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Posterior lumbar facet arthroplasty versus fusion for the treatment of spondylolisthesis: 3-year results from the Total Posterior Spine System investigational device exemption study

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OBJECTIVE The optimal surgical treatment for lumbar spinal stenosis (LSS) with degenerative spondylolisthesis (DS) remains controversial. Posterior lumbar facet arthroplasty preserves motion after decompression and may address some of the limitations of fusion techniques. The Total Posterior Spine System (TOPS) investigational device exemption trial compared decompression with facet arthroplasty to decompression plus fusion (open with interbody). This study reports the 3-year outcomes from this trial.

METHODS This randomized, controlled, multicenter trial enrolled 321 patients with LSS and grade I DS across 37 sites (2:1 randomization of arthroplasty to fusion). Eligible patients were 35–80 years old, had failed ≥ 6 months of nonsurgical treatment, and met thresholds for disability and leg pain. The primary endpoint was a composite clinical success score at 36 months, defined by four criteria: 1) no reoperation or lumbar injection, 2) no major device adverse events, 3) ≥ 15-point improvement in the Oswestry Disability Index (ODI), and 4) no new/progressive neurological deficit. Secondary outcomes included the ODI score, visual analog scale (VAS) scores for back and leg pain, the Zurich Claudication Questionnaire (ZCQ), device-related adverse events, and reoperations.

RESULTS One hundred seventy-nine patients in the arthroplasty (TOPS) group and 74 in the fusion group were eligible for the 36-month analysis. The composite clinical success achievement rate was significantly higher in the arthroplasty group (76.0%) than in the fusion group (56.8%; p = 0.0038). The rate of reoperation or lumbar injection was significantly lower for the arthroplasty group (14.0%) compared to the fusion group (25.3%; p = 0.0222). Arthroplasty was associated with a significantly higher minimal clinically important difference (MCID) achievement rate for VAS back pain score compared with fusion (85.2% vs 72.2%; p = 0.041). Although there was no significant difference in ODI score, VAS leg pain score, or ZCQ component scores between groups, the arthroplasty group trended toward higher MCID achievement rates across all patient-reported outcome measures. There was no significant difference in reoperation failure rates between groups (5.8% for arthroplasty vs 9.5% for fusion; p = 0.329).

CONCLUSIONS Decompression and dynamic stabilization with lumbar facet arthroplasty was associated with statistically significantly superior clinical outcomes and lower rates of secondary invasive procedures, including reoperations and injections, compared with decompression and fusion. Long-term follow-up is critical in defining the role of lumbar facet arthroplasty for the treatment of DS.

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KEYWORDS degenerative spondylolisthesis; motion preservation; TOPS device; posterior lumbar arthroplasty

ABBREVIATIONS DS = degenerative spondylolisthesis; IDE = investigational device exemption; LSS = lumbar spinal stenosis; MCID = minimal clinically important difference; ODI = Oswestry Disability Index; PROM = patient-reported outcome measure; TOPS = Total Posterior Spine System; VAS = visual analog scale; ZCQ = Zurich Claudication Questionnaire.

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Lumbar spinal fusion remains a widely used surgical intervention for various degenerative pathologies. The number of elective lumbar fusions increased by nearly 66% in the last decade, with the most significant rise observed in patients diagnosed with spondylolisthesis.[1] The superior surgical treatment for lumbar spinal stenosis (LSS) with degenerative spondylolisthesis (DS) has not yet been established. The two predominant surgical strategies include decompression alone versus decompression and fusion. While fusion effectively eliminates motion at the diseased segment and provides structural stability, it has been associated with an increased risk of adjacent segment degeneration due to altered biomechanical loading. Decompression alone has been associated with high reoperation rates due to ongoing or progressive instability following removal of the posterior elements.[1–4] Two level I studies arrived at conflicting results regarding the outcomes of decompression alone versus decompression and fusion.[2,5]

Motion-preserving alternatives such as lumbar facet arthroplasty have emerged to address the shortcomings described. Lumbar facet arthroplasty for the treatment of LSS with DS allows for robust decompression of the posterior elements with motion-preserving stabilization. Maintenance of segmental mobility may eliminate adjacent-level stresses that accompany fusion techniques. The Total Posterior Spine System (TOPS; Premia Spine) is a pedicle screw–based facet arthroplasty device designed to restore physiological motion while preventing pathological translation. The device was the subject of a recently completed FDA investigational device exemption (IDE) trial comparing the relative efficacy of lumbar facet arthroplasty versus fusion to treat lumbar grade I DS with stenosis. Interim results were reported by Nassr and colleagues in 2024.[6] Primary and secondary outcomes both favored lumbar facet arthroplasty over fusion. There were no significant differences in surgical variables or complications, including reoperation rates. The results were consistent with those of existing retrospective studies on the TOPS device as well as the single-arm interim review of the TOPS IDE trial.[7–10] A limitation of this study was that it did not report the complete 2-year dataset: only 113 (56%) of 202 patients in the investigational arm had reached 2 years of follow-up and were eligible for analysis. In this paper, we report the complete 3-year dataset of the TOPS IDE trial.

