

retrolisthesis of L4 vertebra were analyzed with the Student *t* test. The confidence level for significance was  $p > T0.05$ .

**RESULTS:** The mean cross-sectional area of the L4-5 intervertebral foramen of the anatomic spine was  $171.70 \pm 36.38 \text{ mm}^2$  at the left side and  $170.68 \pm 37.28 \text{ mm}^2$  at the right side. No significant difference was found between the left and right sides ( $p > .05$ ). No significant difference was found between the measured values using Aquarius Image software of the CT scanner and NIH image J software in the computer ( $p > .05$ ). The L4-5 intervertebral foraminal area decreased approximately 13% with each 1-mm incremental L4-5 disc space narrowing and simultaneous retrolisthesis of the L4 vertebra.

**CONCLUSIONS:** There is a significant decrease in inferior foraminal area after disc space narrowing and simultaneous retrolisthesis of lumbar vertebra. The size of the intervertebral foramen is directly related to the degree of the disc degenerative changes.

**FDA DEVICE/DRUG STATUS:** This abstract does not discuss or include any applicable devices or drugs.

**CONFLICT OF INTEREST:** No conflicts.

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4:40

**112. Does Lumbar Facet Fluid Detected on MRI Correlate With Radiographic Instability in Patients With Degenerative Lumbar Disease?**

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**BACKGROUND CONTEXT:** Although never formally studied, it has been suggested that fluid collection within the lumbar facet detected on MRI is indicative of spinal segment instability.

**PURPOSE:** The purpose of this study was to analyze the relationship between lumbar facet fluid detected on MRI and sagittal instability detected on flexion lumbar radiographs in patients with degenerative lumbar disease at L4/5. We hypothesized that the amount of facet fluid on MRI correlates with sagittal instability on the flexion radiograph.

**STUDY DESIGN/SETTING:** Retrospective.

**PATIENT SAMPLE:** See methods section.

**OUTCOME MEASURES:** Radiographic and MRI measurements

**METHODS:** We studied 53 patients with degenerative lumbar disease at L4/5 who had preoperative lumbar MRI and flexion/extension radiographs available for review. 26 underwent laminectomy/fusion (LF); 27 underwent laminectomy alone. Axial T2 MRI images through the L4/5 facets were analyzed for facet fluid. The facet fluid index (FFI) was calculated at the widest cross-sectional facet area. The FFI is the ratio of the sum of the width of fluid in each facet (bilateral) to the sum of the width of each

facet (bilateral). Instability on the flexion radiograph was measured as percentage of anterior slip at L4/5.

**RESULTS:** Of the 26 LF patients, 2 had facet fractures and were not included in the study. 4/24 LF patients had no facet fluid but did have instability. 20/24 (83%) had facet fluid and instability. The mean FFI and percent slip for these 20 patients were 0.14 (range, 0.06-0.36) and 14.5% (range, 10%-30%), respectively. There was a positive linear relationship between these values, with a Pearson correlation coefficient of 0.93 ( $p < .01$ ) (Fig. 1). Of the 27 laminectomy patients, 19/27 had no facet fluid or instability. 8/27 had facet fluid, two of whom had instability. Thus, 6/27 (22%) had facet fluid with no instability. The calculated sensitivity and specificity when using the presence of L4-L5 facet fluid on MRI as an indicator of radiographic lumbar instability were 85% and 76%, respectively. Patients with facet fluid had far greater likelihood of having instability than those without facet fluid (OR=17.4).

**CONCLUSIONS:** The majority of patients with instability on flexion radiograph had facet fluid on MRI. There is a close linear relationship between the FFI and the amount of instability at L4/5. The presence of facet fluid on MRI should raise high suspicion of instability.

**FDA DEVICE/DRUG STATUS:** This abstract does not discuss or include any applicable devices or drugs.

**CONFLICT OF INTEREST:** No conflicts.

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Friday, September 29, 2006

9:31–10:14 AM

General Session: Motion Segment Replacement

9:31

**113. Lumbar Total Disc Replacement With the ProDisc-L Artificial Disc versus Fusion: A Prospective Randomized Multi-Center Food and Drug Administration IDE Trial**

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**BACKGROUND CONTEXT:** Total disc replacement (TDR) is intended to address discogenic pain and preserve physiologic motion between two vertebral bodies in a patient with degenerative disc disease which may prevent long-term subsequent accelerated degeneration at adjacent disc levels.

