SAS8 ABSTRACT PAPERS

Papers are listed in numerical order (example: 1., 2., 3.) in the index pages.

To view an abstract paper, “click” on the paper title within the index and it will take you to the placement of the full abstract within this document.

All electronic transmissions and attachments thereto, in any form whatsoever, shall remain at all times the property of Spine Arthroplasty Society. The information contained in or attached to this electronic document constitutes confidential information. Any unauthorized disclosure, copying, distribution or dissemination of this information, is strictly prohibited.
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1. Experience in 150 Cases with the TranS1 Minimally Invasive Fusion Technique at L5-S1

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Objective: The TranS1 technique (axialLIF) of access to the L5-S1 interspace is a new and unique approach for surgical treatment of degenerative disc disease at the L5-S1 level. Access is through a small incision (<20mm) at the tip of the coccyx. A cannula is passed through the pre-sacral fat pad in the midline. This space is void of neural and major vascular elements. A 10 mm channel is created through an entry point in the anterior sacrum at the S1-S2 level to gain entry into the central portion of the disc space. The annulus is not violated and its integrity is preserved in this approach.

Method: This is a report of 150 consecutive patients, age range from 19 to 71, treated with the TranS1 technique at the Mayfield Clinic from June 2005 to September of 2007. All patients underwent a pre-operative MRI evaluation of the pre-sacral space to rule out any aberrant vessels and to determine that there were no sacral anomalies to prevent an appropriate trajectory into the disc space. A pre-operative bowel prep was routinely prescribed. The entire procedure was performed with bi-planar fluoroscopy and air was injected into the rectum in all but a few cases to outline the bowel during the procedure. The arthrodesis was accomplished with placement of autograft from the sacral channel, BMP and allograft extenders. The majority of cases were treated with posterior fixation with percutaneous pedicle screws, and more recently percutaneously placed facet screws. A small number of patients were treated with a standalone interbody fusion (an off-label use of the device). A more recent approach, in 18 patients, is a trend to treat in the outpatient setting.

Results: Surgery was successfully completed in every patient as planned. There were no intra-operative complications identified at the time of surgery. One patient did suffer a bowel laceration, not identified at the time of surgery, that presented with a fever and pre-sacral abscess on post-op day four. Air was not injected into the bowel in this case. This was successfully treated with open drainage and diversionary colostomy that was reversed in 90 days. The disc space never became infected. Occasionally a pre-sacral hematoma has been identified on post-operative CT scans. However there were no symptomatic hematomas and none was surgically explored in this group. There were no device related complications or failures and none of the TranS1 screws have been removed. In the first 50 patients in this cohort who have reached a one year follow-up evaluation, 3 cases of pseudarthrosis were identified on thin section multi-planar CT. Only one was surgically treated with a posterior revision of the inter-transverse fusion.

Conclusions: The TranS1 approach to the L5-S1 interspace has been a safe and easily reproducible operation in 150 consecutive cases at the Mayfield Clinic. It has been safely performed in the outpatient setting. The axialLIF procedure is an effective, minimally invasive procedure for L5-S1 arthrodesis. This approach offers intriguing possibilities for an outpatient L5-S1 motion preservation procedure that does not compromise the annulus.

2. 2 Year Clinical Results of X STOP Interspinous Distraction Device in the Management of Symptomatic Lumbar Canal Stenosis

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Aim: To measure the clinical effectiveness of Xstop interspinous distraction device in patients with neurogenic claudication due to lumbar canal stenosis. X stop is a dynamic interspinous distraction device which maintains the spinal segment in flexion thus increases the spinal canal area and foraminal area without causing any significant effect on the kinematics of the spine

Methods: Forty one patients with unilateral or bilateral leg pain due to lumbar canal stenosis, who had significant relief from sitting or flexing the lumbar spine now have completed 2 year follow up. Clinical outcome was assessed by Zurich Claudication Questionnaire (ZCQ), visual analogue score, Oswestery Disability index and SF36 questionnaires preoperatively and at 2 years. ZCQ has three components Symptom severity, physical function and patient satisfaction. ZCQ is considered most precise, reliable and condition specific questionnaire for lumbar spine stenosis with neurogenic claudication (Pratt. et.al Spine Volume 27, Number 1, pp 84-91)

Results: Out of 41 patients 1 patient died due to unrelated causes, 3 patients withdrew from study leaving 37 patients in the study. Thirty five, 33 & 30 patients completed ZCQ, ODI, and SF36 respectively. M:F ratio 18:23. The mean age was 71(53-94). Xstop device was inserted at double levels in 21(51%) and single level in 20 (49%) patients. By 24 months 77% reported improvement in symptom severity, 62% in physical function, 71% were satisfied with the procedure. The overall 51% made a clinically significant improvement. The mean VAS improved by 1.2 from 5.3 to 4.1. The average improvement in Oswestery Disability Index was noted by 12 points from 43 to 31. Average hospital stay for the procedure was 1.6 days. One patient stayed for 10 days for investigation unrelated to the procedure. The results are almost same as the 1 year results previously reported. None of the patients had any major complications.

Conclusions: The results of our study shows that Xstop remains clinically effective by the end of 2 years. Xstop is relatively less invasive procedure which can be performed as a day case procedure without any major complications.
3. A Randomized Trial of Balloon Kyphoplasty and Nonsurgical Care for Patients with Acute Vertebral Compression Fractures: One Year Results

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Background: Balloon kyphoplasty is a minimally invasive treatment for acute vertebral fractures that aims to reduce and correct vertebral deformity by inserting expandable balloon tamps and then stabilize the body by filling it with bone cement. The effect of balloon kyphoplasty on quality of life has not been tested in a randomized trial.

Methods: Patients with up to 3 non-traumatic acute vertebral compression fractures were enrolled within 3 months of diagnosis and randomly assigned to receive either balloon kyphoplasty (N=149) or usual nonsurgical care (N=151). Measurements of quality of life, back pain and function, and days of disability and bed rest and spine radiographs were assessed through 12 months of follow-up.

Results: Compared with those assigned to nonsurgical care, participants assigned to balloon kyphoplasty had 5.2 points (95% CI, 2.9 to 7.4; p<0.0001) greater improvement in the physical component of the SF-36 quality of life questionnaire at one month and 1.5 points (95% CI, 0.8 to 3.8; p=0.2) at twelve months. Those in the balloon kyphoplasty group also had greater improvement in quality of life by the EuroQol questionnaire at one month (4.0 points; 95% CI, 1.0 to 7.0; p=0.0003) and twelve months (0.12 points; 95% CI, 0.01 to 0.22; p=0.025) and improved disability by the Roland-Morris scale at one month (4.0 points; 95% CI, 2.6 to 5.5; p<0.0001) and twelve months (2.6 points; 95% CI, 1.0 to 4.1; p=0.0012). Balloon kyphoplasty patients had less back pain on a 0 to 10-point numeric rating scale at seven days (2.2 points; 95% CI, 1.6 to 2.8; p<0.0001) and twelve months (0.9 points; 95% CI, 0.3 to 1.5; p=0.0034) and reported fewer days of limited activity at one month (2.9 days per 2 weeks; 95% CI, 1.3 to 4.6; p=0.0004) and twelve months (1.6; 95% CI, -0.1 to 3.3; p=0.068). Fewer patients assigned to balloon kyphoplasty took pain medications or used walking aids during follow-up. There was no significant difference in the number of patients with adverse events or serious adverse events in the kyphoplasty and nonsurgical groups. New radiographically detected vertebral fractures occurred in 41.8% of subjects in the balloon kyphoplasty and 37.8% in the nonsurgical group (4% difference; 95% CI -7.5 to 15.6; p=0.5) and were not statistically different. Conclusion: Compared to nonsurgical treatment, balloon kyphoplasty safely improved quality of life and reduced back pain, disability and the use of pain medications and walking aids. Significant improvements in multiple measurements of quality of life, pain and disability continue for at least 1 year. Balloon kyphoplasty did not increase adverse events including the risk of vertebral fractures.

4. Long-Term Outcomes of Minimally Invasive versus Open Transforaminal Lumbar Interbody Fusion: Surgical Results and Outcomes in a Series of 128 Patients

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Objectives: Minimally invasive interbody and pedicle screw instrumentation techniques have become increasingly applied. The purpose of this study is to serve as one of the only comparative surgical, functional, and fusion long term outcome data from patients treated by minimally invasive unilateral transforaminal interbody fusion (MITLIF) versus that of matched group of open TLIF patients.

Methods: This is a nonrandomized, prospective series of patients treated with open or MIS TLIF by a single surgical group, for diagnoses of spondylolisthesis, disc herniations with radiculopathy and/or back pain, and degenerative disc disease in a group with mean age of 48 years. For each MIS procedure, a minimally invasive ipsilateral hemilaminectomy and total facetectomy was performed through a 20mm tubular access for decompression followed by discectomy and oblique interbody graft placement and a single interbody cage placement through the same portal under microscopic, fluoroscopic and EMG surveillance, along with percutaneous segmental pedicle screw instrumentation. Open procedures were done through standard wide dorsal exposure and open instrumentation and cages placement.

Results: There were 34 open and 96 minimally invasive cases of single and two level TLIFs. The average MIS surgical data were as follows: 105 cc/level blood loss, 156 minutes/level surgical time, and total hospital stay of 2.9 days. The open surgical data were respectively 275 cc/level, 206 min/level and 4.2 days stay. On postoperative CT imaging, all but 2 TLIF cages (96% accuracy) crossed midline with pedicle accuracies of grade 0-58%, grade 1-42%, grade 2-8%, grade 3-2%. Accuracies were similar for open cases. Complication rates were 65% higher in the open surgeries with three times more infections, incidence of medical complication and transfusion rate. Mean Oswestry scores were preoperatively 54.7, at 3 months postoperative follow-up 39.5, at 6 months 32.8, at 9months 29.5, and at12months 24.2. Mean back pain scores were preoperatively 61.1, and 9, 8.5, and 8 at 3, 6, and 12 months posteroperatively respectively. ODI and VAS scores were similar for open surgery although VAS and ODI scores were superior at 6 and 12 weeks in the MIS group (p<.01). Of those able to return to full-time work, 58 % of the MIS and 40% of the open group are working at the time of
Conclusions: This is one of the first studies to prospectively demonstrate that MI-TLIF can be performed safely with superior surgical and functional outcomes as compared to open TLIF while still attaining nearly identical radiographic fusion rates in the hands of an experienced minimally invasive surgical group.

5. The Multiple Causes of Atypical Pre-operative Sciatica and Post-operative Dysesthesia: An Anatomic and Approach Related Risk of the Paramedian and Foraminal Approach to the Lumbar Spine

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Purpose: The paramedian and lateral trans-foraminal approach to the lumbar spine has known pitfalls from operating near the dorsal root ganglion. With foraminal endoscopic surgery, however, documentation and visualization of patho-anatomy has identified additional, but lesser known causes of sciatica and post-operative dysesthesia.

Method: Pre-operative and post-operative dysesthesia in patients undergoing endoscopic decompression for painful degenerative conditions of the lumbar spine are prospectively studied and retrospectively reviewed. Inflammatory conditions and patho-anatomy identified with the endoscope recorded in vivo serve as the data base for study. Discogenic pain, identified through intra-operative chromo discography was correlated intra-operatively by evocative chromo discography performed as an integral part of the endoscopic transforaminal decompression procedure.

Indigocarmine dye, mixed 1:10 with Isovue 300, stains degenerative nucleus and foraminal structures in the path of the transforaminal needle. The dye pattern helps differentiate foraminal and intradiscal anatomy. Findings: Post-operative dysesthesia occurred 5-15% of the time in a review of over 1000 consecutive procedures for herniated lumbar discs and painful degenerative conditions of the lumbar spine. The most common pathologic endoscopic finding was inflammatory tissue in the foramen, annulus, and disc. The presence of inflammation in normal tissue denotes pain. This endoscopic finding correlated well with severe back pain and sciatica produced by low pressure low volume discography. Its severity is post-operatively correlated with the extent of thermal annulopasty and the presence of anomalous furcal nerves in the foramen. These "anomalous" nerves in the foraminal zone identified pain generators in vivo that has not been emphasized in the literature. Foraminal branches of either the traversing or exiting nerve (furcal nerves) contribute to the pre- and post-operative symptom complex. Furcal nerves may be difficult to differentiate from a conjoined nerve. Autonomic nerves confirmed by endoscopic excisional biopsy, have also been identified.

Discussion: Working near the Dorsal Root Ganglion is a risk by itself, that is well known risk factor in all transforaminal surgery. Ablation or removal of nerves in the inflammatory membrane results in decreased axial back pain and sciatica, but may also produce a side effect of dysesthesia of varied severity. Furcal nerves, when identified, may be correlated with temporary dysesthesia if ablated. Dysesthesia is usually mild, self limited, and temporary, but a major concern to patients who get it post-operatively. Permanent residuals are rare, but may result in residual numbness and extremity weakness. Post-operative dysesthesia responds well to Lyrica or Neurontin, foraminal nerve blocks, and lumbar sympathetic blocks. Co-morbidities such as peripheral neuropathy, and seizure disorders are additional risk factors.

Conclusion: Post Operative neuropathic pain staying the same or worsening may not be able to be completely eliminated, and is a risk of the endoscopic procedure. Pre-operative Consent should include neuropathic pain, usually transient, but with a possibility of permanent numbness or weakness. A thorough discussion of the risks associated with foraminal endoscopic surgery must be explained to any patient undergoing open or endoscopic foraminal surgery. Knowledge of the effect of foraminal epidural injections intra-operatively, post-operatively, and in the management of post-operative dysesthesia will decrease this adverse side effect of foraminal surgery. The overall risks and surgical morbidity are still less than posterior trans-canal surgery.


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Objectives: Open trans-thoracic approaches, considered the standard in treating thoracic disc herniation (TDH), are associated with significant co-morbidities. We describe a minimally-invasive lateral-extracavitary tubular based approach for disectomy and fusion (MI-ECTDF) to treat TDH.

Methods: In 13 myelopathic patients (5 men, 8 women, mean age: 51.8 years) with 15 non-calcified TDHs, a far-lateral trajectory was achieved by dilating percutaneously to a 20-mm working portal docked on the transverse process-facet junction which then provided a corridor for near total disectomy, bilateral laminotomies, and interbody arthrodesis with
minimal cord retraction. A cohort of 11 demographically comparable patients treated via transthoracic approaches was used as control.

**Results:** Preoperative Frankel grades were B:1,C:4,D:5, and E:3 patients, while at mean of 10 months postop, 11 were grade E, and 2 were grade D. Mean surgical metrics were OR time: 86.5 min, blood loss: 33 cc, and hospital stay: 3.1 days. Complications included 4 transient paresthesias, 1 CSF leak, 1 abdominal wall weakness, and 3 non-wound infections. 1-year postop MRI revealed full decompression in all cases without cage migration. Mean VAS scores at preop, 6 weeks, 3 months and 1 year were 5.6, 4.5, 3.2, and 1.2 respectively. No difference existed in preoperative clinical and radiographic profile of the study and control groups. Compared to controls, the MI-TDF group, achieved superior scores in all metrics (p<.01) except for equivalent 1-year neurological outcomes.

**Conclusions:** Compared to transthoracic procedures, MI-ECTDF effectively decompressed the spinal canal with identical radiographic and clinical outcomes at 1-year, while achieving superior clinical scores in the interim. MI-TDF is, thus our treatment of choice for TDH.

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**Introduction:** Dynamic instability is an important but often unrecognized contributor to chronic low back pain. Although the multifidus muscle is considered clinically important as a lumbar stabilizer, its architectural properties are not completely understood. Detailed cadaveric and in vivo architectural studies show that the human multifidus muscle is designed to produce unusually high forces over short distances. This design is unique as compared to other paraspinal muscles, supporting the hypothesis that the multifidus is the most important dynamic stabilizer of the lumbar spine.

**Materials and methods:** Cadaveric Study: Whole spines (T12 to sacrum) from eight cadaveric specimens were excised en bloc, dissected free of skin and superficial subcutaneous tissues covering the deep spinal muscles, and immersion-fixed. Multifidus muscles were isolated from each vertebral level, permitting measurements of muscle length (Lm), muscle mass and raw muscle fascicle length (Lfraw). Laser diffraction was used to measure fascicle sarcomere length (Ls) thus permitting calculation of normalized fiber length (Lfn), physiological cross-sectional area (PCSA), and the ratio Lfn/Lm. One-way repeated measures ANOVAs were used to compare Lfn and Ls among segmental levels of origin. In Vivo Study: Intraoperative biopsies obtained during spinal surgery were used to determine sarcomere lengths. The position of the spine at the time of biopsy was compared with lumbar spine range of motion obtained from preoperative flexion-extension radiographs to determine their position on the sarcomere length-tension curve.

**Results:** Cadaveric studies showed that average raw Lf for the lumbar multifidus was 4.79 ± 1.01 cm, average Ls was 2.20 ± 0.06 µm, yielding an average normalized Lfn of 5.84 ± 1.07 cm. Average muscle mass was 149.2 ± 11.4 g, average PCSA was 24.8 ± 4.53 cm², and average Lfn/Lm was 0.17 ± 0.8. These architectural data demonstrate that the multifidus muscle is, by a factor of two, the strongest muscle in the lumbar spine. In vivo sarcomere length measurements obtained during spinal surgery ranged from 1.98 ± 0.15 µm in extension/neutral to 2.56 ± 0.10 µm in flexion demonstrating that the multifidus muscle becomes progressively stronger as the spine is flexed forward.

**Discussion:** The architectural design of the human multifidus muscle is to create large forces over short distances. This design is best suited to provide a stabilizer function. This corresponds well its anatomic position on the lumbar spine where it is placed centrally and in direct apposition to the posterior spinal elements. Furthermore, in vivo sarcomere length measurements suggest that the multifidus muscle becomes stronger as the spine is flexed. The forward-flexed posture is known to produce high intradiscal pressures and cause increased low back pain in patients with degenerative disk disease. These results suggest that the multifidus muscle is a major dynamic stabilizer of the human lumbar spine, exerting its maximal effect when the lumbar spine is in its most vulnerable position.
Failed Fusion Surgery treated by Endoscopic Lumbar Decompression & Foraminoplasty (ELDF) - A 3 Year Review

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Background: Recent randomised controlled clinical trials of fusion surgery have demonstrated an inadequate outcome in approximately 30% of interventions. Consequently many require ongoing pain management and Cognitive Behavioural Therapy. Endoscopic Foraminoplasty has been shown to bring benefit in cases of Failed Back Surgery.

Purpose: To examine whether Endoscopic Lumbar Decompression and Foraminoplasty (ELDF) can benefit patients with Failed Fusion Surgery (FFS).

Study design: A prospective study of "ambulatory" Endoscopic Lumbar Decompression and Foraminoplasty.

Patient sample: During 2000, ELDF was performed on 37 males, and 28 females with FFS and a mean age of 58 years (Range: 42-81, SD:10.4) and reviewed at 12, 24 and 36 months. The average preoperative duration of symptoms was 9.2 years (Range: 5-27, SD: 4.2). Patients had undergone 153 previous open operations (Range 1-7, mean 2.4). 10 patients had undergone a caged ALIF, 16 an ALIF and instrumented Pedicle Fixation, 20 an instrumented PLIF with intervertebral caging or mesh, 12 Instrumented Pedicle Fixation alone & 7 uninstrumented posterolateral bone grafting. Further open surgery had been deemed unlikely to be of benefit in their treating centre. 35 had had a multi-level fusion. In all cases Flexion / Extension radiography failed to detect intervertebral micromovement.

Outcome measures: A 50% or greater reduction in back AND leg pain and the Oswestry Disability score deemed the threshold for a good clinical impact (GCI).

Methods: Patients completed a questionnaire containing the Oswestry Disability Questionnaire and a Visual Analogue Pain Score prior to ELDF and at yearly intervals. A single level ELDF was selected by the production of concordant symptoms during Spinal Probing and Discography.

Results: The mean pre-operative pain score of 8.6 (SD: 1.4) was reduced to 3.0, 3.2,& 3.3 over subsequent years. Cohort integrity was 100%, 98% & 92% annually which included 2 deaths. Concordant symptoms were produced by spinal probing & discography at a non operated level in 13 patients. The percentage gain was 63%,50% & 60% annually. Consequently a "GCI" was recorded in 56 patients at year 1, 50 at year 2 and 44 at year 3. By year 3, 2 ELDFs had had to be revised, 1 patient required ELDF for causalgic symptoms and 1 at a level additional within the fusion and 3 at an additional level adjacent to the original fusion. There were no post-operative infections. 7 patients had a flare of symptoms lasting 3 - 8 weeks manifest as back pain and 4 had a transient parasthesiae lasting up to 12 weeks.

Conclusions: Transforaminal ELDF allows many patients deemed inoperable to be offered amelioration over a sustained period. Aware state Spinal Probing and Discography allows the definition of post fusion pain sources and ELGF outcomes demonstrate the importance of foraminal extradiscal pathology in the causation of lumbar axial and referred pain.

Results of the Prospective, Randomized, Multi-Center Food and Drug Administration Investigational Device Exemption Study of the ProDisc®-C Total Disc Replacement versus Anterior Discectomy and Fusion for the Treatment of 1-Level Symptomatic Cervical Disc Disease

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Background: Cervical total disc replacement (TDR) is intended to address discogenic pain and preserve functional motion between two vertebral bodies in patients with symptomatic cervical disc disease (SCDD). TDR may thus prevent long-term subsequent accelerated degeneration at adjacent disc levels. Purpose: The purpose of this trial is to compare the safety and efficacy of the TDR, ProDisc®-C (Synthes Spine Company, L.P., West Chester, PA) to anterior cervical discectomy and fusion (ACDF) surgery for the treatment of one level disease between C3-C7.

Study design/setting: The study was conducted at 13 sites. A non-inferiority design with a 1:1 randomization was utilized.

Patient sample: Two hundred nine patients were randomized (106 ACDF; 103 ProDisc®-C).

Outcome measures: Visual Analog Scale (VAS) Pain and Intensity (Neck and Arm), VAS Satisfaction, Neck Disability Index (NDI), neurological exam, device success, adverse event occurrence, and SF-36 standardized questionnaires.

Methods: A prospective, randomized controlled trial was performed. Patients were enrolled and treated in
10. Comparison of BRYAN Cervical Disc Arthroplasty with Anterior Cervical Decompression and Fusion: Clinical Results of a Randomized Controlled Clinical Trial

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We conducted a randomized controlled multicenter clinical trial involving 463 patients with cervical radiculopathy or myelopathy who met the study’s enrollment criteria. Of these patients, 242 were assigned to the investigational group, which received the BRYAN® Cervical Disc, and 221 patients were assigned to the control group, which underwent a single-level anterior cervical discectomy, decompression and fusion with allograft bone and a cervical locking plate. Patients completed clinical and radiographic follow-up examinations at regular intervals for 2 years after surgery. Analysis of 12- and 24-month postoperative data showed improvement in all clinical outcome measures for both groups; however, at 24 months after surgery, the investigational group patients treated with the artificial disc had a statistically superior improvement in Neck Disability Index scores than the control group (P=0.030). They also had a significantly higher rate of overall success (P=0.012). With regard to implant or implant/surgical procedure-associated serious adverse events, the investigational group had a rate of 1.7% and the control group, 3.2%. There was no statistical difference between the 2 groups with regard to the rate of secondary surgical procedures performed subsequent to the index procedure. Patients who received the artificial cervical disc returned to work nearly 2 weeks earlier than the fusion patients (P=0.016). Results indicate that cervical disc arthroplasty is a viable alternative to anterior cervical discectomy and fusion with cervical disc disease.

The investigational group patients treated with the artificial disc had a statistically superior improvement in Neck Disability Index scores than the control group; the investigational group patients had a significantly higher rate of overall success; and arthroplasty patients returned to work 13 days earlier than fusion patients.

11. Cervical Spine Arthroplasty for the Treatment of Cervical Spondylotic Myelopathy and Clinical Outcome

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Background: cervical spine arthroplasty for the treatment of degenerated disc disorders (DDD) has been performed in many spine centers. The early and midterm clinical outcome and radiological evidence reported in the literature is satisfactory. The majority cases of cervical spine arthroplasty presented in the literature is cervical radiculopathy due to soft disc protrusion. Some authors suggested that the cervical spondylotic myelopathy (CSM) should be a contraindication for the total disc replacement (TDR).

Objective: To study the clinical and radiological outcome of CSM treated with cervical spine arthroplasty.

Method: 121 cases of CSM were treated with cervical spine arthroplasty during the period of Dec.2003 to Jun. 2007. Patient’s age was range 22-62 years old. 99 cases had prosthesis of Bryan Disc and 31 cases had Prodisc-C. There were 103 cases of single-level, 16 cases of double-level and 2 cases of three-level TDR with total 141 disc replaced in this
clinical outcome was assessed with JOA 17 score scale and Odom’s criteria. Radiological assessment including range of motion and heterotopic ossification of operated level were recorded.

**Result:**

1. **Pathology:** There were 54 discs that had only soft disc protrusion compressed on the spinal cord with posterior longitudinal ligament intact and 45 discs that ruptured causing severe spinal cord compression. There were 42 discs protrusion complicated with osteofyte formation causing spinal cord compression. 23 cases had developmental stenosis of cervical spinal canal (on X-ray) but only had anterior spinal cord compression (on MRI). There was no case of ligamentum flavum impingement into spinal canal.

2. **Clinical outcome:** 89 out of 99 cases with Bryan Disc prosthesis obtained follow-up ranging 12 to 40 months. 26 out of 31 cases with Prodisc-C prosthesis obtained follow-up ranging 6 to 12 months. Pre-operative JOA score was 8.5 and post-operative one was 15.5 on average. According to the Odom’s criteria 75 cases had an excellent outcome, 32 good, 8 fair, and no case of poor result in total 115 cases at final follow up. Patients were discharged 4 days (2 to 6 days) with soft collar protection for 8 days (5-12 days) after the operation. There was no subsidence of implant and no worsening of pre-operative symptoms.

3. **Radiological result:** Motion was observed at operated level in most of cases at final follow up. The heterotopic ossification (HO) around the prosthesis was observed in 7 cases and only 1 case lost movement in single-level Bryan Disc replacement. There were 3 HO cases found in double-level Bryan Disc replacement and only 1 case lost movement. There was no HO case found in three-level Bryan Disc replacement and Prodisc-C replacement. 23 patients who had developmental stenosis of cervical spinal canal on X-ray had no more spinal cord compression on MRI after the surgery.

**Conclusion:** Cervical spine arthroplasty for the treatment of CSM will offer a satisfied clinical and radiological outcome. The heterotopic ossification may relatively easily occur in the cases with Bryan Disc prosthesis.

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12. **Cervical Facet Degeneration after Total Disc Replacement 272 levels in 158 Patients. 4 Years Follow up**

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**Introduction:** Many information and classifications about lumbar facet joint degeneration after lumbar total disc replacement are available, but nowadays in the cervical spine this concept is unknown. We show our experience and propose a MRI classification to evaluate a degenerative facet joint disease after cervical arthroplasty in four years follow up.

**Methods:** After 4 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 in the operated levels using MRI, and we compared with preoperative images. MRI, 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 MRI images, we found four different stages of facet degeneration. For this propose, we propose a MRI 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 MRI facet degeneration and clinical results in these stages, except in grade III and IV that outcomes scales had a worsening.

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13. **Factors Affecting Re-Operations after ACDF within and outside of an FDA IDE Cervical TDR Trial**

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**Introduction:** Anterior cervical discectomy and fusion (ACDF) has been considered standard treatment for symptomatic cervical spondylotic. More recently cervical total disc replacement (TDR) has been performed with proponents claiming that maintained motion at the operated level will reduce the incidence of adjacent level degeneration and improve clinical outcomes compared to ACDF. The excellent clinical results of the USA FDA trial for the first approved cervical TDR (Prestige, Medtronic) have been published. In this prospective, randomized study, superiority of TDR was claimed with 12.1% of control ACDF patients requiring additional related cervical surgery within 2 years vs. 2.9% receiving the
Prestige TDR. This rate of re-operation within 2 years after ACDF seems alarmingly high. The goal of the current study was to assess the rate of re-operation within 2 years of ACDF in a cohort of patients receiving the fusion as part of their customary care and therefore not enrolled in an IDE study.

Methods: At our institution, 193 patients with spondylotic radiculopathy or myelopathy underwent ACDF by 3 surgeons between 2001 and 2005. All patients had at least 2 years of follow-up with final follow-up within 6 months of completion of this study. Review of medical records was completed to determine the number of patients who had undergone a revision cervical procedure at the same or adjacent level.

Results: At final follow-up, complete data was available for 176 ACDF patients. Of the 64 patients who underwent single-level ACDF at the authors' institution and would have met criteria for inclusion in the Prestige IDE TDR study, two patients (3.1%) required additional surgery within 2 years (duration of follow-up of Prestige study) with both patients requiring adjacent level fusion. Of the 176 patients who received single or multi-level ACDF’s, at a mean follow-up of 3.5 years, twelve patients (6.8%) had undergone revision cervical surgery with three patients (1.7%) undergoing same-level revisions (posterior fusion) and nine patients (5.1%) undergoing adjacent anterior level fusions. Patients who underwent revision same level surgery typically had the intervention within the first year (mean: 11 months) whereas those requiring adjacent level fusions typically had surgery later (mean: 29 months).

Conclusions: The current study identifies a 3.1% rate of repeat surgery within 2 years of a single-level ACDF performed during routine clinical practice which is substantially lower than that reported in the control ACDF arm of the Prestige FDA trial (12.1%). Even with longer follow-up of more complex (multi-level) cases, our re-operation rate (6.8%) compared favorably to the IDE rate. This discrepancy may reflect different thresholds for re-operation in the control arm of a device IDE study when compared to routine clinical practice. Additionally, patients enrolled in the single-level only FDA trial may have in fact received multi-level procedures outside of the study. This discrepancy may result in a higher rate of short-term, adjacent level fusions. These data suggest that we need to better understand factors driving treatment and in particular decisions to re-operate in the context of an FDA device trial.

14. Serum Metal Levels in Patients with Stainless Steel Metal-on-Metal Cervical Disc Replacements

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Introduction: Total disc arthroplasty is a recent alternative treatment to fusion for degenerative disc disease. All joint replacement implants will generate some degree of wear particles in vivo. For example, in metal-on-metal total hip replacements, corrosion and wear results in elevated levels of cobalt and chromium in the serum, erythrocytes, and urine [1,2]. This study examines the serum chromium (Cr) and nickel (Ni) levels in patients with stainless steel (SS) metal-on-metal cervical disc replacements.

Methods: This is a prospective, longitudinal study consisting of a group of twenty-five patients implanted with the PRESTIGE® Cervical Disc (Medtronic, Memphis, TN). This system consists of a 316L stainless steel (ASTM F138) metal-on-metal ball-in-trough articulation. Serum samples were collected pre-operatively and at 3, 6, and 12-months post-operatively. Serum was assayed for Cr and Ni using a high-resolution inductively-coupled plasma-mass spectrometer (Element2, Finnigan MAT, Germany). The detection limits were 0.015 ng/mL for Cr and 0.17 ng/mL for Ni. Values below the detection limits were assigned a value of half the detection limit. Longitudinal statistical comparisons were made using the Friedman test.

Results: The median serum Cr levels at pre-op, 3, 6, and 12 months were 0.075, 0.11, 0.13, and 0.17 ng/mL, respectively. The median serum Ni levels were 0.085, 0.18, 0.22, and 0.18 ng/mL at the same time points. For Cr, the difference was statistically higher (p<0.01) between serum levels at the 3, 6, and 12-month time periods compared with pre-op levels. In addition, the 6-month Cr levels were statistically higher (p<0.01) than the 3-month levels and the 12-month levels were statistically higher (p<0.01) than the 6-month levels. For Ni, the serum levels were statistically higher (p<0.02) at 6-months than at 3-months; differences between Ni levels at other time points were not statistically significant. Generally, the values for Ni were low with many samples having levels below the detection limit (13, 12, 8, and 12 samples at pre-op, 3, 6, and 12 months, respectively). It is interesting to note that the median serum Cr values were an order of magnitude lower than those from a group of patients with cobalt-chromium (CoCr) alloy metal-on-metal surface replacements of the hip and total hip replacements at comparable time intervals [1]. This is consistent with the lower service loads and sliding distances of the cervical spine compared with the hip and the different Cr concentrations between SS (18% Cr) and CoCr alloy (30% Cr). Compared with reported metal ion data for patients with posterior spinal arthrodesis with stainless steel instrumentation [3,4], the cervical disc cohort showed up to an order of magnitude lower Ni and Cr metal ion levels.
Conclusions: These results indicated that short-term metal levels are lower than those observed in SS posterior spinal instrumentation and CoCr alloy metal-on-metal hips. Continued surveillance of this patient cohort is ongoing and will provide longer-term follow-up data for this cervical disc replacement system.

References:
[1] Skipor et al, ORS, 2004;

15. Comparison of Secondary Operations between Arthroplasty and Anterior Cervical Fusion

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Introduction: Secondary operations after anterior cervical discectomy and fusion often result in prolonged disability and increased costs. One of the theoretical advantages of cervical arthroplasty over arthrodesis is that preservation of motion decreases stress on the adjacent levels which should result in fewer re-operations at other cervical levels. If adjacent segment degeneration is decreased by arthroplasty then fewer surgeries at adjacent levels will be necessary. Furthermore, avoiding arthrodesis eliminates reoperations for pseudarthrosis and other complications related to bone graft and instrumentation. For these reasons we hypothesize that secondary cervical spine procedures occur less frequently in patients treated with cervical arthroplasty. The aims of this investigation are to compare rates of additional cervical spine procedures in patients with single-level radiculopathy or myelopathy who were randomized to decompensation with arthrodesis or decompression with arthroplasty from a large prospective multi-center investigation.