Methods

Study Design

Patients with grade I spondylolisthesis with symptomatic stenosis were randomized in a 2:1 ratio to either decompression plus lumbar facet arthroplasty (TOPS) or decompression plus fusion (open with interbody and posterolateral instrumentation; Fig. 1).[6] Site-specific randomization with randomly varying block sizes was used. IRB approval was obtained at all participating institutions, and all patients provided written informed consent. Patients remained blinded to their procedure until after surgery. Surgeons and study coordinators were not blinded to randomization.

Patient Population

Patients with LSS and grade I DS were eligible for inclusion. Participants were required to be between 35 and 80 years of age and to have undergone a minimum of 6 months of nonsurgical therapy. Patients were also required to have an Oswestry Disability Index (ODI) score of at least 40 of 100 and a visual analog scale (VAS) score for leg pain of at least 40 of 100 for at least 1 leg at baseline. Patients were excluded if more than 1 motion segment required a surgical procedure, radiographs revealed substantial disc collapse (disc height < 4 mm at the index level), a prior surgery had been performed at either adjacent level, or instrumented lumbar spine surgery had been performed at any level. Full exclusion and inclusion criteria have been previously published.[6,7,9]

Outcomes

The primary outcome for this study was a 36-month composite clinical success measure as mandated by the FDA. Clinical success was defined as meeting all 4 of the following criteria: 1) the absence of reoperation, lumbar

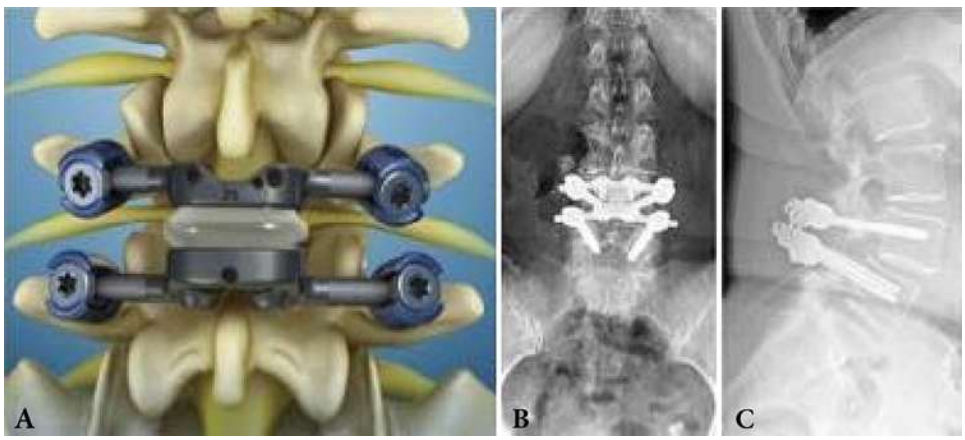

FIG. 1. Schematic (**A**), and anteroposterior (**B**) and lateral (**C**) radiographs demonstrating the pedicle screw–based TOPS device.

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TABLE 1. Clinical composite success at 36 months

Clinical Success Component	TOPS			Fusion			p Value
	Total	No.	%	Total	No.	%	
Overall composite clinical success	179	136	76.0	74	42	56.8	**0.0038**
No SSI or LI	207	178	86.0	95	71	74.7	**0.0222**
No reoperations	207	195	94.2	95	86	90.5	0.3290
No LIs	207	185	89.4	95	78	82.1	0.0963
No device breakage or disassembly	165	165	100	67	66	98.5	0.2888
ODI reduction ≥15 points	163	156	95.7	54	48	88.9	0.0938
No new or worsening neurological deficit	184	175	95.1	76	72	94.7	>0.999
No sensory deficit	183	175	95.6	76	72	94.7	0.7514
No muscle strength deficit	184	183	99.5	76	76	100.0	>0.999

LI = lumbar injection; SSI = subsequent surgical intervention.
Clinical composite success at 36 months was defined as: 1) no subsequent reoperation or lumbar injections, 2) no hardware failure (breakage or disassembly), 3) ODI improvement, and 4) no new or worsening neurological deficit. The p values are derived from Fisher's exact test comparing TOPS to fusion control. Boldface type indicates statistical significance.

injection, or spinal cord stimulator implantation; 2) no device breakage or disassembly; 3) a reduction in the ODI of ≥ 15 points; and 4) the absence of a new or progressive neurological deficit.