**PURPOSE:** To compare clinical outcomes, radiographic motion, and patient satisfaction in patients treated with lumbar disc replacement with a semi-constrained artificial disc (ProDisc-L, Synthes Spine) versus those treated with circumferential fusion in a randomized clinical trial.

**STUDY DESIGN/SETTING:** A multi-center prospective, randomized clinical trial was completed to assess the safety and efficacy of the ProDisc-L prosthesis.

**PATIENT SAMPLE:** The IDE trial consisted of 17 centers. A total of 236 patients were treated in the randomized trial. There were 161 patients

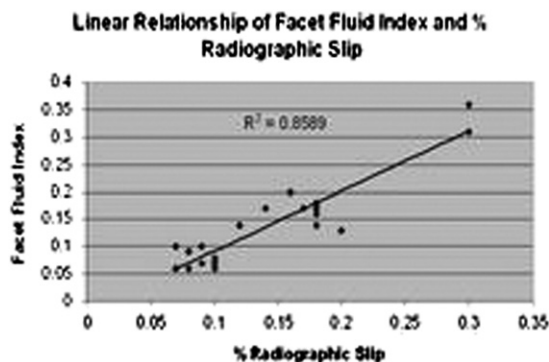


Fig. 1. Scatter plot demonstrating the linear relationship between the facet fluid index and the percent of radiographic slip.

treated with ProDisc-L (PD) and 75 patients treated with circumferential fusion (F).

**OUTCOME MEASURES:** Oswestry (ODI), SF-36, VAS, radiographs (ROM), physical examination.

**METHODS:** Randomization was performed at a 2:1 ratio of disc replacement to circumferential fusion. Patients were assessed preoperatively and postoperatively at 6 weeks, 3, 6, 12, 18, and 24 months.

**RESULTS:** Demographics were similar between the two patient groups (ProDisc: 38.7 years $\pm$ 8.0, 51% males; Fusion: 40.4 years $\pm$ 7.6, 45% males). The operative time (min) was significantly greater for Fusion (229 $\pm$ 75.9) than ProDisc (121 $\pm$ 59.2) treated patients ( $p$ <.0001). The estimated operative blood loss (cc) was significantly higher for Fusion (465 $\pm$ 440) than ProDisc patients (204 $\pm$ 231.3) ( $p$ <.0001). Hospital stay was significantly more days for Fusion patients (F: 4.4 days $\pm$ 1.54 vs. PD: 3.5 days $\pm$ 1.29). ODI scores, VAS pain were significantly less compared with presurgery at all follow-up visits for both treatment groups ( $p$ <.0001). ODI success (15 point decrease) was significantly greater for ProDisc (68%) than Fusion patients (55%) ( $p$ <.04). Significant improvement (<-20 mm VAS) was seen in 67% of ProDisc and 61% of Fusion patients. Satisfaction (VAS) was significantly greater in the ProDisc patients (77 mm ProDisc vs. 67 mm Fusion,  $p$ <.01). Neurologic success (improvement or maintenance) was significantly greater in the ProDisc patients (PD: 91% vs. F: 81%,  $p$ <.03). At 24 months, 97% of the Fusion patients were radiographically fused and ROM measurements for the ProDisc patients averaged 7.7°. ProDisc-L patients had significantly higher overall success defined as a composite of primary measures compared with fusion ( $p$ =.005). Overall complications were similar in the two groups. There were 6/161 (4%) reoperations in ProDisc and 4/75 (5%) reoperations in Fusion patients. No postoperative infections in ProDisc patients and 2 in Fusion patients (3%). DVT occurred in 2 ProDisc (1%) and in 1 Fusion patient (1.3%).

**CONCLUSIONS:** This is the first IDE randomized study to show statistical superiority of an artificial disc compared with Fusion. It is also the first IDE study to include Range of Motion as a component of the overall success primary endpoint. The ProDisc-L artificial disc replacement is a safe and effective alternative to fusion for 1-level symptomatic lumbar disc disease in properly selected patients.

**FDA DEVICE/DRUG STATUS:** ProDisc-L: Approved for this indication.

**CONFLICT OF INTEREST:** Author (RBD) Consultant: Synthes Spine; Author (RBD) Grant/Research Support: Synthes Spine.

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replacement and 7 patients had 2 levels replaced. Magnetic resonance imaging (MRI) follow-up was possible in 51 patients. Two independent neurosurgeons evaluated the grading of facet degeneration by the method modified from the grading system proposed by Fujiwara et al., and the degeneration of discs at the index level and adjacent levels by the classification proposed by Pfirrmann et al.

