 to 33) 18 points. SF 36 also showed statistically significant improvement from baseline to present.

**Conclusion:** The hybrid technique is a new innovative surgical approach in the treatment of lumbar degenerative disc disease. Our preliminary results of functional and radiographic evaluation at two years are satisfactory. Long term follow up will be needed to fully assess continual function improvements and the decrease in the incidence of adjacent level disc disease.

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**Paraspinal Muscle Changes after Dynamic Stabilization and Lumbar Fusion**


**Purpose:** Paraspinal muscle injury and atrophic change after posterior lumbar surgery can cause low back pain and failed back surgery syndrome. Recently, many studies of postoperative paraspinal muscle change have been published. But there are no studies of muscle change after dynamic stabilization (DS). In this study, we compared not only muscle changes of the DS with them of the lumbar fusion (LF), but also paramedian and midline approaches.

**Material and methods:** Our study population consisted of 38 consecutive patients who underwent lumbar spine surgery with posterior instrumentation between February 2005 and January 2008. The alteration of the paraspinal muscle after the DS in 24 patients and the LF in 14 patients were evaluated. There were 16 paramedian interfascial approaches and 22 traditional midline approaches. The preoperative and postoperative cross-sectional areas of paraspinal (multifidus+longissimus), multifidus, psoas muscles were measured by computed tomography. Transaxial sections in L4 level were obtained, because the paraspinal and psoas muscles are best visualized in this sections. We evaluated the changes in paraspinal and psoas muscle area at more than 6 months after surgery.

**Results:** The rates of decreasing paraspinal muscle were significantly greater in the LF group than the DS group(-11.8% and 2.41%, respectively, p< 0.01). In the LF, the rates of decreasing multifidus and psoas muscles were -27.68%(p< 0.05) and -5.35%(p>0.05). In the DS, they were -0.97%(p< 0.05) and 0.56%(p>0.05), respectively. Moreover, in the DS with paramedian and midline approach group, the changes in paraspinal muscles were 3.18% and 1.95% postoperatively. But, in the LF groups, they were -17.15% and -6.45%, respectively(p< 0.01).

**Conclusion:** DS showed good preservation of paraspinal and psoas muscles. Especially DS with paramedian approach may preserve more paraspinal muscles due to less manipulation and retraction.

**Key words:** Dynamic Stabilization, Fusion, Paraspinal Muscle, Lumbar Spine

Abstract: 395

**The Effectiveness of Posterior Dynamic Stabilization Using IsoBar TTL Dynamic Rods Combined with Decompression as a Treatment for Elderly Patients with Unstable Grade I L4-S Spondylolisthesis and Spinal Stenosis: A Comparison with Decompression Alone**


**Objectives:** To compare the effects of decompression alone and decompression combined with posterior dynamic stabilization (PDS) using IsoBar TTL Dynamic Rods as a treatment for elderly patients with unstable grade I degenerative spondylolisthesis and spinal stenosis, for whom fusion may be too risky.

**Material and methods:** Thirty-eight patients ages 65 or older with unstable grade I L4-S degenerative spondylolisthesis and spinal stenosis who underwent surgical treatment were retrospectively analyzed. Patients who had symptomatic foraminal stenosis at the same level were excluded. All cases had American Society of Anesthesiologist (ASA) class III. In Group A, 21 patients (the T-score of BMD ≥ 2.0mm) were treated with unilateral laminotomy for bilateral microdecompression. In Group B, 17 patients (the T-score > 2.0) were treated with bilateral laminotomy combined with PDS using IsoBar TTL Dynamic Rods. Data were collected preoperatively and at 3 months, 6 months, 1 year, and every subsequent year postoperatively. A comparative analysis was made between the two groups using clinical (Visual Analog pain Scale (VAS) and Macnab criteria) and radiologic (the degree of lysisis (DL) and mobility by dynamic plain films) measures.

