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CLINICAL ARTICLE

Prospective, randomized controlled multicenter study of posterior lumbar facet arthroplasty for the treatment of spondylolisthesis

***Domagoj Coric, MD,[1,2] Ahmad Nassr, MD,[3] Paul K. Kim, MD,[1,2] William C. Welch, MD,[4] Stephen Robbins, MD,[5] Steven DeLuca, DO,[6] Donald Whiting, MD,[7] Ali Chahlavi, MD,[8] Stephen M. Pirris, MD,[8] Michael W. Groff, MD,[9] John H. Chi, MD, MPH,[9] Jason H. Huang, MD,[10] Roland Kent, MD,[11] Robert G. Whitmore, MD,[12] Scott A. Meyer, MD,[13] Paul M. Arnold, MD,[14] Ashvin I. Patel, MD,[15] R. Douglas Orr, MD,[16] Ajit Krishnaney, MD,[16] Peggy Boltes, RN,[1,2] Yoram Anekstein, MD,[17] and Michael P. Steinmetz, MD[16]**

[1]Carolina Neurosurgery and Spine Associates, Charlotte, North Carolina; [2]Department of Neurosurgery, SpineFirst, Atrium Health, Charlotte, North Carolina; [3]Department of Orthopedic Surgery, Mayo Clinic, Rochester, Minnesota; [4]Department of Neurosurgery, University of Pennsylvania, Philadelphia, Pennsylvania; [5]Wisconsin Bone and Joint, Milwaukee, Wisconsin; [6]Orthopedic Institute of Pennsylvania, Harrisburg, Pennsylvania; [7]Department of Neurosurgery, Allegheny Health Network, Pittsburgh, Pennsylvania; [8]Department of Neurosurgery, Ascension St. Vincent, Jacksonville, Florida; [9]Department of Neurosurgery, Brigham & Women's Hospital, Boston, Massachusetts; [10]Department of Neurosurgery, Baylor Scott & White Medical Center, Temple, Texas; [11]Axis Spine Center, Coeur d'Alene, Idaho; [12]Department of Neurosurgery, Lahey Medical Center, Burlington, Massachusetts; [13]Department of Neurosurgery, Altair Health Spine, Morristown, New Jersey; [14]Carle Neuroscience Institute, Urbana, Illinois; [15]Kennedy-White Orthopaedic Center, Sarasota, Florida; [16]Department of Neurosurgery, Cleveland Clinic Foundation, Cleveland, Ohio; and [17]Department of Orthopaedics, Sackler School of Medical of Medicine, Tel Aviv, Israel

OBJECTIVE The purpose of this study was to evaluate the safety and efficacy of a posterior facet replacement device, the Total Posterior Spine (TOPS) System, for the treatment of one-level symptomatic lumbar stenosis with grade I degenerative spondylolisthesis. Posterior lumbar arthroplasty with facet replacement is a motion-preserving alternative to lumbar decompression and fusion. The authors report the preliminary results from the TOPS FDA investigational device exemption (IDE) trial.

METHODS The study was a prospective, randomized controlled FDA IDE trial comparing the investigational TOPS device with transforaminal lumbar interbody fusion (TLIF) and pedicle screw fixation. The minimum follow-up duration was 24 months. Validated patient-reported outcome measures included the Oswestry Disability Index (ODI) and visual analog scale (VAS) for back and leg pain. The primary outcome was a composite measure of clinical success: 1) no reoperations, 2) no device breakage, 3) ODI reduction of ≥ 15 points, and 4) no new or worsening neurological deficit. Patients were considered a clinical success only if they met all four measures. Radiographic assessments were made by an independent core laboratory.

RESULTS A total of 249 patients were evaluated (n = 170 in the TOPS group and n = 79 in the TLIF group). There were no statistically significant differences between implanted levels (L4–5: TOPS, 95% and TLIF, 95%) or blood loss. The overall composite measure for clinical success was statistically significantly higher in the TOPS group (85%) compared with the TLIF group (64%) (p = 0.0138). The percentage of patients reporting a minimum 15-point improvement in ODI showed a statistically significant difference (p = 0.037) favoring TOPS (93%) over TLIF (81%). There was no statistically significant difference between groups in the percentage of patients reporting a minimum 20-point improvement on VAS back pain (TOPS, 87%; TLIF, 64%) and leg pain (TOPS, 90%; TLIF, 88%) scores. The rate of surgical reintervention for

ABBREVIATIONS AE = adverse event; CCS = composite clinical success; IDE = investigational device exemption; ITT = intention to treat; ODI = Oswestry Disability Index; ROM = range of motion; TDR = total disc replacement; TLIF = transforaminal lumbar interbody fusion; TOPS = Total Posterior Spine; VAS = visual analog scale; ZCQ = Zurich Claudication Questionnaire.

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* Y.A. and M.P.S. contributed equally to this work.

facet replacement in the TOPS group (5.9%) was lower than the TLIF group (8.8%). The TOPS cohort demonstrated maintenance of flexion/extension range of motion from preoperatively (3.85°) to 24 months (3.86°).

CONCLUSIONS This study demonstrates that posterior lumbar decompression and dynamic stabilization with the TOPS device is safe and efficacious in the treatment of lumbar stenosis with degenerative spondylolisthesis. Additionally, decompression and dynamic stabilization with the TOPS device maintains segmental motion.