**RESULTS:** Mean ODI and VAS preoperatively of the Charité group were 78.1% and 8.2. They improved after disc replacement, being 16.5% and 2.3 respectively. ODI and VAS of the ProDisc group showed improvement from preoperative 81.7% and 8.9 to postoperative 19.8% and 2.3. The improvement rates of the ODI and VAS score were not statistically significant between the two groups ( $p$ =.935,  $p$ =.13, respectively). Clinical success was 93.9% (31 out of 33) in the Charité group and 83.3% (20 out of 24) in the ProDisc group. This difference in the success rate was not statistically significant ( $p$ =.227). Intra-observer and inter-observer reliability test for radiologic evaluation was done and showed high reliability. Among 33 segments replaced with Charité that were followed with MRI, 12 segments (36.4%) showed degradation of the facet joint by one grade. In the ProDisc group, 8 out of 25 segments (32%) showed facet degradation. The degradation rate of facet degeneration between the two groups was not significantly different ( $p$ =.729). Degradation of disc degeneration at the adjacent level above the index level was seen in 19.4% (6 out of 31 segments) in the Charité group and 28.6% (6 out of 21 segments) in the ProDisc group. This difference between these two groups was not significant ( $p$ =.439). Mean segmental range of motion (ROM) at L4-L5 in the Charité group was 9.3 preoperatively and 11.7 postoperatively. At L5-S1, the ROM was 8.8 preoperatively and 11.2 postoperatively. In the ProDisc group, ROMs at L4-L5 were 6.5 and 10.6. At L5-S1, mean ROMs were 7.7 and 5.6. Post-operative mean ROM at L5-S1 in the ProDisc group was statistically significantly less than that of Charité ( $p$ =.007). Device subsidence was observed in 1 patient in the Charité group and 2 in the ProDisc group.

**CONCLUSIONS:** Overall, clinical outcomes of both Charité and ProDisc groups were fairly good, but, the facet joint of the index level and the motion segment at the adjacent level showed aggravation of degeneration in a significant number of patients, regardless of the device used, at a minimum 3-year follow-up. These findings raise concerns of possible late consequences of total disc replacement, especially as it relates to facet arthropathy and adjacent level disease.

**FDA DEVICE/DRUG STATUS:** S-B Charité: Approved for this indication; ProDisc: Approved for this indication.

**CONFLICT OF INTEREST:** No conflicts.

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### 9:37

#### 114. S-B Charité versus ProDisc: A Comparative Study of Minimum 3-Year Follow-Up

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**BACKGROUND CONTEXT:** Total disc replacement (TDR) has become an option for the treatment of degenerative disc disease of the lumbar spine. There are two devices that have been widely used for TDR, S-B Charité and the ProDisc.

**PURPOSE:** To retrospectively evaluate and compare clinical and radiological outcomes of S-B Charité and ProDisc.

**STUDY DESIGN/SETTING:** Retrospective study.

**PATIENT SAMPLE:** Among a total of 61 patients who underwent total disc replacement from Oct. 2001 through Oct. 2002, 57 patients were followed and enrolled in the study.

**OUTCOME MEASURES:** Oswestry Disability Index (ODI), Visual Analogue Scale (VAS).

**METHODS:** There were 30 males and 27 females. S-B Charité was used in 33 patients and ProDisc in 24. Fifty patients underwent single-level

### 9:43

#### 115. Factors Related to the 20 Best and 20 Worst 24-Month Outcomes of Total Disc Replacement in Prospective FDA-Regulated Trials

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**BACKGROUND CONTEXT:** Overall results of total disc replacement (TDR) have been promising. However, as with any surgery, even in the rigorously defined FDA-regulated trials, there are some patients who have poor outcomes.

**PURPOSE:** The purpose of this study was to identify the 20 best and 20 worst outcomes of TDR and to determine if differentiating factors could be identified in these prospective studies.

**STUDY DESIGN/SETTING:** Data for the study were collected at a single spine specialty center participating in the FDA-regulated clinical trials evaluating Charité and ProDisc. Both were prospective studies.

**PATIENT SAMPLE:** A study database from one center was reviewed for patients in the Charité and ProDisc clinical trials. The 203 patients