Additional prespecified outcomes included mean ODI scores, VAS back and leg pain scores, Zurich Claudication Questionnaire (ZCQ) scores, complications, and reoperations. The proportion of patients achieving the minimal clinically important difference (MCID) on the ODI (≥ 15-point improvement), VAS score for back pain (≥ 20-point improvement), VAS score for leg pain (≥ 20-point improvement), and ZCQ score (≥ 0.5-point improvement) was determined based on established MCID values in the literature.[11,12] Patient-reported outcome measures (PROMs) for patients who had early treatment failure requiring reoperation or lumbar injections were censored in subsequent analyses to avoid confounding the results of the primary treatment with successful secondary treatments.

Statistical Analysis

Baseline demographics and operative characteristics were compared between the treatment groups using mean differences and 95% confidence intervals (CIs) for continuous variables, differences in percentages and 95% CIs for binary variables, and Fisher's exact test for categorical variables.

Results

Patients

Baseline characteristics of the patients assigned to the arthroplasty and fusion groups have been previously described. There were no differences between treatment groups.[6]

Primary Outcome

One hundred seventy-nine patients in the arthroplasty (TOPS) group (86.9% of randomized patients) and 74 patients in the fusion group (77.9% of randomized patients) had reached 3 years of follow-up or had been deemed an early clinical failure. A statistically significantly higher proportion of patients achieved composite clinical success in the arthroplasty group (136 patients, 76.0%) compared with the fusion group (42 patients, 56.8%; p = 0.0038; Table 1). The proportion of patients undergoing subsequent surgical intervention or lumbar injection was significantly lower in the arthroplasty group (14.0%) compared to the fusion group (25.3%; p = 0.0222). There were no significant differences between groups with respect to other components of the composite clinical success score.

Secondary Outcomes

The arthroplasty group demonstrated significantly lower VAS back pain scores at all postoperative time points, including at the 3-year follow-up (Fig. 2). At 3 years, 85.2% of arthroplasty patients versus 72.2% of fusion patients had achieved the MCID for VAS back pain score (p = 0.041). Both the arthroplasty group and fusion group demonstrated high rates of MCID achievement on the ODI at 3 years follow-up (95.7% vs 88.9%; p = 0.094). There was no significant difference in the rate of MCID achievement between groups for VAS leg pain score at 3 years.

Surgical variables have been described previously, and there were no significant differences identified.[6,7] There was no statistically significant difference in reoperation failure rates between the arthroplasty group compared with the fusion group (5.8% vs 9.5%, p = 0.329). Three-year surgical intervention failures (those requiring reoperation related to the index procedure) are characterized in Table 2. Ten of 12 reoperations in the TOPS cohort included device removal. One patient with symptomatic screw loosening presented after a fall from a truck. The loose screw was upsized and the TOPS device re-implanted. One patient underwent revision for pedicle screw misplacement during the index surgery. Both of these pa-

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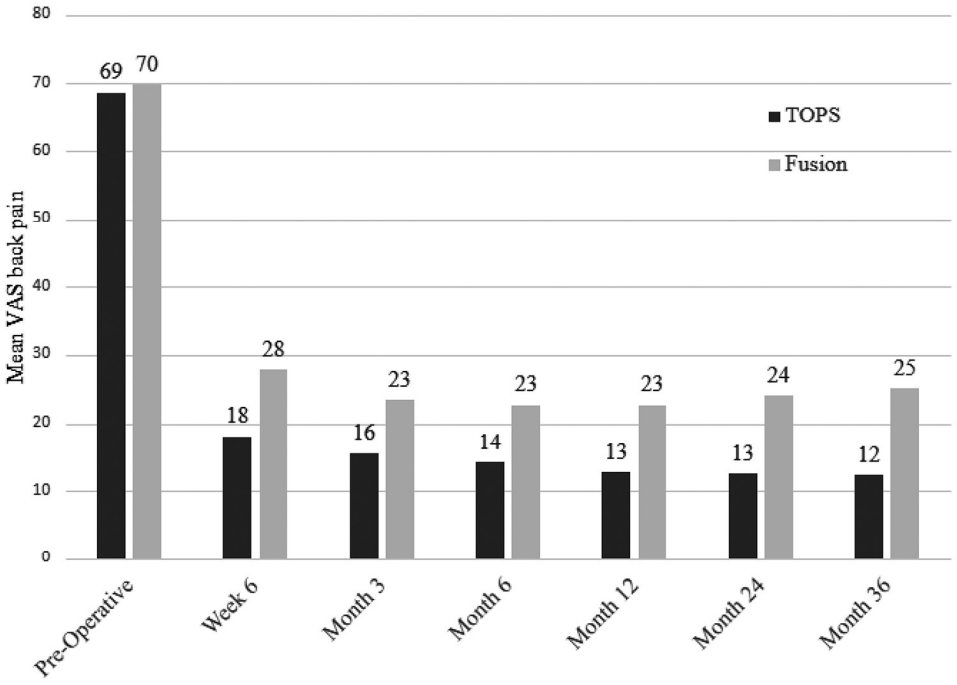