Clinical trial registration no.: NCT03012776 (ClinicalTrials.gov)

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

The etiology and clinical presentation of stenosis due to degenerative spondylolisthesis has been well characterized,[1–6] but its treatment remains controversial.[7–10] There is evidence dating back decades supporting the efficacy of surgical treatment, but debate exists whether decompression alone or decompression and stabilization with arthrodesis is the best treatment.[11–13] Decompression alone is a less morbid procedure in terms of operative dissection and recovery time, but this procedure is predicated on the concept that there is enough intrinsic spinal stability remaining at the operative segment even after removal of supporting structures such as lamina, ligaments, and a portion of the facets. Primary modes of failure involving this procedure include inadequate decompression to preserve stability as well as postoperative instability due to decompensation following decompression. Decompression and stabilization are typically achieved with laminectomy followed by instrumented fusion. This procedure results in greater morbidity in terms of soft-tissue dissection and recovery time, but it allows for aggressive decompression and interrupts the degenerative process by imparting stability on the operated segment. This necessarily results in loss of segmental motion while placing increased stresses on adjacent levels.[14–16]

Spinal arthroplasty has experienced increasing adoption since its introduction in the US with the FDA approval of the Charité lumbar total disc replacement (TDR) in 2002.[16,17] Cervical TDR has received more rapid acceptance compared with lumbar TDR. There are currently only two lumbar TDR devices that are FDA approved and marketed in the US, ProDisc-L (Centinel Spine) and activ-L (Aesculap), which are placed through an anterior retroperitoneal approach. Both are indicated to treat mechanical low-back pain due to lumbar spondylosis.[18,19] There are no FDA-approved devices for posterior arthroplasty or facet replacement. Several facet replacement devices have entered FDA investigational device exemption (IDE) studies over the past 2 decades, including the Anatomical Facet Replacement System (Globus Medical), the Total Facet Arthroplasty System (Globus Medical), and the Total Posterior Spine (TOPS) System (Premia Spine), but only the TOPS device remains in an active IDE trial. The TOPS device has been used outside the US with more than 10-year clinical and radiographic follow-up.[20–23] Dynamic stabilization with spinal arthroplasty offers several theoretical advantages over traditional rigid stabilization with fusion, including the preservation of normal kinematics and load distribution of the natural spine without increasing adjacent-level stresses.[24–26]

This paper reports the preliminary results from the TOPS FDA IDE trial comparing the investigational TOPS System cohort with the transforaminal lumbar interbody fusion (TLIF) control group.

Methods

Device Design

The TOPS System is a posterior, pedicle screw–based artificial facet replacement device. The TOPS System consists of a motion device (TOPS motion implant) and four pedicle screws. The TOPS motion implant is a device comprising two titanium endplates connected by a polycarbonate urethane boot. Housed between the titanium endplates is an internal motion mechanism made of titanium and polycarbonate urethane articulating parts and an interlocking woven polyetheretherketone ribbon (Fig. 1). The top and bottom articulating parts are attached to their respective upper and lower titanium endplates. The flexible boot and the internal articulating parts allow relative movement between the endplates, so the device can maintain a normal range of motion (ROM) in axial rotation, lateral bending, extension, flexion, and translation when implanted into the human spine. The boot not only encapsulates the articulating core but also protects the neighboring soft tissue and dura from being compressed by the moving parts and contains any potential wear debris. The TOPS motion implant is available in various sizes to meet a range of human anatomy and for implantation at the spinal levels of L2–3, L3–4, or L4–5. The device is intended to provide dynamic stability and maintain motion following decompression with laminectomy and facetectomy.

This FDA IDE trial initiated enrollment in 2017 with a prospective, randomized controlled multicenter study (clinical trial registration no.: NCT03012776, ClinicalTrials.gov). Patients with grade I spondylolisthesis with symptomatic stenosis were randomized 2:1 TOPS versus TLIF according to individual site-specific randomization allocations with randomly varying block sizes of 6 or 9 patients. No stratification was performed in the randomization. Institutional review board approval was obtained at all participating institutions, and all patients provided written informed consent. Patients were qualified for inclusion in the study and consented to participate in the trial. Thereafter, the clinical site was informed of the device randomization by an independent third party. Patients remained blinded to their procedure until after surgery. Surgeons and study coordinators were not blinded to randomization. Inclusion and exclusion criteria are provided in Table 1.

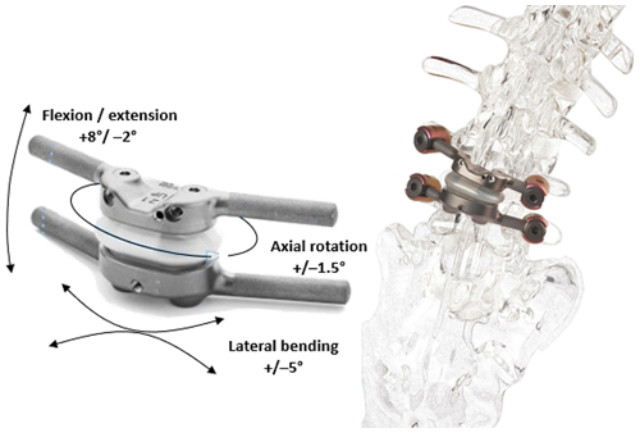

FIG. 1. The TOPS device investigated in the current study. The device consists of titanium articulating elements with polyurethane buffers and a polyurethane housing to contain any wear debris. © Premia Spine Ltd., published with permission. Figure is available in color online only.