Methods: Two prospective randomized controlled trials were performed to evaluate the safety and efficacy of the Bryan and Prestige cervical disc replacements compared to fusion. All patients who underwent a cervical re-operation, either at the index level or at another level for whatever reason, were included in this study. The number of re-operations for both groups were tabulated, and the reasons for the re-operations as well as the time from the index operation, was noted.

Results: No statistically significant differences in demographics or disease state between control and investigational groups were present at baseline. Significantly more re-operations occurred in the arthrodesis group as compared to the arthroplasty group, 48 (8.8%) compared to 25 (5.0%), p<0.0001). In the fusion group, a total of 29 patients had 32 operations at the index level, while in the arthroplasty group, 18 patients had 18 operations. The difference was highly statistically significant (p<0.001). At the adjacent level, 19 fusion patients had 20 operations while 9 arthroplasty patients had 10 operations. This difference too was highly statistically significant (p<0.001).

Discussion: The purported advantages of cervical arthroplasty over arthrodesis include preservation of motion, and the potential for decreased adjacent segment degeneration. While arthroplasty has been shown to preserve motion in a number of studies, there are few studies that have demonstrated that arthroplasty results in fewer operations at the adjacent segment as compared to arthrodesis. We undertook this study to compare re-operation rates following arthroplasty versus arthrodesis in a large group of patients who were part of two prospective, randomized, controlled, multi-center studies with a minimum two-year follow-up. To our knowledge, this is the first such study.

We found definite evidence that arthroplasty reduces the need for additional operations both at the index and the adjacent levels.

16. Heterotopic Bone Formation and Secondary Fusion after Cervical TDR with over 24 Months Follow-Up

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Purpose: The Mobi-C® cervical disc prosthesis is a second generation, three-piece, non-constrained device, designed to replicate the normal disc motion. The purpose of this study is to assess the safety and efficacy of Mobi-C® and to evaluate the onset of segmental heterotopic ossification (mobile) or fusion (non mobile).

Methods: 35 patients, included in a prospective study on Mobi-C® across 8 sites in France, have achieved their 24 months follow-up control. Indications were disc herniation and/or neurologic compression causing radiculopathy and/or myelopathy at one or several levels between C3 and C7. Efficacy was assessed by auto-evaluation, including Neck Disability Index (NDI) and SF-36 scores, Visual Analog Scale for cervical and arm pain, and Satisfaction Index.
Complications, analgesic requirements, employment status were also documented. X-rays and Ranges of Motion (ROM) from flexion/extension views were analyzed.

Results: Average age of patients was 44 years (23-66), with 43% of men. Single-level implantation concerned 30 patients and 5 patients were operated on at two levels. Mean VAS for cervical pain decreased from 61.3pts to 21.5pts after 2 years (p<0.05). Arm pain also decreased significantly (70.9pts pre-operatively vs 25.2pts post-operatively, p<0.05). Functional improvement was relevant, with NDI score decreasing from 49.9% pre-operatively to 26.6% after 2 years (p<0.05). Consistent with pain decrease and functional improvement, SF-36 quality of life score showed significant improvement with mean PCS increasing from 37.3% pre-operatively to 48.5% after 2 years and mean MCS increasing from 35.2% to 48.2%. Finally, 64% of the patients experienced an improvement of the NDI score of at least 15pts compared to pre-operative value, and 78% had an improvement of the VAS cervical pain of at least 20pts. 85% and 76% of patients declared satisfaction regarding cervical and arm pain respectively, and 96.6% would undergo the surgery again. Mean duration of sick leave after surgery was 2.8 months. Only 7% of patients were on sick leave one year after surgery, vs 53% pre-operatively. 97% of the population was under analgesic treatment before the surgery vs 18% after 2 years. There was no migration, no subsidence and no sub-luxation of the implant. Mean ROM was 8.8° (range 0-25) post-operatively, with 93.6% and 88.9% of the prostheses having a ROM superior or equal to 2° and 5° respectively. Heterotopic ossifications have been reported on 11/40 implanted levels (8 patients): 8/40 calcified segments are still mobile (20%), and 3/40 are fused (7.5%).

Conclusion: The study demonstrates an excellent safety profile with no reported device-related complications. Both the pain decrease and functional improvements occurred within 1 month and were maintained over 2 years. The Mobi-C® prosthesis is a very promising device with a simple implantation technique. The absence of keels or screws allows both single and multi-level implantation, achieving excellent stability of the implant. Radiological evaluation has shown in most cases a long-lasting restoration of the segmental motion. Though secondary fusions are to deplore at latest follow-up, the fusion rate is often related to inaccurate implant sizing or positioning, and should decrease with surgical experience.

17. Bryan Cervical Disc Prosthesis: 5 Years Follow-Up
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Purpose: The replacement of moderately degenerated cervical discs by mobile artificial prostheses, instead of interbody fusion, is supposed to maintain segment motion and to prevent increased stress on the adjacent segments. The aim of the study was to evaluate retrospectively the efficacy of the Bryan cervical disc prosthesis using radiological and clinical parameters.

Methods: In 2001 and 2002 20 patients with 26 symptomatic cervical disc herniations were selected for artificial disc replacement surgery. All segments showed significant motion. The series included 13 male and 7 female patients with an age range between 37 and 64 years. All patients received nonsteroidal anti-inflammatory medication for at least 10 days and underwent routine follow-up with ap, lateral, flexion and extension x-rays, which were analyzed for size and position of the implant and for heterotopic ossification, fusion and motion of the segment and evidence of adjacent segment degeneration. The clinical outcome was monitored with the Neck Disability Index and VAS.

Results: 5 segments were not suitable for implanting the Bryan artificial disc: 3 due to poor bone quality with loosening of the scaffolds anchor pins, 1 with insufficient x-ray conditions and 1 with iatrogenic instability. Artificial discs were implanted in single level (9), two segments (2), three segments (2) and in combination with adjacent fusion (2). All implants were in proper position. No subsidence or dislocation occurred. The size was adequate, except of three segments with a larger diameter than the biggest available implant (18mm). 1 patient died after the 3 year follow-up from oesophageal cancer. At that time he showed grade III ossification. 4 patients had subsequent cervical spine surgery: 2 revision and fusion, 1 revision and fusion + adjacent segments, 1 decompressive laminoplasty because of posterior osteophytes and adjacent segment degeneration. The 5 reoperated segments had grade IV ossification at the time of surgery. At the 5 year follow-up frequent heterotopic ossification was observed: grade 0: 2 segments, grade I: 0, grade II: 1, grade III: 3, grade IV: 9. 3 segments are in a severe kyphotic position. Mean Neck Disability Index improved to 32, VAS for neck-pain to 35. No significant correlation between clinical outcome and ossification was observed. Patient’s self-assessment provides a very good result in 2, a good in 4, an average in 4 and a bad result in 6 cases.

Conclusion: The results indicate that the Bryan artificial cervical disc can maintain motion only in a limited number of cases. Probably the surgical technique for the preparation of the implant-bed with bone-drilling might be a cause for the high fusion-rate compared to other cervical prostheses. The potential benefit of motion-preservation must be confronted with the high revision-rate and the disadvantages of the more invasive approach and the increased implant cost compared to interbody fusion.
18. Consequences of Athletic Activity in the Lumbar and Cervical Total Disc Replacement: A Multi-Center Non-Randomized Prospective Study

**Study design:** Prospective, non-randomized, longitudinal, multi-center, minimum 2 year follow-up

**Objective:** To evaluate the consequences of differing levels of athletic activity on the clinical and radiographic outcomes of lumbar and cervical disc arthroplasty.

**Background:** The influence of athletic activity on the clinical and radiographic outcomes of lumbar disc arthroplasty has not been evaluated to the best of our knowledge.

**Methods:** The prospective records of 3 major arthroplasty centers in 3 continents (North America, Europe, and Australia) were analyzed for the pre-operative and post-operative athletic activities of lumbar and cervical total disc replacement (TDR) patients. Athletic activities prior to the onset of spinal injury, after the onset of spinal injury, and post-TDR surgery were assessed. Activities were classified professional vs. amateur as well as into contact/vigorous, moderate, and light in terms of effect on involved spinal segments. Complications were assessed both radiographically as well as clinically.

**Results:** Lumbar. A total of 1003 lumbar patients full-filled all follow-up criteria including 2 year follow-up. There were 255 Charite and 748 Prodisc prostheses. Of the Charite discs 56 participated in sports prior to spine injury. Following TDR, 48/56 participated in athletic activities (22 contact/vigorous, 11 moderate, and 15 light). Five were professional and 43 were amateur. There were no implant complications. Five patients complained of radiculopathy symptoms during participation. No implant related complications occurred during any type of activity. Of the Prodisc cases 172 participated in sports prior to spine injury. Following TDR, 158/172 participated in athletic activities (34 contact/vigorous, 27 moderate, and 97 light). Eight were professional and 150 were amateur. Seven patients complained of radiculopathy symptoms during participation. Three L5/S1 subluxations occurred with heavy weight lifting and 1 implant loosening occurred after a bike injury.

**Results:** Cervical. A total of 210 cervical patients full-filled all follow-up criteria including 2 year follow-up. There were 45 PCM discs and 167 Prodiscs. Of the PCM discs 18 participated in sports prior to spine injury. Following TDR, 8/18 participated in athletic activities (3 contact/vigorous, 5 moderate, and 0 light). Three were professional and 5 were amateur. There were no implant complications. No implant related complications occurred during any type of activity. Of the Prodisc cases 138 participated in sports prior to spine injury. Following TDR, 87/138 participated in athletic activities (16 contact/vigorous, 47 moderate, and 24 light). None were professional. No implant complications occurred.

**Conclusions:** Athletic activities of varying degrees appear to be well tolerated following both cervical and lumbar TDR surgery in single and multi-level cases. Contact-vigorous athletic activities do not appear to result in high levels of clinical or radiographic complications in the lumbar TDR patients except for heavy weight lifting activities in patients who have undergone L5/S1 Prodisc surgery in which we experienced 3 PE subluxations. In our limited number of cervical TDR patients who were involved with contact-vigorous activities, no implant complications occurred in either implant type. Further biomechanical and clinical studies are necessary before general recommendations can be made.

19. Results of a Prospective, Randomized, Multi-Center Clinical Trial of PCM Cervical Disc Replacement: Two Year Clinical Outcomes

**Purpose:** The use of Cervical Disc Replacement for surgical treatment of cervical radiculopathy or myelopathy, particularly adjacent to previous cervical fusion, has become a promising alternative to anterior cervical discectomy and fusion (ACDF). Preliminary results are reported from five sites in a prospective randomized study comparing PCM and PCM-V disc replacement to ACDF for the treatment of symptomatic cervical spondylosis, including in “training” cases, myelopathy and at levels adjacent to previous fusion.

**Methods:** Study inclusion criteria identified patients between 18 and 65 years old with single-level symptomatic cervical radiculopathy and/or myelopathy unresponsive to at least 6 weeks of non-surgical therapy, or experiencing progressive neurological symptoms. Patients may have had a successful previous single level ACDF. Each site was entitled to enroll up to four initial non-randomized “training” PCM cases. Thereafter, enrolled patients were randomized to receive either...
PCM/PCM-V disc replacement or ACDF using structural allograft and plating, and were blinded to their assignment until after surgery. At the five centers, 226 patients were enrolled. Of these, 18 training, 65 PCM, and 36 control patients and five training, 18 PCM, and eight control patients have completed one- and two-year follow up visits respectively. Neck VAS, arm VAS, and Neck Disability Index (NDI) scores, as well as all complications and adverse events were recorded at various follow up intervals.

**Results:** Analysis revealed no significant differences in patient demographics between the PCM “training”, PCM, or control groups. Clinical outcomes for each group are as follows:

**Clinical Outcomes (Preoperative/6wk/12wk/26wk/1yr/2yr):**

<table>
<thead>
<tr>
<th>Measure</th>
<th>Training (N=214)</th>
<th>PCM (N=574)</th>
<th>Control (N=574)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDI:</td>
<td>28/15/14/11/13/12</td>
<td>28/16/13/12/10/12</td>
<td>28/20/16/14/15/18</td>
</tr>
<tr>
<td>Arm VAS:</td>
<td>69/27/31/27/31/30</td>
<td>69/31/27/27/22/30</td>
<td>75/38/35/34/33/33</td>
</tr>
<tr>
<td>Neck VAS:</td>
<td>70/21/22/19/28/28</td>
<td>72/27/25/24/24/39</td>
<td>75/29/33/32/29/37</td>
</tr>
<tr>
<td>Subsequent surgery performed</td>
<td>1/19 (5.2%)</td>
<td>3/117 (2.6%)</td>
<td>2/90 (2.2%)</td>
</tr>
<tr>
<td>Implant migration</td>
<td>1/136 (0.7%)</td>
<td>0/136 (0%)</td>
<td>0/136 (0%)</td>
</tr>
</tbody>
</table>

**Results:** Duration of surgery differed significantly (p=0.001) for the PCM “training”, PCM and control groups at 116, 88 and 71 minutes respectively. Adjacent level concerns were reported in 3/136 (2.2%) disc replacement cases and 6/90 (6.7%) control group patients. Other complications, including reports of post operative neck or arm symptoms were comparable between groups. While adverse event reports were higher, clinical outcome scores for patients with previous fusion surgery receiving disc replacement were comparable to those without.

**Conclusion:** Cervical disc replacement with the PCM and PCM-V implants is safe and effective in the short term for the treatment of degenerative cervical radiculopathy and myelopathy in patients with up to one level of previous ACDF surgery. When compared to ACDF in a prospective and randomized fashion, duration of surgery is longer, especially in initial cases, but preliminary outcomes demonstrate comparable complication and adverse event rates, and trend toward quicker resolution of symptoms within the first 6 weeks of surgery and lower NDI scores at the later postoperative intervals.

### 20. Absence of Bias between Non-Randomized and Randomized Cases in Three Prospective Randomized FDA Studies of Cervical Disk Replacement-788 Cases

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**Introduction:** This is the largest prospective randomized analysis of cervical arthroplasty (Kineflex-C, PCM, Secure-C) ever compiled - Level I Study = 788 total subjects. These were the only three IDE studies on cervical arthroplasty which had both 1) utilized training cases and 2) completed enrollment so there was no study selection involved. The goal was to perform the appropriate “intent to treat” analysis in a randomized prospective FDA IDE trial with non-randomized initial (training) cases followed by randomized cases when both clinically validated and non-validated regulatory outcome measures are collected. Enrollment differences or bias between 1) the initial non-randomized and 2) the randomized portion of clinical study groups could potentially prevent the pooling of these two “new” technique groups prespecified in the randomization scheme of the study.

**Methods:** The complete to date data (788 patients) from three prospective randomized FDA IDE studies on cervical arthroplasty (Kineflex-C, PCM, Secure-C) was analyzed (non-randomized (N=214) and randomized subjects (N=574)).

**Results:** Age, gender, and vertebral levels of surgery were similar between the groups. Height = 100% (98.5% to 101.5%); weight = 101.2% (97.7% to 104.9%); BMI = 102% (99.2% to 104.9%); Baseline NDI = 100.7% (97.0% to 104.4%) and Baseline VAS = 100.8% (90.2% to 112.6%). The mean baseline VAS was (71.8±19.94 and 71.0±20.82), and the NDI (60±12.57 and 59.5±12.12), for the non-randomized and randomized cases respectively. A learning/experience effect was observed: surgery time improved from 106 minutes ±40.8 from the early non-randomized cases to 84.3 minutes ±34.4 (p < .0001) for the randomized cases and EBL improved from 61.3 cc ±50 to 50.6 cc ± 39.9 (p = .02) consistent with surgeon experience in all new procedures.

**Conclusions:** Such uniform consistency is rarely encountered to this degree in prospective randomized trials. The “intent to treat” analysis of the entire study for validated clinical scales and complications can be performed on the pooled non-randomized and the randomized “new” device patients. This analysis can then be compared against the reference group, even though for regulatory purposes only the randomized subset of data was planned to test the non-validated FDA scale. The concept of an initial set of non-randomized (training) cases should be considered as not being inherently biased and can be pooled with the randomized group of the “new” device for the safety and validated clinical scale outcome analysis. This statistical approach is useful in prospective randomized clinical surgical trials to decrease the total number of patients entered. The analysis maximizes the use of a larger number of patients to get a more accurate picture of the true device related complication rate.
21. Heterotopic Ossification at the Index Level after ProDisc®-C Surgery: What Is the Clinical Relevance?
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Introduction: Heterotopic ossification (HO) has been defined as the abnormal formation of new bone at joints and within soft tissue. HO is a multi-factorial bodily response. It has been reported after trauma, surgery, and peripheral events. Causal theories of HO include genetic predisposition, muscle and tissue damage, surgical implantation technique, and peri-operative measures. The incidence of HO following cervical total disc replacement (TDR) should be interpreted based on a classification system of clinical and motion relevance (as proposed below) rather than the current radiograph based system. The authors retrospectively investigated the clinical relevance of HO in patients treated with the ProDisc®-C TDR.

Methods: 117 patients treated with the ProDisc®-C TDR were retrospectively evaluated at 2-5 years post-surgery. Radiography determined the presence of anterior ossification. Patients can be classified without a CT scan or MRI. HO was assessed according to a clinical classification system: C0 - ossification present but not clinically relevant; C1 - ossification present and clinically relevant, based on no improvement in Neck Disability Index (NDI) scores; M0 - ossification present but not motion relevant; M1 - ossification present and motion relevant, based on Range of Motion (ROM). Patients were rated using a combination of these four classifications. Those patients classified as having C1 ossification had significant clinical consequences.

Results: At 2-5 years post-surgery, radiographic evaluation of ProDisc®-C patients identified 9.4% as having HO. The mean flexion/extension (F/E) ROM for HO patients was comparable to the mean F/E ROM for the entire group of patients. Of these HO patients, none were classified as C1 based on their NDI scores. Although HO may exist on radiographs, the clinical relevance of such findings in and of themselves is inconsequential. Patients not classified as C1 were not experiencing greater pain associated with HO, nor was there a statistically different range of motion as a result of the HO formation in comparison to the remaining patient population.

Conclusions: HO formation following cervical TDR appears to be a result of surgical technique. HO may be prevented by peri-operative interventions, including: using pharmacological agents such as NSAIDS, Indomethacin, or Diphosphonates; rinsing the surgical site to remove bone fragments; reducing retraction forces on the lungus colli muscle to lessen soft tissue trauma; reducing bone surface by using the largest appropriate device footprint, cutting off the rim of the vertebral body, and using bone wax to seal surfaces; and by positioning the center of rotation at least to the 50% margin (area of equilibrium).

22. Finite Element Analysis of Cervical Spine Following Bilevel Fusion, Bilevel Total Disc Replacement and Fusion plus Total Disc Replacement at Adjacent Levels
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Introduction: Motion preservation devices such as artificial discs are being pursued because of the aim to preserve physiological motion of the cervical spine. As TDRs gain popularity, different combinations of TDR and fusion will possibly be performed in patients. For example, one patient may have bi-level TDR (BTDR) while another may have fusion plus TDR (F+TDR) at adjacent levels. The aim of the present study is to investigate the biomechanical differences among the above surgical procedures using a ball and socket type disc implant.

Methods: Three different finite element models were created by modifying the current experimentally validated C3-C7 model to incorporate all three surgical procedures. In the first model, to simulate the bilevel fusion (BLFu), bone grafts were placed at the C4-C5 and C5-C6 disc spaces following the removal of intervertebral discs at the respective levels. The bone grafts consist of a cancellous core which is surrounded by a cortical layer. In the F+TDR model, the bone graft at C5-C6 level was replaced by a ball and socket type disc implant (DMT, Inc, Florida) while the bone graft at the C4-C5 level was retained. For the third model, both the bone grafts at C4-C5 and C5-C6 levels were replaced by disc implants, simulating BTDR scenario. The intact model was loaded with 75N of follower load using a set of springs. A moment of 1.5 Nm was also applied to simulate physiologically relevant flexion and extension motions of the intact spine. However, for the BLF, BTDR and F+TDR models, a hybrid protocol (displacement control protocol) was employed for load application.

Results: BLFu model required 4.1 Nm of extension moment to achieve the same C3-C7 motion as predicted for the intact spine. For F+TDR and BTDR models, these moment values were 1.05Nm and 0.8Nm, respectively. Compared to the intact spine, the C3-C4 and C6-C7 extension motions increased by more than 100% in the BLFu model. The corresponding motion changes in the F+TDR model were only -1% and -9%, respectively. However, for the BTDR model,
the corresponding changes were -40% and -37%, respectively. BLFu, F+TDR and BTDR models required 3.4Nm, 1.2Nm and 1.5Nm of flexion moments, respectively to achieve the flexion intact motion. C3-C4 and C6-C7 flexion motions increased by approximately 100% in the BLFu model, as compared to an intact model. Corresponding motion changes in F+TDR model were 36% and 22%, respectively, as compared to intact. In the BTDR model the corresponding motion changes were 5% and -6%, respectively.

**Discussion:** The BLFu restricts the motion at fused levels while significantly increasing the motion at adjacent levels. BTDR preserves the motion by redistributing it over all the segments. BTDR can potentially prevent the excessive adjacent level degeneration by mimicking the kinematics similar to intact spine. F+TDR model also reduces the higher adjacent level motion by yielding greater motion at the TDR implanted level. BTDR and F+TDR models provide biomechanics closer to intact spine for ball and socket type TDR.

### 23. Kinematics of Cervical Total Disc Replacement Adjacent to a Two-Level, Straight vs. Lordotic Fusion

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+ M. Tzermiadianos
+ R. Havey
+ S. Kenner
+ G. Carandang
+ C. Abjornson
+ A. Patwardhan

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**Purpose:** Anterior cervical discectomy and fusion (ACDF) is considered the gold standard for treatment of symptomatic cervical degenerative disc disease. However, fusion of cervical segments may result in progressive degeneration of adjacent levels in the cervical spine. Cervical total disc replacement (TDR) may be a promising alternative to fusion of a symptomatic adjacent level after prior cervical fusion. However, little is known about the behavior of a TDR in this setting. The aims of this study are to characterize the response of a cervical TDR above a 2-level fusion, and to study the effect of fusion alignment the on the response of the TDR.

**Methods:** Eight fresh-frozen human cadaveric cervical spine specimens (C2-T1, age: 59±8.6) were tested (i) first intact, (ii) after a simulated 2-level fusion at C4-C6 first in lordotic alignment (3.5 degrees more than neutral posture) and then in straight alignment (3.5 degrees less than neutral posture), and (iii) after insertion of a Pro-Disc C implant at C3-C4. Fusion was performed using an external fixator-styled stabilization apparatus that allowed easy adjustment of C4-C6 lordosis, as well as restoration of intact mobility. This allowed testing of TDR alone, fusion alone and TDR above fusion of different alignments, using a combination of load-control (±1.5Nm) and displacement-control protocols. Segmental range of motion (ROM) was measured at all levels using optoelectronic instrumentation and monitored using digital fluoroscopy.

**Results:** C3-C4 flexion-extension ROM significantly decreased with the TDR compared to the intact spine from 10.7 to 8.5 degrees (p=0.008). Both flexion and extension moments needed to bring the spine to similar endpoints significantly increased for TDR above a lordotic fusion compared to TDR alone (1.52 vs. 0.70 Nm, p<0.001; -1.44 vs. -1.03 Nm, p=0.002). There was no significant difference in segmental ROM at C3-C4 between TDR above straight or lordotic fusion (8.9 vs. 9.0 degrees, p=0.204). Interestingly, the flexion moment to reach the same endpoints was significantly increased for TDR above a lordotic fusion compared to the straight fusion (1.52 vs. 1.11, p<0.001), while the extension moment was significantly increased for the TDR above a straight fusion compared to the TDR above a lordotic fusion (-2.20 vs. -1.44, p<0.001).

**Discussion:** Although there was no significant difference in segmental ROM of the TDR at C3-C4 between the two fusion alignments, the corresponding flexion and extension moments to reach the same displacement endpoints were significantly different. This suggests that more force is required to bring the spine with a TDR into extension when the spine is fused in a straight alignment and conversely more force is required to bring the spine into flexion when fused in a lordotic alignment. Increased loading may adversely affect the survivorship of the TDR. Refinements in cervical disc replacement design criteria may become necessary as we contemplate performing an arthroplasty adjacent to fusions with differing sagittal alignments. Further clinical studies are required to determine the long-term implications of increased loading of the TDR above a fusion.

### 24. Consequences of Whiplash Injury Following ProDisc-C Total Disc Replacement: Evaluation of Cervical Kinematics During Low Speed Rear-end Impact

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Introduction: Whiplash injuries are very common following low speed rear-end automotive impacts. The potential for harm following such accidents for cervical total disc replacement patients is yet unknown. As this procedure nears FDA approval and widespread implantation becomes reality, questions of occupant safety must be addressed. This study is the first to test full body post mortem human subjects (PMHS) under low speed rear-end impacts for cervical response in the orthopedic literature, per the authors’ knowledge. The purpose of this work is to evaluate the biomechanical response of the cervical spine following ProDisc-C implantation in low speed rear-end impact.

Methods: 8 PMHS specimens had 3.2 mm diameter lead markers implanted from C1 through C7 (Figure 1). Markers were placed in the vertebral body and spinous process of each vertebra percutaneously under fluoroscopic guidance. Previous studies have tested the isolated head neck complex. Such work does not consider compressive loads developed in the spinal column by straightening of spinal curvature or occupant-seat interactions, thus resulting in altered kinematics and kinetics.

Each PMHS was positioned in a standard car seat. A crash sled imparted a peak acceleration of 14 g and a peak velocity of 14 kph. Planar high speed fluoroscopy, at 1000 frames per second, captured head and cervical spine motion. Motion of the vertebrae during impact and segmental range of motion were assessed.

Each PMHS was first tested in the intact state as a control and then retested after the implantation of a ProDisc-C at C5-6. Two specimens were tested with the headrest in the bottom position, two were tested with the headrest raised (to make initial contact at or above the center of gravity of the head), two were tested with the headrest raised while the body was placed in a forward prone position, and two were tested with the headrest removed.

Results: None of the ProDisc-C disc replacements implanted in the PMHS specimens demonstrated any signs of loosening, subsidence, motion with respect to the endplate or failure of the ProDisc-C prosthesis. Post-test implant retrieval analysis demonstrated no signs of damage or wear.

Conclusions: Whiplash injuries frequently result from low speed rear-end impacts. These experiments demonstrate that the ProDisc-C prosthesis is stable in the event of such an automotive impact. While not even under the most severe testing condition without a headrest was the implant affected, a substantial decrease in loading was observed when the headrest was in place and properly positioned. The results of this study address the safety of occupants in a low speed rear-end impact following ProDisc-C total disc replacement in the most critical post-operative period.

25. Prospective Randomized U.S. Trial Comparing Kineflex/C® Cervical Total Disc Replacement to Fusion for Single-level Disc Degeneration

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Purpose: Cervical total disc replacement (TDR) has not been investigated as much as its lumbar counterpart. The goal of cervical TDR is to relieve pain, restore function, and maintain motion of the operated segment. Preserving more normal segmental biomechanics may minimize adjacent level stress and subsequent degeneration. Numerous cervical disc arthroplasty designs are in the clinical trial process. We report the preliminary data from two institutions.
participating in the ongoing prospective randomized multi-center US IDE trial comparing the Kineflex\textsuperscript{\textregistered}C TDR—composed of a mobile cobalt-chrome-molybdenum (CCM) core and two CCM endplates incorporating a small keel—to anterior cervical discectomy and fusion (ACDF) in the treatment of single-level disc degeneration with radiculopathy.

**Methods:** Patients aged 18 to 60 years with symptomatic single-level cervical DDD from C3 to C7 who failed non-surgical treatment were randomized in a 1:1 ratio to receive Kineflex\textsuperscript{\textregistered}C or anterior cervical discectomy, allograft and plating. Outcome measures included preoperative and 6 week, 3, 6, 12 and 24-month postoperative visual analog score (VAS, 0-100 scale), Neck Disability Index (NDI, 0-100 scale) and patient satisfaction. Radiographic parameters included disc height and range of motion (ROM). Perioperative data included operative time, estimated blood loss, hospitalization, and adverse events. The primary endpoint of >20% improvement in NDI was calculated. Statistical analyses were performed for data within and between treatment groups.

**Results:** A total of 57 patients were enrolled (32 Kineflex\textsuperscript{\textregistered}C, 25 ACDF). Six Kineflex\textsuperscript{\textregistered}C training cases are included. At one year, mean NDI decreased from 64 to 27 (58%, \(p<0.001\)) for Kineflex and from 66 to 28 (57%, \(p<0.001\)) for ACDF. Mean VAS decreased from 74 to 32 (58%, \(p<0.001\)) for Kineflex and from 78 to 34 (56%, \(p<0.001\)) for ACDF at one year. There was no significant difference in postoperative improvement in NDI or VAS between groups. NDI decreased by at least 20% in 93% of Kineflex\textsuperscript{\textregistered}C and 76% of ACDF at one year (\(p<0.05\)). Operative time, estimated blood loss and hospitalization did not differ between groups. Mean ROM for Kineflex\textsuperscript{\textregistered}C versus ACDF differed significantly (8.7 vs. 1.5 degrees, \(p<0.001\)). Range of motion was greater than 3 degrees for 83% of Kineflex\textsuperscript{\textregistered}C. Post-operative disc height was greater for Kineflex\textsuperscript{\textregistered}C vs. ACDF (5.7 mm vs. 4.8 mm, \(p=0.013\)) while there was no preoperative difference (3.0 mm vs. 3.1 mm). Ninety-one percent of patients were very satisfied or satisfied. There were no major device related adverse events: no implant subsidence, extrusions or revisions. Adverse events were similar between groups.

**Conclusions:** These preliminary results suggest Kineflex\textsuperscript{\textregistered}C is at least equivalent to ACDF in clinical outcome. Kineflex\textsuperscript{\textregistered}C may be superior in percent of patients achieving the primary outcome measure of at least 20% NDI improvement. The outcomes for Kineflex\textsuperscript{\textregistered}C were achieved while maintaining significantly greater range of motion than ACDF. The pooled multi-center data may reveal further significant differences between groups. Long term data is needed to determine if TDR will decrease the incidence of adjacent level disease.

### 26. Biomechanics of Multilevel Cervical Arthroplasty and Combined Arthrodesis and Arthroplasty

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**Introduction:** Little research exists on the biomechanics of combined cervical arthroplasty/arthrodesis and multilevel arthroplasty. Simply studying the range of motion of these conditions in vitro provides little useful information. Therefore, a new experimental protocol was used to investigate how these conditions affect posture and distribution of segmental angles under physiologic loads.

**Methods:** Seven human cadaveric C3-T1 specimens were studied (age 32-67 years). After completing normal tests, C4-C5, C5-C6 and C6-C7 discs were replaced with ProDisc-C (Synthes Spine, Paoli, PA). Then, using a rigid screw-rod system fixated at 3 points per vertebra, various combinations of fusion ("f") adjacent to arthroplasty ("A") were simulated at C4-C5, C5-C6 and C6-C7 respectively: fAA, fAf, AfA, ffA, AfF, fAf, ffA, C3-C4 and C7-T1 were left intact during all tests. A compressive belt apparatus simulated normal muscle co-contraction and gravitational preload. This apparatus controlled the angle of C3 relative to T1 but did not interface with intermediate levels. All motion segments (C3-C4, C4-C5, C5-C6, C6-C7 and C7-T1) were individually monitored using a 3D optical tracking system. Parameters studied were segmental compensation to restore the original neutral postural balance, tendency for buckling while maintaining global neutral postural balance, and shift in sagittal plane axis of rotation.

**Results:** During all 7 conditions in which one or more ProDisc-C levels were mobile, the arthroplasty levels preferentially moved toward upright posture more easily than the normal intact levels. This difference was significant in the AAA, fAA, fAf, ffA configurations (\(p<0.05\), paired Student’s t-tests). To keep a global, upright posture of 0\(^\circ\), the buckling (sum of unsigned segmental angles) was greatest for 3-level arthroplasty, less for 2-level arthroplasty, and least for 1-level arthroplasty (Figure 1). Among the three 1-level arthroplasty groups (fAf, ffA, AfF), arthroplasty at the caudalmost level resulted in significantly greater buckling than when arthroplasty was in the rostralmost or middle segment (\(p<0.04\), ANOVA/Holm-Sidak). The IAR location was related to buckling--anterior IAR shift resulted in extension and posterior IAR shift resulted in flexion. Although there was a tendency for worse buckling to occur with greater shifts in the axis of rotation, this correlation did not reach significance (\(p=0.112\)).
Conclusions: Arthroplasty levels provide the “path of least resistance,” through which the initial motion is more likely to occur than normal levels. This phenomenon may in part explain focal kyphosis observed clinically with cervical arthroplasty. The tendency for specimens to buckle under vertical compression became greater as more arthroplasty levels were introduced. Buckling appeared more severe with arthroplasty more caudal. Malpositioning of the arthroplasty device would be expected to cause shifts in IAR and therefore more buckling. Buckling only moderately correlated to shifts in IAR, meaning slight malpositioning of the devices would not necessarily predispose the patient to buckling.