FIG. 2. Bar graph showing the mean VAS low back pain scores from baseline to 36-month follow-up for the TOPS and fusion cohorts.

tients have been asymptomatic following revision with the TOPS implant in place.

Discussion

The 2-year interim analysis of the TOPS IDE trial revealed a statistically significant difference in composite clinical score achievement rate in favor of lumbar arthroplasty compared with fusion. Only approximately one-half of the randomized patients were included in this primary outcome analysis. Importantly, there is precedence for early conclusion of a clinical trial when larger-than-expected between-group differences are encountered.[13,14] In the present study, we describe the full 3-year outcomes of these cohorts. The arthroplasty treatment group achieved a statistically significantly higher rate of clinical success. In the primary outcome analysis by Nassr et al.,[6] the composite clinical success score included a fifth component, i.e., fusion status. The significantly lower rate of composite clinical success in the fusion group was largely driven by high rates of radiographic fusion failure at 24 months' follow-up. The fusion failure rate in the arthroplasty cohort (evidence of fusion at the index level) was exceedingly low. A subgroup analysis did reveal that the statistically significant difference in composite clinical success was maintained even if the fusion status criterion was removed.

The higher rate of composite clinical success at 3 years in the arthroplasty cohort was primarily driven by two factors. First, there was a significantly higher rate of reoperation or subsequent lumbar injection in the fusion group compared with the arthroplasty group. Second, the pro-

TABLE 2. Surgical intervention failures at 36 months

Surgical Intervention Failure	TOPS, n = 207			Fusion, n = 95		
	No.	%	Average Days	No.	%	Average Days
Durotomy	2	1.0	23	—	—	—
Adjacent segment disease	3	1.4	761	6	6.3	672
Pedicle screw misplacement	1	0.5	5	—	—	—
Screw loosening/implant migration	4	1.9	572	1	1.1	32
Implant noise	1	0.5	876	—	—	—
Unresolved pain	1	0.5	197	2	2.1	323
Total reoperations	12	5.8	406	9	9.5	342

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portion of patients achieving the MCID on the ODI was higher in the arthroplasty group compared with the fusion group.

The surgical re-intervention rate for patients undergoing treatment for grade I DS remains a relevant outcome measure. Healthcare costs associated with nonsurgical management, including lumbar injections, are substantial.[15,16] Reoperation rates are a critical differentiating factor between traditional surgical treatment options for stenosis with spondylolisthesis, i.e., decompression alone versus decompression and fusion. Two prospective, randomized trials, published in the same *New England Journal of Medicine* issue, came to diametrically opposite conclusions based primarily on differing reoperation rates. Försth and associates[5] reported that decompression alone was associated with only a marginally, non–statistically significantly different reoperation rate between decompression alone (21%) compared with decompression and fusion (22%). These authors concluded that decompression alone was the preferred surgical treatment option. Conversely, in the Spinal Laminectomy versus Instrumented Pedicle Screw (SLIP) study, Ghogawala and coauthors[2] found a statistically significantly higher rate of reoperation among patients who underwent decompression alone (34%) compared with decompression and fusion (14%; $p = 0.05$). Interestingly, the reoperation rate for the fusion group in the present study (9.5%) was similar to the rate for the fusion group in the SLIP study (14%) as well as the rate for the fusion cohort from another prospective randomized trial (9.1%).[2,5] The reoperation rate for lumbar posterior facet arthroplasty appears similar to that of fusion and noticeably lower than the reoperation rate of decompression alone reported across these similar prospective randomized studies.