Clinical Outcome Assessment

Patients were evaluated preoperatively; at hospital discharge; at 6 weeks; and at 3, 6, 12, and 24 months after surgery. Patient-reported outcome measures included the Oswestry Disability Index (ODI) and visual analog scale (VAS) for back and leg pain. The primary outcome was a composite measure of clinical success, at 24 months, consisting of 1) no revision, removal, or supplemental fixation; 2) no device breakage; 3) ODI reduction of ≥ 15 points; and 4) no new or worsening neurological deficit. Patients were considered a clinical success if they met all four measures. Secondary outcome evaluations included the percentage of patients achieving minimal clinically important difference in the ODI of 30% improvement, and VAS for back and leg pain with a 20-point improvement as well as patient-reported use of narcotic medication and patient satisfaction. Primary and secondary outcomes were assessed among the per-protocol group, which included patients in the intention-to-treat (ITT) group who underwent either the investigational or the control procedure and did not have significant protocol deviations. Three patients (2 in the TOPS group and 1 in the TLIF group) were adjudicated by an independent Clinical Events Committee, comprising 3 spine surgeons, to have significant protocol deviations and were excluded from the per-protocol group.

Safety was assessed by evaluating adverse events (AEs), subsequent index-level surgical procedures, and maintenance or improvement in neurological status. AEs were recorded by the investigators, and the Clinical Events Committee reviewed all events and categorized them according to severity (mild, moderate, and severe) and relation to implant and procedure (definitely, probably, possibly, and not related). The rate of supplemental surgical intervention was documented in both treatment groups. All safety evaluations were assessed among the ITT group.

Imaging Outcome Assessment

All images were evaluated by an independent core laboratory specializing in image assessment. Radiographic evaluation included ROM of the treated levels based on flexion/extension and lateral bending radiographs. MRI was performed preoperatively and at 24 months postoperatively for both cohort groups.

Statistical Design and Analysis

The primary efficacy endpoint for this study utilized a composite clinical success (CCS) endpoint in a responder analysis assessed at 24 months of follow-up. An individual patient was considered to have achieved CCS if at 24 months there was an improvement of at least 15 points from baseline on ODI and there was no new or worsening neurological deficit. Additionally, a case in which a patient underwent surgical reintervention or demonstrated device breakage or disassembly on radiographic imaging was considered a failure. Secondary clinical endpoints included clinical improvements in VAS scores for back and leg pain, narcotics use over time, and patient satisfaction. Differences in binary endpoints were summarized using differences in proportions with associated 95% confidence intervals and compared between treatment arms using Fisher's exact tests when applicable. The objective of the prospective IDE trial was to assess superiority and noninferiority of TOPS versus TLIF with the final sample size based on predictive probabilities at multiple prospectively defined interim analyses, the first occurring after 240 patients are enrolled. The minimum sample size is 300. The current analysis, in this paper, coincides with the first prospectively defined interim analysis, which is scheduled to occur after 240 patients are enrolled and is a descriptive analysis of clinically relevant endpoints at 24 months of follow-up. The primary measure of 24-month success was considered only at 24 months. Variables reported at other time points were considered independently and are important in considering trajectory of outcomes over time. There were no covariates. The primary endpoint for the IDE trial (superiority/noninferiority) is not being tested in this current analysis.

Descriptive statistics were used to compare baseline characteristics for both treatment groups using standardized mean differences and 95% confidence intervals for continuous variables, differences in percentages and 95% confidence intervals for binary variables, and Fisher's exact tests for categorical variables.

Results

A total of 249 patients were evaluated comparing the investigational TOPS group (n = 170) with the control TLIF group (n = 79). There were no statistically significant differences between implanted levels (L4–5: TOPS, 95% and TLIF, 95%) or blood loss. An overview of the groups is provided in Table 2. There were no statistically significant differences between groups with respect to demographic data, levels operated, operative time, or estimated blood loss. The overall composite measure for clinical success was statistically significantly higher in the TOPS group (85%) compared with the fusion group (64%) (p = 0.0138) (Fig. 2). Among the individual measures of the CCS endpoint, the TOPS group trended toward better outcomes in all four measures compared with the TLIF