27. Comparison of Adverse Events between the Bryan Artificial Cervical Disc and Anterior Cervical Arthrodesis

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Objectives: Cervical disc arthroplasty as a substitute for fusion has been developed to maintain motion and, theoretically, prevent adjacent segment degeneration. Currently, cervical arthroplasty devices are undergoing clinical testing for safety and efficacy. The evaluation of safety is performed by critical analysis of all adverse occurrences following surgery to determine if the new device has a beneficial risk profile for the patient. The objective of this study is to compare the rates of adverse events associated with disc arthroplasty versus those of anterior cervical discectomy and arthrodesis with allograft and plate.

Methods: Adverse events associated with Bryan Disc arthroplasty and arthrodesis were compared in a prospective randomized study. Four hundred sixty-three (463) patients having cervical radiculopathy and or myelopathy at a single level were treated at 31 sites. A total of 242 patients received the disc and 221 patients had anterior cervical discectomies and arthrodesis (ACDF). All patients were evaluated preoperatively and at 1.5, 3, 6, 12, and 24 months post-operatively. Adverse events were recorded concurrently and categorized by severity and as medically or surgically related.

Results: No differences in overall medical events occurred between groups. Surgically related events occurred more frequently in the investigational group secondary to more complaints of postoperative dysphagia and late medical events occurred more frequently in the investigational patients. However, the more severe WHO grade 3 and 4 events occurred more frequently in the arthrodesis patients related to treatment of pseudoarthrosis and persistent symptoms. Significantly, more cervical spine re-operations occurred in the fusion group. Only one spinal cord injury occurred and it was in the arthrodesis group and no patients had deep infection or death related to either procedure.

Conclusion: Bryan cervical disc replacement and anterior cervical fusion are both safe procedures with a low incidence of significant adverse events related to the procedure. Statistically, more serious adverse events and re-operations occurred in the fusion group while a greater number of less serious surgical related events were seen in the investigational group.

28. The X-ray and MRI Assessment of Upper and Lower Adjacent Level Degeneration after Minimal 2 Years Single Level Bryan Disc Replacement

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Object: To assess the degenerative process on the adjacent segments by means of X-ray and MRI after single level Bryan disc replacement. The clinical outcome and the motion of operated level were reviewed.

Method: From Dec.2003 to Aug.2005, 51 patients received single level Bryan disc replacement. 26 cases including 18
of myelopathy and 8 of radiculopathy obtained minimal 2 years follow up (average 29.5 months, range from 24 to 40 months). The pre-operative and post-operative X-ray and MRI scan were evaluated by two independent observers. Following measurement on X-ray films were recorded: the height ratio of disc space and vertebral body (DS/VB) at upper and lower adjacent level; the range of movement (ROM) of operated level; the heterotopic ossification (HO) around prosthesis. The disc degeneration of superior adjacent segment (SAS) and inferior adjacent segment (IAS) on MRI was recorded according to Pfirrmann’s classification. The invasion ratio of disc protrusion and ligamentum flavum budge to the duro sac of SAS and IAS were measured and recorded respectively on MRI T2 weighted image. The clinical outcome was recorded according to JOA score scale and Odom’s grade.

Result: (1) On X-ray: The DS/VB at upper adjacent level was 0.442 before surgery and 0.430 (P>0.05) after surgery. The DS/VB at lower adjacent level was 0.457 before surgery and 0.451 (P>0.05) after surgery. The ROM of operated level was 6.9 degrees (range from 2 to 12 degrees) pre-operatively and 7.8 degrees (range from 1 to 14 degrees) post-operatively (P>0.05). There were 7 cases of HO seen around the implant but only one case lost movement (1 degree flexion/extension movement) recorded as spontaneous fusion. (2) On MRI scan: Two orthopaedic surgeons assessed the adjacent disc degeneration independently according to Pfirrmann’s classification and there was no statistic difference between observers (P>0.05). The majority adjacent discs remained same grade on final follow up. There was one disc changed from grade 1 to grade 2 and two discs changed from grade 2 to grade 3 on the SAS, respectively. For the IAS, there was one disc changed from grade 2 to grade 3 and one disc changed from grade 3 to grade 4, respectively. The invasion ratio of disc protrusion changed from 17.9% to 19.1% (P<0.05) on SAS and from 18.4% to 19.5% (P<0.05) on IAS after the operation. The invasion ratio of ligamentum flavum increased from 8.9% to 9.4% (P>0.05) on SAS and from 11.5% to 11.8% (P>0.05) on IAS after the operation. (3) The JOA score was increased from 8.5 before surgery up to 16 on final follow-up in the cases of myelopathy with 86% average improvement rate. All symptoms disappeared in the cases of radiculopathy. 15 patients were in excellent result, 7 in good and 4 in fair according to Odom’s grade.

Conclusion: The adjacent segment degenerative process was not aggravated after Bryan disc replacement. This technology has offered an excellent clinical outcome for the treatment of cervical disc disorders. Radiographic evidence supports the effect of motion preservation of the target segment.

29. Clinical Outcome and Radiological Analysis Following TCDR with ProDisc C at the 24 Months Follow-Up

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Introduction: Dynamic reconstruction of a degenerative “functional spinal unit” is a rapidly growing field in spinal surgery. Due to the implantation of a total disc prosthesis the concerned segment should be kept mobile to decrease the load for the adjacent levels. Aim of the study is to prove the function of the implanted prosthesis and the registration of radiological changes after total cervical disc replacement.

Methods: This clinical/radiological study was enrolled in one center (Munich) as part of a prospective European multi-center study with ProDisc C. The X-Rays (active flexion and extension preoperatively 3,6,12 and 24 months after surgery) of 45 patients (in total 66 implanted prosthesis) were analysed 24 months after TCDR with a ProDisc C prosthesis (Spine Solution, Tuttlingen). The measurement to determine the ROM of the implanted prosthesis was done electronically with MedImage V5.0 (Vepro AG, Pfungstadt, Germany).

We classified the heterotopic ossifications (HO) in 5 grades. For clinical parameters the Visual Analog Scale (VAS) and the Neck Disability Index (NDI) were evaluated preop and 1 year postoperative. Findings: The clinical parameters improved significantly. The NDI improved in average from preoperatively 20.5 points out of 50 to 9.5 points. In the VAS the patients improved from 6.3 (VAS arm) and 6.3 (VAS neck) to 1.6 resp. 1.8 two years postoperatively in average. The preoperative ROM of the treated segment was in average 8.4 degrees. It increased in the 2 years control up to 9.7 degrees in average, excluded the 5 cases (7.6%) of solid fusion due to heterotopic ossifications (included 8.7 degrees in average). 24.2% (n=16) of the treated segments didn’t show any signs of HO. Grade I HO appeared in 15.2% (n=10), Grade II in 33.3% (n=22) and Grade III in 19.7% (n=13).

Discussion: In most cases we could prove a satisfactory maintained mobility of the treated segment. The clinical parameters improved significantly. The rate of high-grade heterotopic ossifications makes us expect a high fusion rate in the future.

So far the TCDR fulfill the requirements as expected, but the rate of spontaneous fusions will decide the fate of total cervical disc replacement. A very important issue is to develop strategies to avoid the origin of HO.
30. Validation of ISO Total Disc Wear Testing Using Retrieved Metal-on-Metal Cervical Disc Replacements

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The short-term in vivo wear performance of metal-on-metal cervical total disc replacements (TDRs) has been characterized1. However, it remains unknown how many cycles of in vitro wear testing correspond to the duration of implants in vivo. The Prestige® cervical TDR (Medtronic, Memphis, TN) consists of a superior ball articulating against an inferior trough. Previous wear tests employed a custom test sequence producing similar wear mechanisms as retrievals, however the abrasion was more severe than what was observed in vivo1. Because our current retrieval collection consists of all short-term retrievals, a study to characterize the short-term wear response within the first 1.0 MCycles was conducted. The objective of this study was to test the hypothesis that wear patterns and surface morphology produced by an in vitro test protocol replicate those exhibited by retrievals.

Three 316L stainless steel TDRs (Prestige® ST) were tested at 2.0Hz on a six-degree-of-freedom MTS Spine Wear Simulator (MTS, Eden Prairie, MN) in accordance with the cervical loading and motion profiles prescribed by ISO/FDIS 18192. To evaluate the short-term in vitro wear behavior, the simulator was stopped after 0.05, 0.1, 0.2, 0.3, 0.4, 0.5 and 1.0 MCycles and interval analyses performed. These analyses consisted of photogrammetry and white light interferometry. The results from each interval analysis were compared to a Prestige® ST retrieval collection analyzed from nine patients ranging from 0.7 to 3.3 years in vivo.

After 0.1 MCycles all components exhibited a faint wear scar, produced by abrasive wear. This wear mechanism was consistent with short-term explants. The average surface roughness of the worn regions for both the retrievals and in vitro tested components was measured to be 0.12 ± 0.08µm and 0.16 ± 0.07µm, respectively. Furthermore, the photogrammetry data showed that the average percentage of total worn area for both the retrievals and in vitro tested components at 0.1 MCycles was 46.8 ± 21.3% and 65.4 ± 15.7%, respectively. The surface roughness and worn area percentages were compared using an ANOVA (JMP, SAS, Cary, NC) and found not significantly different (p=0.69 and p=0.21, respectively).

The results of this study suggest that the ISO/FDIS 18192 standard test method replicates the short-term in vivo wear patterns in TDRs within the first MCycles of testing. The same mechanism of abrasive wear is occurring at the bearing surface of both the retrievals and wear-tested components, although the greater worn surface area in the wear-tested components may indicate that the ranges of motion are more extensive than those experienced by TDRs in vivo. Overall, the study suggests that shorter-term test durations may generate surface morphology consistent with short-term in situ wear. Previous studies have suggested that a patient may undergo as few as 100,000 cervical loading cycles per year2. Similarly, comparing the ISO simulator testing to the collection of short-term retrievals, one can begin to see similar wear patterns as early as 100,000 to 200,000 cycles of wear testing for this ball-in-trough articulation.


31. The Reliability of CT and MRI Grading of Lumbar Facet Arthropathy in TDR Patients

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Introduction: With the advent of motion preservation technologies for treatment of lumbar spine disorders, new interest has arisen in evaluation of the lumbar facet joints and their degree of arthropathy. Devices have been introduced including mechanical total disc replacements, nuclear replacements, and non-fusion posterior stabilization systems, with the success of all considerably dependent upon the degree of facet joint disease. Both Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) are commonly utilized to evaluate facet arthropathy, and grading systems have been devised for both imaging modalities. This study compares the interrater and intrarater reliability of MRI and CT for grading of facet arthropathy among spine surgeons in a clinical setting as well as the interrater and intrarater reliability of MRI and CT for grading of facet arthropathy as a contraindication to Total Disc Replacement (TDR).

Method: Ten fellowship-trained orthopaedic spine surgeons and three orthopaedic spine fellows concurrently evaluated 50 spinal levels from L3-4 through L5-S1 on parallel axial MRI (T1 and T2) and CT images. The degree of osteoarthritis was graded on the same four-point scale (Fujiwara (MRI) :Pathria (CT)) according to previously published criteria for grading of facet joint osteoarthritis on CT, and adapted and validated for MRI. Surgeons also were asked to evaluate whether the degree of facet disease represented a contraindication to treatment at that level with a mechanical disc replacement given no other contraindications. Images were obtained from the files of surgical patients and were of representative quality used in an academic clinical practice for surgical decision-making. Grading was repeated during an
identical second session 3 weeks later. Weighted kappa statistics were used to describe interobserver and intraobserver agreement.

**Results:** The inter-observer reliability for MRI was 0.21 and 0.07 (fair to slight agreement) among attending surgeons and fellows, respectively. Inter-observer reliability for CT was 0.33 and 0.27 (fair agreement), respectively. The mean intraobserver reliability for MRI was fair, 0.36 (attendings) and 0.26 (fellows). The mean intraobserver reliability for CT was moderate, 0.52 (attendings) and 0.51 (fellows).

After looking at the facets as a possible TDR contraindication, the inter-observer reliability for MRI was 0.22 and 0.01 (fair to slight agreement) among attending surgeons and fellows, respectively. Inter-observer reliability for CT was 0.33 and 0.45 (fair agreement), respectively. The mean intraobserver reliability for MRI was fair, 0.36 (attendings) and 0.26 (fellows). The mean intraobserver reliability for CT was moderate, 0.52 (attendings) and 0.51 (fellows).

**Conclusions:** The existing grading system for facet arthropathy has only fair agreement. CT is slightly more reliable for grading lumbar facet arthropathy. Intraobserver reliability was only fair for MRI and moderate when employing CT. When evaluating potential surgical levels on cross-sectional imaging, only limited agreement existed between surgeons as to the extent of facet disease that would pose a contraindication to treatment with lumbar total disc replacement.

### 32. Incidence of Dysphagia Comparing Cervical Arthroplasty and ACDF with Internal Fixation

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**Introduction:** Dysphagia after anterior cervical discectomy and fusion with plating is a well known complication. It appears that approximately 80% of these patients have resolution of their symptoms at 12 months leaving 12.5-20% with persistent dysphagic symptoms. These symptoms include difficulty swallowing and dysphonia. The etiology of this complication is unknown in a majority of patients. Vocal fold paresis is only identified in 1.3% of patients and adhesions to the plate or just irritation of the soft tissues of the anterior neck are felt to contribute to dysphagia. When dysphagia is severe enough plate removal and adhesion lysis can be attempted if the vocal folds appear to be functioning appropriately. Reports show improvement of symptoms to little or none in 87% of patients treated in this manner. There has been concern that the rates of dysphagia may be higher with arthroplasty procedures because of the amount soft tissue mobilization to place the prosthesis in the proper position and the additional instrumentation required.

**Methods:** 87 patients with cervical spondylosis with radiculopathy and/or myelopathy who fit the inclusion criteria for the prodisc-C trial were randomized to receive a prodisc-C arthroplasty or ACDF and plating procedure. 45 patients were randomized to receive a prodisc-C arthroplasty, and 42 patients were randomized to the ACDF and plate. Both groups had completed at least 12 months follow-up. All surgical interventions were between C3-7. Complaints of dysphagia and dystonia were recorded in a prospective manner and a Bazaz dysphagia questionnaire was administered by phone in a blinded fashion. *

**Results:** An average of 18.2 months of follow up were completed. 76 of 87 patients participated in the survey (87.4%). 6 of 38 patients reported ongoing dysphagic complaints (15.8%) in the Prodisc-C group, and 16 of 38 in the ACDF and plate group (42.1%). The ACDF patients had significantly more dysphagic symptoms (p=0.03). One patient required removal of the plate with improvement in symptoms. Grading of dysphagia severity by the Bazaz questionnaire for the ACDF group demonstrated 9 mild, 6 moderate, and 1 severe dysphagia symptoms. The prodisc-C group grades were 2 mild, 2 moderate, and 2 severe dysphagia symptoms.

**Conclusions:** This study demonstrates that the added soft tissue mobilization and additional instrumentation during implantation does not cause an increase in the amount of dysphagia compared to similar group undergoing ACDF. There were significantly less complaints of dysphagia with Prodisc-C compared to the ACDF and plate group. This may be related to the absence of an anterior plate that potentially leads to higher rates of soft tissue adhesions after anterior cervical surgery.

### 33. The Loss of Water Content within the Intervertebral Disc through an Accumulation of Advanced Glycated Endproducts

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**Introduction:** Advanced glycated endproducts (AGEs) are compounds that form through a nonenzymatic interaction between collagen and glucose. The accumulation of AGEs within the extracellular matrix has been implicated in the degeneration of cartilage and other soft tissue structures. The effect of AGEs on the intervertebral disc has not been well characterized. It is hypothesized that the accumulation of AGEs within the nucleus pulposus (NP) competitively...
inhibits the binding of water to the proteoglycans within the intervertebral disc (IVD) and thus leads to an accelerated dehydrated state.

**Materials and methods:** Twenty lumbar and thoracic intervertebral discs were removed from two sheep spines. 40 strips of dog-bone shaped tissue samples approximating 10mm x 5mm x 1mm were taken from the nucleus pulposus (NP) and from the annulus fibrosis (AP). Using a previously established in vitro ribosylation procedure, the tissues were grouped by disc location to undergo a 0, 2, 4, 6, 8 day incubation period in a ribose-rich solution. The samples were then stored in PBS with enzymatic inhibitors. After the incubation process, the tissues were mounted and tested in tension under stress relaxation using an Enduratec ELF 3200 desktop system. An instantaneous 10% strain was applied to the tissues, and the tissues were allowed to relax over a 120 second period.

The tissues were first massed under hydrated conditions, and then massed again after a 48-hour desiccation period at 50°C to determine the percentage water content. The tissues were subsequently digested in 6N HCl at 60°C for 24 hours, and the extent of autofluorescence of the hydrolysates were determined at 370nm excitation and 440nm emission. Collagen content was quantified from the lysates using a colorimetric assay. The AGEs measure was then normalized by collagen content of the tissues.

One-way ANOVA was used to determine the effects of incubation period due to NEG on water content, AGEs accumulation as indicated by tissue-fluorescence, and mechanical behavior of the tissues. Multiple regression analyses were used to determine relationships between AGEs and water content; and between AGEs and mechanical behavior.

**Results:** Fluorescence per collagen increased significantly in a dose-dependent manner with incubation time in both the AF (p<0.001) and NP (p<0.001) tissues. In addition, water content in both tissue types decreased significantly with incubation time in both the AF (p<0.001) and NP (p<0.001) tissues. Regression analyses show a significant inverse relationship between decreasing water content and increasing AGEs; furthermore, the decrease in water content in the NP tissue is more susceptible to increases in AGEs than in AF tissues.

**Discussion:** In this study an increase in AGE was correlated with a loss of water content within both the NP and AF. This effect was noted to have a stronger correlation within the nucleus pulposus than the annulus fibrosus. This study suggests that the accumulation of AGEs may competitively inhibit the binding of proteoglycans to water and thus result in an accelerated dehydrated state within the IVD. Future strategies to regenerate the IVD through rehydration may require consideration of compounds that can breakdown these AGEs.

### 34. Analysis of Postoperative Pain Patterns Following Total Lumbar Disc Replacement

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**Introduction:** Although a variety of biomechanical laboratory investigations and radiological studies have highlighted potential problems associated with total lumbar disc replacement (TDR), no previous study has performed a clinical failure analysis and systematically investigated postoperative pain patterns. The objectives of this study were therefore to perform a failure analysis following TDR, identify postoperative pain sources, establish the incidence of postoperative pain patterns and investigate the effect on clinical outcome.

**Methods:** The study design is an analysis of postoperative pain patterns following total lumbar disc replacement with ProDisc II. The results from fluoroscopically guided spine infiltrations were correlated with the postoperative outcome from patients of an ongoing prospective study. Patients that reported unsatisfactory results at any one of the FU-examinations received fluoroscopically guided spine infiltrations as part of an intensified diagnostic and conservative treatment program. Pain sources were identified in patients with a reproducible (≥2x) significant (50%-75%) or highly significant (75%-100%) pain relief upon the infiltrations. Results were correlated with outcome parameters Visual-Analogue-Scale (VAS), Oswestry-Disability-Index (ODI) and the subjective patient satisfaction rates.

**Results:** 175 patients were included with a mean FU of 29.3 months (range 12.2-74.9 months). N=342 infiltrations were performed in n=58 patients (33.1%) overall. Facet joint pain, predominantly at the index level (86.4%), was identified in n=22 patients (12.6%). The sacroiliac joint was a similarly frequent cause of postoperative pain (n=21, 12%). Pain from both structures influenced all outcome parameters negatively (p<0.05). Patients with an early onset of pain (≤6 months) were 2x-5x as high at risk of developing persisting complaints and unsatisfactory outcome at later FU-stages in comparison to the entire study cohort (p<0.05). A significant influence of the level of TDR on postoperative outcome was detected. Best results were achieved for TDR’s above the lumbosacral junction at L4/5 (incidence of posterior joint pain 14.8%). Inferior outcome and a significantly higher incidence of posterior joint pain was observed for TDR at L5/S1 (21.6%) and bisegmental TDR L4/5/S1 (33.3%), respectively.

**Conclusion:** Reported problems associated with TDR include postoperative hyperlordosis with subluxation of the facet joints, increased segmental (rotational) instability, up to 2.5x increased load on posterior structures and abnormal stress distribution patterns with sudden rather than gradual load increase. All of these factors could potentially impair postoperative outcome. In contrast to lumbar fusion procedures, however, no previous clinical study has performed a systematic failure analysis following TDR. As the results from this study show, pain from the lumbar facet- and...
sacroiliac joints are a frequent and currently underestimated source of postoperative pain and the most common reason for unsatisfactory results following TDR. In the light of rapidly increasing market volumes of TDR worldwide further failure-analysis studies are required and adequate salvage treatment options need to be established with respect to the underlying pathology of postoperative pain. Future studies will have to investigate if TDR compromises the index-segment in an attempt to avoid adjacent segment degeneration. Whether TDR will reduce the incidence of posterior joint pain, previously attributed to lumbar fusion procedures, remains unknown.

35. A Finite Element Study to Evaluate the Biomechanical Effects of the Artificial Disc Components’ Shape on the Cervical Spine

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Introduction: The articulation between the ball and socket components of the artificial disc may use a hemispherical ball rolling over a curved surface. Other variations of the spherical design, such as an oval shape, are also feasible. The main purpose of the present study is to understand the biomechanics of the cervical spine following implantation of two different B&S type artificial discs. These discs use hemispherical and oval shaped ball components rolling over curved surfaces of socket components.

Methods: An experimentally validated, three dimensional, ligamentous, finite element (FE) model of C3 -C7 cervical spine segments was modified to create four different models to accommodate the TDR in various configurations. In the first model an oval shaped ball component rolls over the inferior socket component (OSB), while in the second model, the ball and socket components were switched, so the socket component rolls over the inferior oval ball component (OBB). Corresponding models were also created with a hemispherical ball type disc. These models had a spherical socket at the bottom (SSB) or a spherical ball at the bottom (SBB). The artificial disc implants were placed at the C5-C6 level following the removal of the anterior longitudinal ligaments, the nucleus and part of the annulus. All of the models were loaded with 75N of follower load using a set of springs. Once activated, these springs applied a constant load of 75N throughout the simulation. A moment of 1.5 Nm was also applied to simulate physiologically relevant flexion and extension motions.

Results: The extension motion at the implanted C5-C6 level for SSB, SBB, OSB and OBB models were 15.2, 12.1, 14.7, 15.8 degrees, respectively as compared to 8.0 degrees in the intact spine. The corresponding flexion motions were 6.9, 7.2, 5.5, 8.5 degrees as compared to 6.4 degrees in the intact spine. With all four types of implants, the motions at the adjacent levels were close to the corresponding intact motion values.

Facet loads on the C5-C6 left facet for intact, SSB, SBB, OSB and OBB models were 54N, 62N, 88N, 70N and 67N, respectively. The corresponding facet loads on the C5-C6 right facets were 41N, 94N, 106N, 112N and 125 N, respectively.

Discussion: The biomechanical response of the cervical spine varies with variations in the shapes and configurations of B&S type implant. Out of the four configurations studied, the design with a spherical ball at the bottom (SBB) yielded motion closer to the intact spine. Nevertheless, as compared to intact, a 50% increase in extension motion and a 13% increase in flexion motion at the implanted level were observed for this design as well. For the other designs, corresponding increase in extension motion ranged from 85%-95% and the increase in flexion motion ranged from 10%-35% at the implanted level. The designs of ball and socket components and their placements are relevant variables that may affect the above results. We are studying the effects of these variables.

36. Does Placement of the Axis of Rotation of the Cervical Spine Affect Motion Segment Mechanics During Flexion and Extension?

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Objective: Different paradigms exist in the design of nucleus or disc arthroplasty devices that may constrain motion to pure rotation, as in a ball and socket device, or may use a less constrained mobile or compliant design in an attempt to emulate the coupled (translation and rotation) movements of the healthy human spine. Motion segment unit (MSU) mechanics may also be sensitive to not only anterior-posterior (A-P) device placement but also cephalad-caudal location
of the center of rotation (CoR) inherent with a device design. The objective of this research was to investigate the effects of placement of the CoR of the cervical spine on segmental mechanics. The null hypothesis tested was forcing a fixed CoR on sub-axial cervical spinal motion segments that did not coincide with the motion segment’s real CoR would not expose the tissue to unnatual (unphysiological) excessive loads throughout normal flexion or extension movement.

**Methods:** Six fresh human cadaveric cervical MSUs were procured and mounted in a custom designed spine robot. The spine robot was programmed to rotate the specimen about selected points of rotation: three upper points located along the plane of the disc in the A-P direction at 1) the mid-point of the disc (C1), 2) half way between the mid-point and anterior aspect of the disc (A1), 3) and half way between the mid-point and posterior aspect of the disc (P1). The three remaining lower points were located 4mm below the upper points (A2,C2,P2) in the subjacent body. The MSUs were rotated about the six designated points until a target moment of 3.0Nm of flexion or extension was reached or stopped if the shear or compressive forces exceeded 250N. For all test conditions, the MSU tension/compression and A-P shear forces across the MSU, and sagittal bending moment were measured and compared using a one-way ANOVA (P=0.05).

**Results:** At common end limits of applied load (+/-2.5Nm) significantly more motion occurred in flexion than extension at all fixed points of rotation. Significantly more flexion occurred at the midpoints and more extension at the posterior points. Further in both flexion and extension, significantly more motion occurred at the mid-points compared to the anterior or posterior points and at the posterior points compared to the anterior points.

**Conclusion:** A new testing protocol was developed that prescribed a given motion pattern to cervical spine motion segment units and measured the load response to accommodate the motion. Flexion about a posterior point was limited by excessive compression of the anterior aspect of the intervertebral disc, whereas flexion about an anterior point was limited by tension in the posterior ligaments. Extension about midline and anterior points resulted in excessive compression across the facets. These findings suggest that the rotational axis of the cervical spine varies between flexion and extension. In this study the facets remained active throughout the movement and contributed to the loading response. If a spinal device was designed to eliminate or minimize facet involvement, the loading mechanics would likely differ from our findings.

### 37. Cervical Hybrid Constructs: A Reliable and Effective Option in the Treatment of Multilevel Degenerative Disc Disease

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**Purpose:** To analyse the clinical and radiological results of a prospective, multicentre, study, with 7 to 35 months follow-up, on the safety and effectiveness of an hybrid technique combining arthroplasty and arthrodesis during the same surgical procedure in the treatment of symptomatic, multilevel degenerative disc disease (DDD).

**Materials and methods:** Between November 2004 and March 2007 24 patients (15 males), mean age 46.7 years, affected by neck pain and myeloradiculopathy secondary to multilevel DDD, either soft disc hernia or spondylosis, with different stages of degeneration per each level, underwent a single-stage combination of intervertebral cages and artificial discs.

SF-36 and Neck Disability Index (NDI) questionnaires and radiographs, with flexion and extension views, CT and MR scans were performed before and after surgery for clinical and radiological evaluation.

CFRP and Cornerstone CFC cages were used for ACDF and either ProDisc-C, Prestige LP or Bryan disc for arthroplasty. Treated disc levels were C3-C7. Fifteen patients underwent a two-level procedure, seven patients a three-level and two a four-level implant, respectively. Prestige LP prostheses were used in two patients, Prodisc-C in 17 cases and Bryan discs in 5. A total of 59 devices (19 Prodisc-C, 3 Prestige LP, 5 Bryan, 27 CFRP cages and 5 Cornerstone cages) have been used. The TDR/fusion ratio at different disc levels is as follows: C3-C4: 4/4; C4/C5: 10/2; C5/C6: 11/12; C6/C7: 2/14. Rationale for choosing arthroplasty or ACDF is based on an algorithm, developed to decide which technique is most suitable at each level. Type and degree of DDD per segment, segmental range of motion (ROM), residual ROM evaluated by intra-operative fluoroscopy after neural decompression, presence of adjacent degenerated levels not operated and degree of uncoarthrosis were analysed.

Patients were assessed at 1, 3, 6, 12, 18, 24 months and at regular intervals after surgery using the same parameters. A radiologist, blinded to the clinical outcome, independently analysed imaging studies to assess either ROM or changes in the sagittal alignment, particularly with regard to lordosis, or presence of heterotopic ossification.

**Results:** Mean NDI score decreased from 31.5% to 13.3% after surgery. Mean preoperative SF-36 (PCS and MCS) values were, respectively, 38.7% and 48.2%; postoperative values changed to 53.2% and 56%, respectively. All scores are statistically significant (p < 0.05). Follow-up flexion-extension x-rays demonstrated a 3° to 18° ROM. In all cases fusion was shown through cages; McAfee grade 2 ossification was found in two patients. No complications related to the devices (dislocations, subsidence, loosening) or to the technique were registered. None of the patients required surgery for persisting or recurrent symptoms.
Conclusions: This is the study on cervical hybrid constructs with the longest available follow-up in Italy. The proposed hybrid, single-stage, fusion-non fusion technique (HSSFNFNT) is a safe, reliable and effective surgical strategy. It can relieve symptoms and preserve segmental motion, while achieving fusion in severely degenerated levels, preventing raised stress on adjacent segments, a recognised possible cause of further degeneration, and avoiding iatrogenic instability or painful conditions secondary to induced mobilization of markedly degenerated segments.

38. F.D.A. I.D.E. Prospective Randomized Comparison of Three Lumbar Artificial Disc Replacements (A.D.R.) with Minimum Two-year Follow-Up

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Purpose: To establish safety, efficacy, and possible clinical superiority between the Maverick™ (M), Charité™(C), and Kineflex™ (K) A.D.R.’s.

Method: Three ADR’s performed by two surgeons at one I.D.E. site were compared in a prospective randomized minimum two-year follow up. All of the A.D.R.’s were one level at L4-L5 or L5-S1. There were 25 Maverick, 31 Charité, and 35 Kineflex patients. Average age was 42.5 in each group. B.M.I. averaged 25. The majority of A.D.R.’s were performed at L5-S1 vs. L4-L5 (M) 19 to 6, (C) 19 to 12 and (K) 28 to 7. Inclusion/exclusion criteria will be discussed. All results are based on audited F.D.A. I.D.E. study forms.

Results: O.R. time was similar (M) 99 min. (C) 84 min. (K) 84 min. Blood loss averaged 30 cc. Hospital stay averaged 24 hours. Re-operations included: (M) 1 infection (eighteen months post ADR), (C) 3 implant complications (all within eight weeks ADR), (K) 1 implant complication (one day post ADR). These cases will be presented.

ODI results for all groups: Pre-op = (M) 57.6, (C) 63.8, and (K) 61.1; One-year post-op = (M) 16.3, (C) 27.3, and (K) 20.4; Two-year post-op = (M) 14.6 (p<0.001), (C) 20.5 (p<0.001), and (K) 19.3 (p<0.001)

VAS results for all groups: Pre-op = (M) 74.1, (C) 85, (K) 83.9; One year post-op = (M) 27.9, (C) 31.4, and (K) 27.3; Two-year post-op = (M) 20.5 (p<0.001), (C) 33.8 (p<0.001), and (K) 26.9 (p<0.001)

All A.D.R. had statistically significant improvement from pre-op to two-year follow-up on ODI and VAS. F.D.A. clinical success was met in (M) 90%, (C) 83.5%, (K) 90.5% of patients. Patients basically "pain free" (VAS less than 2) (M) 68%, (C) 29%, (K) 47%. Patients with basically "normal" function (ODI less than 10) occurred in (M) 67% (C) 33%, (K) 52%

Patient satisfaction with their A.D.R. at two-year follow up was (M) 96%, (C) 84%, and (K) 91%

The clinical results of Maverick were statistically superior to Charité and Kineflex in terms of ODI improvement (p<0.05) and the Charite in VAS (p<0.05) improvement.

Conclusions: All three A.D.R.’s demonstrated safety with a trend to more device related complications with (C) 3 compared to (M) 1 and (K) 1. They all showed efficacy with a statistically significant improvement in ODI and VAS at two year follow-up (p<0.001). F.D.A. clinical success was (M) 90%, (C) 83.8%, (K) 90.5%. The Maverick demonstrated statistical superiority in ODI measurements compared to the Charité or Kineflex and VAS compared to Charite.

39. Results of the Prospective, Randomized, Multicenter Food and Drug Administration Investigational Device Exemption Study of the ProDisc®-L Total Disc Replacement versus Circumferential Fusion for the Treatment of 2-Level Degenerative Disc Disease


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Objective: To evaluate the safety and effectiveness of the ProDisc®-L (Synthes Spine Company, L.P., West Chester,
PA) lumbar total disc replacement (TDR) compared to circumferential spinal fusion for the treatment of discogenic pain at two vertebral levels between L3-S1.

**Methods:** Two hundred thirty-seven (237) patients were treated on protocol, randomized in a 2:1 ratio (ProDisc®-L: fusion). Patients were evaluated pre-operatively and post-operatively, at 6 weeks, 3, 6, 12, 18, and 24 months. Evaluation at each visit included patient self-assessments, physical and neurological examinations, and radiographic evaluation.

