

**Abstract: 415**

**Treatment of Lumbar Spinal Stenosis with a Total Posterior Arthroplasty Prosthesis versus Posterior Lumbar Fusion: A Prospective Report on 145 Patients**

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

**Methods:** Forty-two patients were enrolled in a nonrandomized, multicenter, prospective pilot study outside the US. An additional 103 patients were enrolled in a randomized, multicenter, prospective, IDE study in the US (53 patients received the TOPS device, 50 patients received the fusion control). The combined average age for TOPS patients was 61 years (43-73) and for control patients was 58 years (41-71). All patients had spinal stenosis with or without spondylolisthesis at L3-4 or L4-5 due to facet arthropathy. Radiographs and scores on outcome measures including the visual analog scale (VAS) for pain, Oswestry Disability Index (ODI), Short Form-36, and Zurich Claudication Questionnaire were prospectively recorded before surgery and at 6-week, 3-month, 6-month, 12-month, and 24-month intervals after surgery (and annually thereafter). Prior to instrumentation in both TOPS and fusion patients, a bilateral facetectomy and laminectomy at L3-4 or L4-5 was performed via a standard midline posterior approach. After decompression, either a posterior lumbar fusion with instrumentation or the TOPS device was implanted. TOPS pedicle screws were inserted into four pedicles with triangulating trajectories to achieve maximal purchase. An appropriately-sized TOPS arthroplasty implant was then applied.

**Combined US and OUS findings:**

ODI Pre-op 6 wks 3 mos 6 mos 12 mos 24 mos 36 mos 48 mos

TOPS 55.9 30 23.6 20.1 21.2 17.6 27.6 28.3

Fusion 55.2 31.3 21.4 21.1 17.8 24 N/A N/A

VAS Back TOPS 70 24 22 20 26 22 52 N/A

Fusion 76 26 22 29 27 28 N/A N/A

VAS Leg TOPS 70 15 16 18 15 17 25 36 Fusion 64 13 15 15 13 17 N/A N/A

The mean surgical time for the TOPS surgery was 2.7 hours (1.3-5.4) versus 2.5 hours (1.3-4.9) for the control.

Radiographic analysis showed that in the TOPS patients, lumbar motion was maintained, disc height was preserved, and evidence of screw loosening was found in 1/300 screws (0.33%). In the TOPS group, three device-related adverse events (3/75, 4.0%) were reported which required removal of the device and subsequent fusion, one of which was due to a misplaced pedicle screw. In the control group, two patients required revision surgery for pseudoarthrosis, and one patient required further surgery for adjacent level disease (6/50, 12%).

**Conclusions:** The TOPS surgical and outcome data indicate that it can be safely applied via a traditional posterior approach with low surgical morbidity. And when compared to traditional posterior instrumented fusion, the TOPS device

demonstrates excellent 2-year functional and radiographic outcomes in patients with stenosis with or without degenerative spondylolisthesis and facet arthrosis.