TABLE 1. Inclusion and exclusion criteria

Inclusion Criteria
Age btwn 35 & 80 yrs
Must demonstrate at the level to be treated (L2–3, L3–4, or L4–5) all of the following: degenerative spondylolisthesis or retrolisthesis up to grade I, as determined by the investigator based on flexion/extension radiographs; at least moderate lumbar spinal stenosis, defined as >33% reduction in the central canal, lateral recess space, &/or foramen when compared w/ an adjacent level, as determined by the investigator based on MRI; & thickening of the ligamentum flavum &/or scarring of the facet joint capsule as identified by the investigator based on MRI
Have had at least 6 mos of failed conservative treatment prior to op (e.g., physical therapy, use of anti-inflammatory medications at maximum recommended dosage; administration of epidural/facet injections &/or nerve block)
Have a baseline ODI score of ≥40/100
Have leg pain w/ a baseline VAS score of ≥40/100 for at least 1 leg
Neurogenic claudication (as defined by worsening leg/buttock symptoms when walking or standing, which is reduced when sitting or bending forward)
Be psychosocially, mentally, & physically able to fully comply w/ the clinical protocol
Be willing to adhere to the follow-up schedule & protocol requirements
Be willing & able to understand & sign the study-specific, IRB-approved consent form
Exclusion Criteria
>1 motion segment involved in degenerative pathology that requires op
Presence of free fragment disc herniation or prior discectomy at index level or either adjacent level
<4 mm of disc height at the index level
Spondylolisthesis > grade I
Traumatic or dysplastic spondylolisthesis
Lytic spondylolisthesis
Back or nonradicular leg pain of unknown etiology
Stenosis caused by an extruded spinal disc fragment (e.g., herniation) or where the etiology is considered congenital, iatrogenic, posttraumatic, or metabolic
Known allergy or sensitivity to PEEK, titanium, cobalt chrome, &/or polyurethane
Prior op at any lumbar vertebral level w/ instrumentation; prior op at index vertebral level or either adjacent lumbar vertebral level w/o instrumentation (exception: prior intervention of posterior elements at index level)
Clinically compromised vertebral bodies at the affected level due to any traumatic, neoplastic, metabolic, or infectious pathology
Scoliosis >10° by major Cobb angle (both angular & rotational)
Morbid obesity defined as BMI >40
Osteoporosis (lumbar spine T-score < −2)
Paget's disease, gout, osteomalacia, osteogenesis imperfecta, thyroid &/or parathyroid gland disorder, &/or any other metabolic bone disease that has not been stabilized w/ ongoing medication for ≥1 yr
Active infection, systemic or local
Active hepatitis
AIDS, HIV, rheumatoid arthritis, or other autoimmune disease
Tuberculosis, active or in the past 3 yrs
Active malignancy, history of any invasive malignancy (except nonmelanoma skin cancer) unless prior treatment w/ curative intent & there have been no clinical signs or symptoms of the malignancy for ≥5 yrs
Any medical condition requiring treatment w/ any drug known to potentially interfere w/ bone/soft-tissue healing or receiving radiation therapy that is expected to continue for study duration
Cauda equina syndrome or neurogenic bowel/bladder dysfunction
Vascular claudication due to severe arterial insufficiency of the legs (prospective subjects will be screened by physical examination for diminution or absence of dorsalis pedis or posterior tibialis pulses; if diminished or absent by palpation, an arterial ultrasound is required w/ vascular plethysmography; if the absolute arterial pressure is <50 mm Hg at the calf or ankle level, the pt has severe arterial insufficiency & must be excluded)
Sustained pathologic lumbar fractures of the vertebra or multiple lumbar fractures of the vertebra or hip
Significant peripheral neuropathy causing decreased sensation in a stocking-like or nonradicular & nondermatomal distribution in the lower extremities
Insulin-dependent diabetes mellitus (unless well controlled, defined as HbA1c <7%)
Immunologically suppressed, receiving steroids >1 mo of the past yr
Currently taking anticoagulants other than aspirin unless the subject can be taken off anticoagulant prior to & during op

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TABLE 1. Inclusion and exclusion criteria

Exclusion Criteria
Life expectancy <3 yrs
Currently experiencing an episode of major mental illness (psychosis, major affective disorder, or schizophrenia), or manifesting physical symptoms w/o a diagnosable medical condition to account for the symptoms, which may indicate symptoms of psychological rather than physical origin
History of or current chemical/alcohol dependency
Smoking habit of >1 pack of cigarettes/wk &/or frequent users (>1/wk) of chewing tobacco
Pregnant or interested in becoming pregnant in the next 3 yrs (due to need for radiographs)
Currently involved in active spinal litigation
Currently having a workers' compensation claim
Currently incarcerated
Participation in any other investigational drug, biological, or medical device study w/in 30 days prior to study op

Pt = patient.

group. The percentage of patients reporting a minimum 15-point improvement in ODI score was 93.1% for the TOPS group versus 80.6% for the TLIF group. The incidence of removal, revision, or supplemental fixation was 2.9% in the TOPS group and 6.3% in the TLIF group. No patients in the TOPS group experienced device breakage or disassembly (0.0%), whereas 1 patient (3.2%) in the TLIF group had device breakage or disassembly. Finally, a new or worsening neurological deficit was reported in 3.4% of patients in the TOPS groups versus 12.1% of patients in the TLIF group. The rate of surgical reintervention among all treated patients, ITT group, for facet replacement was lower in the TOPS group (5.8%) than in the TLIF control group (8.8%).

Patient-Reported Outcome Measures

Successful outcome on the ODI, defined as a score improvement of at least 30% (on scale of 100) at the 24-month follow-up, occurred in 95.0% of the TOPS group and 73.1% of the TLIF group ($p = 0.004$). The mean ODI scores improved significantly in both the TOPS and TLIF groups from preoperatively (TOPS, 56.9; TLIF, 56.4) to the 6-week follow-up (TOPS, 23.7; TLIF, 30.6). Both groups remained significantly improved throughout the 24-month follow-up, with the TOPS group showing mean improvement of 48.4 and the TLIF group showing mean improvement of 36.2.