**Results:** The mean follow-up duration was 27.4 months (range 24 to 36 months). The mean preoperative scores on VAS for lower back pain (LBP) in Groups A and B were 5.05±1.47 and 5.29±0.99, respectively, and decreased after postoperative 2 years to 4.62±1.91 and 2.18±0.64, respectively (p>0.05 and p<0.05, respectively). The incidence of persistent LBP (the score of VAS ≥ 3) in Group A (71.4%) was significantly higher than that in Group B (17.6%) at a two-year follow-up evaluation (p< 0.05). The mean preoperative scores on VAS for leg pain in Groups A and B were 7.76±0.77 and 7.59±0.71, respectively, and decreased after surgery to 2.14±0.91 and 1.29±0.77, respectively (p>0.05 and p<0.05, respectively). The rates of patients with excellent or good outcomes in terms of the Macnab criteria in Groups A and B were 66.7% and 82.4%, respectively (p>0.05). In Group A, DL and mobility increased with time. The incidence of greater than 3% (slip ≥ approximately 1mm) of an increase in DL on flexion plain film at postoperative 2 year was 61.9%. In case of a patient with persistent LBP, the incidence was 80.0%. In Group B, DL and mobility decreased postoperatively and no significant change in them was noted during the follow-up period. There was no significant difference in the major or minor complication rate between

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**The Effectiveness of Posterior Dynamic Stabilization Using IsoBar TTL Dynamic Rods Combined with Decompression as a Treatment for Elderly Patients with Unstable Grade I L4-S Spondylolisthesis and Spinal Stenosis: A Comparison with Decompression Alone**


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Introduction: One potential use for flexible pedicle-screw-based systems is in a “topping off” fusion montage, in which rigid fixation transitions to flexible fixation at the distal rostral level of instrumentation. It is hypothesized that the gradual transition in flexibility maintains motion at the transition level and helps protect the transition level and adjacent levels from abnormal stresses caused by the fusion that might later lead to degeneration. In this study, the biomechanical behavior of such a construct was compared to rigid and intact conditions through in vitro study of range of motion (ROM), axis of rotation, and facet loads.

Methods: Seven unembalmed human cadaveric L2-S1 segments were used (24-68 years). Specimens were tested (1) intact, (2) after L5-S1 rigid pedicle screw-rod fixation, (3) after L4-S1 rigid pedicle screw-rod fixation, (4) after hybrid fixation with the rigid rod portion spanning L5-S1 and the flexible rod portion (NFlex, Synthes Spine) spanning L4-L5. The order of testing of fixated conditions was varied to avoid bias. Specimens were loaded using pure moments (maximum 7.5 Nm) to induce flexion, extension, lateral bending, and axial rotation while recording motion optoelectronically. Additionally, for kinematic and adjacent level study, specimens were loaded in flexion/extension using a simplified muscle model with a 400-N compressive follower load. Sixteen strain gauges measuring laminar strains were used to extract facet loads at L3-L4 and L4-L5 using a neural network algorithm.

Results: For the hybrid construct, range of motion (ROM) at the transition segment (L4-L5) was significantly reduced relative to normal, and was slightly but significantly greater than the ROM of the rigid 2-level construct during lateral bending and axial rotation (p<0.05, RM-ANOVA/Holm-Sidak, Figure 1). Axis of rotation at L4-L5 was shifted significantly posteriorly and rostrally with rigid 2-level and hybrid constructs (p<0.003), but was significantly farther posterior and farther rostral with rigid 2-level fixation than with hybrid fixation (p<0.02, Figure 2). Both rigid and hybrid fixation altered facet load during flexion and extension at L4-L5 but no construct altered facet loads at L3-L4 significantly.

Conclusions: In a laboratory model using this particular rod system, a hybrid construct allowed transition from rigid to semi-rigid to normal ROM. The effect of this construct on the kinematics of the transition level was less pronounced than with rigid fixation. With no decompression or destabilization at the transition level, this experimental model is expected to demonstrate the smallest difference between rigid and hybrid conditions.
V) were excluded in this study. All patients were evaluated according to radiographic changes at the time of postoperative two years and a final follow-up, and were compared with preoperative data.