**Results:** Overall patient demographics showed no statistically significant differences between treatment groups in age, gender, race, smoking status, height, weight, body mass index (BMI), baseline Oswestry Low Back Pain Disability Questionnaire [Oswestry Disability Index (ODI)], or prior surgical treatment. Intra-operative/peri-operative data showed the investigational group was significantly lower, both statistically and clinically relevant, with regard to intra-operative time, estimated blood loss, and hospital stay (p < 0.0001, p = 0.0006, p < 0.0001, respectively). At 24 months, 90.0% of investigational and 86.7% of control patients reported improvement in ODI from pre-operative levels and 73.3% of investigational and 55.9% of control patients met the > 15 point ODI improvement criteria. Overall neurological success in the investigational group was superior to the control group (89.2% - investigational, 77.9% - control; p = 0.0260). At all follow-up time points, the ProDisc®-L patients recorded SF-36 scores significantly higher than the control group (p = 0.0523). The visual analog scale (VAS) pain assessment showed statistically significant improvement from pre-operative scores regardless of treatment (p < 0.0001). At 24 months, the investigational group showed significantly higher pain reduction than the control group (p = 0.0466). VAS patient satisfaction at 24 months showed a statistically significant difference favoring investigational patients over the control group (p = 0.002). Radiographic range of motion was maintained within a normal functional range.

**Conclusions:** ProDisc®-L has been found to be effective for the treatment of discogenic pain at two vertebral levels. In properly chosen patients, ProDisc®-L has been shown to be superior to circumferential fusion at two levels by multiple clinical criteria.

40. Interaction between Finite Helical Axes and Facet Joint Forces under Combined Loading

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Finite helical axes (FHA) in a functional spinal unit can indicate mechanical disorders and are relevant for the development of new arthroplasty techniques. The facet joints protect the intervertebral discs from excessive movements. The relationship between the FHAs and facet joint forces is not well understood, since previous studies have separated both, spinal motion and facet forces.

A finite element model of a lumbar spinal segment L4-5 was utilized to simulate axial compression load of 500 N together with moments starting from zero to 7.5 Nm in single anatomical main-planes. Load combinations of 7.5 Nm were generated by changing the load direction in steps of 15° between each pair of the three anatomical main-planes. For single axes loading, the FHAs were found to be in the center of the disc under small moments, independently from load directions. The facet joints were only slightly loaded. Higher moments increased the forces in facet joints up to 105 N in axial rotation, followed by extension (50 N) and lateral bending (36 N). Combined moments did not essentially increase the facet forces compared to the same moment applied in an anatomical main direction. High facet forces might have directed the FHAs to migrate posteriorly, especially for axial rotation. This situation resulted in FHAs outside the disc towards the compressed facet joint.

Results of this study suggest that axial rotation alone tend to maximal facet forces. These high facet forces caused the FHA to migrate posteriorly, outside the disc. A previous study showed that axial rotation or axial rotation in combination with other load applications, especially with lateral bending or flexion generated the largest fiber and shear strains in the annulus fibrosus. This means that axial rotation alone or in combination with other directions can lead to the highest risk of injuries in a spinal segment. For clinical practice, this would mean that patients immediately after an operation as well as patients with pathological changes of facet joints should reduce or avoid these complex motions.

41. Prodisc-L Prosthesis Height: What Effect Does Increasing Height Have on Lumbar Spine Kinematics and Foraminal Size?

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**Purpose of the study:** To evaluate the effect of lumbar artificial disc height on the kinematics of the implanted segment.
Methods: Seven fresh-frozen human lumbar spines (age: 54.4±11.4, L1-sacrum) were tested. The spines had no serious bone pathology or bridging osteophytes and had no previous spinal surgery. The spines were tested intact and after discectomy at L4-5 and sequential insertion of ProDisc-L implants of increasing heights. All available implant heights (10, 12, and 14mm) were tested. The specimens were tested in flexion (8Nm) and extension (-6Nm) with a 400N compressive follower preload. They were then tested in lateral bending (LB, ±6Nm) and axial rotation (AR, ±5Nm) without preload. An optoelectronic motion measurement system was used to measure the three-dimensional motion of each lumbar vertebra relative to the sacrum. Finely graded cylindrical probes were used to assess the smallest foraminal width at L4-L5 for the intact spine and after each implantation. Multiple comparisons were made with Bonferroni correction between specimens implanted with the 10mm and 12mm inserts, the 10mm and 14mm inserts, and the 12mm and 14mm inserts.

Results: With increasing implant height, the amount of flexion-extension (F-E) and LB motions significantly decreased compared to the ROM with the smallest height implant. In F-E using a 10mm Prodisc-L implant at L4-5, the specimens averaged 9.2±1.9 degrees of motion compared to 7.7±2.0 degrees with a 12mm implant (p<0.05) and 5.8±2.4 degrees with a 14mm implant (p<0.05). The difference in F-E motion between the 12mm and 14mm implants was also significant (p<0.05). In lateral bending with a 10mm implant at L4-5, the specimens averaged 5.7±2.8 degrees of motion compared to 4.6±2.6 degrees with a 12mm implant (p<0.05) and 3.6±1.7 degrees with a 14mm implant (p<0.05). In axial rotation with a 10mm implant at L4-5, the specimens averaged 3.9±1.9 degrees of motion compared to 3.2±2.0 degrees with a 12mm implant (p<0.05) and 3.0±2.2 degrees with a 14mm implant (p<0.05). Foraminal width also significantly increased as the implant height increased. Foraminal width with a 10mm implant at L4-5 averaged 9.4±1.3mm, compared to 9.7±1.3mm with a 12mm implant (p<0.05) and 9.9±1.4mm with a 14mm implant (p<0.05).

Conclusions: Implanting a relatively larger prosthesis into the lumbar disc space adversely affected the range of motion (ROM) of the L4-L5 segment. Increasing implant height significantly decreased ROM in flexion-extension by up to 37±21%, in lateral bending by up to 33±18%, and in axial rotation by up to 29±28%. The increase in foraminal size, while significant, was only 4.6±3.2%. A possible explanation for the relatively small increase in the foraminal width with increasing implant height is that increasing implant height also increased segmental lordosis, thus minimizing the effects of disc space distraction. These results suggest that a smaller implant height should be used to optimize the ROM of the implanted segment. In addition, neuroforaminal decompression should be performed via direct decompression rather than distraction with a larger implant.

42. TDR Oxidative Properties Following Gamma Sterilization in Air and First-Generation Barrier Packaging

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Introduction: The clinical significance of in vivo oxidation of polyethylene in the spine following gamma sterilization in an air or inert environment remains unclear. We previously conducted a pilot study of polyethylene oxidation in total disc replacement (TDR), finding significantly higher oxidation in the rim as opposed to the dome. The Charité TDR was sterilized in air prior to 1997, after which a first-generation, polymeric barrier package was used that was permeable to air. The Charité is currently produced by DePuy Spine (Raynham, MA), and the polyethylene is gamma sterilized in an impermeable metal foil-based package. This study’s aim was to extend our previous research to a larger collection of retrievals and to investigate the oxidation potential of the polyethylene in the context of the sterilization environment. Our main hypothesis was that the rim region would exhibit greater oxidation and oxidation potential than the dome.

Methods: We analyzed polyethylene oxidation, oxidation potential, and dome penetration of 40 Charité (SBIII) implants from 34 patients (74% female). The cores were implanted for 7.2 y (range: 1.8 - 16.1 y). 12/40 of the TDRs (30%) were gamma sterilized in air. 5/40 (13%) were identified as sterilized in a polymeric barrier packaging. The sterilization method was not traceable in 23/40 retrievals. The oxidation index was calculated in accordance with ASTM F2102. Sections were then exposed to NO for >16 hours to convert hydroperoxides to nitrates. Hydroperoxide content represents the oxidation potential for polyethylene in the long-term. The maximum oxidation and hydroperoxide indices at the rim and the dome were compared within the same core (paired t-test), as well as between the same regions in the controls (ANOVA with Dunnett’s Test).

Results: First-generation barrier packaging exhibited similar oxidation magnitudes as those that were gamma sterilized in air. The control TDRs had comparable levels of oxidation and oxidation potential at the rim and the dome. Moderate oxidation (OI > 1) was detected at the dome in 6/40 retrievals (ave dome OI: 0.64), and at the rim in 29/40 cases (ave rim OI: 2.9). The average dome hydroperoxide index was 0.36 while at the rim it was 0.57. Oxidation and hydroperoxide index was significantly higher at the rim, as compared with the dome of the cores (p < 0.0001).
Discussion: This is the first study to compare the in vivo oxidation and oxidation potential of polyethylene in TDRs following gamma sterilization in historical and first generation barrier packaging. Our data support our hypothesis that, for the two types of historical packaging methods employed by Link, oxidation and oxidation potential were significantly higher at the rim as opposed to the dome. Because variations were not apparent in the never-implanted controls, we can infer that the rim oxidation occurred in vivo. These findings are consistent with previous observations from acetabular components from total hip replacement, which showed elevated oxidation at the rim. Our findings have clinical significance in cases of chronic impingement, when the rim has to support repeated loading for the lifetime of the implant.

43. Polyethylene Particle Load in TDR and THR Retrieval Tissue Using Polarized Light Microscopy

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Introduction: Advances in polymeric bearing surfaces have revolutionized total joint arthroplasty. However, material wear remains a major long-term concern. Particulate wear can cause foreign body reactions in periprosthetic tissue, which can activate the production of cytokines and contribute to osteolysis and loosening. The purpose of this study was to compare polyethylene (PE) wear particle load of periprosthetic tissue from total disc replacement (TDR) with results from total hip replacement (THR) at the time of revision surgeries.

Methods: Periprosthetic tissue samples were collected from eight patients during revision surgery of Charité disc prostheses. This device is currently produced by DePuy Spine (Raynham USA). TDR implants were revised after an average of 8.1y (range: 2.2-16.2y). One patient exhibited sacral osteolysis underneath the prosthesis. Tissue samples were collected from four THA revisions of uncemented PE hip components, whose average implantation time was 14.2y (range: 9.6-18.9y). The implants were revised for osteolysis, wear, and/or aseptic loosening. Tissue samples were fixed in formalin, dehydrated, and embedded in paraffin. Paraffin-embedded tissue samples were sectioned into 6 micron-thick slices, mounted onto glass slides, and stained with hematoxylin and eosin. Slides were imaged by brightfield and polarized light microscopy. PE particles have been shown to exhibit birefringence when viewed by polarized light microscopy [1].

PE in TDR changed in 1997, from gamma sterilization in air to gamma sterilization in a first-generation polymeric barrier package. Therefore, TDR tissue samples were separated into pre- and post-1998 groups. Five images of each tissue were acquired at 40x objective magnification and scored from 0 to 3. A score of 0 was assigned to fields of view with no visible particles; 1 for small isolated groupings of particles (n<10); 2 for moderate particle load (10<n<100); 3 for elevated particle load (n >100). Image scores were summed for all five fields. Summed scores of polyethylene particle load were displayed as an average for tissue samples from Pre-1998 TDR (n=4), Post-1998 TDR (n=4), and Pre-1998 THR (n=4) implant cohorts.

Results: PE particles were present in all tissues, however PE particle load for pre-1998 TDR tissue was significantly greater as compared to post-1998 TDR components (Student’s t-test, t < 0.001). Periprosthetic tissue from historical TDR and THR exhibited elevated numbers of polyethylene particles; these long-term implant tissues exhibited similar numbers of micron-sized particles. Image analysis and implementation of scoring criteria were shown to be repeatable for multiple observers.

Conclusions: Our findings are the first to demonstrate a particle load comparison between TDR and THR periprosthetic tissue from historical and current implant cohorts. Polyethylene particle load for historical TDR implants was comparable to historical THR and statistically greater than the post-1998 gamma sterilized TDR components. Acknowledgements: Supported by NIH R01 AR47904, DePuy Spine, and Medtronic.

References:

44. Assessment of Motion Quality Following Lumbar Total Disc Arthroplasty and Lumbar Discectomy

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Introduction: The maintenance of motion following lumbar total disc arthroplasty (TDA) has been well established and
quantified. Unfortunately, there has so far been very little attention of the quality of this motion in the clinical setting. The kinematics of a spinal segment is quite complex, in addition to the intended motion, paradoxical and coupled motions do occur and can have adverse effects on the motion segment and the facet joint. Paradoxical motion is defined as a motion opposite of intended motion, whereas a coupled motion is defined as a motion in planes perpendicular to the intended motion. This study was designed to evaluate the quality of motion by measuring the paradoxical and coupled motions seen following lumbar TDA in comparison to lumbar discectomy.

Methods: Ten patients (14 levels, 6 males & 4 females, 47±7yrs) with lumbar disc degeneration at L2/3, L4/5 and/or L5/S1 that were treated with Prodisc™-L (Synthes, Inc.) TDA and eight patients (8 levels, 4 males & 4 females, 41±6 yrs) with lumbar disc herniation at either L4/5 or L5/S1 that were treated using lumbar microdiscectomy were followed postoperatively at 1 month, 1 year and 2 years. Standard surgical technique was followed and tantalum beads were placed into the vertebral bodies intraoperatively. At each post-operative follow-up, biplanar standing-neutral, flexion and extension radiographs were obtained and 3D segmental rotations were measured for each sagittal motion in both groups using the Radiostereometric Analysis (RSA). The coupled motions following each sagittal plane motion and the frequency of paradoxical motion were statistically analyzed over the follow-up period.

Results: The sagittal motions did not significantly change over the follow-up times in both groups. The flexion and overall sagittal ROM were measured at 1.8±3.3°, 3.5±2.4° in the TDA and 2.8±2.6°, 4.7±2.2° in the discectomy groups, respectively. The differences between the two groups were not significant. The extension ROM was significantly smaller in the TDA when compared to the discectomy group (-0.6±1.1° vs. -2.2±1.6°, p=0.004). There were no significant differences in coupled motions over the 2 year follow-up (Figure 1). TDA exhibited significantly higher rate of paradoxical motion when compared to the discectomy group (26.4% vs. 6.7%, p<0.001). In the TDA group, the rate of paradoxical motion at 1 month (40%) was significantly higher than at 1 year (21.1%, p=0.001) and at 2 years (25.0%, p=0.001). The presence of paradoxical motion was significantly less frequent at L4/5 (19.2%) than at L5/S1 (31.3%, p<0.001) or at L2/3 (36.4%, p=0.001).

Conclusions: In our series, the range of motion following lumbar TDA was similar to the range of motion following lumbar discectomy except for extension; however, the quality of motion was significantly different between the groups. Following TDA, significantly higher rate of paradoxical motion was noted when compared to discectomy. This rate was also dependent on follow up time point and the motion segment involved. The clinical significance of this paradoxical motion and its long-term effect on the motion segment will require further evaluation.

45. 5-year Results of the Prospective, Randomized, Multicenter FDA IDE ProDisc®-L Trial

Methods: Two hundred thirty-six patients had surgery at one of 17 investigational sites across the United States in the randomized portion of the trial. The randomization was weighted in a 2:1 ratio to receive either ProDisc®-L (investigational) or circumferential fusion (control). The clinical status of each patient was evaluated pre-operatively and post-operatively at 6 weeks, 3, 6, 12, 18, and 24 months. Evaluation at each visit included patient self-assessments, e.g., Oswestry Low Back Pain Disability Questionnaire (ODI), SF-36 Health Survey, Visual Analog Scale (VAS) for Pain and Satisfaction; physical and neurological examination, and radiographic evaluation.

Results: Patients in both groups improved significantly following surgery. Baseline preoperative ODI values were not different (investigational: 63.4±12.6, control: 62.7±10.3; p = 0.6125). At 24 months, ProDisc®-L patients trended toward
reflect a precision diagnosis, appropriate patient selection, and a standardised surgical technique. The outcomes supported by the data, with documented significant relief of pain and improvement in functional scores. The outcomes of both procedures are measured using Visual Analogue Back and Leg (VAS), Oswestry Disability Index (ODI), and SF-36. Patients were assessed preoperatively and at 3, 6, and 12 months postoperatively; and annually thereafter.

Results: Mean follow-up was 37.8 months (range = 13mos-9.2yrs). Results at latest follow-up vs. baseline were compared. For the 2TDR group, the ODI score was reduced from 48.2 (14-90) at baseline to 17.0 (0-64) at follow-up (-64.7%). For the HYB group, the ODI score was reduced from 51.0 (0-100) at baseline to 25.8 (0-45) at follow-up (-50.4%). The mean follow-up was 38.0 months (range = 13mos-9.2yrs). The primary indications for 2TDR was proven 2 level discogenic back pain and failed conservative management. HYB is considered over 2TDR when the posterior structures contra-indicate 2TDR (facet arthritis, spondylolisthesis, previous laminectomy, and deformity). A precision diagnosis was obtained by the use of clinical history, MRI, electrophysiological studies, and discography. A standardised surgical technique was employed. Clinical outcomes were measured using Visual Analogue Back and Leg (VAS), Oswestry Disability Index (ODI) questionnaire, Roland-Morris Disability questionnaire (RMDQ), and SF-36. Patients were assessed preoperatively and at 3, 6, and 12 months postoperatively; and annually thereafter.

Conclusions: This is the first reported five year IDE prospective, randomized, multi-center study following lumbar total disc replacement with the ProDisc®-L. The data shows that significant clinical improvement was achieved and maintained in the ProDisc®-L out to 5 years with no deterioration of outcomes from 2 year levels. These results support earlier reports in the literature that total disc replacement with the ProDis®-L is a safe and effective surgical treatment of discogenic pain in patients who met the patient selection criteria.

46. Clinical Results of Two-Level Lumbar Arthroplasty vs. Combined Arthroplasty & Fusion (Hybrid Procedure)

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Objectives: The surgical treatment of multilevel lumbar degenerative disc disease (DDD) requires a precise diagnosis. The pathology at each spinal motion segment dictates what technology can be applied to that level. This paper compares two-level lumbar total disc replacement (2TDR) with a hybrid procedure, combining TDR with fusion (HYB).

Methods: A prospective case cohort study involving 227 patients with multilevel DDD, who underwent either a 2TDR or HYB with a minimum one year follow-up. 143 males and 84 females. 120 patients had a 2TDR and 107 had a HYB. The average age for the 2TDR group was 45.5yrs (range = 26-66yrs) and 51.0yrs for the HYB group (range = 32-69yrs). The mean follow-up was 38.0 months (range = 13mos-9.2yrs). The primary indications for 2TDR was proven 2 level discogenic back pain and failed conservative management. HYB is considered over 2TDR when the posterior structures contra-indicate 2TDR (facet arthritis, spondylolisthesis, previous laminectomy, and deformity). A precision diagnosis was obtained by the use of clinical history, MRI, electrophysiological studies, and discography. A standardised surgical technique was employed. Clinical outcomes were measured using Visual Analogue Back and Leg (VAS), Oswestry Disability Index (ODI) questionnaire, Roland-Morris Disability questionnaire (RMDQ), and SF-36. Patients were assessed preoperatively and at 3, 6, and 12 months postoperatively; and annually thereafter.

Results: Mean follow-up was 37.8 months (range = 13mos-9.2yrs). Results at latest follow-up vs. baseline were compared. For the 2TDR group, the ODI score was reduced from 48.2 (14-90) at baseline to 17.0 (0-64) at follow-up (-64.7%). For the HYB group, the ODI score was reduced from 51.0 (0-100) at baseline to 25.8 (0-45) at follow-up (-50.4%). The mean follow-up was 38.0 months (range = 13mos-9.2yrs). The primary indications for 2TDR was proven 2 level discogenic back pain and failed conservative management. HYB is considered over 2TDR when the posterior structures contra-indicate 2TDR (facet arthritis, spondylolisthesis, previous laminectomy, and deformity). A precision diagnosis was obtained by the use of clinical history, MRI, electrophysiological studies, and discography. A standardised surgical technique was employed. Clinical outcomes were measured using Visual Analogue Back and Leg (VAS), Oswestry Disability Index (ODI) questionnaire, Roland-Morris Disability questionnaire (RMDQ), and SF-36. Patients were assessed preoperatively and at 3, 6, and 12 months postoperatively; and annually thereafter.

Conclusions: This is the first reported five year IDE prospective, randomized, multi-center study following lumbar total disc replacement with the ProDisc®-L. The data shows that significant clinical improvement was achieved and maintained in the ProDisc®-L out to 5 years with no deterioration of outcomes from 2 year levels. These results support earlier reports in the literature that total disc replacement with the ProDis®-L is a safe and effective surgical treatment of discogenic pain in patients who met the patient selection criteria.

47. Evaluation of the Influence of TDR Positioning on Subsidence and Facet Arthrosis

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Intro: Complications with lumbar total disc replacement (TDR) include subsidence of the metal footplates into the vertebral body and facet arthrosis at the implanted level. One of the suspected contributing factors is improper placement of the implant. The objective of the current study was to evaluate how TDR implantation and positioning contribute to implant subsidence and facet joint arthrosis.

Methods: A FE model of a ligamentous L3-L4 motion segment was generated from QCT data. Bone mineral density (BMD)-dependent orthotropic material properties were assigned to the vertebral bodies. Material properties for the remaining bone, disc, and ligaments were assigned from the literature. The intact model was validated using disc pressures, cortical and endplate strains, and kinematic data. An appropriately sized model of the ProDisc-L was placed in the intervertebral disc space at two locations. The implanted and intact models were exercised in flexion (7.5 Nm), extension (7.5 Nm), right axial rotation (7.5 Nm), and right lateral bending (7.5 Nm) with a 500 N compressive follower load. The facet contact forces (FCFs), vertebral body cancellous bone von Mises (VM) strains, and ranges of motion (RoM) were determined.

Results: Facet contact forces (FCFs) increased with implantation of the TDR for flexion and axial rotation regardless of implant positioning. ROM increased with implantation of the TDR for all modes of loading. Anterior placement of the TDR allowed more ROM in flexion while posterior placement allowed for more extension. The decreased FCF in extension for the posteriorly placed TDR coincided with an increased range of motion. The opposite trend was true for flexion. Contour plots of VM strain indicated high strains around the posterior edge of the metallic endplate in flexion and extension for both positions (Figure 1).

Discussion: Data from the current study suggest an increased dependence on the facets to limit range of motion after TDR. Facet arthrosis documented clinically in spinal segments with TDR may be the result of increased loading from greater joint mobility regardless of implant positioning. Anterior placement of the TDR resulted in a reduced area of high strain around the posterior edge of the device in extension. This coincided with increased FCFs, suggesting that vertebral body loading in extension is reduced when the facets participate in resisting the load. Areas of high strain were also documented along the anterior edge of the TDR in flexion, suggesting that implant subsidence and anterior migration may be the result of activities that place the spine in flexion.

48. Prospective, Randomized, Multicenter FDA IDE Study of CHARITÉ Artificial Disc vs. Lumbar Fusion: Effect at 5-year Follow-up of Prior Discectomy on Clinical Outcomes Following Lumbar Arthroplasty

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Purpose: To evaluate the clinical outcomes at 5-year follow-up of lumbar arthroplasty and arthrodesis on patients with prior discectomy.

Methods: All patients included in the randomized controlled multicenter 5-year CHARITÉ IDE study were analyzed herein. Fusion and arthroplasty patients were further divided into 2 groups: Fusion patients with prior discectomy (FPD) vs. fusion patients without prior discectomy (FNPD), and arthroplasty patients with prior discectomy (APD) vs. arthroplasty patients without prior discectomy (ANPD). Demographic, surgical and clinical data were analyzed for both groups.

Results: In the 90-patient CHARITÉ cohort, 21 had prior discectomy. In the 43-patient BAK cohort, 6 had prior discectomy.
For the arthroplasty groups, surgical outcomes indicated small non-statistical trends towards less surgical time (95.6±29.42min for PD vs. 112.0±49.50min for NPD, p=0.3010) and less blood loss (145.2±124.64cc for PD vs. 232.8±258.39 for NPD, p=0.2846) for the PD group. There was no difference in duration of hospitalization between both groups.

For the fusion groups, less surgical time (81.8±29.14min for FPD vs. 128.6±68.51min for FNPD, p=0.0539) but comparable blood loss was observed between FPD and FNPD groups. A trend towards longer hospitalization was observed in the FNPD group (3.5±0.55days for FPD vs. 4.4±1.88days for FNPD, p=0.1613).

Pain and disability were further analyzed for all groups. For the arthroplasty groups, changes in VAS scores were comparable with -36.5mm improvement for the PD group and -39.4mm improvement for the NPD group (p=0.7468). Changes in ODI indicated a small, non-statistical trend towards greater improvements in the NPD vs. the PD group (changes in ODI: -17.6 points for PD vs. -26.0 points for NPD, p=0.1677). This trend was not observed on SF-36 PCS scores, for which both groups averaged similar improvements (12.4 points for PD vs. 12.6 points for NPD, p=0.9705).

For the fusion groups, changes in VAS scores showed trends towards improved VAS scores in the FNPD group (-26.7 for FPD vs. -42.2 for FNPD, p=0.3499). A greater trend was also noted in ODI scores, where FPD group (change in ODI: -10.7) experienced far less improvement than the FNPD group (change in ODI: -30.2; p=0.0515). These differences were reflected as well in SF-36 PCS changes: FPD group showed a mean SF-36 PCS of 4.3 points whereas FNPD group showed a mean SF-36 PCS improvement of 13.6 (p=0.1188).

Conclusions: All CHARITÉ patient groups, with or without prior discectomy, experienced significant clinical improvements from preoperative to the 5-year post-operative time point, as seen in VAS, ODI and SF-36 changes. However, BAK patients with prior discectomy showed trends towards reduced clinical outcomes. This analysis provides evidence that the CHARITÉ can be utilized after a prior discectomy with similar results as expected from patient without prior discectomy.

49. Medico-economical Evaluation of Total Disc Replacement Based on French National Health Care (Sécurité Sociale) Data’s

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Background: Disc prosthesis exists since 1984 but it still can’t get it paid for by French National Health Care. Few data are available on medicoeconomical background in France. Our objective was to evaluate the clinical and radiological outcomes, and also the medical cost before and after operation.

Methods: We present a prospective, descriptive study of the first 20 patients treated by a total disc replacement in two centers. Operations were realized on 16 women and 4 men with mean age of 41 years (24-57), using SB CHARITE(9), MOBIDISC(6), MAVERICK (3), PRODISC(2) prosthesis on L4L5 (8) and LSS1 (12) levels. Only patients less than 60 years old with single level disc pathology were included without sagittal or frontal deformity. Patients with workers compensations were excluded Clinical outcome was evaluated with VAS, Oswestry disability index, MOS SF 36, and the ability to return to work.

The placement accuracy of prosthesis was determined by computed analysis. We evaluate the medical cost with help of French National Health Care by consulting their own bill’s archives for each patient(in France it represents the all cost). Statistical analysis was based on Kruskall Wallis, Wilcoxon, and Mann Whitney tests for mean comparision and Spearman test for correlations between clinical and economical parameters.

Results: One complication with peroperative endplate fracture needed a revision surgery.

The mean follow up is 15 month before operation and 24 month after for the 20 patients. The VAS for back pain decreased from 7.6 to 3.9 at 3 month postoperatively and maintained at 3.9 at 2 years of follow up.

The ODI score and global SF36 score decreased respectively from 46,3 and 33,1 to 28,8 and 64,5 at 3 month postoperatively and maintained at 29,6 and 62,7 at 2 years of follow up.

75% of patients was satisfied and very satisfied at the last follow up and 65% returned to work at the same or less level. The radiographic study showed 70% of disc space occupation on coronal and 83% on sagittal view. The disc height reconstruction was at 134% compared to superior level. The mean mobility in flexion extension was 8° of range and most of the time < 5° in lateral bending. The economic study showed 455 122 € of bill for 20 patients on 39 month of follow up. A significant reduction of mean cost compared before (846.46 € +/-567.86) to after operation (590.3 € +/-750.27) (p=0.03) was found. A statistic correlation was found between Vas (p=0.05, r= 0.53), ODI (p=0.03, r= 0.6), SF36 (p=0.03 r=-0.6) and the global cost. It was the same for satisfaction (1187.2 € +/-1187.7 with non satisfied against 391.3 € +/-437.3 for satisfied p=0.04).

Discussion: This is the first French report on economical cost of total disc replacement with the help of French National Health Care.
We found good short-term clinical results and reduced economical outcomes after total disc replacement with patients who complain about chronic low back pain.

50. The Effect of Adverse Events on Clinical Outcome: Analysis of Data from an FDA IDE Trial

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Objectives: Comorbidities have been reported to be related to lumbar spine surgery outcome. Adverse events (AE, any change in the medical condition of a patient occurring during the course of a study, may or may not be related to the study device or the surgery) include a wide variety of problems including injury due to vehicular accidents, cancer, hand surgery, initiation of asthma treatment, etc. In some respects, adverse events recorded in clinical trials may be viewed as “transient comorbidities”, that is, during the study, these events may be active or may have resolved. At any follow-up period during the study, a patient may have none or more than one active AE. The AE may or may not resolve by the next follow-up visit and may or may not be related to the study procedure. The purpose of this study was to determine if the presence of active adverse events have an impact on clinical outcome in an FDA IDE trial.

Methods: The study group was 220 patients enrolled in the ProDisc-L FDA IDE trial, randomized and continued access arms, at a single site. Per study protocol at each visit, adverse events were assessed including date of onset, severity (mild, moderate, severe), relationship to the study procedure (related, unrelated or inconclusive), and date of resolution vs. ongoing status was recorded. Clinical outcome was determined based on the percentage improvement on visual analog scales (VAS) assessing pain and Oswestry scores from pre-operative to the various follow-up visits. For this abstract, the 24-month follow-up data were reported. The mean improvement in VAS and Oswestry scores at each study follow-up visit were compared using ANOVA analysis across the severity and relationship categories, as well as across the number of active AEs within a patient at the time of the follow-up visit.

Results: There was a significant relationship between the presence of active AEs and clinical outcome. Among patients with no AEs present the mean improvement in the VAS pain score was 74.2%, compared to 58.9% in patients with one AE, 30.0% with two AEs and 40.6% among patients with three or more active AEs (p<0.01). Oswestry scores were also significantly related to the number of active AEs (p<0.01). With respect to AE severity, patients with no AEs improved statistically significantly more on VAS scores than did patients with moderate or severe AEs (74.2% vs. 43.1% and 42.3%). Patients with mild AEs (mean improvement 54.3%) did not differ significantly from those with no AEs. Patients with AEs related to the surgery had less favorable VAS scores than patients with no AEs or unrelated AEs.

Conclusions: This study represents the first investigation of the impact of adverse events on clinical outcome in a spine clinical trial. We found that the presence of active AEs significantly influenced clinical outcome. Rigorous recording of AEs appears to be important not only for assessing the safety of a device but also explain part of the variance in post-operative results.

51. A Prospective Randomized Comparison of Two Lumbar Total Disc Replacement Devices

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Objectives: Total disc replacement (TDR) has been available for many years in Europe. After completion of the FDA trials, these implants are gaining acceptance in the United States. Previous randomized studies have compared TDR to anterior lumbar interbody fusion or combined anterior/posterior instrumented fusion. In these studies, TDR results were as good as fusion, and better on some outcome measures. To date, there has not been prospective, randomized study comparing two TDR devices. The purpose of this ongoing study, was to compare the results of TDR using Charité to Kineflex.

Methods: A total of 85 patients 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 patients were treated for single-level symptomatic disc degeneration at either the L4-5 or L5-1 level. The majority of surgeries were performed at L5-1. Data collection included peri-operative data, 12-month clinical outcomes based on the Oswestry and visual analog scales assessing pain, adverse events and re-operations, and radiograph evaluation assessing disc height and range of motion.

Results: The mean operative time was very similar in the two TDR groups, almost 59 minutes in each. The length of hospitalization was 2.4 days in the Kineflex group and 2.7 days in the Charité group. Estimated blood loss was higher in the Kineflex group (113.9 vs. 64.1 cc). Clinically, both groups improved significantly with respect to VAS scores assessing pain and Oswestry scores assessing function. VAS scores in the Kineflex group improved from 83.0 to 19.0 at 12 month follow-up and the Charité group improved from 81.7 to 30.3. The mean pre-operative Oswestry score in both
groups was about 57. In the Kineflex group, it improved to 20.6 at 12 month follow-up and to 23.4 in the Charité group. The incidence and types of adverse events in the two groups were very similar. Radiographic assessment data was available through 6 month follow-up. In both groups, disc height increased after TDR (Kineflex: 8.1 to 14.6 mm; Charité: 8.4 to 15.7 mm). The pattern of change in range of motion at the implanted level, as measured from flexion/extension radiographs, was similar in the two groups. Pre-operatively, the mean range of motion in the Kineflex group was 4.9 degree and at 6 months was 4.0 degrees. In the Charite group, the range of motion was 5.2 degrees pre-operatively and 5.0 degrees at 6 months post-operative.

**Conclusions:** This study provides preliminary data for two sites participating in the FDA-regulated trial evaluating the Kineflex artificial disc by comparing it to the Charite 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. The 24-month follow-up will be collected as patients reach that point. Also, data is being collected at other sites in accordance with the same protocol. This study reinforces that when rigorously adhering to a well-defined patient selection criteria, similar results are produced across different TDR implants.

### 52. Wear Testing of Metal-on-Metal Total Disc Replacement Components

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**Introduction:** Lumbar total replacement disc (TDR) designs are, in general, based upon technology used in highly successful total hip arthroplasty (THA). Recently, metal/UHMWPE lumbar TDR’s have been approved by the FDA for sale in the US. Wear testing of these components, under the ISO proposed standard, has shown TDR wear rates significantly below that of THA components. Presently, Metal-on-Metal (MoM) lumbar TDR’s are in clinical evaluation. There have been TDR wear rates reported, but these have not been based on the most current ISO standard. The purpose of this investigation was to simulate the mechanical performance of MoM TDR’s when experiencing ISO specified conditions and to analyze the wear by determining volumetric wear rates and observing contact surfaces.