Back and Leg Pain

A statistically significant difference in the improvement in back pain, defined as a minimum 20-point improvement in the VAS score, was observed at the first postoperative time point (6 weeks), where 83.5% of patients in the TOPS group met the improvement criteria versus 65.8% of the TLIF group ($p = 0.004$). This trend continued at 24 months, where a statistically significant difference was again observed between the TOPS group and the TLIF group (TOPS, 87.0%; TLIF, 64.0%; $p = 0.015$).

Improvement in leg pain, defined as the percentage of patients reporting a minimum 20-point improvement on VAS, was significant for both groups, where 90% of the TOPS group and 88% of the TLIF group met the improvement criteria (Fig. 3).

Narcotics Usage

Narcotics use over time followed similar trends for both treatment groups, and no statistically significant difference was observed at any time point. However, at 24 months, only 9.9% of TOPS patients used opioid pain medication compared with 25.3% of patients preoperatively. In comparison, 22.2% of patients in the TLIF control group used opioids at 24 months compared with 30.4% preoperatively. This difference, 9.9% versus 22.2%, although not statistically significant, is clinically meaningful given the addictive potential of opioid medication.

Patient Satisfaction

A significant portion of both the TOPS and TLIF control groups demonstrated a greater than 2.5-point improvement at each follow-up time point. Specifically, at the 6-week follow-up time point, 96.2% (n = 153/159) of patients in the TOPS group demonstrated a greater than 2.5-point increase in Zurich Claudication Questionnaire (ZCQ) satisfaction score compared with 94.5% (n = 69/73) of TLIF control subjects ($p = 0.511$). This treatment benefit was maintained throughout the 24-month follow-up, where 92.5% (n = 74/80) of TOPS subjects demonstrated a greater than 2.5-point increase in ZCQ satisfaction scores compared with 88.5% (n = 23/26) of fusion control subjects ($p = 0.686$).

Safety

Safety was evaluated by the absence of new or worsening neurological deficit at 24 months, AEs beginning at the onset of surgery, and radiographically identified breakage or disassembly. Three patients (3.4%) in the TOPS group experienced a new or worsened sensory deficit, and no patients (0.0%) experienced a new or worsened motor deficit. Four patients (12.1%) in the TLIF group experienced a new or worsened sensory deficit, and no patients (0.0%) experienced a new or worsened motor deficit.

TABLE 2. Baseline demographics

	TOPS						TLIF						TOPS − TLIF*		
	No. of Pts	Mean	SD	Med	Min	Max	No. of Pts	Mean	SD	Med	Min	Max	Difference	LB	UB
Patient demographics															
Age, yrs	170	63.3	8.3	64.0	38.0	79.0	79	64.2	8.8	66.0	43.0	80.0	−0.9	−3.2	1.4
Height, inches	170	66.9	3.9	66.5	58.0	80.5	79	66.7	4.2	66.0	53.8	74.0	0.2	−0.9	1.2
Weight, lb	170	187.7	37.6	184.2	105.0	280.0	79	189.3	39.7	185.0	118.0	295.0	−1.5	−11.8	8.8
BMI	170	29.4	4.8	28.7	17.4	40.3	79	29.9	5.4	29.3	19.6	39.7	−0.5	−1.8	0.9
Baseline functional status															
VAS low-back pain score	170	68.6	23.5	73.0	0.0	100.0	79	68.3	23.2	75.0	0.0	99.0	0.3	−6.0	6.6
VAS rt leg pain score	170	65.0	30.4	74.5	0.0	100.0	79	66.2	31.2	78.0	0.0	100.0	−1.2	−9.5	7.0
VAS lt leg pain score	170	66.3	30.6	79.0	0.0	100.0	79	66.2	32.3	77.0	0.0	100.0	0.1	−8.3	8.4
VAS worst leg pain score	170	83.5	13.2	87.0	40.0	100.0	79	85.2	10.5	87.0	50.0	100.0	−1.7	−5.1	1.6
VAS other leg pain score	170	47.8	32.4	51.5	0.0	100.0	79	47.2	34.3	57.0	0.0	99.0	0.6	−8.3	9.4
ZCQ symptom severity scale	170	3.76	0.58	3.71	2.43	5.00	79	3.67	0.57	3.71	2.57	5.00	0.1	−0.1	0.2
ZCQ physical function scale	170	2.95	0.39	3.00	2.00	3.80	79	2.92	0.43	3.00	1.60	4.00	0.0	−0.1	0.1
ODI score	170	56.9	12.2	56.0	34.0	98.0	79	56.4	13.3	54.0	38.0	100.0	0.6	−2.8	3.9
SF-12v2 physical health T-score	169	25.3	6.8	25.0	8.6	45.1	78	27.3	7.2	27.7	12.1	46.7	−2.0	−3.9	−0.2
SF-12v2 mental health T-score	169	46.1	12.3	46.3	15.5	70.1	78	44.2	12.4	42.7	16.3	69.0	1.9	−1.5	5.2
Hospital demographics															
Op duration, mins	170	184.0	59.4	173.5	74.0	359.0	79	178.1	58.7	163.0	77.0	357.0	5.9	−10.0	21.7
Length of hospital stay, days	169	2.86	3.91	2.00	0.00	51.00	79	2.95	1.85	3.00	0.00	14.00	−0.09	−1.00	0.82
Estimated blood loss, ml	170	200.8	154.7	150.0	0.0	900.0	79	223.1	133.3	200.0	0.0	550.0	−22.3	−62.1	17.5

LB = lower bound; UB = upper bound.