**Results:** Both groups did not show any significance in age, gender, follow-up time, preoperative clinical symptoms, and radiographic data related to instability. No pseudoarthrosis was found in all patients. There was one screw loosening inserted into the L3 pedicle in S-group. Radiographically, three patients could be definitely regarded as breakdown of soft stabilization because of tore radiographic markers of artificial ligamentous bands. Preoperative range of motion at L3/4 significantly decreased at the time of postoperative two years and final follow-up in spite of no significant difference between two groups. In both groups, disc height tended to decrease gradually during follow-up periods in spite of no statistical significance. There were one patient showing more than 50 % decrease of disc height in S-group and three in D-group. In MRI study, five patients in S-group and 15 in D-group demonstrated progression of adjacent stenosis. Progression of disc degeneration was also found in 3 patients of S-group and 8 of D-group. Postoperative clinical symptoms were not directly correlated with these MRI findings during follow-up periods. Although clinical outcomes in both groups indicated satisfactory results at the time of final follow-up, we performed additional operations on L3/4 in one patient of S-group and three of D-group.

**Conclusion:** In this study, preventive effects of soft stabilization for transition syndrome in patients who underwent PLIF were demonstrated even in an average of 6-year follow-up. Soft stabilization may be one of the options for prevention of transition syndrome.

**Abstract:**

**Is There a Need for Dynamic Stabilization of the Adjacent-segment to Fusion in Multilevel Degenerative Disc Disease?**

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**Background context:** Adjacent segment degeneration is common after fusion but symptomatic adjacent segment disease is infrequent. Posterior Dynamic Stabilization is often recommended to supplement fusion in presence of multilevel degenerative disc disease, to prevent rapid deterioration of the degenerated adjacent segment. There is no clinical data supporting the need for such adjacent segment stabilization.

**Purpose:** The objective of this study was to explore any clinical evidence to support the indication for adjacent segment stabilization.

**Study design:** This is a prospective study, with independent assessment, comparing the clinical outcome of spinal fusion in presence or absence of adjacent segment degeneration, with minimum 2 years follow-up.

**Methods:** 103 patients (M-57, F-46, Age range 24-66yr) with degenerative low back pain was treated with posterior spinal fusion, following discogram to assess the status of adjacent segment. Fusion of an individual motion segment was selected only when the segment showed positive degeneration (MRi Pfirrmann grade ≥3), and positive pain provocation (≥3 from baseline) as well as abnormal discogram morphology (Adam’s grade ≥3). Clinical improvement of back-pain was assessed at 2-yr follow-up by an independent observer from prospective data. Clinical outcome was classified as successful (patient satisfied, ODI and VAS-back improvement ≥15%, and in SF-36, PCS score improved by ≥ 5 points) or failed, who did not meet all four criteria. Improvement of leg pain alone was not considered a measure of success.

**Results:** Overall success was 68% (n=70). Patients with all the degenerated segments (one to three) fused, and all the remaining segments normal (Pfirrmann I and II) and negative discogram (n=35), had a high (77%) clinical success rate. When one or more segments adjacent to fusion had black disc (Pfirrmann ≥ III), and discogram was negative for pain provocation, success rate dropped to 70.5%. When adjacent segments with black discs (Pfirrmann III or more) showed moderate pain provocation (≤2/10), or discogram morphology was Adams grade ≤3 (n=51), success rate dropped further to 60.7%.

**Conclusions:** Absence of adjacent segment disc degeneration in MRI scan produced a high level of successful clinical outcome following fusion. Presence of adjacent segments degeneration, but negative discogram, produced an inferior clinical outcome. In contrast, presence of disc degeneration, in association with an abnormal discogram finding in the remaining unfused segments predicted poor outcome. The study established that the segments adjacent to fusion should preferably be stabilized, if they are degenerated, particularly with mild pain provocation in discogram.

**INNOVATIVE TECHNIQUES LIGHTNING ROUND**

**Abstract:**

**BoneWelding® Technology: Enhanced Primary Stability for Load Bearing Spinal Implants**

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**Introduction:** The BoneWelding process employs ultrasonic energy to liquefy a thermoplastic interface between orthopaedic implants and host bone. The liquefied thermoplastic polymer penetrates the pores of the surrounding bone and, following a rapid solidification due to immediate cooling, forms a strong and uniform bond between implant and bone. This gives enhanced stability [1], reduces surgical time [2] and has a potential to avoid migration of the implant even in osteoporotic bone [3]. The BoneWelding process uses current resorbable orthopaedic polymers like polylactides. The in vivo safety of the process has been demonstrated in a number of sheep studies for various indications and implant configurations, including pelvis and spine [3]. Clinically, the technology is successfully applied in cranio-maxillofacial surgery (SonicWeld RX, KLS Martin).