**Methods:** Testing consisted of the evaluation of two metal-on-metal Maverick TDR’s and a prototype TDR design. Components consisted of CoCrMo alloy articulating surfaces (surface finishes (Ra) ranging from 9 to 19nm). Clearances for the ball-and-socket of the Maverick TDR’s were -196 and 130µm and for the prototype TDR ranged from 74 to 162µm. Testing was performed at EndoLab Mechanical Engineering GmbH. Testing included a time-varying force (600-2000N, 2Hz) and coupled flexion/extension (6°/3°, 1Hz), lateral bending (±2°, 1Hz), and axial rotation (±2°, 1Hz) motions. Components were oriented at a 0° shear angle. Testing was performed in a bovine calf serum for a total of 5 million cycles. The average volumetric wear rate was calculated using linear regression analysis. Wear surfaces were described. 

**Results:** The Maverick TDR’s showed an average run-in wear rate of 8.9mm³/Mc and a steady state rate of 4.34mm³/Mc. For the prototype TDR, an average run-in wear rate of 1.4mm³/Mc and a steady state rate of 5.12mm³/Mc were calculated. All articulating surfaces showed severe scratching.

**Discussion:** Limited data has been reported on wear testing of metal-on-metal components according to the proposed ISO standard. In this study, a current MoM TDR under IDE investigation and a prototype MoM TDR were tested. Prototype TDR design parameters were based upon a literature review of successful THA designs. Previously, Mathews has reported a wear rate of 1.2 to 1.4mm³/Mc for the Maverick TDR. It is not possible to compare our results in that specifics of their test method were not reported. Pare has recently reported steady state wear rates for Maverick components on the order of 0.33 to 0.43mm³/Mc. Their results are based upon the ASTM guideline for wear testing which tests at a significantly lower load than the ISO test. Additionally, the Mavericks tested had clearances of 38±7µm, which are considerably less than the clearances of the off-the-shelf Mavericks tested in this study. The wear rate determined in this study is considerably greater than those previously reported. Additionally, it is at least 15 times greater than the steady state wear rates reported for THA MoM designs. This study suggests that MOM TDR implant parameters thought to affect wear (diameter, material, clearance, surface finish, etc.) must be optimized in order to achieve MOM wear improvements similar to those seen in THA.

### 53. Is Preoperative Disc Height a Predictive Factor to Lumbar Total Disc Arthroplasty

**Results?**


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Introduction: Criteria to determine the best indications for disc arthroplasty include clinical and radiological endpoints. Degenerative Disc Disease (DDD) and Modic classification at the MRI, and discogenic pain during discography are usually used to define the best surgical procedure. For some surgeons, preoperative narrowing of the disc height is also necessary to pursue Total Disc Arthroplasty. We report a prospective study result comparing the outcomes of lumbar disc arthroplasty according to the preoperative disc height at the operative level.

Methods: 51 consecutive patients who received Mobidisc prostheses (disc prosthesis designed with a mobile nucleus) implanted at L3L4, L4L5 or L5S1 levels have been followed-up prospectively for 12 months. 30 disc prostheses have been implanted for degenerative disc disease with disc height narrowing (Group 1) and 21 for degenerative disc disease with no disc height narrowing (Group 2). Clinical evaluation included VAS (0-10 scale) for back and leg pain, Oswestry Disability Index (ODI) and radiological assessment included Range of Motion (ROM) measurement from dynamic x rays.

Results: The mean age in Group 1 was 40 years vs. 36 in Group 2. 50% were female in Group 1 vs 36% in Group 2. Mean lumbar VAS scores decreased significantly compared to pre-operative values from 6.5 to 2.5 (Group 1) and from 6.2 to 2.4 (Group 2). Mean leg VAS scores decreased significantly compared to pre-operative values from 6.7 to 2.5 (Group 1) and from 7.0 to 4.0 (Group 2). Average ODI score decreased significantly compared to pre-operative values from 51% to 23% (Group 1) and from 46% to 19% (Group 2).

Conclusion: According to Oswestry score and back pain, functional results at one year are similar between both groups of patients. The decrease of leg VAS score is better in case of preoperative disc narrowing than not (4.2 pts vs 3 pts). Nevertheless, disc arthroplasty statistically improves leg pain, back pain and Oswestry scores even without preoperative disc height narrowing. This study demonstrates that Total Disc Arthroplasty is an effective surgical procedure to treat degenerative disc disease even without narrowing of disc height at the operative level with equivalent satisfaction index of the patients towards the surgical procedure in both groups.

54. Minimally Invasive Lateral Lumbar TDR: 24 Months Follow-Up

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Purpose: Current lumbar total disc replacement (TDR) devices require an anterior approach for implantation. The anterior approach to place lumbar TDR devices has inherent limitations, including risks to abdominal structures, and resection of the anterior longitudinal ligament (ALL). Placement of a TDR device from a true lateral (XLIF) approach allows for easier, less invasive access to the disc space, as has been shown in reports of XLIF for fusion procedures. Lateral implantation of TDR also preserves the stabilizing ligaments, which are a natural restraint to excessive rotations and translations, and thereby help to minimize facet stresses. Importantly, implantation from a lateral approach leaves greater opportunity for safer revision surgery, if necessary, by avoiding scarring of anterior vasculature. Additionally, the footprint of the lateral TDR device capitalizes on the biomechanical support of the ring apophysis.

Methods: A TDR device designed for implantation through a true lateral, retroperitoneal, transpsoas approach (XLIF) was implanted in 25 patients with discography-confirmed 1- or 2-level DDD. Clinical and radiographic outcomes assessments were prospectively collected.

Results: Patients included 12 males and 13 females, average age 43 yrs (24-60). Surgeries included 8 1-level, 3 2-level, and 14 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 2.2 at two 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 12 at 2 years. Average postoperative ROM remains steady, not significantly different from preoperative values.

Conclusion: Mid-term results of a laterally placed TDR device demonstrate maintenance of pain relief and functional improvement. The benefits of this technique -- minimal morbidity, avoiding mobilization of the great vessels, preserving the anterior longitudinal ligament, biomechanically stable orientation, and broader revision options - suggest a promising new direction for TDR procedures.
Aims: In patients with chronic low back pain (LBP) that is discogenic and unresponsive to conservative treatment, lumbar fusion is considered the "gold standard" of surgical treatment. Total disc replacement (TDR) has been introduced as an alternative treatment. The purpose of this study was to compare TDR and lumbar fusion in terms of clinical outcome.

Methods: The study design was a prospective, randomized, controlled comparison (RCT) between TDR and instrumented lumbar fusion. All included patients had failed a conservative treatment program. LBP was the predominant symptom. Diagnosis was made on the basis of clinical examination, radiographs, MRI, and in some cases, diagnostic injections. Clinical outcome was determined by means of The Swedish Spine Registry and included Visual Analogue Scale (VAS; back and leg), Oswestry questionnaire, SF-36, Euroqol, and the patient's global assessment of back and leg pain.

Results: A total of 152 patients were included. Eighty underwent TDR, and 72 had instrumented fusion. The mean age was 40±8 years (range 21-55), and 59% of the patients were female. The follow-up rate was 100% at one year and so far 78% have completed two-year follow-up. All main clinical outcome parameters improved for both groups. After one year the TDR group had a larger improvement with regard to pain (VAS), Oswestry Disability Index, Euroqol, and global assessment than the fusion group. In the TDR group, 29% of the patients reported total relief with regard to back pain compared to 10% in the fusion group (p<0.01). There was no change in results between one and two years, however we can not show all the significance differences between groups due to lower follow-up rate so far.

Conclusions: The superiority of TDR compared to fusion in clinical outcome at one year seems to stay on at two-year follow-up. Even so, a new treatment option needs a longterm perspective, so these patients will again be checked and compared at 5 and 10 years from surgery.

66. TRIUMPH™ Posterolateral Artificial Disc Biomechanics: The Effect of Posterior Tethering


Objectives: Posterior Total Disc Arthroplasty may involve resection of the facet joints depending on the amount of decompression required and implant design. A dynamic stabilization device may be used as a posterior tether to stabilize the implanted level. The aim of this study was to evaluate the in vitro biomechanical characteristics of a posterior dynamic stabilization device (PDS) adjunct to a posterolateral total disc arthroplasty (PL-TDA) for reconstruction of the lumbar spine. The primary objective was to quantify the change in kinematics of the 3 joint complex due to posterior intervention and subsequent dynamic stabilization.

Methods: Seven cadaver lumbosacral spines (L1-S1) were tested in a six-degree of freedom spine tester in the following sequences: (1) Intact specimen, (2) bilateral facetectomy at L4-L5; (3) PL-TDA at L4-L5 (4). PL-TDA (TRIUMPH™) + PDS (TRANSITION™). A hybrid test protocol was used for flexibility testing with moments of ±8Nm used for flexion-extension, lateral bending and axial rotation; range of motion (ROM) and intradiscal pressure (IDP), were recorded from both operated (L4-5) and adjacent level (L3-4). The data were normalized to the intact spine (100%).

Results: In flexion and extension, bilateral facetectomy increased L4-L5 ROM to 110.3±16.14% and 128.6±41.3% respectively. Insertion of PL-TDA restored ROM closer to intact (103.09±3.71% in flexion and 113.37±39.1% in extension). The PDS + PL-TDA further stabilized ROM to 34.4±39.2% in flexion and 41.5±43.1% in extension. Lateral bending was minimally affected with bilateral facetectomy (106.1±15.7%) and also, with PL-TDA (104.7±7.9%). Addition of PDS further reduced ROM to 38.4±14%. Axial rotation was significantly increased after bilateral facetectomy (175.3±13.6%) which was not corrected with the insertion of PL-TDA alone (180.8±21.6%). Addition of PDS to this construct restored the motion close to intact (108.82±21.6%). IDP in the proximal adjacent segment (L3-L4) in flexion was increased following bilateral facetectomy (114.2±48.4%), reduced after PL-TDA alone (65.1±52.46%) and increased again after addition of PDS (169.6±34.6%) The inferior adjacent segment (L5-S1), the IDP changed in a similar direction (123.2±21.8% with facetectomy, 67.4±28.8% with PL-TDA and 148.3±25.8% with PL-TDA+PDS). In extension, IDPs at L3-L4 were 99.5±44%, 94.86±61% and 49.3±58% respectively for the three
constructs, while L5-S1 experienced IDPs of 108.5±33.4%, 106.3±9.2, and 99.6±22.7%

**Conclusions:** The results indicate that PL-TDA reconstruction after bilateral facetectomy increased operative level ROM in all three physiologic planes compared to the intact; more specifically in axial rotation than in other directions. Posterior tethering with PDS stabilized the spine and reduced ROM in all directions and particularly restored axial rotation close to intact. This study provides a biomechanical foundation for posterior tethering a PL-TDA device using a PDS system when bilateral facetectomy is required for decompression.

![Figure 1](image)

**Fig 1.** Axial rotation total ROM at operative (L4-L5) and adjacent motion segments (L3-L4, L5-S1). Posterior dynamic stabilization reduces the ROM at operative level compared to the PLTDA reconstruction with bilateral facetectomy.

57. Does Chronic Rim Impingement Influence Dome Wear in Mobile Bearing TDRs?

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**Introduction:** Impingement has been observed in retrieved TDRs, however the clinical consequences of chronic rim impingement remain poorly understood. In total hip replacements, rim impingement has previously been associated with elevated liner shell-relative motion and backside wear. We evaluated our retrieval collection of polyethylene mobile bearing TDRs to determine whether rim impingement adversely affected dome penetration.

**Methods:** We analyzed the motion patterns and dome penetration of 40 Charité (SBIII, manufactured by Link) implants from 34 patients (74% female) from the United States and Europe. All of the TDRs were revised for intractable back pain. 28/40 (70%) cores, implanted for 2-16 years (7.9y ave), were classified as exhibiting chronic rim impingement based on observations of plastic deformation, burnishing, and/or fracture of the rim. In addition to pain, chronically impinged cores were also revised for subsidence (n=10), anterior migration (n=3), core dislocation (n=2), lateral subluxation, endplate loosening, and osteolysis (n=1). 10/40 (25%) of the cores, implanted for 2-10 years (5.1y ave), showed evidence of mild or negligible rim contact, and one case was revised for loosening. For 2 cores the impingement pattern could not be determined. Dome and rim penetration was measured using a calibrated micrometer in all but one case. Linear regression and multivariate analysis of variance were used to explore relationships between implantation time, dome and rim penetration, and chronic impingement.

**Results:** Dome penetration was comparable in chronically impinged cores (ave: 0.3, range: 0.1 to 0.9 mm) as compared with non-impinging cores (ave: 0.3, range: 0.1 to 0.5 mm). Rim penetration was significantly greater in chronically impinged cores (p < 0.05). Using linear regression, the dome penetration rate for cores with negligible impingement (0.036 mm/y, 95% CI: 0.012 to 0.061 mm/y) appeared slightly higher than in cores with chronic impingement (0.021 mm/y, 95% CI: 0.005 to 0.038 mm/y), however the difference was not significant. The average dome penetration rate for all the components in our study was 0.022 mm/y (95% CI: 0.009 to 0.036 mm/y).

**Discussion:** The results of this study did not support our hypothesis, that chronic rim impingement would be associated with greater dome penetration. We estimate that the power of our analysis to detect a 50% decrease in wear rate is <80%, therefore a greater number of retrievals is necessary to definitively refute our hypothesis. However, at present our findings would suggest that dome wear and impingement are effectively decoupled phenomena, and may be studied independently of each other. Although the majority of retrievals in our collection (70%) showed signs of chronic rim impingement, the findings from revisions represent clinical failures and are not necessarily representative of the prevalence of impingement in patients with well functioning TDRs.
58. Prospective, Randomized, Multicenter FDA IDE Study of CHARITÉ Artificial Disc vs. Lumbar Fusion: Effect at 5-year Follow-up of Age on Clinical Outcomes Following Lumbar Arthroplasty

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Objectives: To evaluate the effect of age on 5-year clinical outcomes, for patients implanted with the CHARITÉ Artificial Disc.

Methods: All arthroplasty patients included in the randomized controlled multicenter 5-year CHARITÉ IDE study were analyzed herein. Patients were divided into 2 groups by age at implantation (18-45 and 46 to 60). Demographic and surgical data was recorded for both groups separately. Clinical outcomes evaluated herein included VAS, ODI, SF36, patient satisfaction and work status.

Results: Of the total 90 CHARITÉ patients, 67 were included in the 18-45 year-old group (referred below as the “18-45 group”), and the remaining 23, in the 46-60 year-old group (referred below as the “46-60 group”). There was no statistical difference in gender (46% female and 54% male in 18-45 group vs. 52% female vs. 48% male in 46-60 group, p=0.6381) or body mass index (26.2±4.44 in 18-45 group and 26.9±3.06 in 46-60 group) between groups. A majority of implanted levels were at L5-S1 for both groups (69% for 18-45 group and 78% for 46-60 group, p=0.4364). Albeit not statistically significant, a trend of increased operating time was observed in the 46-60 group (101.9±39.87min for the 18-45 group and 126.3±57.66 for the 46-60 group, p=0.1485). Similarly a small trend of increased blood loss was observed in the older group (185.3±181.43cc for 18-45 group and 289.1±342.69cc for 46-60 group, p=0.1265). Duration of hospitalization was similar between groups.

Pain and disability scores both showed a slight, non-statistical trend of increased improvement in the 46-60 group as compared to the younger cohort. From baseline to 5-year post-operative, changes in VAS scores reached -36.8mm for the 18-45 group and -44.1mm for the 46-60 group (p=0.2080). Changes in ODI scores reached -21.9 points for the 18-45 group and -30.2 points for the 46-60 group (p=0.1474). Changes in SF-36 PCS scores were also non-statistically greater in the older group: 1.8 points in the 18-45 group and 14.7 points in the 46-60 group (p=0.2853). Patient satisfaction was similar across groups (89% “satisfied” or “somewhat satisfied” in the 18-45 group and 96% “satisfied” or “somewhat satisfied” in the 46-60 group). A slight, non-statistical difference was also observed in everyday activity levels: 42% of the 18-45 group had “definitely more everyday activity” as compared to 61% in the 46-60 group. Employment figures were also similar between groups: 74% of 18-45 group and 65% of the 46-60 group were employed part- or full-time.

Conclusions: Overall both patient age groups demonstrated significant pain and disability improvements. Patient age divided at 45 (range 18-60) did not statistically affect clinical outcomes by the 5-year follow-up time point.

59. Effect of Intervertebral Disc Degeneration on Spinal Stability - Relevance for Dynamic Stabilisation

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Purpose of the study: Intervertebral disc degeneration is known to affect the stability of the spine. According to Kirkaldi-Willis and Farfan (1982) lumbar disc degeneration may be divided into three stages: (1) temporary dysfunction, (2) unstable phase and (3) stabilisation. Based on this classification, mild or moderate intervertebral disc degeneration could be one of the clinical indications for dynamic stabilisation devices. These devices are intended to restabilise unstable segments but still allow some movements in order to prevent the progression of adjacent level diseases. However, in the literature, there are also data reported, which indicate the opposite: stability continuously increases from the lowest towards the highest degree of degeneration. Thus, it is still not known whether mild or moderate intervertebral disc degeneration is always equivalent to instability, and, thus could be treated with dynamic stabilisation devices. The aim of the present study therefore was to correlate the degree of intervertebral disc degeneration with the segmental flexibility based on data from a large in vitro database and to discuss the impact of the results on dynamic stabilisation.

Methods: The flexibility data from all spine specimens tested in our institute so far were collected in a large in vitro database. From this database, all lumbar spine specimens were selected, which had been tested for flexibility in
flexion/extension, lateral bending and axial rotation under pure moment loads of ±7.5Nm and for which radiographs were accessible. 203 segments from 111 donors with an age of 19 to 99 years (median 56 years) met these criteria. Their radiographic degree of disc degeneration was determined on a scale from 0 (no degeneration) to 3 (severe degeneration). For this purpose, three criteria were rated: height loss, osteophytes and sclerosis. The overall degrees of degeneration were then correlated to the respective range of motion and neutral zone. Since the different lumbar levels differ in flexibility, a statistical model was created which allowed to pool them together.

**Results:** The statistical model predicted a continuous decrease of the range of motion from grade 0 to 3 in flexion/extension and lateral bending. This decrease was 3.1° in magnitude in flexion/extension and 3.4° in lateral bending (p<0.05). Only in axial rotation the range of motion tended to increase, however not only from grade 0 to 1 but continuously towards grade 3 (by 0.2°; p>0.05). The neutral zone was affected by the degree of degeneration in a similar way but to a smaller degree. Thus, an unstable phase, as described by Krikaldji-Willis and Farfan was not found.

**Conclusion:** The results of this study indicated that early stages of intervertebral disc degeneration do not necessarily cause instability. In contrast, the results showed that stability continuously increased in flexion/extension and lateral bending. Only in axial rotation stability tended to decrease. From these results it may be concluded that dynamic stabilisation devices should mainly stabilise in axial rotation and may be suitable not only in mild but in all degrees of degeneration.

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**60. Variability among 10 Production Lots of a Single Demineralized Bone Matrix (DBM) Product**

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**Introduction:** There are over 17 demineralized bone matrix based products (DBMs) commercially available as bone graft extenders for fusion procedures. Few of these “off-shelf” DBMs have been evaluated for reliability and fusion efficacy. Recent studies have shown both intra-product variability (due to production lots) and inter-product variability (product formulations) [1]. The purpose of this study was to assess lot-to-lot variability of one DBM product (intra-variability) using both in vitro and in vivo assays. In particular, can BMP-2, BMP-7 and/or alkaline phosphatase (AP) assays accurately predict the in vivo osteoinductive potential of individual DBM lots from a single vendor? The inconsistency of fusion outcomes from previous DBM studies [5] warrants the development of a screening method for ensuring optimal osteoinductivity in clinical settings. Materials and

**Methods:** 10 individual production lots of a commercially available DBM putty. In vitro methods: 1) BMP-2 and BMP-7 concentrations in each of 10 DBM lots were measured using ELISA. 2) Mouse myoblasts were incubated with each DBM lot, and the extent of subsequent osteoblast differentiation was detected using an AP assay.

In vivo osteoinductive potential: 40 mature athymic nude female rats were used (170g, Harlan Sprague Dawley, IN). L4-L5 posterolateral intertransverse process fusion was performed with decortication of only the L4 and L5 transverse processes (lamina and facet joints were left intact without decortication). Wounds were irrigated. An aliquot from each of 10 DBM lots (0.3 cc per side) was implanted into 4 rats (n = 4 rats / each 10 lots, n=40 rats). Rats were sacrificed at 8 weeks. Radiographs and histology were done. Explanted segments were manually tested for intersegmental motion.

**Results:**

**In vivo study:** 96% of the rats showed de novo bone formation on high resolution radiographs of explanted lumbar spines after sacrifice at 8 weeks (example radiographs, Fig 1). There was significant manual fusion variability across lots (p<0.04) where 23% of the rats were completely manually fused at 8 weeks. While 2 lots almost always promoted fusions, 5 lots consistently failed.

[Figure1]
In vitro study: From lowest to highest, there was a five-fold difference in amounts of BMP-2 and a three-fold difference for BMP-7 revealing lot-to-lot variability among the aliquots. There was a positive correlation between amount of BMP-2 and BMP-7 in lots of DBMs \((r = 0.77, p<0.0001)\). Most notably, BMP-2 and BMP-7 concentrations positively predicted the rate of successful manual fusions across lots of DBM (BMP-2 \(p < 0.01\); BMP-7 \(p<0.009\), Fig 3. The same 2 lots that induced the highest fusion rate (75%) also contained the highest concentrations of both BMP-2 and BMP-7.

Conclusion: There is significant lot-to-lot variability in BMP levels, extent of AP induction, and in vivo fusion rates. This is the first of a series of studies to test in vitro predictors of in vivo lot-to-lot variability in one product of DBM in one study.

61. Revision Problems in Anterior Lumbar Surgery

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Background: Anterior lumbar surgery revisions remain a most challenging problem facing spine surgeons. This study presents results, management issues and complications in a consecutive series of revisions performed by the author.

Methods: 62 patients had surgery between February 2000 and September 2007. 34 were females and 28 were males. BMI ranged from 22 to 40 and age from 21 to 67. 23 patients had the same level re-exposed for removal or repositioning of the prior device. Of these, 7 had a failed total disc replacement (TDR) and 16 had pseudoarthrosis after anterior lumbar interbody fusion (ALIF). Of the failed TDR’s, 6 were at L5-S1 and 1 at L4-5. Two patients with devices removed at L5-S1 also needed fusion of L4-5 and the one removed at L4-5 required fusion of L5-S1. 3 of the 23 were re-explored within 1 to 10 days while the rest were approached after that (6 weeks to 23 months). 39 patients had adjacent level degeneration. 6 of these had an artificial disc deployed at L3-4 after L4 to S1 anterior surgery. Of the remaining 32, 9 had L5-S1 fused after fusion above, 6 had L4-5 fused after L5-S1 and 3 after L3-4. 6 had L3-4 fusions after prior L4 to S1 ALIF. The remainder had L2-3 and/or L1-2 fused after lower level fusions. In all patients left ureteral catheters were placed (bilaterally for L5-S1 revisions), the cell saver was used and groins were prepped in expectation of endo-vascular repairs. A venogram was done for an anteriorly extruded core at L4-5. Proximal and distal control of major vessels was not obtained in any case. The retroperitoneal approach was used in all but 3 patients. Opposite side for L5-S1 and antero lateral for L4-5 and above.

Results: There were 3 venous injuries (4.8%), 3 arterial injuries (4.8%) and 1 ureteral injury (1.6%). All were treated successfully with no deaths or major sequelae. One revision for pseudoarthrosis at L5-S1 was aborted after the vein injury was repaired. Another venous injury occurred while removing an artificial disc from L5-S1 and required ligation of the vena cava and both common iliac veins after completion of the arthrodesis. This patient recovered and had a posterior instrumentation 2 weeks later. The three arterial injuries occurred while doing a TDR at L3-4 after prior L4 to S1 surgery. All three devices were deployed successfully and the arterial problem treated with good resolution. One intimal disruption was repaired with endovascular stents after thrombectomy via groin approach and the one ureteral injury was identified by the ureteral catheter. 1 of 2 males revised at L5-S1 reported retrograde ejaculation. There were no other complications.

Conclusions: Although revisions remain extremely challenging, especially returning to L4-5 and exposing L3-4 after L4-5, the success rate can be high with relatively low complication rates. Careful planning is mandatory with precautionary measures, such as ureteral catheters and groin preps. Surgeon’s experience is key to good results. Minimum 5 years with 200+ cases is recommended.

62. Serum Metal Levels in Patients with Cobalt-Alloy Metal-on-Metal Lumbar Disc Replacements

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Objectives: Total disc replacement is a recent alternative treatment for degenerative disc disease. Corrosion of metallic wear particles can lead to increased metal ion release in the body. This study examines the serum chromium (Cr) and cobalt (Co) levels in patients with cobalt-chromium (CoCr) alloy metal-on-metal (MOM) lumbar disc replacements out to 12 months.

Methods: A prospective longitudinal study was performed consisting of a group of patients implanted with the MAVERICK® Lumbar Disc (Medtronic, Memphis, TN). This system consists of a MOM CoCr alloy (ASTM F1537) articulation. Serum samples were collected pre-operatively \((n = 24)\) and at 3 \((n = 24)\), 6 \((n = 24)\), and 12 \((n = 23)\) months post-operatively. Serum was assayed for Cr and Co using high-resolution inductively-coupled plasma-mass spectrometry \((Element2, Finnigan MAT, Bremen, Germany)\). The detection limits were 0.015 ng/mL for Cr and 0.04 ng/mL for Co. Values below the detection limits were assigned a value of half the detection limit. Longitudinal statistical comparisons were made using the Friedman test.
Results: The median serum Co levels at pre-op, 3, 6, and 12-months post-op were 0.10, 1.03, 0.96, and 0.98 ng/mL, respectively. The median serum Cr levels at pre-op, 3, 6, and 12-months post-op were 0.06, 0.49, 0.65, and 0.43 ng/mL, respectively. Co levels were statistically higher (p < 0.01) at the 3, 6, and 12-month time periods compared with pre-op levels. Cr levels were statistically higher (p < 0.01) at the 3, 6, and 12-month time periods compared with pre-op levels. The median serum Co levels at 12 months post-op appear to be equivalent to Co serum levels in a group of CoCr alloy MOM surface replacements of the hip and CoCr MOM total hip replacements [1]. The median serum Cr levels in this lumbar disc replacement cohort appear to be lower than those reported in a group of CoCr alloy MOM surface replacements of the hip and CoCr MOM total hip replacements at the 12-month post-op time period [1]. Additionally, when compared with reported Cr metal ion data for patients with posterior spinal arthrodesis with stainless steel instrumentation [2,3], this lumbar disc cohort reported lower Cr metal ion levels.

Conclusions: In general, these results indicated that short-term metal ion levels are of the same order of magnitude as those observed in well-functioning metal-on-metal hips and lower than those observed in posterior spinal arthrodesis. Continued surveillance of this patient cohort is ongoing and will provide longer-term follow-up data for this lumbar disc replacement system.

References:
[1] Skipor et al, ORS 0124, 2004;

63. Total Disc Arthroplasty: An Effective Operative Treatment of Degenerative Disc Disease in Patients with Previous Surgical Discectomy


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Introduction: In some cases, surgical discectomy fails to treat back or leg pain. In some others, after post-operative healing, degenerative disc disease appears and leads to recurrent back or leg pain. Options for iterative surgery include re-discectomy with or without fusion; usually with poor results. We report multi-center prospective study results comparing the outcomes of disc arthroplasty following discectomy to no previous surgery.

Methods: 130 consecutive patients who received Mobidisc prostheses (disc prosthesis designed with a mobile nucleus) have been followed-up prospectively for 12 months. 35 disc prostheses have been implanted after discectomy due to disc herniation (Group 1) and 95 for primitive degenerative disc disease with no previous lumbar surgery (Group 2). We evaluated VAS (0-10 scale) for back and leg pain, Oswestry index and performed a radiological study including lordosis measurement and dynamic x rays.

Results: The mean age in Group 1 was 40 years vs 42 in Group 2. 70% were female in Group 1 vs 69% in Group 2. L5-S1 was operated on in 81% of Group 1 vs 67% of Group 2. All the patients were reviewed at a follow-up of 12 months in both groups.

Mean lumbar VAS scores decreased significantly compared to pre-operative values from 6.4 to 2.6 (Group 1) and from 6.4 to 2.3 (Group 2). Regarding back pain 72% of the patients were satisfied in Group 1 vs 75.5% in Group 2. Mean leg VAS scores decreased significantly compared to pre-operative values from 5.9 to 3 (Group 1) and from 5.4 to 2.4 (Group 2). Regarding leg pain, 60% of the patients were satisfied in Group 1 vs 76% in Group 2. Average Oswestry index decreased significantly compared to pre-operative values from 49% to 28% (Group 1) and from 49% to 19% (Group 2). A decreasing of at least 15% of the Oswestry index appeared in 67% of the patients from Group 1 vs 71.5% in Group 2. Finally, 83% (group 1) and 86% (group 2) of the patients were satisfied or very satisfied about the surgical procedure. 90% should undergo this surgery again. Lordosis at the operated level increased from 4.5° (preoperatively) to 11.5° (at follow up) in Group 1 and from 7° to 13° in Group 2. Preoperative and follow up Mean Range of Motion at the operated level was similar in both groups: respectively 4° (0-18°) and 7° (0-17°).

Conclusion: Disc arthroplasty statistically improves leg pain, back pain and Oswestry scores even with previous surgical discectomy which represents 27% of its indications. According to Oswestry score and leg pain, functional results at one year seem to be better in the group of patients with no previous surgery. Nevertheless, this study demonstrates that disc arthroplasty is an effective alternative solution to treat degenerative disc disease following discectomy due to disc herniation. In these cases, disc arthroplasty seems to be the best surgical procedure.
64. Prospective, Randomized Trial of Lumbar Metal on Metal Total Disc Replacement: Initial Treatment of Degenerative Disc

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Introduction: The FlexiCore® Intervertebral Disc (Stryker, Allendale, NJ) is a lumbar metal on metal total disc replacement device currently being studied for the treatment of degenerative disc disease (DDD) under an investigational device exemption (IDE) granted by the United States Food and Drug Administration. This study examines the outcomes of the FlexiCore® as compared to traditional circumferential fusion for the treatment of single level DDD.

Methods: 111 patients from four of the study sites were randomized in a 2:1 fashion (FlexiCore®:Fusion). 71 patients were treated with the FlexiCore® (F) and 40 patients were treated with fusion (C). Disability and pain were assessed using the Oswestry Disability Index (ODI) and the Visual Analog Scale (VAS). Prospective data was collected preoperatively and postoperatively at 6 weeks and 3, 6, 12, and 24 months.

Results: The mean ODI scores were 61(F) and 60(C) preoperatively, 37(F) and 48(C) at 6 weeks, 30(F) and 34(C) at 3 months, 28(F) and 31(C) at 6 months, 26(F), 31(C) at 12 months, and 23(F) and 22(C) at 24 months. The FlexiCore® had significantly better ODI scores at the 6 week follow-up (p=0.006) when compared to fusion (Graph 1).

The mean VAS scores were 87(F) and 83(C) preoperatively, 37(F) and 31(C) at 6 weeks, 36(F) and 28(C) at 3 months, 36(F) and 31(C) at 6 months, 30(F) and 33(C) at 12 months, and 32(F) and 34(C) at 24 months. There was no significant difference in VAS scores between fusion and the FlexiCore® (Graph 2).

Discussion: These results represent 111 of the 400 patients randomized under an IDE protocol for the treatment of symptomatic lumbar single level DDD. These initial results from four study sites show that the FlexiCore® compares favorably to circumferential fusion in such treatment.

65. Two Year Interim European Clinical Results of Nucleus Replacement Using an In Situ Cured, Balloon Contained, Injectable Polyurethane Device

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**Introduction:** Nucleus replacement has received renewed interest as a treatment alternative to alleviate discogenic pain. The DASCOR® device is a two-part *in situ* cured nucleus replacement device designed to alleviate discogenic pain and restore/maintain disc height and segmental mobility in the mild to moderate stages of degenerative disc disease (DDD). The device is made from a two-part *in situ* cured polyurethane core and an expandable balloon. The liquid polyurethane is implanted under controlled pressure in the expandable balloon using a minimally invasive procedure. The device is a CE Mark approved product. A post-market European study is currently underway. The purpose of this European multi-center prospective, non-randomized, clinical study was to evaluate the interim two-year safety and effectiveness of the DASCOR® device in patients.

**Methods:** Eight-four eligible patients with mild-moderate single-level DDD, concordant provocation discography, significant back pain, six-month failed non-operative care and no prior fusion surgery were enrolled in the study. A standardized retroperitoneal anterolateral or lateral approach was used for nucleus removal and device implantation. Outcome parameters such as the Oswestry Disability Index (ODI), visual analog scale (VAS), analgesic medication use, and plain film or MRI radiographic assessments were collected preoperatively and throughout the duration of follow-ups. Clinical success was defined as at least a 2 and 15 point decrease in VAS and ODI scores, respectively. A repeated measures ANOVA was used to statistically compare outcomes across follow-up timepoints.