* Estimated mean difference and 95% confidence interval between TOPS and TLIF.

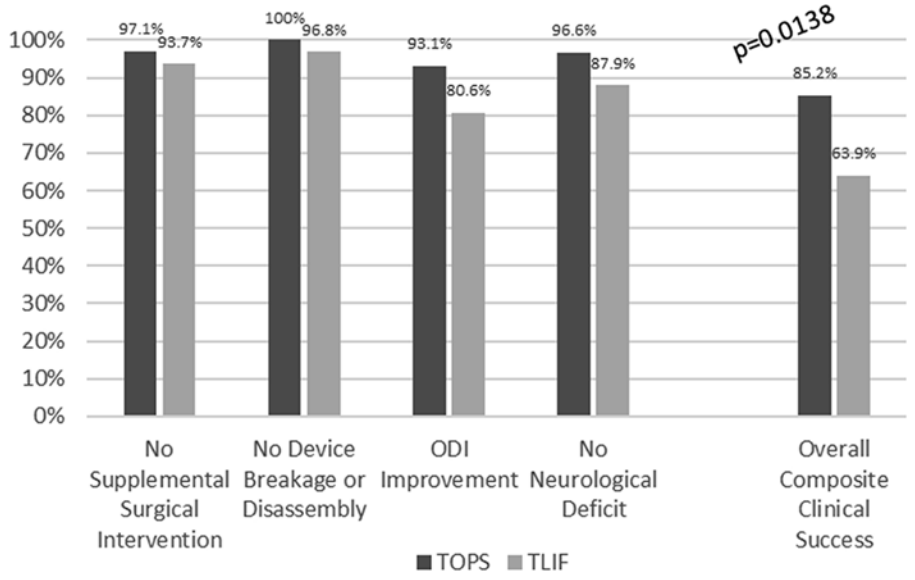

FIG. 2. CCS at 24 months, defined as 1) no revision, removal, or supplemental fixation; 2) no device breakage; 3) ODI reduction of ≥ 15 points; and 4) no new or worsening neurological deficit.

Surgical Reintervention

Surgical reintervention was classified as any revision, removal, reoperation, or supplemental fixation at any lumbar level. In the TOPS group, 10 patients (5.8%) reported at least one surgical reintervention, and in the TLIF group, 7 patients (8.8%) reported at least one surgical reintervention (Table 3). The most common reasons for these reinterventions were unresolved pain and wound complications.

Range of Motion

Among patients with a minimum of 24 months of follow-up, the ROM in both flexion/extension and left/right lateral bending was measured at the index level preoperatively and at 12 months and 24 months after surgery in both treatment groups. Preoperative ROM measurements for both treatment groups were similar in flexion/extension (TOPS, 3.75°; TLIF, 4.39°) and left/right lateral bending (TOPS, 3.25°; TLIF, 3.34°). Postoperatively, at both 12 months and 24 months, the TOPS group demonstrated maintenance of motion. There was almost no change in flexion/extension from preoperatively to 12 months (–0.07°) and 24 months (0.01°), while change in left/right lateral bending increased slightly from preoperatively to 12 months (–0.68°) and 24 months (0.50°).

The TLIF group, as expected, demonstrated a significant reduction in ROM in both flexion/extension and left/right lateral bending at the postoperative time points. ROM at 12 months and 24 months in flexion/extension decreased –3.33° and –3.18°, respectively. Similarly, ROM in left/right lateral bending decreased –2.22° at 12 months and –2.46° at 24 months (Fig. 4).

Discussion

The surgical treatment of lumbar spinal stenosis due to spondylolisthesis remains hotly debated.[6–8,27] In a recent randomized controlled trial, Austevoll and associates reported that decompression alone was noninferior to decompression with instrumented fusion at the 2-year

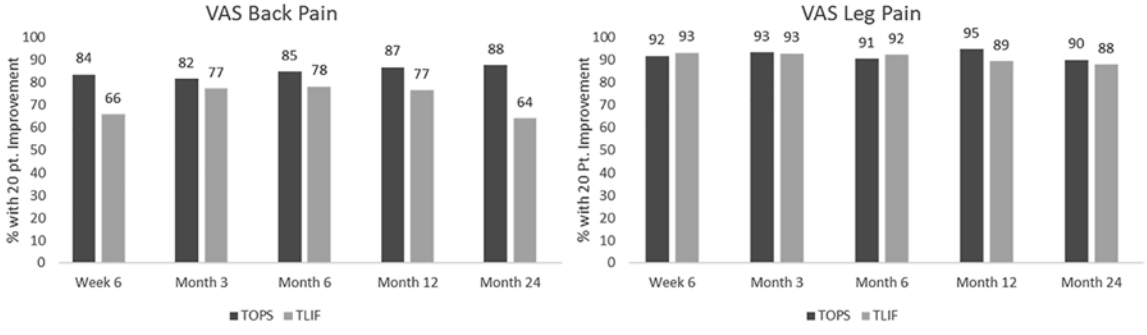

FIG. 3. Percentage of patients reporting an improvement of at least 20 mm on VAS pain scales for back pain (**left**) and leg pain (**right**). Pt. = point.