The aim of the presented study is to show the potential of the BoneWelding technology to provide enhanced primary stability for load bearing spinal implants, e.g. pedicle screw systems for dynamic fixation.

**Methods:** The biomechanical stability of ultrasonically (20KHz) inserted titanium rods (insertion length 40mm, diameter 5.0 mm, Grade 5, figure 1, lower left) coated with polylactide (PLDLLA 70/30, LR706, Boehringer Ingelheim, Germany) has been compared to bone screws of comparable size. Pullout test were conducted in human cadaver calcaneus brevi (figure 1, upper left). The failure interface has been evaluated by radiographic and optical inspection. Furthermore, the potential of different hybrid designs, compared to classic pedicle screws, was evaluated in a FEM study.

**Results:** It could be shown that a homogenous infiltration of the polymer along the implant can be achieved and that infiltration depth can be controlled by the thickness and volume of the polymer coating. In the calcaneus model, the ultrasonically inserted, coated titanium rods showed...
significant higher pull-out performance than the screw (+100-200%) due to the strong micro infiltration interphase between polymer and trabeculae (figure 1, right). This strong micro infiltration was confirmed in SEM analysis. The FEM study indicated significant reductions for stress levels in the implants (up to 90%) and strains (up to 80%) in the host bone along with increased implant rigidity for bending optimized implant designs.

Conclusions: The improved mechanical performance of implants placed using the ultrasonic insertion process can be attributed to the favourable mechanical micro-environment created by the excellent interdigitation between bone and polymer. The obtained results indicate the great potential of the BoneWelding technology for enhanced primary fixation of pedicle screws as well as other load bearing implants that might profit from additional fixation e.g. intervertebral disc implants.

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A Randomised Placebo-Controlled Trial of Intradiscal Methylene Blue Injection for the Treatment of Chronic Discogenic Low Back Pain
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Background: A preliminary report of clinical study revealed that chronic discogenic low back pain could be treated by intradiscal methylene blue (MB) injection. We investigated the effect of intradiscal MB injection for the treatment of chronic discogenic low back pain in a randomised placebo-controlled trial.

Methods: We recruited 136 patients who were found potentially eligible after clinical examination and 72 became eligible after discography. All had discogenic low back pain lasting longer than 6 months, with no comorbidity. Thirty-six were allocated to intradiscal MB injection and 36 to placebo treatment. The principal criteria to judge the effectiveness included alleviation of pain, assessed by visual analog scale (VAS), and improvement in disability, as assessed with the Oswestry Disability Index (ODI) for functional recovery.

Results: At the 24 month follow-up, both groups differed substantially with respect to the primary outcomes. The patients in MB injection group showed a mean reduction in pain measured by VAS of 5.25, a mean reduction in Oswestry disability scores of 35.58, and satisfaction rates of 91.5%, compared with 0.70, 1.68, and 14.3% respectively in placebo treatment group (p<0.001, p<0.001, and p<0.001 respectively). No adverse effects or complications were found in the group of patients treated with intradiscal MB injection.

Conclusion: The injection of methylene blue into the painful disc is a safe, effective and minimally invasive method for the treatment of intractable and incapacitating discogenic low back pain.

Key words: discogenic low back pain; discography; methylene blue; injection

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Minimally Invasive AxiaLIF L5-S1 Interbody Fusion for Anterior Column Support at the End of a Long Segment Fusion: 1 Year Clinical and Functional Outcome
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Introduction: Long segment fusion to the sacrum has been reported to have a high pseudoarthrosis rate and complications in comparison to fusions ending at L5. Lower pseudoarthrosis rate at L5-S1 has been demonstrated by providing anterior column support at L5-S1. Traditionally this has been performed through ALIF, TLIF or PLIF. Nevertheless this may add considerable amount of operative time and blood loss and could contribute to patient morbidity. We report 1 year results of patients undergoing minimally invasive LS-S1 Trans1 AxialIF fusion in patients undergoing long segment spinal fusion and correction for adult lumbar degenerative scoliosis

Methods: Ten patients have had Minimally Invasive Trans1 AxialIF L5-S1 fusion at the end of a long segment construct. We report on ten consecutive patients with minimum 12-month follow-up. All underwent circumferential long segment lumbar deformity correction with direct lateral transpsoas interbody fusions at the proximal levels. At L5-S1 they all underwent L5-S1 Trans1 AxialIF fusion. Two patients underwent open posterior instrumentation and fusion while 8 underwent percutaneous pedicle screw and rod instrumentation with the CD Horizon Longitude system. Visual Analog Scores (VAS), Treatment Intensity Scores (TIS), SF-36, Oswestry Disability Index (ODI) and radiographs were recorded at preop visit and each follow-up visit.

