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BACKGROUND CONTEXT: Lumbar interbody fusion from a posterior approach affords the advantage of adding interbody fusion to a posterolateral fusion while avoiding the added morbidity of an anterior spinal approach. Transforaminal lumbar interbody fusion (TLIF) provides anterior column support through a single posterolateral approach to the disc space with minimal neural retraction and disruption of only one facet joint. TLIF has been shown to be safe with relatively few complications. While the cross-sectional area of bone required to obtain an adequate arthrodesis remains unclear, case series consistently report high fusion rates for TLIF. However, prior studies have demonstrated difficulty in removing sufficient disc material through a unilateral approach.

PURPOSE: The purpose of this study was to quantitatively and qualitatively analyze the cross-sectional area of vertebral end plate prepared for fusion using a unilateral TLIF approach.

STUDY DESIGN/SETTING: A human cadaveric in vitro analysis of vertebral end plate preparation in a TLIF model.

PATIENT SAMPLE: 10 human cadaver torsos.

OUTCOME MEASURES: Mean percentage of end plate cross-sectional area exposed for fusion.

METHODS: The lumbar disc levels of 10 cadavers were exposed and prepared using a standard unilateral TLIF approach by 4 spine surgeons experienced with TLIF. The spines were harvested and transected through each disc level. The opposing end plates were digitally photographed and three blinded, independent examiners determined the percent surface area exposed for fusion by calculating the amount of end plate prepared over the total end plate within the annulus using Scion Image, an image processing and analysis program (Fig. 1).

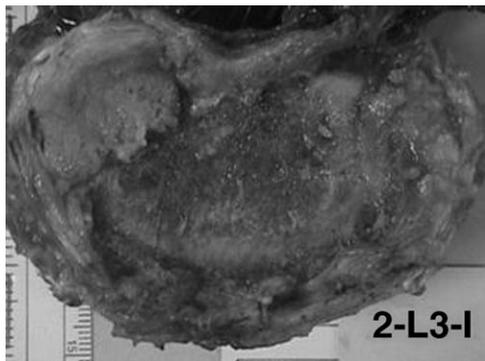


Fig. 1. Vertebral end plate prepared for TLIF.

RESULTS: 44 intervertebral discs were excised and 88 vertebral end plates were prepared. The overall mean percent of end plate surface area exposed through the TLIF approach was 60.42% (range: 48.8%–72.6%) of the total available end plate surface area. The contralateral posterior quadrant of the disc space was the area with the most residual disc material after preparation. The lateral and anterolateral disc space on the ipsilateral side also had residual disc material left behind. Overaggressive end plate cartilage removal results in perforation and excavation of the bony end plate. The contralateral anterior annulus was most at risk for perforation by instruments.

CONCLUSIONS: It is believed that a larger area of bony contact between the grafts and the vertebral bodies heightens the chances of successful interbody fusion. Cloward advocated removal of almost the entire disc, leaving the adjacent surfaces of the vertebrae completely clean of all soft tissue. The current study shows a substantial amount of end plate can be prepared through a TLIF approach. However, specific regions of the disc space, such as the contralateral posterior quadrant, remain difficult to access with conventional instruments and techniques.

DISCLOSURES: No disclosures.

CONFLICT OF INTEREST: No conflicts.

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P99. Artificial disc replacement as a salvage treatment for failed back syndrome

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BACKGROUND CONTEXT: Spinal fusion has been a standard surgical salvage for patients with failed prior invasive procedures such as discectomies, laminectomies, or nucleoplasties—failed back syndrome (FBS). Artificial disc replacements have been developed as an alternative to fusion, and have successfully completed clinical trials in the US, but only for patients meeting stringent criteria. The semi-constrained ProDisc-II prosthesis is designed to be inherently more stable than a non-constrained disc (eg SB Charité III), and also has porous-coated end plates with small keels for immediate fixation. Unlike other artificial discs, the ProDisc-II device has undergone clinical trials for multi-level disc replacement. There are no reports however about the results of spinal arthroplasty for failed back surgeries, especially when involving more than one level.

PURPOSE: To examine the clinical and radiographic outcomes of single and multi-level semi-constrained total disc replacement versus fusion as salvage for failed back syndrome.

STUDY DESIGN/SETTING: Prospective, randomized, and controlled clinical trial for the ProDisc-II prosthetic disc.

PATIENT SAMPLE: Patients enrolled in the U.S. FDA artificial lumbar disc clinical trials at one institute.

OUTCOME MEASURES: Visual Analog Scale, Oswestry Disability Index, patient satisfaction scores, postoperative computed tomography scans, and sequential radiographs.

METHODS: 120 randomized patients were included in the study. 66 patients with continued intractable low back or leg pain after prior lumbar surgical procedures underwent spinal arthroplasty versus fusion as part of a USFDA Clinical Trial. The clinical outcomes of TDR (N=44) were compared with fusion controls (N=22) and spinal arthroplasties without prior surgery (N=54). Outcome measures included the Oswestry Disability Index (ODI), the Visual Analog Scale (VAS), and radiographs (at 6 weeks, 3, 6, 12, 18 and 24 months).

RESULTS: Patients with FBS generally described more preoperative pain and disability than their counterparts with primary degenerative disc disease. When treated with lumbar disc replacement, patients with FBS had significantly reduced pain and disability from their initial status as measured by the ODI and VAS scores (both decreased by over 60% at 24 months). The results are comparable with spinal arthroplasty patients with no prior spinal procedures (VAS and ODI also decreased by over 60%). In the early to intermediate postoperative period, both groups did better than fusion patients (VAS from 7 to 3.75, and ODI from 30 to 22 at 18 months). Motion restoration and preservation was noted radiographically in both groups of arthroplasty patients. After approximately one year, the clinical outcomes of arthroplasty and fusion converge, with significantly more motion in the arthroplasty group. However, patient satisfaction in both arthroplasty groups (over 90%) far exceeded the fusion group (55%).

CONCLUSIONS: Patients with FBS are also candidates for disc arthroplasty as long as other inclusion and exclusion criteria of arthroplasty are met. They can benefit as much from spinal arthroplasty as those without prior back surgery. Having had tissue-removing but not destabilizing prior invasive spinal procedures, does not appear to compromise the results of TDR. Design characteristics of the ProDisc-II, such as the semi-constrained nature, porous-coated end plates, and stabilizing keels are likely advantageous in such cases. Patient satisfaction and motion are superior with spinal arthroplasty compared with fusion, regardless of prior surgery status.

DISCLOSURES: FDA device/drug: ProDisc-II prosthetic disc. Status: Investigational/not approved.

CONFLICT OF INTEREST: No conflicts.

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P100. Osteogenic protein-1 in high-risk spinal fusion patients: a prospective clinical trial in 28 consecutive patients with long-term follow-up and independent outcomes-based assessments