TABLE 3. Surgical reinterventions

	TOPS (n = 172)			TLIF (n = 80)		
	No. of SRs	No. of Pts (%)	Mean No. of Days	No. of SRs	No. of Pts (%)	Mean No. of Days
Durotomy	4	2 (1.2)	23	1	1 (1.3)	11
Wound complication	3	3 (1.7)	33	0	0 (0.0)	0
Drain complication	2	2 (1.2)	27	0	0 (0.0)	0
Adjacent-segment disease	0	0 (0.0)	0	3	3 (3.8)	380
Pseudarthrosis	0	0 (0.0)	0	1	1 (1.3)	771
Pedicle screw misplacement	1	1 (0.6)	5	0	0 (0.0)	0
Implant migration/loosening	1	1 (0.6)	517	1	1 (1.3)	32
Unresolved pain	3	3 (1.7)	483	3	2 (2.5)	323
Total	14	10 (5.8)	180	9	7 (8.8)	261

SR = surgical reintervention.

follow-up.[6] The primary outcome measure was a mean reduction in the ODI score of at least 30%, with 71.4% of the decompression-alone group and 72.9% of the decompression and fusion group meeting that threshold. The mean reductions in ODI scores were 20.6 and 21.3, respectively. The reoperation rate was higher in the decompression-alone group (12.5%) versus the decompression and fusion group (9.1%), although the difference was not statistically significant. The present study showed a nearly identical minimum 30% mean ODI reduction in the TLIF group (73.1%), but significantly higher rates of minimum 30% ODI reduction in the TOPS group (95%). The surgical reintervention rate was notably lower in the present study for the TOPS group (5.8%). This finding is especially noteworthy considering that the high rate of reoperation is a common criticism of decompression alone.

In 2016, two separate randomized controlled trials evaluating decompression alone and decompression and stabilization for the treatment of stenosis and spondylolisthesis produced different results with diametrically opposite conclusions.[7,8] Försth and associates reported no significant difference in ODI scores between the decompression-alone and decompression and fusion cohorts.[7] The mean ODI score reductions were only modest, with mean reductions of 17 in the decompression-alone group and 15 in the decompression and fusion group. Furthermore, Försth et al. reported nearly identical reoperation rates for the decompression-alone and decompression and fusion cohorts at 21% and 22%, respectively. The authors concluded that in patients with lumbar spinal stenosis, with or without spondylolisthesis, decompression and fusion did not result in better clinical outcomes. This conclusion appears rooted in similar, modest improvements in disability as well as similar reoperation rates for both the decompression-alone and decompression and stabilization groups. At 24 months, the present study demonstrated a relatively high mean ODI reduction of 36.2 points in the TLIF group and an even more robust mean ODI reduction of 48.4 points in the TOPS group.

Ghogawala and coauthors also reported a nonstatistically significantly different ODI score reduction at 2 years of 17.9 for decompression alone versus 26.3 for decompression and fusion.[8] However, there was a significantly higher reoperation rate in the decompression-alone cohort (34%) compared with the decompression and fusion group (14%) ($p = 0.05$). The authors concluded that the addition of fusion produced clinically meaningful improvement over decompression alone. This conclusion appears based on similar, modest clinical improvements in both groups but significantly lower reoperation rates in the fusion cohort.

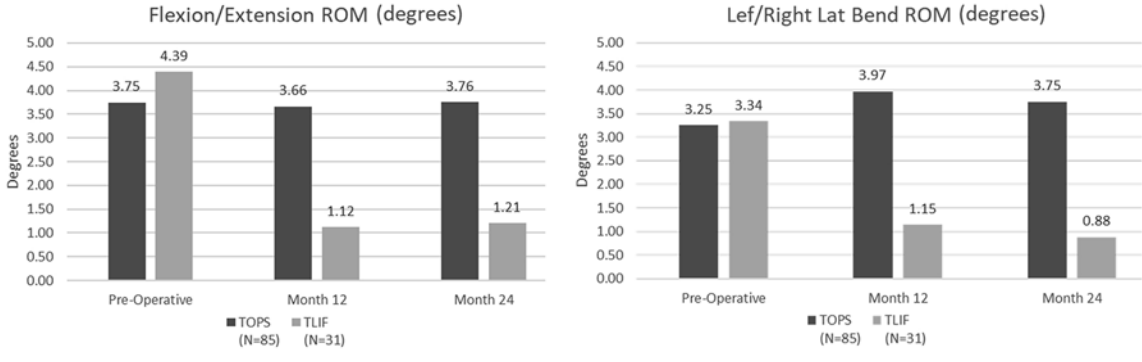

FIG. 4. Angular ROM in flexion/extension (**left**) and left/right lateral bending (**right**).

In the present study, we report statistically significant clinical improvements in both groups from baseline as well as relatively low reoperation rates. The composite measure for clinical success was statistically significantly higher in the TOPS group (85%) compared with the TLIF group (64%) ($p = 0.0138$). Additionally, a minimum 15-point improvement in ODI favored arthroplasty over fusion (93.1% vs 80.6%, $p = 0.078$). The clinical results of fusion patients in the present study are consistent with the previous fusion cohorts and are inferior to the clinical results of the arthroplasty cohort.[1,6,7,10,12,27] Decompression with dynamic stabilization allows for aggressive decompression with total facetectomy followed by dynamic stabilization. This procedure allows for a more thorough decompression characterized by fusion procedures while still maintaining motion at the index level without placing increased stresses at adjacent levels.