Results: Average preoperative Cobb angle measured 22.37° (SD 12.32). Average postop Cobb was 7.27° (SD 8.88). Mean follow up was 16 months (range: 12 to 22 months). Preoperative mean VAS and TIS scores were 7.75 and 58 respectively (SD 1.5 and 24.6). Postop mean VAS and TIS scores were 3 and 27 (SD 1.6 and 8.9). Mean ODI preop was 50.67 (SD 17.13); postop was 26.67 (SD 21.7). Mean length of stay was 7.17 (SD 4.35) days. There were no ICU admissions or blood transfusions. There were no intraoperative complications noted with the L5-S1 AxialIF fusion. Solid arthrodesis at L5-S1 as evidenced by bridging trabeculae (and in 3 cases bone across the disc space on CT) was noted in all patients.

Conclusions: AxialIF L5-S1 minimally invasive interbody fusion may be a viable alternative for providing anterior column support for long segment fusions to the sacrum. This procedure may provide similar fusion rates at the L5-S1 disc space while being theoretically associated with less surgical risk when compared with more traditional procedures. These results at 1 year are very promising and we continue to follow these patients.

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Biomechanical Comparison of an Interspinous Distraction Device with a Novel Interlaminar Dynamic Stabilization System in the Lumbar Spine
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Introduction: We investigated a novel form of dynamic stabilization based on laminar hook fixation. Although the biomechanical performance of hook fixation has been well characterized for rigid implants, this new application has three aspects that deserve additional study. First, the hooks will be applied between adjacent lamina which is not a traditional location of this implant. In addition, we will be testing PEEK (poly ether-ether ketone) rod fixation which likewise has not been previously studied (Figure 1). Finally, we will be looking at dynamic stabilization in order to characterize the kinematics of motion restraint. The purpose of this study is to assess the stability afforded by the PEEK rod/hook construct to the laminectomized spine. The interlaminar dynamic stabilization system will be compared with an existing interspinous distraction device, the X-stop®. This is the most appropriate comparative device for three reasons. Both systems are applied to the posterior elements, both are anchored through ligamentous distraction, and both have a very similar surgical approach.

Results: Following the laminectomy, there were decreases in bending stiffness for flexion, extension, and left lateral bending (-30%, -50%, -19%, -22%, respectively; Figure 2). The X-Stop condition was stiffer in extension, flexion and left bending (10%, 146% and 22%), but more flexible in right bending (13%). The PEEK rod/hook was more rigid in all modes of testing (75% for extension, 504% for flexion, 187% for left bending and 47% for right bending). Although there were strong trends showing superiority of the PEEK rod/hook construct in flexion/extension and lateral bending, the small sample size prevented the results from reaching statistical significance.

Conclusions: Interlaminar PEEK rods provided increased stability in all tested motion planes when compared to the other three groups. Further testing will be required to achieve statistical significance. However, the early results suggest clinical significance regarding the device’s biomechanical performance. This device is a novel technique in the expanding area of dynamic stabilization. It combines the ability to decompress the interlaminar space while providing enhanced stability. This device can be applied through a single midline minimally-invasive incision with potential benefits to patients with degenerative spondylolisthesis or spinal stenosis.

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A Study of the Static and Dynamic Biomechanical Properties of Guided Oblique Lumbar Interbody Fixation in a UHMWPE Vertebrectomy Model
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Purpose: To determine the static and dynamic biomechanical properties of guided oblique lumbar interbody fixation (GOLIF).

Background: Oblique transpedicular interbody fixation has been used for stabilization of degenerative spondylolisthesis at the lumbosacral junction. Using a similar technique, guided oblique lumbar interbody fixation (GOLIF) involves inserting a pair of screws with robotic guidance through the pedicles of the inferior body that passes diagonally through both endplates to end at the anterior cortical rim of the superior body. Biomechanical properties as assessed by static and fatigue testing in ultra high molecular weight polyethylene (UHMWPE) of this technique has not yet been investigated. The purpose of this study was to determine the static and dynamic biomechanical properties of guided oblique lumbar interbody fixation (GOLIF) using the F1717-04 ASTM protocol.