**Results:** Of the patients implanted (mean age: 39±8yrs; 45 male, 39 female), 67, 50 and 18 patients were followed for 6, 12 and 24 months, respectively with 98% of expected patient visits completed. Eight, 36 and 40 patients were implanted at the L3/4, L4/5, and L5/S1 levels, respectively. Mean operating time and blood loss was 88.6 minutes and 42.0cc, respectively. Mean pre-operative VAS (7.6) and ODI scores (58) improved significantly after 6 weeks (4.0 & 36) and throughout the 2 years (3.1 & 19). Although most patients met the clinical success criteria, patients implanted at the L5/S1 level, compared to those at the L4/5 or L3/4, experienced a more significant decrease in ODI and VAS within the first year. Analgesic medication use decreased dramatically over time, with patients eliminating the use of narcotic analgesics after six weeks and almost all anti-inflammatory drugs after one year. Radiographic results demonstrated, at a minimum, preservation of disc height, lordosis and range of motion, with no significant Modic changes beyond Type I, nor any expulsion.

**Conclusions:** The two-year clinical experience using the nucleus replacement device demonstrated high clinical-radiographic safety based on significant postoperative pain reduction, functional improvement, and low complication rate. The ability to implant the device using a small annulotomy along with the large contact area for axial load transmission provided by the device is believed to be responsible for the positive results of this study.

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**66. A Comprehensive Wear Assessment of NUBAC**

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**Objective:** To provide a comprehensive wear assessment of NUBAC under different motion profiles and environmental conditions.

**Methods:** Four groups (n=6) of NUBAC devices manufactured from PEEK-OPTIMA (PEEK) were tested on a spine simulator. The implants were submersed in newborn calf serum (20g/l) at 37°±2°C. Group 1 consisted of ±7.5° flexion/extension to 10 million cycles (Mc) followed by ±7.5° lateral-bending to 10 Mc. This sequence was alternated to 40 Mc. Groups 2-4 consisted of ISO/DIS 18192-1 to 10 Mc, except that group 3 incorporated frequency shifting to insure a non-repetitive load and motion profile. Groups 1-3 were exposed to 30 kGy gamma sterilization in air. Group 4 was exposed to the combined effects of 200 kGy followed by simulated aging. The simulated aging process was similar to ASTM F2003-02, which was developed to measure accelerated ageing in UHMWPE packaged in air, except that the aging time was extended from 14 days to 40 days. All studies incorporated a load magnitude of 225-1024 N. The average wear rates were determined using linear regression analysis with significant differences between groups (p<0.05) determined via one-way ANOVA.

**Results:** Groups 2-3 displayed a wear-in period from 0-1 Mc and groups 2-4 displayed a bimodal wear rate (Figure 1). Therefore, wear rates were calculated from 1-5 Mc and from 5-10 Mc. The wear rate remained consistent at 0.28 mg/Mc from 10-40 Mc. From 1-10 Mc, the wear rate for group 1 was significantly less than all groups with groups 2-4 not significantly different from each other. Except for group 1, all wear rates were seen to decrease after 5 Mc.
Conclusion: The lack of accelerated wear from 10-40 Mc for group 1 suggests that self-mating PEEK does not undergo strain hardening during unidirectional motion. This is different for UHMWPE, which undergoes strain hardening with a significant increase in wear after perpendicular motion. In addition, for metal on UHMWPE it has been reported that frequency shifting can increase the wear several orders of magnitude, and accelerated aging of UHMWPE from chain scission via oxidative processes can result in a significant increase in wear. Groups 3 and 4 did not incur a significant increase in their wear rates as compared to group 2, suggesting that self-mating PEEK is insensitive to these wear increasing parameters. The higher wear rates for groups 2-4 as compared to group 1 are expected due to the additional degree of freedom introduced in the motion profile generating longer motion trajectories. Overall, the results of this study suggest that PEEK can be a durable material for the intended application.

References:
3. Nechtow W. 52nd ORS, 0118;

67. Nucleus Pulposus Replacement Material Stiffness Properties Affect Vertebral Body Strains and Remodeling Response

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Introduction: Nucleus pulposus replacements (NPRs) are interventional therapies that restore stiffness and height to mildly degenerated intervertebral discs (IVDs). A stiff NPR may induce implant subsidence from overloading of the vertebral body (VB). A less stiff device might unload the central portion of the VB, resulting in alterations in IVD load bearing. The objective of this study was to use a validated finite element (FE) model of a single functional spinal unit (FSU) to evaluate the effects of a range of NPR stiffnesses. We hypothesized that an optimum NPR stiffness would minimize the likelihood of implant subsidence, but also minimize the potential for bony resorption.

Methods: A FE model of an L3-L4 FSU was generated from cadaveric QCT data with bone mineral density-dependent orthotropic material properties. Material properties for the IVD and ligaments were based on published data. Specifically, incompressible fluid elements with a bulk modulus of 1667 MPa were used to simulate the nucleus pulposus (NP). An “intact” model with normal IVD properties was validated against published disc pressures, endplate and cortical strains, and kinematics. The NPR simulations were created by replacing the NP of the intact model with a range of NPRs. The NPRs were modeled as linear elastic and nearly incompressible with Young’s moduli of 0.1, 1, 4, and 100 MPa and a Poisson’s ratio of 0.48. 1000 N of axial compression was applied. VB strains and bony remodeling stimulus were reported.

Results: L4 VB strains for the physiologic nucleus were under 1%. NPRs with moduli of 0.1 and 1 MPa generated strains above 1% adjacent to the AF. A 4 MPa NPR demonstrated no strains above 1% and was most similar to the physiologic NP. The 100 MPa NPR showed a large region of strains above 1% directly adjacent to the NPR, and a decrease in strains adjacent to the AF as compared to the intact model. Remodeling analysis indicated that a 0.2 MPa NPR would result in bony resorption adjacent to the NPR in the central VB. This was not true for the 1 MPa scenario, but both the 1 MPa and 0.1 MPa NPRs indicated bone growth adjacent to the AF. The 4 MPa NPR showed some bony growth under the NPR while the 100 MPa NPR indicated bone growth throughout the entire central VB with bone resorption at the edges.

Discussion: Our results indicate that a modulus of 4 MPa for a nearly incompressible material provides a physiologic
response in terms of VB strains. Very soft material resulted in central VB bone resorption, which could lead to implant subsidence and an increase in strains adjacent to the AF. This suggests a transfer of load to the AF, which could hasten DDD. Stiffer materials, while providing load transfer to initiate bone growth under the implant, resulted in higher VB strains, indicating a higher likelihood of implant subsidence from overloading. Thus, NPR material properties have important consequences not only for mechanical device cooperation with surrounding tissues, but also for the remodeling response of those tissues.

68. Motion Segment Stiffness and Subsidence with Hydrated and Dehydrated Nucleus Arthroplasty Devices

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Objective: Hydrogel-based devices represent one type of nucleus arthroplasty (NA) option. Generally, these devices are inserted dehydrated and hydrate over time in vivo. As with any interbody construct, NA devices may introduce the risk for device subsidence. A previous study evaluated isolated endplate-device interface subsidence using hydrated hydrogel-based NA devices ([1] Beaubien, SAS, 2008). The objective of the current study was to assess subsidence of dehydrated NA, hydrated NA (HydraFlex) and interbody (PEEK) devices using an unconstrained spinal motion segment model.

Methods: DEXA scans were obtained for nine cadaveric motion segments. Specimens were tested in the intact and denucleated states using a compressive load of 1600 N with flexion/extension and AP translation unconstrained. Motion segments were randomized for implantation of a dehydrated Hydraflex, hydrated Hydraflex or PEEK spacer and testing was repeated. All specimens were then tested to failure in compression using load increments of 200N. Failure testing was performed under fluoroscopic visualization to identify the onset of endplate failure and subsequent catastrophic failure. Load-displacement data was used to calculate the change in disc height at 20N and 1600N.

Results: During nucleotomy, an overall median of 3.4cc of material was removed with a corresponding median unloaded loss in disc height of 1.7mm and 2.6mm, for NA and PEEK devices, respectively. Following implantation, the unloaded disc height was restored to within 0.5mm of the intact for the PEEK spacer and hydrated Hydraflex groups; dehydrated devices had the least restoration (Fig.1). Conversely, at 1600N, the compliant hydrated devices showed the least restoration. Fluoroscopy revealed more FSU flexion with increasing compressive load in the NA groups (“induced flexion”). On average, the hydrated NA device group had higher subsidence initiation loads, while dehydrated NA device and PEEK spacer groups were generally similar (Table 1).

Table 1: Failure Results

<table>
<thead>
<tr>
<th>ID Level Group</th>
<th>DEXA (T Score)</th>
<th>Failure (N) Initiation</th>
<th>Failure (N) Catastrophic</th>
<th>Failure Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 L45 PEEK</td>
<td>2.9</td>
<td>3800</td>
<td>Sup VB Rim flx</td>
<td></td>
</tr>
<tr>
<td>6 L23 PEEK</td>
<td>-3.2</td>
<td>3000</td>
<td>Sup VB Rim flx</td>
<td></td>
</tr>
<tr>
<td>5 L45 PEEK</td>
<td>-0.8</td>
<td>3500</td>
<td>Inf subsidence/ VB rim flx</td>
<td></td>
</tr>
<tr>
<td>6 L45 Hydrated</td>
<td>-3.7</td>
<td>3200</td>
<td>3600</td>
<td>Inf subsidence</td>
</tr>
<tr>
<td>5 L23 Hydrated</td>
<td>-0.9</td>
<td>6400</td>
<td>6600</td>
<td>Inf subsidence</td>
</tr>
<tr>
<td>2 L45 Hydrated</td>
<td>0.3</td>
<td>4200*</td>
<td>4600*</td>
<td>VB Flx (Endplate intact to 70%)</td>
</tr>
<tr>
<td>4 L23 Dehydrated</td>
<td>-0.5</td>
<td>3400*</td>
<td>4800*</td>
<td>VB Flx (Endplate intact to 40%)</td>
</tr>
<tr>
<td>2 L23 Dehydrated</td>
<td>1.5</td>
<td>4000</td>
<td>6000</td>
<td>Inf subsidence</td>
</tr>
<tr>
<td>3 L45 Dehydrated</td>
<td>-2.0</td>
<td>2600</td>
<td>3400</td>
<td>Inf subsidence</td>
</tr>
</tbody>
</table>

*Subsidence not seen at indicated load. Vertebral body (VB) fracture due to induced flexion.

[Table 1]
Discussion: Appropriately sized PEEK spacers and hydrated Hydraflex devices approximately restored unloaded disc height whereas dehydrated devices did not. Hydrated Hydraflex devices were compliant under load, which may have allowed high failure loads in spite of low bone density and central positioning. The similarities in device failure load between the PEEK spacer and dehydrated NA device may be related to the clinical intent: PEEK spacers are intended to immediately distract the disc space to restore height, while dehydrated NA devices are intended to maintain height at insertion, thereby sharing load with the surrounding annulus [1]. Overall, the dehydrated NA devices showed a subsidence risk similar to the PEEK spacers.

69. Clinical Experience with NUBAC™ Disc Arthroplasty

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Purpose: While most patients with degenerative disc disease (DDD) can be successfully treated conservatively, patients with disabling low back pain often seek surgery. NUBAC™, a two-piece design with an inner ball and socket articulating joint, manufactured from polyetheretherketone (PEEK), was designed to treat symptomatic discogenic back pain with mild to moderate DDD. This is a prospective, non-randomized study evaluating the worldwide clinical experience with NUBAC using all three surgical approaches; lateral, anterolateral, and posterior.

Methods: NUBAC is indicated for back pain with or without leg pain caused by DDD in patients who have failed conservative care for at least 6 months. Patient pathology and surgeon preference determined which of the three surgical approaches was used to implant NUBAC. A small annulotomy window provides access to the disc followed by a complete nucleotomy and implantation of NUBAC. In this series, the patients were followed at 6 weeks, 3, 6, 12 and 24 months postoperatively. VAS, ODI, SF36 and radiographs were collected at each visit. The data from the patients enrolled between December 2004 and October 2007 are presented.

Results: The NUBAC has been implanted in the lumbar spine of 131 patients with near even distribution between the gender at 135 levels from L2-S1 with more than 90% at L4/5 and L5/S1. Mean age is 40.7 years (21-70). No major intra-operative neurological or vascular complications occurred. The average operating time was 96 minutes and the average EBL was 60 cc. Most patients were discharged from the hospital 1-2 days after the surgery. The clinical results showed that good pain relief was established and maintained from six weeks through 2 years (VAS 78 at baseline to 30, 30, 26, 26 and 23 at 6 weeks, 3, 6 months and 1 and 2 years, respectively). Function using the Oswestry Disability Index questionnaire showed continuous improvement at all visits (53 at baseline to 31, 26, 23, 23 and 10 at 6 weeks, 3, 6 months and 1 and 2 years, respectively). Radiographic examination showed that the index disc height was maintained when comparing the last follow-up disc height to the pre-op disc height.

Conclusions: The data demonstrate that NUBAC is capable of relieving the symptoms of discogenic back pain. This series demonstrated that NUBAC is clinically viable for all three major surgical approaches. The pain relief, improvement in function, lack of intra-operative and postoperative neurological complications and maintenance of the
disc height suggested that NUBAC is an alternative to fusion and total disc replacement surgery. From the average OR time, EBL, patient hospital discharge time, and nature of the procedure which does not require large amount of tissue dissection, the NUBAC appears to be less invasive and less bridge-burning than fusion and total disc replacement.

70. Hybrid Treatment of DDD with the PDN-SOLO Device Combined with Suture Anchorage and Interspinous Ligamentoplasty

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Objectives: One of the clinical goals of nucleus replacement is the prevention of post discectomy disc collapse with subsequent pain. The PDN-SOLO device was developed with these goals in mind but suffered an approximate 10% incidence of device migration. Taking into consideration total column support, the use of an interspinous ligamentoplasty was used for posterior column stability. However, imaging out to 7 years using ligamentoplasty alone indicates an overall disc height loss of approximately 50%. We hoped to positively affect these events with the addition of suture anchorage and ligamentoplasty. This study was undertaken to use this combined approach to address both anterior and posterior column support in an effort to improve segmental stability and restore disc function. With the addition of these two modalities the PDN-SOLO device migration rate is null.

Material and methods: Nineteen patients with degenerative disc disease were selected from the population of the National Rehabilitation Institute. All patients meeting the inclusion criteria have completed a minimum of 24 month follow-up. Using suture anchors (Smith & Nephew, London, UK), all patients had suture placed through the lateral edges of the device jacket taking care not to damage it. With the aid of fluoroscopy, the screw anchor was positioned 1 cm from the anterior portion of the cephalad vertebra, with a penetration depth of 5 mm into the endplate. Additionally, an interspinous ligamentoplasty composed of a knitted polyester band (Dallous Prosthesis, Tricomed, S.A., Lodz, Poland) was placed between the spinous processes of the affected disc space. All patients were evaluated using the Oswestry Disability Index (ODI), serial plain x-rays and Magnetic Resonance imaging. Statistical analysis was made using the “Students t-test” method.

Results: Ten men and nine women were included, with a mean age of 36.7 years, and a mean follow-up of 30.6 months. The mean preoperative ODI was 50.1; the mean height of the intervertebral disc space (IDS) was 7.6 mm. At 24 months, the ODI had declined to a mean 22 (<0.001); the IDS was increased to 10.2 mm, with an average improvement of 2.6 mm related to the preop measurement.

The prosthesis had minor movement as it related to the initial positioning in fourteen of the patients. There were neither Modic changes nor subsidence seen on MRI. There were no reoperations.

Conclusions: The implantation of the PDN-SOLO device resulted in improvement in the clinical condition of all of the patients with absence of any significant radiological changes. There were no significant Modic changes or subsidence. As there was no device migration and only minor movement noted it is concluded that the suture anchorage was effective and prevented an adverse event associated with the device. Additionally, the use of the ligamentoplasty appears to provide posterior column stability with the result being elimination of abnormal device movement.

71. Effect of Lumbar Nucleus Arthroplasty on Adjacent Segment Degeneration; Report of 240 Cases with 2 to 10 Year Follow-Up

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Purpose: Adjacent segment degeneration or transitional level syndrome are terms associated with development or progression of degenerative changes at levels cranial or caudal to a fused segment in the spine. The incidence of the phenomenon varies widely in the literature ranging from 10% to 52% in posterior arthrodesis to 5% to 15% with anterior arthrodesis. The majority of these studies involved analysis of plain radiographs. Nucleus arthroplasty is a motion preservation technology suggesting a theoretical advantage of reducing the rate of adjacent segment degeneration. The purpose of this study is to examine the effect of nucleus arthroplasty evaluating the PDN device on adjacent segment degeneration utilizing high-resolution MRI.

Methods: 240 patients implanted with paired or PDN-SOLO devices were analyzed preoperatively and postoperatively with MRI and Flex/Ext. plain films. No patients in this group demonstrated PDN device migration and all maintained or improved range of motion at the operative level. Disc spaces were graded on a 4-point degeneration scale on MRI studies. Follow up ranged from 2 to 10 years.

Results: All patients demonstrated grade 0 or normal discs adjacent to the implanted level on preoperative MRI. At L4-5, 1 patient (0.9%) demonstrated grade 1 or mild degeneration with no patients at grade 2 or 3 (moderate to severe). At L5-S1, 1 patient (0.8%) demonstrated grade 2 degeneration. The combined incidence of adjacent segment degeneration
Conclusion: The rate of adjacent segment degeneration above or below the PDN nucleus arthroplasty level is significantly less than reported rates with rigid arthrodesis.

72. Identifying Appropriate Intervventional Timepoints for Nucleus Pulposus Replacements: Impact of Degeneration-Dependent Mechanical Properties of the Cartilaginous Endplate

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Objectives: Appropriate interventional timepoints for nucleus pulposus replacements depend on the mechanical properties of retained tissues and the effect of degeneration on those properties. For instance, understanding endplate (EP) tensile mechanical behavior may help prevent implant subsidence. The EP is loaded in compression as the intervertebral disc (IVD) is compressed, and is likely also to be loaded in direct tension. The fibers of the annulus fibrosus (AF) anchor directly into cartilaginous EP, and are subjected to tension as the IVD is loaded. The AF fibers thus may transfer a tensile stress component directly to the EP. The objective of this study was to measure tensile mechanical properties of human IVD cartilaginous EP and to evaluate the effects of disc degeneration and direction dependence.

Methods: Human lumbar spines were obtained under an IRB approved protocol and imaged with MR. Degenerative grade was determined from MR and gross images by two clinicians. Ten samples (n=5 radial and n=5 circumferential) were taken from superior EPs and tested in stress-relaxation using a Bose Enduratec LM1 in a PBS bath at 37±4°C. Strain was applied in 2% increments to 16%, or failure. Equilibrium toe- and linear-region moduli (Etoe and Elin) and transition strain (e*) were calculated from equilibrium stresses and strains. Pearson’s correlation coefficients were calculated between IVD grade and mechanical properties. Paired t-tests assessed the effect of sample orientation (sig. at p<0.05).

Results: Gross degenerative grade was 2.8±1.2 and MRI grade was 2.6±0.4. Circumferential properties were: Etoe=7.81±3.45MPa (n=4); Elin=33.3±9.15MPa (n=5); e*=0.04±0.02. Radial: Etoe=0.75±0.77MPa (n=4); Elin=4.11±3.17MPa (n=5); e*=0.05±0.02. The effect of sample orientation was significant for Etoe and Elin. Circumferential Elin decreased significantly with degeneration (r=-0.87). Etoe showed a similar trend (r=-0.44, ns; Fig. 1).

Conclusions: Tensile mechanical properties of the cartilaginous EP were degeneration- and direction-dependent. Radial moduli were an order of magnitude less than circumferential. As the fibers of the AF anchor directly into the cartilaginous EP, this direction-dependence may be influenced by AF anisotropy. AF tensile properties are less stiff than the EP properties reported here. Thus, the EP is important to distribution of loads across the bone-IVD interface. Gross degenerative grade corresponds to a decrease in Elin, which may increase the likelihood of EP fractures. The fact that circumferential modulus decreases with degeneration, but radial modulus does not, indicates a decrease in tissue anisotropy with degeneration. This may affect the ability of the EP to transmit IVD loads, and also predispose it to fracture as degeneration progresses. Understanding EP mechanical property changes in the context of IVD degeneration is important for identifying appropriate interventional timepoints for the success of EP-retaining IVD degeneration therapies.

Acknowledgements: The authors thank Dawn M. Elliott, Ph.D. for her assistance, and Synthes Spine for research grant support.

[Figure 1]

73. Endplate Geometry in the Lumbar Spine; A Potential Predictor in Success or Failure for
Nucleus Arthroplasty

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Purpose: Disc size and annular competency are important factors to consider when contemplating a nucleoplasty procedure. Little to no attention has been paid to endplate geometry. The purpose of this study is to analyze natural variations in curvature of the endplates at L4-5 and L5-S1 and to determine if any geometries are predictive of outcomes after a disc or nucleus replacement procedure.

Methods: 750 Lumbar MRI’s in patients presenting with back and/or leg pain were retrospectively reviewed with attention to endplates at L4-5 and L5-S1. A grading system was devised accounting for variations in endplate contour ranging from flat to significant concave deformity. Previously described congenital defects were recognized and excluded from this study. 100 patients implanted with the PDN-SOLO device were reviewed pre and two years post surgery. Outcomes were correlated with endplate geometry as a single variable.

Results: The grading system used is as follows: grade 0=flat endplate; grade 1=continuous concave slope; grade 2=posterior concavity; grade 3=anterior concavity. In the non-operative group, 410(82%) were grade 0-1; 90(18%) were grade 2-3 with 85% of the grade 2-3 changes occurring at L5. In the PDN-SOLO operative group 87 were grade 0-1; 13 were grade 2-3. In the subgroup of grade 2-3 endplate changes, evidence of device migration, subsidence or focal endplate damage was present in 10(76%) of patients. In grade 0-1 patients, device or endplate complications were identified in 5(6%) of patients.

Conclusion: Differences in endplate geometry can be categorized and occur naturally in the lumbar spine. Certain patterns particularly at the L5-S1 level may play a role in predicting surgical and clinical success when contemplating a nucleus arthroplasty type procedure.

74. A Finite Element Study of L5-S1 Spinal Biomechanics Comparing Different Surgical Therapies

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Objective: Surgical therapies in the L5-S1 disc space vary in terms of their biomechanical effects. Many finite element models have been developed to help understand the biomechanics of the normal and treated lumbar spine, however few represent the L5-S1 segment due to its complex geometry. This study evaluates the effect of various surgical therapies on the biomechanics of the L5-S1 spinal segment utilizing a finite element model.

Methods: A 3D nonlinear finite element model of the L5-S1 motion segment was developed. Tissue properties were sourced from the literature. In order to accommodate the nonuniform geometry and lordosis of the L5-S1 disc, fibers were modeled as reinforcement layers (rebars) in surface elements for three annular layers. Careful attention was paid to facet geometry to correctly model its role in segmental biomechanics. The model was validated against in vitro data (L5-S1 range of motion (ROM), center of rotation, facet motion) [Beaubien, SAS, 2007], and published values (intradiscal pressure, axial compressive stiffness, fiber mechanics) [Shirazi-Adl, Spine, 1984].

Surgical therapies were simulated by varying the nucleus space contents as follows: normal segment (fluid-filled), denucleated (empty), nucleus implant (in-situ formed silicone), and developing fusion (simulated cortical bone). All segments were subjected to ±7.5 Nm unconstrained flexion and extension with a 400N preload. Segmental ROM, facet contact stress, and stress distributions in disc tissues were analyzed.

Results: Segmental ROM did not change with denucleation compared to normal, slightly decreased with the nucleus implant (13%) and dramatically dropped with the developing fusion (75%). The changes in the maximum facet stresses compared to the normal segment are: 145% increase with denucleation, 32% decrease with developing fusion and 6% increase with the nucleus implant (Fig.1).

The stress distribution in the annulus and endplates indicates that after denucleation, inward annulus bulging provides the main support to the applied loading, creating high stresses in the annulus layers. With a developing fusion, segment stresses are concentrated on the underlying endplate. Nucleus implant placement restores the normal stresses in the annulus and the endplate (Fig.2).
75. **Lumbar Decompression Followed by Coflex™ Interlaminar Implant vs. Pedicle Screw Posterior Lateral Fusion for Treatment of Stenosis**


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**Purpose**: To compare the clinical safety and efficacy of Coflex™ Interlaminar Fixation vs. instrumented fusion following standard decompression for lumbar stenosis.

**Methods**: A prospective randomized comparison of Coflex vs. fusion from four FDA IDE sites are reported. The study was a 2:1 randomization of Coflex vs. fusion. Every patient underwent a standard one or two level decompression (as determined by the treating surgeon) L2 to L5 followed by placement of a Coflex Interlaminar implant vs. pedicle screw fixation with posterior lateral bone graft. Major inclusion criteria included stenosis at one or two levels between L2 and L5. Leg and back pain longer than 6 months, ODI greater than 40, and VAS greater than 50 (on a 100mm scale). All patients failed conservative treatment including a lumbar E.S.I.. Major exclusion criteria included osteoporosis (T-Score of -1.0) or previous lumbar surgery of any type. FDA clinical success was based on Improvement of at least 15 points in the ODI at 24 months compared to baseline, no re-operations, revisions, removals or supplemental fixation and no major device-related complications. Follow up was completed at 6 weeks, 3 months, 6 months, and one year with physical exam, SF-12, VAS, ODI, and radiographic analysis.

**Results**: Patients ranged in age from 51-84 (average 64 years). Twenty-one patients were male and eighteen female. Seven of the patients were smokers. BMI ranged from 24-38 (average BMI 29). There were 28 one level surgeries (19 Coflex and 9 Fusion) and 11 two level surgeries (8 Coflex and 3 Fusion). Average pre-op ODI in the Coflex group was 55 (range 40 to 70). Average pre-op ODI in the fusion group was 59 (range 42-72). Post-op ODI in the Coflex group was 10.5 (range 0-40) a 81% improvement. Post-op ODI in the fusion group was 34.8 (range 14-56) a 41% improvement. Pre-op VAS in the Coflex group was 74.2 (range 56-94). Average pre-op VAS in the fusion group was 73.5 (range 64-90). Post-op VAS in the Coflex group was 15.2 (range 0-68) a 80% improvement. Post-op VAS in the fusion group was 34.2 (range 11-66) a 53% improvement.

**Conclusion**: Both the Coflex and the fusion groups demonstrated safety with no device related complications and no
reoperations or revisions. Both groups showed efficacy with statistical improvement in ODI and VAS at follow up. The subjects randomized to Coflex demonstrated statistical superiority in all clinical measurements compared to fusion.

76. 24-Month Results from a Prospective, Randomized IDE Study of the Dynesys® Dynamic Stabilization System

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Objectives: The results of a prospective, randomized IDE study examining dynamic stabilization with the Dynesys® Dynamic Stabilization System are being reported. This study reports the outcomes of 253 patients following dynamic stabilization (DS) and 114 patients treated with posterior lateral fusion (PLF) at 28 centers.

Methods: Patients enrolled in this study exhibited lateral or central spinal stenosis, degenerative spondylolisthesis or retrolisthesis (up to Grade I), and were appropriate for instrumented fusion at 1-2 contiguous spinal levels (L1-S1). Participants randomly received treatment with DS or instrumented PLF (2:1 ratio) and were evaluated pre-operatively and post-operatively at 3-weeks, 6-months, 1-year, and 2-years.

Results: At 24M, the DS cohort reported 54.8mm improvement in leg pain scores, a reduction in ODI scores of 29.2, 24.8mm improvement in back pain, and 92% of subjects either improved or maintained their level of neurological success compared to pre-op assessment. In the PLF cohort, leg pain scores improved by 45.8mm, ODI scores were reduced by 24.1, back pain scores improved by 18.8mm, and 84% of subjects reported improved or maintained neurological success compared to pre-op evaluation. The improvement in leg pain scores reported at 24-months was significantly different between the study groups (p<0.05). Additionally, 24M data shows the SF-12 Physical Component increased significantly from 27.5 (pre-op) to 41.0 (24M) in the DS group and 27.4 to 37.2 in the PLF group (p<0.05). The SF-12 Mental Component increased from 43.7 (pre-op) to 50.4 (24M) in the DS cohort and 42.4 to 50.9 in the control group. In the DS cohort, 28 subjects (11.1%) required a revision surgery and 11 revision surgeries were reported in the PLF cohort (9.6%). Additionally, there were 39 reported intra-operative adverse events reported in the DS group, 34/39 were durotomy tears.

Conclusions: The 24M clinical shows positive outcomes for patients treated with dynamic stabilization. The subjects implanted with the Dynesys® system show an improvement in back pain, ODI, Neurological Success, and SF-12 scores and a significant improvement in leg pain and SF-12 Physical Component scores.

77. Long Term Follow up of Spinous Process Failure According to Bone Mineral Density in Coflex® Insertion for Lumbar Spinal Stenosis

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Introduction: An interspinous process implant has been developed to treat patients suffering from neurogenic intermittent claudication secondary to lumbar spinal stenosis. As most patients who suffer from spinal stenosis are over the age of 60 and may have weaker bones, it is imperative to know how bone mineral density (BMD) correlates with spinous process failure.

Material & methods: We performed 110 cases of Coflex® insertion into lumbar spinal stenosis patients for 3 years retrospectively. Two levels Coflex® insertion was done in 22 patients. Mean follow period was 3.5 years (24 months - 46 months). The small portion of spinous process cortex was removed for Coflex® insertion in our operative procedure. We divided the patients into two groups according to bone mineral density (BMD); BMD equal or more than -2.5 (Group I, N = 45) and less than -2.5 (Group II, N = 55, osteoporosis). Pre & Post-operative back pain VAS score, leg pain VAS score, X-ray, C-T were checked at post operative 6 months, 1 year and 2 years. The spinous process failure defined as in cases of dislodgement of Coflex® and more than 3 mm impaction into spinous process by Coflex® with back pain development at back motion.

Results: Back pain VAS scores were 7.9, 2.4, 2.3 & 2.5 in Group I and 7.8, 2.4, 5.6 & 6.3 in Group II in preoperative, postoperative 6 months, 1 year and 2 years. Leg pain VAS scores were 8.0, 2.4, 2.3 & 2.5 in Group I and 7.9, 2.4, 2.7, & 3.1 in Group II in preoperative, postoperative 6 months, 1 year and 2 years. There were spinous process failure rate 22.2% (10/45) in Group I and 65.5% (38/55) in Group II at postoperative 2 years. In two levels Coflex® insertion cases, spinous process failure rate were 50% (4/8) in Group I and 85.7% (12/14) in Group II at postoperative 2 years.

Conclusion: There was a significant relationship between the BMD and spinous process failure rate. The significant relationship between BMD and spinous process failure load suggests that patients with lower BMD must be approached with caution such as preservation of spinous process cortex during the implant insertion procedure. Keywords: Spinous process, Lumbar spinal stenosis, Bone mineral density
Introduction: The Dynesys® Dynamic Stabilization System (Zimmer Spine) consists of pedicle screws (Ti alloy), polycarbonate urethane (PCU) spacers, and a polyethyleneterephthalate cord. Prior studies investigating in vivo degradation of spacer components demonstrated small changes in surface chemical composition after up to 5.5y implantation (e.g., Trommsdorff et al., SAS, 2004). The objective of the current study was to examine the deformation, wear, and biostability of retrieved PCU components of Dynesys systems.

Methods: Ten retrieved (mean implantation 1.8y, range: 0.7-4.2y; 44 spacers) and two exemplar implant systems were available. Implants from single (n=3) and multi-level (n=7) systems were examined (44 spacers). Reasons for revision were persistent pain (9/10) and screw loosening (7/10), with 1/10 complications of implant migration. PCU spacers are cut at the time of the index surgery, leaving one cut and one molded end. Changes in chemical structure on the cut and molded ends of all PCU spacers were evaluated using attenuated total reflectance (ATR) FTIR. In addition, regions identified as surface damage were examined in 32/44 components. Baseline-corrected peak areas from 1650-1800 cm⁻¹ were determined and normalized relative to the aromatic peak area (509 cm⁻¹). MicroCT (mCT80, Scanco) and scanning electron microscopy (SEM, JSM-6390LV, JEOL) images were obtained on select components for wear evaluations.

Results: Most of the retrieved spacer components exhibited permanent bending deformation (range 0.0-15.8º, mean 4.0º), which was significantly (p=.0014) but weakly (R²=.22) correlated to PCU spacer length. Other common modes of deformation included screw indentation on spacer ends (43/44 spacers) or cord imprints around the center opening (42/44 spacers). In-vivo fracture or cracking of the spacers (confirmed with microCT and SEM) were rare damage modes (2/44 spacers) unrelated to clinical reason for device removal. A focal region of abrasive wear was observed along the length of 27/44 spacers (likely from impingement with surrounding bony structures). Significant (ANOVA, p<.05) decreases in ATR-FTIR peak areas were observed in damaged regions compared to cut and molded ends (1698 and 1740 cm⁻¹) and compared to exemplars (1698 cm⁻¹). However, increased peaks associated with degradation products of PCU (Christenson et al., J Biomed Mater Res, 2004) were observed in only along the sides of two spacers from a single patient (4.2y implantation).

Discussion: PCU spacers from retrieved Dynesys systems exhibited permanent deformation and, in some cases, focal regions of in vivo wear and surface damage. We found evidence of contact of the PCU spacer with the titanium screws, cord, and adjacent bone. In the current study, chemical changes associated with biodegradation of PCU were only detected on the side surface of 2/44 spacers, where the spacer would be in contact with tissue. All implants were revised for clinical reasons unrelated to wear, surface damage, or biostability. Thus, our observations after short-term revision were judged incidental and of limited clinical relevance for these retrievals. Longer-term retrievals are needed to provide greater context for the clinical implications of our short-term observations.