Stabilization, either rigid with instrumented fusion or dynamic with lumbar arthroplasty, appears to have a positive effect on reoperation rates following decompression in the setting of pre-existing spondylolisthesis. Intuitively, it seems plausible that a certain percentage of patients with spondylolisthesis would develop instability following decompression alone. This subset of patients would be expected to benefit from operative stabilization, either rigid or motion-preserving. Facet arthroplasty would theoretically have the added benefit of altering spinal biomechanics and decreasing stresses on adjacent levels. The TOPS device has demonstrated the ability to restore near-physiological range of motion in all planes while maintaining intradiscal pressures within normal physiological limits.[17] In addition, the device generates lower bending moments on pedicle screws compared with other pedicle-based dynamic stabilization systems, potentially reducing implant-related mechanical stress.[18] Although the arthroplasty group in the present study did not show a statistically significant lower adjacent-level reoperation rate compared with fusion, fewer postoperative lumbar injections in this cohort contributed to the statistically significant difference in composite clinical outcome scores.

Clinical Improvement

With respect to PROMS, both groups demonstrated substantial improvement across all measures from preoperatively to 6 months postoperatively. In the 2-year primary outcome analysis, Nassr and colleagues[6] reported ongoing improvement in almost all PROMs from 6 to 24 months postoperatively in the arthroplasty group. Conversely, the fusion group demonstrated worsening ODI, VAS back pain, VAS leg pain, and all ZCQ component scores during this period. This trend persisted at 3 years' follow-up, with patients in the TOPS cohort experiencing ongoing improvement in ODI, VAS leg pain, and ZCQ component scores when compared with 6-month postoperative scores. The fusion cohort demonstrated worsening across all PROMS from 6 months to 3 years postoperatively. However, all PROMS were similar or improved from 24 months to 36 months. Our results demonstrate a sustained clinical benefit for patients undergoing lumbar facet arthroplasty.

This 3-year analysis of primary and secondary outcomes for patients included in the TOPS IDE trial features a large sample size with an excellent follow-up rate. Adoption of dynamic stabilization in the lumbar spine has been thwarted by major device-related adverse events and unacceptably high reoperation rates. One of the most widely reported concerns related to these systems is the rate of pedicle screw loosening.[19–21] The rate of pedicle screw loosening in the TOPS cohort was not significantly different from that of the fusion cohort at 3 years and was consistent with previously reported rates in single-level lumbar fusion.[22] No patients have experienced device breakage or disassembly.

Limitations of the Study

Limitations of the current study include the short-term postoperative follow-up. Given the relatively low rate of adjacent-level reoperation rates following lumbar fusion (0.5%–4%/year), and the size of the cohort in the current study, the 3-year follow-up would not be expected to show statistically significant differences between groups.[23–25] The cohort would need to be much larger, in the range of thousands of patients, or the follow-up long-term, in the 7- to 10-year range. Consequently, definitive conclusions regarding the long-term durability of lumbar facet arthroplasty and the implications on adjacent segment reoperation remain unclear. Additionally, the strict inclusion and exclusion criteria of this IDE study limit the generalizability of the results to the broader population suffering from degenerative LSS. Patients older than 80 years were excluded from this study. The generalizability of these findings to this rapidly expanding demographic remains uncertain. Finally, as an industry-sponsored study, observer and expectation bias may affect the study results.

Conclusions

Decompression and stabilization with lumbar facet arthroplasty are associated with statistically significantly superior clinical outcomes and lower rates of secondary invasive procedures, including reoperations and injections, compared with decompression and fusion. Definitive conclusions regarding the impact of restored functional motion at the treated level with lumbar arthroplasty on adjacent-level interventions necessitate longer-term follow-up.

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Future studies should compare lumbar facet arthroplasty to minimally invasive, anterior or lateral lumbar interbody fusion techniques in an expanded cohort of patients with long-term follow-up.

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Conception and design: Parish, Welch, Kim, Steinmetz. Acquisition of data: Parish, Nassr, Welch, Kim, Coric. Analysis and interpretation of data: VanHorn, Zeitouni, Nassr, Welch, Kim, Steinmetz, Coric. Drafting the article: VanHorn, Parish. Critically revising the article: VanHorn, Zeitouni, Parish, Nassr, Kim, Steinmetz. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: VanHorn. Statistical analysis: Kim. Administrative/technical/material support: VanHorn, Welch, Kim. Study supervision: Parish, Nassr, Welch, Whiting.

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