Method: The tests were carried out with UHMWPE blocks designed with specific modifications to simulate a worst-case scenario according to instructions given by 1717-04 ASTM protocol. The holes for the screws were prepared at an angle of 10° (anterior) and 50° (lateral), respectively. The space between the blocks was set to 20mm and the horizontal distance between the blocks was set to 40mm. The vertebeectomy model sample was assembled using two UHMWPE blocks to simulate lumbar motion segment. Ti-6Al-7Nb 7.0mm by 100mm screws were completely inserted into the blocks. An axial compression rate of mm/min was used for the static test. The yield load was determined by calculating the 2% offset displacement (=0.4) from the active length (20mm). Static torsion was also tested using 30°/min. The yield load for static torsion was determined by calculating 2% torsion of angular displacement. Dynamic compression testing was then carried out at a frequency of 5 Hz. End point of the dynamic test was reached when either failure of

Methods: Five fresh frozen human cadaveric lumbar and lumbosacral spine motion segments were obtained for this investigation (2 L2/L3, 3 L4/L5). The cranial and caudal vertebrae of each specimen was potted in polyester resin and carefully aligned so that the disc was horizontal. Non-destructive flexion/extension and lateral bending flexibility testing was performed on a material test machine. Each specimen was sequentially tested in four conditions: intact, X-Stop, laminectomy, and laminectomy with PEEK rod/hook construct.
The Use of Posterior Minimally Invasive Approach for Corpectomy

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Background context: Lumbar corpectomy has traditionally been performed using an anterior open approach. The authors of this paper describe a minimally invasive posterior approach to this procedure. This approach allows for spinal decompression as well as anterior column reconstruction without the need to enter either the thoracic or abdominal cavities. This approach was used for the treatment of vertebral body tumors, infections, and fractures.

Methods: Using fluoroscopic guidance, a two level MIS TLIF approach including a total facetectomy and discectomy was obtained cranially and caudally to the vertebra. Resection of the vertebral body was then done through the base of the vertebra's pedicle. Following the corpectomy, an expandable cage was placed anteriorly in the inter-vertebral space. Additional posterior instrumentation was inserted using a percutaneous technique bilaterally. Neuropsychiologic monitoring was used throughout the procedure.

Results: Five patients underwent 10 levels of corpectomy in the past 24 months; one patient for a burst fracture, three patients for chronic osteomyelitis, and one patient for a pathologic fracture due to metastatic thyroid carcinoma. One patient underwent a single-level, three patients underwent two-level, and one patient underwent a three-level corpectomy. The estimated blood loss was 3090cc per surgery (range, 250-7000). The average post-operative stay was 26 days (range, 3-86). Two patients experienced a durotomy, both of which were repaired during the procedure. There were no other adverse effects recorded. All patients had resolution of their radicular symptoms following surgery and were doing well at their most recent follow-up evaluations (range, 2 months-1 year).

Conclusions: The use of a minimally invasive posterior approach can be used effectively to perform a multi-level lumbar corpectomy followed by anterior column reconstruction and posterior column stabilization. The described technique allows for completion of the procedure without the need to enter into the abdominal or thoracic cavity, as is necessary with an anterior approach, and with less soft tissue damage than would be expected using an open approach.

Structural Kyphoplasty: A Novel Approach to Vertebral Fracture Repair Using Stackable Wafers
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Introduction: A new implantable device allows controlled directional vertical correction of osteoporotic vertebral compression fractures (VCFs). Stackable PEEK wafers are inserted through a peri-pedicular approach such that reliable endplate restoration and sagittal plane correction can theoretically be achieved. Since the PEEK wafer stack is permanently implanted, the vertebral body correction can be preserved after deployment and throughout the cementing step. Loss of correction prior to cement placement is often noted during traditional balloon kyphoplasty. This study examines the degree of correction, degree of pain relief, and volume of cement used at a single center during its initial trial using this device.