78. In vivo Deformation, Surface Damage, and Biostability of Polycarbonate-Urethane Spacers from Retrieved Dynesys Systems

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Introduction: The Dynesys® Dynamic Stabilization System (Zimmer Spine) consists of pedicle screws (Ti alloy), polycarbonate urethane (PCU) spacers, and a polyethyleneterephthalate cord. Prior studies investigating in vivo degradation of spacer components demonstrated small changes in surface chemical composition after up to 5.5y implantation (e.g., Trommsdorff et al., SAS, 2004). The objective of the current study was to examine the deformation, wear, and biostability of retrieved PCU components of Dynesys systems.

Methods: Ten retrieved (mean implantation 1.8y, range: 0.7-4.2y; 44 spacers) and two exemplar implant systems were available. Implants from single (n=3) and multi-level (n=7) systems were examined (44 spacers). Reasons for revision were persistent pain (9/10) and screw loosening (7/10), with 1/10 complications of implant migration. PCU spacers are cut at the time of the index surgery, leaving one cut and one molded end. Changes in chemical structure on the cut and molded ends of all PCU spacers were evaluated using attenuated total reflectance (ATR) FTIR. In addition, regions identified as surface damage were examined in 32/44 components. Baseline-corrected peak areas from 1650-1800 cm⁻¹ were determined and normalized relative to the aromatic peak area (509 cm⁻¹). MicroCT (mCT80, Scanco) and scanning electron microscopy (SEM, JSM-6390LV, JEOL) images were obtained on select components for wear evaluations.

Results: Most of the retrieved spacer components exhibited permanent bending deformation (range 0.0-15.8º, mean 4.0º), which was significantly (p=.0014) but weakly (R²=.22) correlated to PCU spacer length. Other common modes of deformation included screw indentation on spacer ends (43/44 spacers) or cord imprints around the center opening (42/44 spacers). In-vivo fracture or cracking of the spacers (confirmed with microCT and SEM) were rare damage modes (2/44 spacers) unrelated to clinical reason for device removal. A focal region of abrasive wear was observed along the length of 27/44 spacers (likely from impingement with surrounding bony structures). Significant (ANOVA, p<.05) decreases in ATR-FTIR peak areas were observed in damaged regions compared to cut and molded ends (1698 and 1740 cm⁻¹) and compared to exemplars (1698 cm⁻¹). However, increased peaks associated with degradation products of PCU (Christenson et al., J Biomed Mater Res, 2004) were observed in only along the sides of two spacers from a single patient (4.2y implantation).

Discussion: PCU spacers from retrieved Dynesys systems exhibited permanent deformation and, in some cases, focal regions of in vivo wear and surface damage. We found evidence of contact of the PCU spacer with the titanium screws, cord, and adjacent bone. In the current study, chemical changes associated with biodegradation of PCU were only detected on the side surface of 2/44 spacers, where the spacer would be in contact with tissue. All implants were revised for clinical reasons unrelated to wear, surface damage, or biostability. Thus, our observations after short-term revision were judged incidental and of limited clinical relevance for these retrievals. Longer-term retrievals are needed to provide greater context for the clinical implications of our short-term observations.

79. A Quantitative Radiographic Analysis of a Posterior Dynamic Stabilization System: Dynamic Parameters and Maintenance of Segmental Disc Height and Lordosis

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Objectives: Posterior dynamic stabilization has been used for segmental fixation without fusion. Favorable clinical results have been reported for stenosis, spondylolisthesis, and recurrent herniation. However, in vivo anatomical characteristics and in situ dynamic parameter characterization following posterior dynamic stabilization is lacking. Concerns have also been raised regarding concomitant changes in disc height, spondylolisthesis, and induction of kyphosis. The purpose of this study is to provide a rigorous, quantitative radiographic analysis of the dynamic parameters and static measurements following treatment with a posterior, dynamic-stabilization system (PDSS).

Methods: Radiographs (lateral, flexion/extension) were obtained pre-operatively and at 6-, 12-, and 24-months post-operatively from patients treated with the Dynesys® Dynamic Stabilization System (n=253) or with instrumented, posteriolateral fusion (PLF, n=114). Quantitative assessments of intervertebral rotation, translation, disc height, lordosis,
and spondylolisthesis were produced using validated, computer-assisted methods. Analysis included 346 and 134 individual levels (Dynesys® and PLF) between L3-S1.

**Results:** Mean pre-operative rotation was 5.8° (PDSS) and 5.8° (control arm). At 24-months, mean rotation was 2.1° for the PDSS cohort and 1.3° for the PLF cohort across all levels. Relative to pre-operative values for the PDSS cohort, 28.1% to 47.1% of the rotational angle was maintained at 24-months. There was a significant decrease in rotation at all post-operative assessments. Mean pre-operative translation was 1.1mm for both the investigational and control arms across all levels. At 24-months, mean translation was 0.5mm for the PDSS cohort and 0.3mm in the PLF cohort. Pre-operative mean intervertebral lordosis was greater in the investigational arm (9.4°) than control (8.0°) arm and increased with descending segment. Mean lordotic angle was reduced to 8.4° (PDSS) and 6.8° (PLF) at 24-months. There was no instance of segmental kyphotic deformities and 65% of levels showed no change or an increase in lordosis. Mean disc height in the investigational arm was 7.8mm preoperatively and at 24-months. Similarly, mean anterior/posterior disc height changed less than 1mm after 24-months. The PLF arm showed comparable results. At 24-months, mean percent spondylolisthesis changed 1.5% in the PDDS (8.5% to 10.0%) and 0.5% in the PLF (9.6% to 9.1%) cohorts.

**Conclusions:** Preliminary 24-month results show the Dynesys® Dynamic Stabilization System controlled motion in both sagittal rotation and translation. A mean of 28.1% to 47.1% of the pre-operative angular rotation was maintained at 24-months. Translation was controlled in a similar manner. Furthermore, slight changes, if any, were observed in segmental lordosis, disc height, and spondylolisthesis for both cohorts at 24-month. Importantly, there were no kyphotic events in levels treated with the Dynesys® system. In conclusion, the spine segments treated with the Dynesys® Dynamic Stabilization System were successfully stabilized without the need for fusion.

**80. Assessment of Lumbar Segmental Range of Motion Following Dynamic Stabilization in Comparison to Lumbar Discectomy and to Posterior Fusion with Pedicle Instrumentation**

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**Introduction:** Lumbar spinal dynamic stabilization systems have been developed as the alternative to lumbar fusion. The proposed advantage of these devices includes the absence of pseudoarthrosis complications, bone graft complication, and the preservation of motion. Biomechanical studies have demonstrated that dynamic stabilization restores the neutral zone and stabilizes the motion segment. These devices decrease the range of motion of the operated segment. Unfortunately, there are limitations to clinical measurement of lumbar motion segment when using routine radiographs. Precise measurement of the lumbar motion segment can be achieved using Radiostereometric Analysis (RSA) which has been shown to be an accurate technique in examining spinal kinematics. The purpose of this study was to measure the sagittal range of motion following dynamic stabilization with RSA and compare it to the motion following posterior lumbar fusion and lumbar discectomy.

**Methods:** Following approval by the institutional review board, four patients with lumbar spondylosis at L3/L4, L4/L5 and/or L5/S1 who were treated decompression and dynamic stabilization (Dynesys® Dynamic Stabilization System, Zimmer Spine) were compared with four patients with similar diagnosis that were treated by posterior lumbar fusion and pedicle screw fixation (PLF) and eight patients that had undergone lumbar microdiscectomy for treatment of radiculopathy at either L4/5 or L5/S1. During the surgical procedure, 3 to 5 tantalum beads were placed into each of the operative segments. The patients were followed post-operatively at 1-month, 1-year and 2-year. At each follow up time point, segmental motions (flexion, extension, and total sagittal rotation) were measured using radiostereometric analysis.

**Results:** Flexion, extension, and sagittal rotation were measured at 0.9±0.9°, -1.5±1.3°, and 2.1±1.3° in the Dynesys group, 1.1±1.3°, -1.5±1.6°, and 2.4±1.3° in the PLF group, and 2.8±2.6°, -2.2±1.6°, and 4.7±2.2° in the discectomy group. A significant difference was not seen between the Dynesys and the PLF groups in flexion, extension or sagittal rotation (Figure 1). A significant difference was seen between the Dynesys/PLF groups and discectomy group in sagittal rotation (p=0.002, p=0.046) and between Dynesys and discectomy in flexion (p=0.031). There was no significant change in the range of motion of the groups over time.

**Conclusions:** In this study, a significantly lower amount of motion was seen following dynamic stabilization when compared to discectomy and much less than the normal 10-20 degrees noted in the literature for a normal lumbar segment motion. The average motion following dynamic stabilization was similar to the motion measured following posterior lateral fusion and is similar to the amount of motion seen in previously published biomechanical studies evaluating the segmental motion following dynamic stabilization. In the current study, the motion following dynamic stabilization during sagittal movements may support the premise of dynamic stabilization controlling abnormal motions, although the clinical significance is currently not yet known.
81. Complications and Adverse Events Observed When Using Dynesys as a Dynamic Stabilization Device

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Objectives: Dynesys consists of titanium hydroxyapatite (HA) coated pedicle screws, flexible cord and polycarbonateurethane spacer and has been used off-label as a dynamic stabilizer of the lumbar spine. Biomechanical studies reveal motion at the level of Dynesys implantation. The theorized benefit of motion is improved outcomes, fewer returns to the operating room and decreased arthritic change at adjacent motion segments. To this point, no one has published postoperative complications observed when using Dynesys off-label as a motion preservation device. This study reviews the complications and adverse events that occurred in our series of 92 patients in the first 2 years following surgery.

Methods: Ninety-two patients underwent implantation of 538 screws from March, 2005 to March, 2007. Patients had 6 to 24 months of follow-up and were seen in the office at 2, 4, 6, 12 and 24 months after surgery. At each visit, AP/Lat lumbar radiographs were taken. Patients with suspicious radiographic findings or clinical symptoms underwent further imaging studies such as MRI, myelogram/CT or discogram. Further treatment was rendered as needed.

Results: 18 of the 92 patients (20%) had events leading to revision surgery in 15 patients (16%). Seven complications (39% of complications) were screw loosening seen on x-ray (screw halo sign) which was confirmed with a CT scan. All loose screws were non-HA coated and located at the cephalad or caudal aspect of the construct. There was also association of loosening with thoracolumbar junctional implantation, T score < -1 and implantation into motion segments with advanced (>50%) disc height collapse. Four of seven patients with screw loosening underwent revisions with larger diameter HA coated screws. All four demonstrated significant clinical improvement.

One patient developed a screw fracture and required revision. One patient had a pars fracture which has not produced symptoms requiring further surgery. Two patients developed spinal stenosis cephalad to the level of implantation. Both patients had a normal spinal canal at the time of the index procedure and both underwent a decompression and extension of the implantation.

Eight patients (44% of complications) underwent revisions and conversions to fusion due to continued low back and leg pain. Two of these patients and two of the seven patients with screw loosening (4% of total patients and 22% of total complications) had developed a deep wound infection and underwent irrigation and debridement with implant removal and conversion to fusion.

Conclusions: Posterior dynamic stabilization using the Dynesys system is an effective treatment for multiple degenerative lumbar pathologies. There are a significant number of complications (20% of patients) seen in the 6-24 months following surgery. About 40% of these complications were related to screw loosening. After correcting for loosening, the complication rate is about 12% overall which is similar to that of fusion. To decrease the complication rate associated with loosening, we recommend: 1) use HA coated screws; 2) avoid implantation at the thoracolumbar junction; 3) avoid implantation in patients with T-score < -1; 4) avoid implantation if discs are significantly collapsed (height < 50% of normal adjacent disc).

82. The Surgical Outcome of Coflex® Interspinous Device in Lumbar Degenerative Disease: Comparative Study between the Conventional and a Modified Surgical Technique

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Objective: The authors performed a comparative study of clinical and radiologic results between the conventional and modified surgical techniques for applying an interspinous stabilization device, Coflex®.

Methods: Since Coflex® was introduced in the clinical field, there have been two techniques used for inserting the device: the one, a conventional technique of removing ligaments structure (CT); the other, a modified technique of preserving ligaments and inserting the device far anteriorly (MT). The selection criteria for the procedure were degenerative spinal stenosis with or without mild degree of instability. We assessed the clinical and radiological differences between the two groups. The clinical outcome was assessed using visual analog pain scale (VAS) and Oswestry disability index (ODI). The disc and foraminal heights were measured pre- and postoperatively by observing follow-up radiological images. The rate of surgical complications was also compared.

Results: In CT group, there were 36 patients, in an average age of 66.9 years (range: 33-84). The follow-up period was ranged from 27 to 38 months (mean 32.1 months). In MT group, there were 13 patients, in an average age of 62.6 years (range: 51-81). The mean follow-up period was 12.4 months (range: 11-15). There was statistically significant improvement of back pain VAS, leg pain VAS and ODI score in both groups at the final follow-up.

In both group, the mean disc height and the mean foraminal height was significantly increased postoperatively immediately, and MT group showed statistically more significant increase in the two parameters (11.7±4.2→17.4±2.9mm (P=0.042) and 17.4±2.9→22.6±3.4mm (P=0.003), respectively) than in CT group (11.9±3.1→13.8±2.9mm, 19.4±2.7→22.4±3.2mm). However, they returned to the preoperative values at the final follow up in both groups. With regard to the other radiological results at the last follow-up, in CT group the loosening of ISU was observed in 19 cases (46.3%). And the other various radiological abnormal findings, such as newly developed or aggravated spondylolisthesis and collapsed disc were also observed at the index levels in 9 patients. However, there was no statistical relationship between the outcome and loosening of device or between the outcome and radiological aggravation (P=0.310). In the meantime, in MT group, the loosening of ISU was observed in 2 cases (15.4%) at the last follow-up. Newly developed spondylolisthesis was observed in only 1 patient. With regard to postoperative complication, a postoperative seroma formation which required revision surgery occurred in 3 patients in CT group, but there was no surgery-related complication including postoperative seroma formation.

Conclusion: Our results demonstrate that Coflex® may not have long-term effects on the widening of the intervertebral foramen by maintaining an artificial extension of the operated segment, regardless of the techniques used. However, based on our results that there was fewer occurrence of postoperative instability such as spondylolisthesis and surgical complications in MT group, Coflex® may have a posterior stabilization effects and decrease various device-related complications when used in proper surgical techniques. Further long-term controlled study is needed.

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83. The Potential Impact of New Technologies on Spine Surgery

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Objective: To determine patient eligibility for new devices in a cohort of patients undergoing lumbar surgery. This study aims to determine the potential impact of new technologies for patients who are currently undergoing lumbar spine surgery.

Methods: We performed a retrospective review of the principal investigator’s most recent lumbar surgeries. Subjects were divided into two groups, each consisting of 100 patients. Only degenerative pathologies were included. The first group consisted of subjects who had undergone any lumbar surgery excluding lumbar fusion. The second group consisted of subjects who had undergone lumbar fusion. Information from patient records were compared to the indications and contraindications for interspinous spacers, facet replacement, and posterior dynamic stabilization (PDS). Indications and contraindications were determined by published data on current or previously published Investigational Device Exemption (IDE) trials. The following percentages were calculated: patients who had the appropriate indications for the device, patients with one or more contraindications for the device, and patients that were eligible for the device. A patient was deemed eligible to receive a device if that patient matched at least one indication and none of the contraindications for a device. Patients eligible to receive all three devices and patients ineligible to receive any of the three devices were also calculated.

Results: In patients undergoing lumbar surgery excluding fusion, the percentage of patient who had appropriate indications for an interspinous spacer, facet replacement or PDS was 47%, 48%, and 47% respectively. 33% of patients had one or more contraindications for an interspinous spacer, 28% of patients had at least one contraindication for a facet replacement, and 31% of patients had contraindications for PDS. The average number of contraindications for the interspinous device, facet replacement, and PDS was 1.27, 1.25, and 1.29 respectively. 25% of patients were eligible to
receive an interspinous spacer, 26% were eligible to undergo facet replacement, and 27% were eligible to receive PDS. 25% of patients were eligible to receive all three devices while 73% were not eligible to receive any of the devices. In patients undergoing lumbar fusions, the percentage of patient who had appropriate indications for an interspinous spacer, facet replacement, or PDS was 84%, 84%, and 89% respectively. 71% of patients had one or more contraindications for an interspinous spacer, 63% of patients had contraindications for a facet replacement, and 62% of patients had contraindications for PDS. The average number of contraindications for the interspinous device, facet replacement, and PDS was 1.51, 1.36, and 1.39 respectively. 22% of patients were eligible to receive an interspinous spacer, 30% were eligible to undergo facet replacement, and 34% were eligible to receive PDS. 23% were eligible to receive all three devices and 65% were not eligible to receive any of the devices.

Conclusions: A significant percentage of patients currently indicated for lumbar surgery are also potentially eligible for nonfusion posterior device implants at our institution. This data suggests that these devices will have a significant impact on spine surgery.

84. Clinical Outcome and Survivorship Analysis 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 44 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 2 years. The data from 33 of these patients, who did not undergo revision surgery and of whom a complete pre- and postoperative dataset was available were analyzed. All 44 cases were used to perform a Kaplan-Meier survivorship analysis.

Results: Within the 2-year follow-up period, 9 of 44 (20%) patients required further surgical intervention. At follow-up, mean improvement for lumbar pain (VAS) was 2.6 (p=0.002) and 5.7 (p<0.001) for radiating leg pain. SF-36 PCS improved 11.9 (p<0.001), MCS 4.8 (p=0.17), the Oswestry Disability Index decreased 20.1 points (p<0.001). Mean walking distance increased from 200m to 2600m (p<0.001). All nine patients that required revision surgery 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 79% for 18 months postoperatively.

Conclusions: The results of this study show a relatively high revision rate, the revision peak lies within the first year after surgery and implant survival after the first year correlates with an overall good outcome whereas lack of clinical improvement within 6 weeks postoperatively seems to be a predictor for revision surgery.

85. Does an Interspinous Device (COFLEX®) Improve the Outcome of Decompressive Surgery in Lumbar Spinal Stenosis (LSS)? A Prospective Comparison Analysis of 60 Patients

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Objectives: The uni- or bilateral undercutting decompression is a well established procedure in the operative treatment of a symptomatic LSS. The decompression of the spinal canal and additional implantation of an interspinous device is currently being investigated as a good alternative which might improve the clinical outcome. Clinical comparison trials (prospectiv, randomised) are still missing.

Methods: A prospective analysis was performed on 60 patients treated for one or two level symptomatic LSS with decompressive surgery. Two groups were build. In Group one (UD) we treated 30 patients with decompression surgery alone and in group two (CO) 30 patients got an interspinous device (COFLEX®) additionally implantet. Pre- and postoperatively disability and pain scores were measured using the Oswestry Disability Index (ODI), the Rowland Morris Score (RMS), the Visual Analog 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 and 12 month including the above mentioned scores as well as patient satisfaction. Minimum follow up one year.

Results: In the UD-Group the ODI improved from 39.4% to 19.9%, the RMS from 11.4 to 4.7, 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 280m 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 one patient had to be fused. In the UD group one patient had to be fused.

Conclusions: In our trial we couldn’t see a benefit in implanting a interspinous device additionally to decompressive
but limiting in this study is the short follow up of one year and the missing randomization of the patients.

86. Long Term Effect of the Intervertebral Dynamic Stabilization as a Protective Technique for Adjacent Levels

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Purpose: Rigid fusion is often associated with adjacent segment degeneration (ASD). Dynamic stabilization devices have been recently designed to palliate this main drawback, by preventing mechanical failures and stress-shielding phenomena. However, there are few comparative studies available, regarding ASD after rigid fusion versus dynamic stabilization. The purpose of the current study was to assess the long-term adjacent level degeneration after dynamic stabilization with a hybrid construct, i.e. semi-rigid fusion with dynamic component, and after rigid fusion in two comparable populations.

Methods: From 1991 to 1997, 60 consecutive patients underwent lumbar interbody vertebral fusion with posterior fixation for isthmic spondylolisthesis and adjacent pathological but non compressive disk:
- Group1: 36 (16 female/20 male) received rigid instrumentation.
- Group2: 24 (10 female/14 male) who underwent dynamic stabilization by means of a hybrid, i.e. rigid-and dynamic, construct (Isobar TTL®, Scient’X, France). Mean age was 32 years [22,51] in Group1 and 29 years [23,47] in Group2. Minimum follow-up was 6 years in both populations (mean= 8.27years, Max = 13years)

The evaluation criteria were:
- Fusion status (intervertebral bone bridges, absence of intervertebral motion on dynamic X-rays, no vertebral endplate subsidence, no fracture or dismantling of the fixation system)
- Radiological ADS (loss of disc height, loss of intervertebral motion, spontaneous facet fusion)
- Clinical outcome with occurrence of recurrent symptoms and requirement for second surgery with extension of the posterior fixation.

Results: No specific complications occurred per-operatively. Post-operative complications occurred in 2 patients with screws or plate breakage in Group 1 versus 0 in Group 2. More than five years after surgery (mean follow-up = 8.27 y.), solid fusion at the treated level was documented in 100% of patients in both groups according to the aforementioned criteria. Radiographic analysis showed ASD in 16 (44.4%) of patients in Group 1 and 1 (4.2%) patient in Group 2. Five patients (13.9%) underwent revision surgery for ASD in Group 1 and none in Group 2.

Conclusion: The results of this retrospective analysis show that dynamic stabilization is an efficient procedure for the assessment of lumbar degenerative diseases, while preserving adjacent levels from early degeneration. Indeed, the biomechanical concept of stabilization through load sharing prevents from excessive loading of adjacent segments, often leading to ADS. Besides, a better load sharing pattern results in less mechanical complications such as hardware breakage and bone fractures, mostly due to the neo-hinge phenomenon between a fused spinal segment and an adjacent overstressed and hypermobile intervertebral segment.

Our long term results after dynamic stabilization are most encouraging. However, our findings need to be confirmed through further prospective comparative studies.

87. Spinous Process Strength Varies with Axial Loading Direction: Implications for Interspinous Device Design

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Introduction: Interspinous implants alter the mechanical demands placed on the spinous process (SP) in vivo. These devices consist of spacers and straps limit relative motion in extension and flexion, respectively, by applying bidirectional axial loading to the SP. Because there has been very little work done to understand the mechanical demands placed on the SP by these devices [Talwar 2007; Shepherd 2000], the goal of this study was to fully characterize the strength of the SP under loads meant to simulate current interspinous products. Our specific aims are to determine whether SP strength depends on 1) axial loading direction, and 2) vertebral bone mineral density (BMD).

Methods: Donor-matched pairs of adjacent human thoracolumbar vertebrae (N=4 pairs; T11-L1; 3 male; 48±3 y.o.; DEXA scanned) were harvested from fresh-frozen spines. The anterior portion of the vertebra was potted in metal cups using bone cement (PMMA) such that transverse processes were completely submerged. One vertebra from each matched pair was potted with the inferior endplate facing the base of the cup, while the other was potted in the opposite orientation. Specimens were attached to a metal test fixture and mounted beneath the LVDT-instrumented actuator of a hydraulic press (MTS 858) fitted with a tension clamp and a load cell (AMTI MC6-5000). A polyester strap was looped around the SP with the ends securely attached to the clamp. Specimens were preconditioned (10 cycles of 50-100N force at 0.1
Hz) to allow the specimen strap to settle onto the bone, and they were then destructively tested in tension at 1mm/min [Buckley 2006].

**Results:** SP strength differed substantially with the direction of the applied axial load (Figure 1 left, p=0.05, paired t-Test). Strength has higher for inferior-directed loading (902±142 N) than superior-directed loading (687±173 N). Within and across loading modes, SP strength did not correlate with BMD (Figure 1 right, p>0.10).

![Figure 1](image)

**Conclusions:** The results of this study indicate that SP strength differs substantially depending on the direction of the axial loading. Superior-directed loading (extension with Wallis® and XStop® devices) is associated with lower strength than inferior loading (flexion with Wallis® device). This asymmetry may be attributed to the concavity on the inferior rim of the SP, which can act as a site of crack initiation under superior-directed axial loads. Our finding that SP strength does not correlate with BMD may be a result of the low sample size used in this study or it could reflect the fact that BMD is preferentially lost in the centrum relative to the posterior elements. Future work will expand the sample size used in this study, and these will be useful in evaluating the safety of current and proposed interspinous products.

88. 1 Year Follow-Up after Insertion of a Minimally Invasive Self Locking Interspinous Implant. Clinical Results and CT Measurements of Foramen Size

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**Objectives:** Spinal stenosis with neural claudication is a common pathology in the elderly. Studies have shown that the diameter of the spinal canal is further reduced during. Based on those findings interspinous implants that decrease unwanted extension have been proposed. Furthermore interspinous implants have been combined with a tension banding system achieving a stabilization effect with unloading of the disc and facets. Most of those implants require a bilateral approach with partial or total sacrifice of the supraspinous ligament, with a destabilizing effect. Objective of the present study is to evaluate clinical results of a novel interspinous implant inserted unilaterally with total preservation of the supraspinous ligament.

**Methods:** The implant, the InSwing, is automatically locked and kept in correct position thanks to a system of self opening and self locking wings. Those wings facilitate and guide introduction of the device in the interspinous space. The implant can be used alone as a stopper or with a tension band adding stabilizing effect. In this study implants were used with the added banding.

39 patients are included with a follow-up of at least 1 year. They presented with degenerative spinal disorders with persistent low back pain in 22 cases, associated with lumbar stenosis involving neurogenic claudication in 15. Average age was 62 and there were 24 men and 16 women. All patients had undergone CT scan and standard Xrays, and most MRI, prior to surgery.

The 12 last patients did undergo a systematic control CT scan at 6 months in order to measure foramen surface, disc height and dural sac diameter compared to preoperative CTs. Results of foramen sizes are reported here.

**Results:** There were no clinical device related complications. One partial spinous process fracture was discovered on a control CT scan without complaints from the patient. No implant had to be removed.

The back pain average VAS score were 6.4 (± 1.5) before surgery and 2.6 (SD ± 1.2) at 1 year (Student test: p=0.01). 12 patients out of the 15 with neurogenic claudication reported an increase of walking perimeter. 82% of patients had an improvement of at least 30% on VAS. Correct lordosis was maintained in most patients.

The CT scans showed an average increase of the size of foramen of 16%. Diameter of the dural sac also showed increase.

**Discussion:** The real place of interspinous implants is still discussed and more control studies are needed to clarify the exact indications. However in a stenosis case with positional claudication, an interspinous implant seems to show a good efficacy. Its place in disc and facet disease is still to precise exactly but makes good biomechanical sense. Moreover, those procedures have low invasiveness, are fast and carry a low complication rate. Furthermore, the technique studied here does not “burn any bridges” by respecting a maximum of anatomical structures. Decompression, fusion
or arthroplasty can be later performed, just as it would be in a “virgin” spine. Our results confirm other studies showing similar results to more aggressive techniques.

89. Kinematics of Facet Arthroplasty: A Comparison of L5-S1 and L3-L4 Levels


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Purpose of the study: Facet arthroplasty is a motion restoring procedure, suggested as an alternative to rigid fixation after facetectomy. While previous studies have reported successful results in reproducing near normal spine kinematics after facet replacement at L4-L5 and L3-L4, there are no data on the viability of facet replacement at the lumbosacral joint. The anatomy of posterior elements and the resulting kinematics at L5-S1 are distinctly different from those at proximal levels, making the task of facet replacement challenging. This study evaluated the kinematics of facet replacement at L5-S1 in comparison to the L3-L4 level.

Methods: Six human cadaveric lumbar spines (L1-S1, 46.7±13.0 years) were tested in the following sequence: (1) intact (L1-S1), (2) complete laminectomy and bilateral facetectomy at L5-S1, and (3) implantation of TFAS-LS™ (Archus Orthopedics) at L5-S1 using pedicle screws. Next, the L5-S1 level was fused using transpedicular rigid fixation and anterior plate and the specimens were retested in the following sequence: (4) L1-L5 (with L5-S1 fusion), (5) bilateral facetectomy of the superior L4 facets, and (6) TFAS-TL™ implantation at L3-L4 using translaminar anchors at L3 and pedicle screw anchors at L4.

Results: Laminectomy-facetectomy at L5-S1 significantly increased the L5-S1 angular range of motion (ROM): F-E ROM increased from 15.3±2.9 to 18.7±3.5 degrees (p<0.05), LB from 8.2±1.8 to 9.3±1.6 degrees (p<0.05), and AR from 3.7±2.0 to 5.9±1.8 degrees (p<0.05). TFAS-LS significantly decreased ROM compared to the laminectomy-facetectomy condition in all tested directions (p<0.05). TFAS-LS restored the L5-S1 ROM to its intact levels in LB and AR (p>0.05). F-E ROM after TFAS-LS implantation (10.1±2.2 degrees) was smaller than the intact value (p<0.05). Bilateral facetectomy of the superior L4 facet significantly increased the L3-L4 ROM in axial rotation from 3.1±1.7 to 6.7±3.1 degrees and in F-E from 9.9±1.6 to 10.6±1.3 (p<0.05), but not in LB (p>0.05). TFAS-TL significantly decreased the F-E and AR ROM values compared to the destabilized condition (p<0.05), restoring them to the intact (L3-L4) values (p>0.05). The ROM in LB (10.5±2.0 degrees) after TFAS-TL implantation was maintained at the intact level (p>0.05). The load-displacement curves after TFAS implantation at both operative levels (L3-L4 and L5-S1) were sigmoidal, demonstrating graded resistance to angular displacement in F-E, LB, and AR.

Conclusion: This is the first report on the kinematic assessment of facet arthroplasty at the lumbosacral joint. The TFAS-LS was able to restore stability to the lumbosacral segment after complete laminectomy and bilateral facetectomy, while allowing near normal motions in all planes. While F-E ROM after TFAS-LS implantation was smaller than the intact value, it was within the physiologic norms for L5-S1. Facet arthroplasty at L3-L4 also restored motions to intact values after bilateral facetectomy; this finding is consistent with previous studies. These results demonstrate that TFAS technology can be adapted to the lumbosacral joint and functions just as well as at proximal lumbar levels.

90. Biomechanical In vitro Study of a Novel Minimally Invasive Interspinous Spacer

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Objectives: The InSpace device (Synthes Spine, Paoli, PA) is a new minimally invasive interspinous spacer (ISS). We sought to evaluate how this device alters lumbar biomechanics through extensive in vitro testing.

Methods: Seven human cadaveric T12-L2 segments were studied (4 male, 3 female; age 36-64 years). Specimens were tested normal and again after inserting the ISS at the L1-L2 motion segment with no alteration to any soft tissues except the interspinous ligament where the device was inserted. Range of motion (ROM), lax zone (LZ), and stiff zone (SZ) were studied during flexion, extension, lateral bending and axial rotation induced using pure moments (7.5 Nm maximum). Instantaneous axis of rotation (helical axis of motion) was measured in 0.5-degree intervals from optical markers during flexion and extension with 400N preload. Foraminal area was measured by inserting quick-setting molding compound in the left neural foramen with the specimen in upright, flexed and extended postures while preloading the spine with 400N, then removing and measuring molds. Facet loads were measured from 8 strain gauges applied to the superior articular processes of L2.

Results: Angular ROM and SZ during extension were significantly reduced after ISS insertion (p less than 0.01); slight reduction also occurred during flexion (p=0.103), while little change was observed during lateral bending or axial rotation
The LZ decreased during flexion-extension, although not significantly; LZ increased during axial rotation after ISS insertion (p=0.012). Foraminal measurements showed a significant (20%) reduction in available area from flexion to extension (p=0.045) in both normal and ISS-implanted cases. However, there was no significant difference in foraminal area available between normal and ISS-implanted conditions (p greater than 0.25). Facet load measurements showed little difference between normal and ISS-implanted cases except during lateral bending. The position of the sagittal plane IAR after ISS implantation was less than 1 mm from the normal position (Figure 2). This displacement was not significant (p greater than 0.18).

**Conclusions:** The primary effect of the ISS on the natural biomechanics of the spine was reduction of extension. The ISS had little effect on motion in other directions and did not affect the facet loading, available foraminal area, or axis of rotation. This outcome reflects usage of spacers sized to fit snugly but not to distract the spinous processes in neutral posture.
91. The Total Facet Arthroplasty System® (TFAS®) in the Treatment of Lumbar Stenosis. Medium Term Clinical Results on 20 Cases

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Purpose: The current standard of care in the surgical treatment of moderate to severe degenerative lumbar spinal stenosis is decompression and instrumented fusion. Non-union, iliac crest donor site morbidity and adjacent level degeneration due to load transfer are some of the potential complications that can result from fusion in these patients. The Total Facet Arthroplasty System (TFAS, Archus Orthopedics, Redmond, WA) is a motion-restoring articulating facet joint prosthesis designed to restore the spinal biomechanics and stabilize the motion segment after wide neural decompression and facetectomy. This report documents the results obtained after the first implantations.

Methods: Twenty patients were implanted with TFAS and followed in this prospective clinical trial. Surgery consisted of a standard midline approach, single or multiple level decompression and bilateral facetectomy at a single level chosen for stabilization with TFAS. The patients were followed prospectively at 1, 3, 6, 12, 24 and 30 months. Clinical evaluation included the Zurich Claudication Questionnaire (ZCQ) and Visual Analogic Scale (VAS). Radiographic evaluation consisted in AP, lateral, flexion and extension radiographs to evaluate device and ROM.