One of the noteworthy distinctions between the studies by Austevoll, Försth, and Ghogawala and their colleagues was the difference in reoperation rates between groups.[6–8] The reoperation rate is lower in the present study for facet replacement (5.8%) compared with its TLIF control group (8.8%), which is similar to the fusion control in the study by Austevoll et al. (9.1%) and lower than the fusion cohort revision rate in the studies by Försth et al. (22%) and Ghogawala et al. (14%). Furthermore, facet arthroplasty offers the potential for less reoperation in the future at adjacent levels due to preservation of motion. Of the 10 patients (5.8%) who underwent reoperation in the TOPS group, none of the surgeries were for adjacent-level disease; only 2 (1.2%) were device-related, one for pedicle screw misplacement and one for pedicle screw loosening. The remaining 8 patients underwent reoperation because of a retained wound drain (2 patients, 1.2%), wound complications of seroma or infection (3 patients, 1.7%), durotomy (2 patients, 1.2%), and unresolved pain (3 patients, 1.7%). Two patients underwent more than one reoperation.

There are no FDA-approved arthroplasty devices for the treatment of degenerative lumbar spondylolisthesis. Furthermore, there are no FDA-approved posterior lumbar arthroplasty devices. There are two FDA-approved lumbar artificial discs, but these devices are placed through the more precarious anterior retroperitoneal approach. Challenges typically associated with anterior lumbar arthroplasty include the need for an anterior exposure surgeon and an inability to directly decompress the neural elements.[16–18] Perhaps the most important distinction between anterior lumbar TDR and posterior facet replacement is the primary surgical indication. Lumbar TDR is primarily indicated to treat axial low-back pain, a controversial indication for surgical treatment. Conversely, posterior lumbar arthroplasty is indicated to treat lumbar neurogenic claudication and radiculopathy due to stenosis and spondylolisthesis. There is solid evidence that stenosis due to degenerative spondylolisthesis represents a reasonable surgical indication, although the ideal procedure remains controversial. Lumbar facet replacement utilizes the familiar posterior approach and allows for a wide decompression with facetectomy and foraminotomy. The posterior approach is the workhorse approach for lumbar spine surgery. Similar to the anterior approach to the cervical spine, the posterior lumbar approach is the most common surgical approach, offers familiar anatomy, and allows for both direct and indirect decompression of the neural elements. Furthermore, the posterior lumbar approach, like the anterior cervical approach, is typically utilized to address neural compression presenting with radiculopathy or neurogenic claudication.

TLIF is a common surgical procedure with a well-characterized efficacy and safety profile. One of the advantages of decompression and stabilization in the treatment of spondylolisthesis includes the ability to interrupt the underlying degenerative process by resecting the offending pathological facets. Furthermore, the decompression can be more thorough compared with decompression alone, which is limited by the need to maintain residual stability. A recent meta-analysis by Pranata and associates compared decompression alone versus decompression and fusion and reported statistically greater clinical efficacy for decompression and fusion.[27] Complications, including reoperations, were not statistically different between the two procedures. The primary disadvantage of TLIF is the loss of motion at the index level as well as the increased stresses placed at adjacent levels.[13] The present study showed improvement in neurological status in the arthroplasty group along with a similar length of surgery, operative blood loss, and AE profile in both groups. This finding indicates that the TOPS device can adequately decompress the neural elements without sacrificing physiological motion, which may explain the improved clinical results compared with fusion. The improvement in back pain seen in the TOPS group may be due to the direct resection of the pathologically degenerated facets as well as the dynamic stability imparted by the artificial facet.

Weaknesses of the present study include adherence to strict inclusion criteria typical of industry-sponsored FDA IDE trials, which may limit generalization to the more heterogeneous real-world population. Furthermore, as an industry-sponsored trial, observer and expectation bias can affect study results. The follow-up is short-term, and any meaningful discussion of adjacent-level disease requires long-term follow-up.

Conclusions

Posterior facet replacement with the TOPS device demonstrates the ability to provide adequate decompression while providing dynamic stabilization by limiting abnormal spinal motion and maintaining physiological motion. Facet arthroplasty serves as a viable alternative to decompression and fusion in patients with stenosis due to degenerative grade I spondylolisthesis.

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Author Contributions

Conception and design: Coric. Acquisition of data: Coric, Nassr, Welch, Robbins, Whiting, Chahlavi, Pirris, Groff, Chi, Huang, Kent, Whitmore, Meyer, Arnold, Patel, Orr, Krishnaney, Boltes, Steinmetz. Analysis and interpretation of data: Coric, DeLuca. Drafting the article: Coric, Kim. Critically revising the article: Coric, Nassr, Kim, Arnold, Anekstein, Steinmetz. Reviewed submitted version of manuscript: Coric, Nassr, Kim, Welch, Robbins, DeLuca, Whiting, Chahlavi, Pirris, Groff, Chi, Huang, Kent, Whitmore, Meyer, Arnold, Patel, Krishnaney, Boltes, Anekstein, Steinmetz. Approved the final version of the manuscript on behalf of all authors: Coric.

Correspondence

Domagoj Coric: Carolina Neurosurgery & Spine, Charlotte, NC. domagoj.coric@cnsa.com.