Methods: Surgical perioperative data, clinical outcome data, and imaging were retrospectively analyzed on an initial series of structural kyphoplasty cases at one physician's center. Using fluoroscopic guidance, the vertebrae body was accessed through an oblique, peri-pedicular 45 degree approach to the vertebral body. PEEK StaXx FX wafers of 1mm height were inserted incrementally. Cement sufficient to fixate the wafer stack was then inserted through a needle about the stack.

Results: Twenty-seven osteoporotic VCFs (T 7–L 5) in 23 patients (11 male, 12 female) were percutaneously treated for fracture repair. The mean patient age was 72 years. On average, fractures were reduced with 15 wafers implying 15mm high stacks. A mean of 2.6 cc of cement was injected about the wafer stack after correction of the vertebral deformity. Mean surgical time was 32 minutes. No neurological complications as a result of the device or the procedure were noted. Vertebral augmentation restored an average of 85% lost anterior height and an average of 85% lost central height. Immediate pain relief was equivalent to the clinical experience associated with balloon kyphoplasty.

Conclusions: A controlled, reproducible, and directional correction of VCFs can be achieved with the structural kyphoplasty technique. Height restoration in this initial trial was superior to published reports of balloon kyphoplasty. Because of the volume occupying permanent wafer stack implant, the immediate correction was sustained throughout the procedure and less cement was required.

Initial Clinical Experience With a Novel Vertebral Augmentation Device for Painful Vertebral Compression Fractures
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Introduction: This single-arm, prospective feasibility trial evaluated the preliminary safety and effectiveness of a new vertebral augmentation device (Kiva™ VCF Treatment System, Bevenvenue Medical, Santa Clara, CA) in the treatment of patients suffering painful vertebral compression fractures (VCF). Unlike the traditional balloon kyphoplasty procedure that pushes cancellous bone peripherally to form a repository for bone cement, the Kiva™ device preserves cancellous architecture using a percutaneously-introduced PEEK implant in a continuous loop to form a
nests, cylindrical column. The implant is delivered over a removable guidewire to provide structural support to the vertebral body and a conduit for bone void filler placement. Vertical displacement by the column results in endplate re-elevation and fracture reduction. Bone cement is delivered through the lumen of the implant, which provides contained interdigitation into the cancellous bone thus stabilizing the fracture and minimizing the risk of extravasation.

Methods: Eighteen patients with radiologically-confirmed VCFs between T10 and L5 underwent treatment with the Kiva™ device for persistent back pain symptoms. Study eligibility required a back pain visual analog scale (VAS) score ≥ 5, fracture age < 6 months, and Oswestry Disability Index (ODI) score of ≥ 30%. Patient reported outcomes (VAS, ODI) were repeated at 6 weeks, and 3 months.

Results: The study group (n=18) had a mean age of 71.4 ± 7.8 yrs, body mass index of 27.2 ± 4.2 kg/m² and consisted of 17 females (94%). Mean pain scores declined from 7.6 ± 1.6 at baseline to 2.8 ± 2.0 and 3.0 ± 2.9 at 6 weeks and 3 months, respectively, representing an average 4.4 ± 2.5 unit improvement or approximately 62% overall (p < 0.0001). Mean ODI scores declined from 61.0% ± 11.8% at baseline to 31.7% ± 20.5% and 25.7% ± 21.5% at 6 weeks and 3 months, respectively, representing an average 34.0 ± 17.9 percentage point improvement or approximately 59% overall (p < 0.0001). There were no device-related adverse events.

Conclusions: These 3 month pilot findings, albeit short-term, suggest robust and consistent clinical improvement for pain and function outcomes following this novel vertebral augmentation procedure in patients with painful VCFs. Clinically relevant gains were realized early postoperatively and maintained through 3 months of follow-up. The device could be deployed and implanted without adverse events.
errors less than 2.3% in lateral bending and 2.1% in flexion-extension.

**Conclusions:** A load sensing calibrated ALIF spacer has been developed that incorporates a maximum number of channels while providing function over a range of implant heights. Data from this device has demonstrated sufficient accuracy, and exceptional precision. This device has immediate use in cadaveric testing, providing data previously not attainable, and serves as a novel technological step towards an implantable interbody device with multi-axis load sensing capability. Such a device could provide novel *in vivo* data on anterior column loading measured at the interbody space.