Results: The average age was 57.1, range 48-78. One patient expired due to pulmonary embolism at 14 days postoperatively. Follow-up was 24-30 months for 13 patients. The shortest follow up was 12 months, with the mean at 21.9 months. Device was intact in all patients at the end of follow-up with evident ROM. Seventeen patients had improved ZCQ symptom and function scores with significant improvement of more than 1.4 with at least 0.5 improvement in 16 patients. Leg pain VAS scores improved in all patients (mean 4.2 points). VAS back pain scores improved in 15 patients (mean 4.3 points). Two patients suffered deep infections which resolved after surgical debridement and antibiotherapy.

Conclusion: The results obtained after a significant follow-up are very encouraging, with no device failures and significant improvement in pain status and function scores. The less expected decrease in back pain may be explained by the elimination of the pain generators at the facet joint level and to the motion restoring qualities of the TFAS device.

92. Indirect Decompression (X-Stop) versus Conventional Decompressive Surgery for Lumbar Spinal Claudication - A Prospective Randomized Trial

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Introduction: Although generally successful, decompressive surgery for lumbar spinal claudication has its complications and requires hospitalization and rehabilitation. Zucherman et al have demonstrated X-Stop patients to fare better than patients given conservative treatment in an RCT.

Aim of the study: To compare the outcomes in terms of function, quality of life and re-operations after indirect decompression versus conventional decompression for LSC.

Patients and methods: Prospective randomized study including patients with central spinal stenosis according to MRI or CT, refractory to conservative treatment and accepting participation in an RCT. Outcome at 6, 12 and 24 months. 50 patients in each group using randomization by envelope. 54 males and 46 females, mean age 70 (45-89) years. Surgical treatment at three spine centres in Sweden. Outcome at 6, 12 and 24 months according to the Zürich Spinal Stenosis questionnaire, SF-36 and the national Swedish register. Registration of re-operations and complications.

Results: To date inclusion is complete and 80/100 have passed 6 months follow-up. When spinous process fracture has been noted in the X-Stop group and these patients and 13 others have been re-operated in this group compared to 4 in the decompressive group. Follow-up (ITT) demonstrate 6 and 24 month outcomes regarding ZSQ and SF-36 to be similar and significantly improved compared with baseline.

Conclusion: Preliminary figures demonstrate that, when successful, X-Stop decompressive surgery may give similar results as decompressive surgery in terms of function and quality of life. An increased rate of secondary surgery is obvious and will be analyzed regarding cause when the follow-up is complete.
93. Load-sharing Property of a Posterior Dynamic Stabilization (PDS) Device as Assessed by Disc Pressure Profilometry - A Biomechanical Study in Cadaver Spine

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Introduction: Chronic low back pain in degenerative disc disease of the lumbar spine is thought to be secondary to spinal instability leading to abnormal loading of the disc. The goal of Posterior Dynamic Stabilization (PDS) device is to share the load with the disc and facet joints, while preserving motion. The present study evaluates the load-sharing property of a novel PDS device, BioFlex™, made up of Nitinol or Titanium coil, by Disc Pressure Profilometry (DPP).

Methods: Five cadaver lumbar spines (L3-S1) were tested in a six-degrees-of-freedom spine tester. In the first test set-up, the intradiscal pressure (IDP) was recorded from the center of the disc space, by a miniature pressure transducer, during flexion-extension (FE), lateral bending (LB) and rotation (ROT) of the spine. In the second set-up the pressure profile across the disc space (DPP) was measured using a needle mounted pressure transducer, drawn across the disc space from posterior to anterior direction, keeping the motion segment in fixed in a position of flexion, neutral and extension with axial load or 100N. The specimens were tested in both set-up in the following sequence, intact, following stabilization with PDS-Ni (Nitinol coils), and PDS-Ti (Titanium coils) applied through pedicle screws to the L4-5 motion segment. The data were normalized for comparison.

Results: In the first test set-up, the IDP was lowest in neutral position and did rise both in flexion (250±38 KPa) and extension (150±35 KPa), in all the three motion segments. A similar pressure rise was noted in a smaller magnitude in lateral bending (105±27 KPa) and rotation (65±17KPa). Following stabilization with PDS-Ni, the pressure rise was normal (100%) in flexion, lateral bending and rotation, but ‘zero’ in extension in the stabilized segment. The distal adjacent segment showed normal pressure rise (100%), but in the proximal adjacent segment the pressure rise was much larger (flexion 120%, extension 116%, lateral bending 250%, and rotation 115%). The PDS-Ti, which is a 25% stiffer that the PDS-Ni, had similar effect.

In the second set-up, the disc pressure profilometry from the intact specimen showed a uniform rise in pressure across the disc space (350±46 KPa). The pressure profile was little higher near posterior annulus in extension and minimal rise near anterior annulus in flexion. Stabilization with both the PDS-Ni and PDS-Ti device reduced the pressure profile across the index disc level in extension (45%) but little effect was noted in neutral and extension.

Conclusion: Both the IDP and pressure profile showed that the Posterior Dynamic Stabilization System unloads the disc at the index level, particularly in extension, which may significantly overload the proximal adjacent segment. The stiffness of the device may need to be adjusted, to prevent an extension block, causing excessive unloading in extension.

94. A Biomechanical Comparison of Different Spinal Implants: Motion Preventing (Fusion), Motion Preserving (Anatomic Facet Replacement) and Dynamic Stabilization (Dynesys)

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Introduction: Facet arthroplasty, a pedicle screw-based stabilization following decompression, is a newly developed technology designed for treatment of spinal stenosis and Spondylolisthesis which allows motion close to normal/intact. Unlike spinal fusion, facet arthroplasty is designed to reduce the risk of potential changes to biomechanics of adjacent level; however the literature on biomechanics of motion preservation and dynamic stabilization devices is sparse.

Objective: Biomechanics of a rigid posterior screw and rod system, dynamic stabilization with the Dynesys device (Zimmer Orthopedics, Warsaw, IN), and total facet arthroplasty with the Anatomic Facet Replacement System (AFRS™) (Facet Solutions, Inc., Logan, Utah) was compared.

Methods: A two part study was undertaken. First, the load-displacement behaviors of both intact spines and those having undergone facet arthroplasty were determined using fresh, ligamentous spines and well established in vitro testing protocols. Next, a finite element (FE) model of the L3-S1 segment was developed to understand the mechanics of facet replacement (Goel et al 2005). The predicted motions were compared with the in vitro cadaver data for both the intact and facet arthroplasty conditions for model validation. Additional models were then created in order to compare the facet arthroplasty condition with both dynamic stabilization and rigid fixation. To simulate facet arthroplasty (FA), the intact FEA model was modified to cause destabilization by removing the facets across the L4-L5, and the facets were replaced with the AFRSTM facet arthroplasty device. To simulate rigid fixation (RF) across the intact L4-L5 segment, a
rigid pedicle screw and rod implant was added, bilaterally. Likewise, to simulate dynamic stabilization (DS) across the L4-L5 segment, the Dynesys system was modeled bilaterally.

**Results:** The predicted ROM from the simulation was in agreement with the cadaver data, both for the intact and FA model. All treatment conditions restored stability at the operated level, but in a significantly different manner. The RF and DS models showed significant reductions in ROM, while the ROM following FA was similar to the intact model predictions. IDP in the RF and DS models was decreased while the IDP for the FA model was similar to that of the intact spine (Figure 1).

![Motion](image1)

![IDP](image2)

*Fig1. Motion and IDP values at different levels*

The FA restored the facet loads back to intact, while the RF and DS models showed significant reductions in facet loads (Table 1).

<table>
<thead>
<tr>
<th>Facet Loads (N)</th>
<th>Left</th>
<th>Right</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Flexion</td>
<td>Extension</td>
</tr>
<tr>
<td>Intact (L4-L5)</td>
<td>0.0</td>
<td>171.8</td>
</tr>
<tr>
<td>AFRS (L4-L5)</td>
<td>0.0</td>
<td>187.0</td>
</tr>
<tr>
<td>Right (L4-L5)</td>
<td>0.0</td>
<td>104.1</td>
</tr>
<tr>
<td>Dynesys (L4-L5)</td>
<td>0.0</td>
<td>186.1</td>
</tr>
<tr>
<td>Intact (L4-L5)</td>
<td>0.0</td>
<td>185.8</td>
</tr>
<tr>
<td>AFRS (L4-L5)</td>
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<td>140.3</td>
</tr>
<tr>
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<td>4.0</td>
</tr>
<tr>
<td>Dynesys (L4-L5)</td>
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<td>11.0</td>
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<tr>
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<td>133.8</td>
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</tr>
<tr>
<td>Dynesys (L5-S1)</td>
<td>0.0</td>
<td>133.9</td>
</tr>
</tbody>
</table>

*Table 1. Facet loads at different levels*

**Conclusion:** These data have demonstrated that facet arthroplasty (AFRS) provides restoration of motion while maintaining normal disc pressures at the operated level, just like the intact motion segment, which may reduce the risk of altered biomechanics at adjacent spinal levels.

95. **Novel DNA Test for Severe Adolescent Idiopathic Scoliosis- Presymptomatic Prognostic Test Identifies Patients Who Might Benefit from Early Application of Non-Fusion Implants**

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**Background:** Adolescent idiopathic scoliosis (AIS) shows polygenic, multi-factorial inheritance. Causative gene(s) have not been identified, but using our unique genealogy and high-throughput, gene discovery resources, we have discovered DNA markers useful for predicting curve progression in AIS.

**Method:** DNA samples and clinical data documenting the progression of scoliosis during adolescence were available for 600 adult AIS patients, collected from spine centers across the United States. 300 subjects had progression to a severe
curve as defined using usual clinical criteria; the other 300 had mild or moderate curves at skeletal maturity. Genotypes were obtained for 20 DNA markers previously discovered by our group to have prognostic utility in scoliosis. Genotypes were weighted based on attributable risks derived through logistic regression on an independent sample set. Clinical risk scores (Lonstein/Carlson criteria; JBJS 1984) were estimated based on the subject’s first radiologic evaluation for scoliosis (blinded to the genetic data). Genetic risk scores for each patient were summed and various risk score cutoffs were considered to classify a patient at “HIGH” risk of progression.

**Results:** The DNA markers selected were able to discriminate surgical patients from the patients with mild or moderate scoliosis (p<0.001). The DNA markers were a better predictor of progression risk than the clinical predictors. Optimal test performance was obtained using a 12 marker subset which showed a specificity of 90% and sensitivity of 93%. Continued refinements in the algorithm are likely as additional markers are considered as components of the test panel.

**Conclusion:** The DNA marker panel derived through these experiments is superior to existing prognostic schema for AIS. Additional improvements are likely as we learn more about the genetic loci involved. Eventually, patients with LOW scores may avoid serial radiologic surveillance. Novel, preemptive care with minimally invasive, non-fusion implants may direct spinal growth in patients at HIGH risk, lessening the need for extensive fusion procedures.

### 96. A Novel Quantitative Measure of Facet Joint Integrity Using T1rho MRI

**Introduction:** Advancements in diagnostic methods and biomarkers of facet arthrosis are needed as emerging motion-preserving technologies to treat degenerative spinal conditions continue to develop. Recent clinical and finite elemental model studies suggest that the facet joints experience increased contact forces following lumbar total disc replacement (TDR), and that progressive facet arthrosis may be a source of continued pain post-operatively. Currently there exists no imaging tool that facilitates a quantitative measure of facet articular cartilage integrity. We have recently validated T1rho MRI as a noninvasive, quantitative, highly reproducible biomarker of nucleus pulposus proteoglycan loss and early degenerative disc disease (DDD). The purpose of this study was to evaluate the feasibility of using T1rho MRI in vitro to quantify facet arthrosis.

**Methods:** Twenty intact human lumbar facet joints were obtained from an IRB-approved source. First, conventional 1.5Tesla T2-weighted axial images were acquired (slice thickness: 3mm, TE/TR = 75ms/3000ms). Facet degeneration was graded using an integer-based grading scheme from 0 (normal facet joints) to 3 (severe facet arthrosis) by two clinicians using the Weishaupt classification system. Second, multiple axial images were acquired using a T1rho-prepped turbo spin-echo based imaging sequence with the following parameters: 3mm slice thickness, acquisition matrix 256x256, and TE/TR = 14ms/3,000ms with eleven echoes per TR. Spin-lock pulse durations ranged from 1 - 60ms. A single user manually segmented the facet cartilage from each T1rho-weighted image, and the average signal intensity value of the segmentation is then fitted to a decaying exponential equation in order to determine the T1rho value. Bivariate nonparametric correlations between T1rho value and degenerative grade of facet arthrosis were performed. Finally, the inter- and intra-observer reliabilities for T1rho measurements and facet degenerative grading using the Weishaupt scale were calculated.

**Results:** Correlation analysis revealed a significant linear relationship between T1rho and MRI grade of facet degeneration (p=0.46, p=0.03). The intra-observer reliability in selecting the region of facet cartilage for calculating T1rho values was high, with $r_p = 0.98$, p<0.001. In contrast, the inter-observer reliability using the integer-based grading scale was moderate, with $r_p = 0.64$, p=0.002, while the kappa values for intra-observer reliability was low, ranging from 0.13-0.19.

**Discussion:** Our previous studies have demonstrated the correlation between T1rho and proteoglycan content in the nucleus, and the ability to use this technique as a noninvasive biomarker for early DDD. The current study demonstrates that T1rho correlates well with clinician grading and suggests the feasibility of using T1rho MRI to provide a quantitative measure of proteoglycan loss and early facet degeneration. Potential advantages of T1rho MRI over ordinal grading scales using CT or T2-weighted MRI include its ability to provide quantitative, highly reproducible, continuous data over a broad dynamic range, and the ability to quantify early subtle changes. T1rho MRI shows promise as a noninvasive, quantitative biomarker of facet joint integrity to study the effects on the facet joints that result from various motion-preserving technologies.

[1] Auerbach, Eur Spine J, 2006;
Adipose-Derived Regenerative Cell Transplantation: Evaluating Intervertebral Disc Repair in a Canine Model

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Aims: Adipose tissue provides a source of regenerative cells that can differentiate into a nucleus pulposus-like phenotype when exposed to the appropriate environment (1). To assess the response of such cells to the post-surgical milieu, and to develop a clinical option for cell placement, adipose-derived cells were collected, concentrated, and transplanted, under fluoroscopic guidance, into a surgically damaged disc.

Methods: Following IACUC approval, adipose tissue was harvested from the super-scapular region of the neck (scruff) from 12 skeletally-mature dogs. From that tissue the cells were separated, collected, and labeled with DAPI. Three lumbar intervertebral disc levels in each of the 12 dogs underwent a partial nucleotomy. Each of the three levels in each dog then received one of the following interventions: 1) adipose-derived cells in hyaluronic acid (HA) carrier (HA plus Cells); 2) HA alone; 3) No Intervention. All deliveries of cells were guided by fluoroscopy. Assessments during the course of the next 12 months were made using MRI and radiography. At the end of 12 months the dogs were euthanized and the harvested disc tissue was analyzed using microscopy, RT-PCR, and ELISA.

Results: The implanted cells from the disc tissue that was harvested from the lumbar spine in each dog were viable at the time of harvest. Matrix composition was assessed; assays were performed for aggregan, Types I and II collagen by both RT-PCR and ELISA. mRNA and protein from each level are presented with respect to normal values defined as the 100 percent expression (Table 1). Table 2 depicts the relative protein levels as measured by ELISA.

[Tables]

The results in Tables 1 and 2 show that the values obtained for HA plus Cells were nearest to those obtained for Control. The data were analyzed using a two samples t-test, comparing Control with interventions at both P<0.05 and P<0.01. Statistical differences were found between the Control and HA, and between Control and No Intervention at P<0.01, whereas the difference between Control and HA plus Cells was only significant at P<0.05. No significant difference could be shown between HA and No Intervention.

Conclusions: In the discs that received HA plus Cells the cells were viable at the time of harvest, disc morphology was maintained, intervertebral disc height was not lost, and the MRI signal remained similar to native control.

References:

Acknowledgements: Support for this project was made possible by Cytori Therapeutics, San Diego, the Atlanta Medical Center, Atlanta VA Medical Center, and Bergmannstrost Klinik.

Prospective, Randomized, Controlled Study of Plasma Disc Decompression Compared to Conservative Care for Treating Symptomatic Contained Cervical Disc Protrusion

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1Policlinico Casilino, U.O.C. Nerusciurgia, Roma, Italy

Objectives: Spontaneous regression of symptoms associated with contained cervical disc protrusion is likely to occur with appropriate conservative care although patients are often reluctant to wait. A past case series study1 showed that plasma disc decompression may be an option but a controlled comparison to conservative care (CC) is required to assess its effectiveness. The purpose of this study is to determine whether plasma disc decompression (PDD) in patients presenting with symptomatic contained cervical disc protrusion is associated with significantly improved clinical outcomes during the 6 months following the procedure compared to conservative care (CC).
Methods: This was a prospective, randomized, controlled single-site clinical study. Patients considered for enrollment were 18-75 years old, herniation-related neck and arm pain, arm pain greater neck pain, reported neck or arm pain ≥50 as measured using a 100-point visual analogue scale (VAS) score, had failed 30 days of conservative care, and had symptomatic focal cervical disc protrusion confirmed by imaging. Patients (n=85) were randomly assigned to receive PDD or continued conservative care. The CC program included transcutaneous electrical stimulation, progressive mobilization of the neck with gradual reduction of collar use, postural rehabilitation, and non-steroidal anti-inflammatory drugs. The PDD was performed using a plasma ablation device (DC SpineWand; ArthroCare Corporation, Austin, TX). Clinical outcomes measures included VAS pain scores (neck/arm), analgesic use, Neck Disability Index (NDI), and quality of life (SF-36) questionnaire. Outcomes were collected at 6 weeks, 3 and 6 months, and 1 year. To date, 120 patients have been enrolled; these interim results include 85 patients who have currently reached 1 year follow-up. Results for the complete cohort will be presented.

Results: Both groups had similar demographics and baseline pain, function, and quality of life scores. At 6 weeks, PDD patients had significantly greater reduction of neck and arm pain than CC patients (PDD, 26.1±24; CC, 57.2±18; p<0.001); significantly more PDD patients than CC patients (49% vs. 16%; p<0.001) had ceased using analgesics. Improvement in SF-36 scores (role physical, p=0.008; bodily pain, p=0.000; physical component score, p=0.013) was significantly greater in PDD patients than CC patients. For NDI, 70% of PDD patients and 39% of CC patients were classified as having ‘no or mild disability’ (p=0.007). At 1 year, PDD patients had significantly greater reduction in pain (p<0.001) and NDI (p=0.04) scores. At 1 year, the proportion of patients with no pain and using no analgesics was 60% for PDD and 6% for CC (p<0.001). At 1 year, PDD patients had significantly better physical functioning (p<0.001), role physical (p=0.011), bodily pain, (p=0.039), general health (p=0.013), role emotional (p=0.036), and physical components (p=0.006) scores than CC patients.

Conclusion: Plasma disc decompression patients experienced earlier resolution of symptoms and functional improvement and had significantly greater pain relief at 1 year compared to patients continuing with a conservative care regimen.


99. Two Levels Presacral Axial Lumbar Interbody Fusion (AxiaLIF). A Prospective 12 Months Follow up: Clinical And Radiological Results

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Purpose: Traditional surgical approaches to the lumbosacral spine involve direct exposure to anterior or posterior segments. Both approaches require muscle and ligament dissection, neural retraction, and annular disruption. A less invasive technique has been developed for axial lumbosacral surgery in two levels that preserves the integrity of the annulus. A clinical study was conducted to assess the safety, effectiveness and reproducibility of presacral percutaneous access to the anterior sacrum with insertion of an axially oriented stabilization construct.

Methods: A prospective single center clinical trial. 10 patients with a median age of 51.6 years (29-70 y/o) underwent for an axial lumbosacral surgery in two levels. Subjects were evaluated preoperatively and postoperatively at discharge, 1 and 6 weeks, and 3, 6, 12 and 18 months. Analyses consisted of measurement of disc height and fusion using X ray films and CT evaluations by an independent radiologist. Pain assessment was conducted by means of Visual Analog Scale (VAS), Oswestry Questionnaire responses, and through SF-36 Health Survey responses. Fixation of lumbosacral junction was performed through a 14 mm access cannula using an axial presacral approach. Treatment of the patients was facilitated by insertion of an axial interbody fusion construct coupled with osteogenic material and posterior minimally invasive pedicle screw instrumentation.

Results: 360 degree minimally invasive stabilization and fusion was accomplished through three small incisions. Mean surgical time was 130.7 minutes. There was minimal post-operative pain. The preoperative mean VAS of 9.2cm (Standard Deviation 0.90) decreased to 2.2cm (Standard Deviation 1.2) at 12 months and decreased 1.1cm ( Standard Deviation 0.8 at 18 months following implantation. The preoperative ODI was 63.3% (Standard Deviation 18.5), and decrease to an average of 17.6% (Standard Deviation 6.5) at 18 months follow up. All data were statistically significant (p<0.05). Six months after surgery the rate of fusion was 60% (6 patients) and at 12 months follow up, the fusion rate increased to 90% (9 patients), and before 18 months the fusion rate increased 100%. The overall satisfaction of patients was 100%.

Conclusions: The clinical data to date indicate that subjects being treated with the AxiaLIF two-level device and procedure have on average improved since their pre-treatment condition and that the fusion implant can be safely delivered utilizing the presacral access technique with a minimal blood loss and hospitalization time.
100. Navigation-Assisted Fluoroscopy in Minimally Invasive Direct Lateral Interbody Fusion: A Cadaveric Study

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Purpose: Improved designs and instrumentation along with expanding experience has brought MIS surgery to the forefront of new spinal technology. Unfortunately, MIS is heavily dependent on intraoperative fluoroscopy for visualization and implant insertion. Increased use of radiation in the operating room significantly increases the surgeon’s exposure to radiation in comparison to other non-spinal procedures. Computer-assisted navigation (NAV) is a potential method of decreasing radiation exposure and improving operating room ergonomics by decreasing the use of a C-arm and minimizing the need for protective equipment. The direct lateral interbody fusion (DLIF) technique is a new MIS method for MIS anterior lumbar interbody fusion. This study assesses the use of navigation for the DLIF procedure (NAV DLIF). Comparisons of radiation exposure and procedure time using navigation versus standard fluoroscopy were assessed. Accuracy of NAV DLIF using a reference frame mounted in the anterior superior iliac spine (ASIS) is also assessed.

Methods: Three fresh whole body cadavers underwent DLIF from T10-L5 using either navigation-assisted fluoroscopy (NAV) or standard fluoroscopy (FLUORO). Radiation exposure to the surgeon and times for specific surgical steps were recorded and compared between each group. One fresh whole body cadaver was used to evaluate the accuracy of the NAV DLIF procedure from L2-3 through L4-5. Accuracy was evaluated by measuring intraoperative deviation from a known marker placed in the vertebral bodies of the lumbar spine and comparing the error found at each level as the surgeon works further from the ASIS tracker.

Results: In comparing navigation with standard fluoroscopy for the DLIF procedure, statistically significant differences were obtained for the set-up, approach, diskectomy and total fluoroscopy times. Approach time for the FLUORO group (19.61±2.52 minutes) was higher when compared to the NAV group (15.91±4.08 minutes, p=0.024). Diskectomy time was also significantly longer for the FLUORO group when compared to the NAV group (8.43±1.99 vs 5.98±1.88 minutes, p=0.009). Total fluoroscopy times for the FLUORO group was nearly double times for the NAV group (43.7±16.6 vs 24.0±10.8 seconds, p=0.004). In contrast, the set-up time for the NAV group averaged 5.81±2.65 minutes, which was higher than the FLUORO group that averaged 3.01±0.84 minutes (p=0.005). There was no statistical significance obtained for cage insertion or total operating times. Radiation exposure of the surgeon for the NAV group was undetectable, unlike the radiation exposure for the FLUORO group (1.50±2.81 mREM per level). The accuracy of the NAV DLIF technique were: L2-3 (0.86±0.08 mm), L3-4 (0.97±0.12 mm), L4-5 (0.78±0.33 mm).

Conclusion: The use of navigation-assisted fluoroscopy for the minimally invasive DLIF procedure is feasible. Accuracy for this procedure is within 1-2 mm over the most common levels (L2-3 to L4-5) which is likely to be sufficient for safe clinical application. Although initial set-up time is longer with NAV, simultaneous AP and lateral imaging with NAV decreases the time for the approach, guide wire insertion and diskectomy, making overall surgery time similar to that of standard fluoroscopy. Navigation also minimizes radiation exposure to the surgical team and eliminates the need for cumbersome lead protective gear.

101. Development of an Elastomeric Disc Prosthesis

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Introduction: The current ‘first’ generation of total disc prostheses has a common design concept of a sliding core that allows free motion but with no, or very little, resistance. Since these first generation prostheses are theoretically unable to protect adjacent tissue structures, a number of next generation disc prostheses utilizing elastomeric core components are being developed. Elastomeric discs have the advantage that not only can they control motion but also may provide appropriate levels of shock absorption. An earlier attempt to use elastomers (Acroflex, Depuy Spine Inc) failed clinically due to failure of the polymer, highlighting the need for exhaustive in-vitro fatigue testing. (1,2)

The purpose of this study is to present the results of fatigue tests conducted upon a new design of total disc, the Physio-L® lumbar disc prosthesis3, constructed from polycarbonate polyurethane elastomer securely fixed to titanium alloy endplates. In order to completely test all possible forms of in-vivo motion, these tests were conducted in compression, flexion-extension bending, lateral bending, torsion and shear.

Methods: Fatigue testing was conducted according to the following conditions: Compression +120N - -1200N @2 Hz; Flexion-Extension ± 8o with a 1200N compressive pre-load @6 Hz Lateral Bending ± 6o with a 1200N compressive pre-load @6 Hz Torsion ± 4o with a 1200N compressive pre-load @6 Hz 45o Shear +50N - -500N @2Hz

All tests were conducted at 37ºC according to ASTM F-2346. Both compression and shear tests were performed using an MTS servo-hydraulic machine while the bending and torsion tests were conducted using custom built multi-station simulators.

A minimum of 3 samples for each loading condition were tested to 10 million cycles. All specimens were subjected to a...
visual inspection daily for any sign of failure. Every 2 million cycles and again at completion, the samples were subjected to dimensional inspection using an optical comparator, gravimetric analysis and visual inspection under a stereo-microscope. Following completion of the flexion-extension experiments, the same samples were then re-tested to a further 10 million cycles under lateral bending and upon completion of these tests to a further 10 million cycles under torsional loading, for a total of 30 million cycles.

**Results:** All samples successfully completed a minimum of 10 million cycles without failure. Microscopic examination revealed that the polymer core remained essentially unchanged through testing without evidence of cracking or other degradation. Gravimetric analysis revealed insignificant changes in weight. For those samples tested to a total of 30 million cycles, no signs of failure were observed.

**Conclusion:** The present study is the first reporting long term fatigue studies on an elastomeric total disc prosthesis. The satisfactory results indicate the possibility of using these materials for restoring normal disc motion after total disc arthroplasty.

1 Serhan H, Ross R, Lowery G, Fraser, R: Biomechanical characterization of a new lumbar disc prosthesis. 28th ISSLS Meeting, June 19-23, 2001
3 Nexgen Spine, Inc. Whippany, NJ

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**102. Oxiplex Intraoperative Surgical Gel: An Adjuvant to Lumbar Disc Surgery for the Reduction of Post Surgical Pain**

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**Purpose:** Postoperative pain following standard lumbar discectomy can be a significant source of morbidity. We performed a prospective, randomized, blinded, parallel group clinical study of 352 patients (Oxiplex treated, N = 177 and surgery only, N = 175) to assess the safety and reduction of neurological sequelae using Oxiplex intraoperative surgical gel (FzioMed, San Luis Obispo, CA) to protect the nerve roots of patients undergoing their first single level laminotomy, laminectomy, or discectomy at L4-L5 or L5-S1.

**Methods:** Patients were randomly selected to receive surgery only or surgery plus Oxiplex placed on and around the nerve root prior to wound closure. The effectiveness of Oxiplex for the reduction of pain and associated symptoms following single level lumbar discectomy was assessed 6 months following surgery using 1) quality of life measure (Lumbar Spine Outcomes Questionnaire [LSOQ], BenDebba et. al., Spine J. 7:118-132), and 2) clinical evaluations.

**Results:** The demographics, surgical procedures, baseline LSOQ scores and baseline clinical evaluations were well balanced between the Oxiplex (N=177) and surgery-only (N=175) groups. There were no cases of CSF leaks associated with the Oxiplex treated group. There were no clinically significant differences in laboratory values or vital signs between groups. Subjects treated with Oxiplex were consistently shown to experience greater reductions in back pain and leg pain at 6 months compared to controls, especially in the challenging group with substantial back pain at baseline (statistically significant reduction of back pain [P=0.0193] and leg pain [P=0.0123] in the Oxiplex group compared to the control group). More subjects in the Oxiplex group were satisfied with the outcome of their surgical treatment than subjects in the control group (P=0.0456). Subjects in the Oxiplex group had less hypoaesthesias, paraesthesias, and sensory loss compared to controls. Subjects in the Oxiplex group had fewer reoperations during the 6-month follow-up than subjects in the control group (1 vs. 6).

**Conclusions:** The results of this study demonstrate that coating the dura, nerve root and laminotomy site with Oxiplex following lumbar spine surgery is associated with a greater improvement in neurological function and less postoperative pain compared to patients undergoing surgery only. Taken together, these data demonstrate a consistent, clinically significant improvement in outcome with the use of Oxiplex gel in lumbar spine surgery.

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**103. Novel Minimally Invasive Percutaneous Multilevel 360 Degree Fusion for Lumbar Degenerative Scoliosis - Feasibility, Technique and Early Results**

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**Introduction:** Age, co-morbidities and blood loss may be limiting factors when considering traditional surgical correction and fusion for Adult lumbar degenerative scoliosis. Minimally Invasive Spine Surgery has been reported to allow for less blood loss and morbidity. Operative results of Circumferential Minimally invasive spine surgery (MISS) for Adult lumbar degenerative scoliosis have not been reported to date. We study circumferential deformity correction and fusion using a combination of 3 novel MISS techniques

**Methods:** 16 patients have had circumferential 360-degree instrumentation and fusion over two or more levels for adult
The prototype device created a larger nucleus cavity than with a rongeur, and damage to the annulus and endplates was minimized. These results will lead to refinements in the device design.

Conclusions: A combination of novel minimally invasive techniques have allowed for multi-segment surgical correction and fusion of adult lumbar degenerative scoliosis. Our early results show less blood loss and morbidity with satisfactory correction and fusion. The results are very promising and we continue to follow our patients with regards to long-term outcome.

104. Initial Cadaver Evaluation of a Mechanical Nucleus Removal Device

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Purpose: A device has been designed for improved nucleus removal to aid in optimum placement and performance of nucleus replacements and other minimally invasive spinal implants. An evaluation of the device’s ability to remove nucleus tissue was performed.

Methods: The device incorporates a rotational shaver that can extend from an articulating tip that can bend over 90°, providing access to the entire nucleus cavity from even a unilateral posterior approach. The device uses a central lumen for aspiration of cut nucleus tissue. The cutting head geometry and related cutting parameters are designed to minimize damage to adjacent annulus and cartilaginous endplate tissue.

Five intervertebral discs (L3 - S1) from three cadaver lumbar spines (mean age = 59yr) were used to evaluate the ability of a prototype device to remove nucleus tissue. The spines were mounted in a frame for unilateral posterior access. Access to the discs was performed via a hemilaminectomy (preserving the facet) and a stab incision through the annulus the full height of the disc. A small amount of nucleus material was removed with an IVD rongeur to create an initial cavity for the prototype device. The prototype device was inserted into the disc space, activated, and manipulated in the nucleus cavity with aspiration for a maximum of 10 minutes. As the prototype device was not designed with an irrigation port, water was occasionally injected into the disc space to hydrate the nucleus and prevent adherence of the cut tissue within the evacuation lumen. The device was occasionally flushed with water to further clear the aspiration tubing. All cut tissue was collected in a filter trap.

The intact discs were dissected, photographed, and analyzed using a visual measurement method. The annulus/nucleus and enucleated cavity borders of each specimen were delineated, then measured with digital video measurement software (Universal Desktop Ruler, avpsoft.com) that converts video pixel count into area after calibration against a known scale. The enucleated cavity area was compared to the total nucleus cavity to calculate a percent of maximum nucleus removed. The results were compared to an earlier nucleus removal study using standard rongeurs in nine lumbar disc specimens.

Results: Mean EBL for anterior procedures (transpsoas disectomy/fusion) was 163.89 cc (SD 105.41) and for posterior percutaneous pedicle screw and rod fixation (and in some cases L5-S1 interbody fusion) was 93.33cc (SD 101.43). Mean surgical time for anterior procedures was 4.01 hours (SD 1.88) and for posterior procedures was 3.99 hours (SD 1.19). Mean Cobb angle preop was 18.93° (SD 10.48) and postop was 6.19° (SD 7.20). Mean preoperative VAS score was 6.8 and TIS score was 54.3. At mean follow-up of 7 months (range: 3 months to 1 year), mean VAS was 2.3; TIS was 22.9. There were no intraoperative complications. Three patients had transient groin pain that resolved completely. No patient needed admission to the ICU and no patient needed a blood transfusion. Fusion is progressing satisfactorily with the first five patients showing solid fusion on radiographs and/or CT Scan.

Conclusions: The prototype device created a larger nucleus cavity than with a rongeur, and damage to the annulus and endplates was minimized. These results will lead to refinements in the device design.