Lumbar Facet Arthroplasty Versus Fusion for Grade-I Degenerative Spondylolisthesis with Stenosis

A Prospective Randomized Controlled Trial

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Background: The comparative effectiveness of decompression plus lumbar facet arthroplasty versus decompression plus instrumented lumbar spinal fusion in patients with lumbar spinal stenosis and grade-I degenerative spondylolisthesis is unknown.

Methods: In this randomized, controlled, Food and Drug Administration Investigational Device Exemption trial, we assigned patients who had single-level lumbar spinal stenosis and grade-I degenerative spondylolisthesis to undergo decompression plus lumbar facet arthroplasty (arthroplasty group) or decompression plus fusion (fusion group). The primary outcome was a predetermined composite clinical success score. Secondary outcomes included the Oswestry Disability Index (ODI), visual analog scale (VAS) back and leg pain, Zurich Claudication Questionnaire (ZCQ), Short Form (SF)-12, radiographic parameters, surgical variables, and complications.

Results: A total of 321 adult patients were randomized in a 2:1 fashion, with 219 patients assigned to undergo facet arthroplasty and 102 patients assigned to undergo fusion. Of these, 113 patients (51.6%) in the arthroplasty group and 47 (46.1%) in the fusion group who had either reached 24 months of postoperative follow-up or were deemed early clinical failures were included in the primary outcome analysis. The arthroplasty group had a higher proportion of patients who achieved composite clinical success than did the fusion group (73.5% versus 25.5%; $p < 0.001$), equating to a between-group difference of 47.9% (95% confidence interval, 33.0% to 62.8%). The arthroplasty group outperformed the fusion group in most patient-reported outcome measures (including the ODI, VAS back pain, and all ZCQ component scores) at 24 months postoperatively. There were no significant differences between groups in surgical variables or complications, except that the fusion group had a higher rate of developing symptomatic adjacent segment degeneration.

Conclusions: Among patients with lumbar spinal stenosis and grade-I degenerative spondylolisthesis, lumbar facet arthroplasty was associated with a higher rate of composite clinical success than fusion was at 24 months postoperatively.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

Lumbar spinal stenosis (LSS) with degenerative spondylolisthesis (DS) is the most common indication for lumbar fusion surgery in the United States[1-4]. Two Level-I studies have presented conflicting results regarding the relative efficacy of decompression alone versus decompression plus fusion[5,6]. The ongoing controversy regarding these competing surgical approaches is further fueled by national database studies and randomized prospective studies demonstrating high reoperation

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A **data-sharing statement** is provided with the online version of the article (http://links.lww.com/JBJS/H987).

rates (10% to 30% at 3 years, 30% to 40% at 10 years) with both decompression alone and decompression plus fusion[6-10]. Given the substantial impact of revision spine surgery on both patient-reported outcome measures (PROMs) and health-care costs (estimated 2-year cost of revision lumbar spine surgery, >$100,000), there remains strong interest in identifying the optimal surgical approach to LSS with DS[8,11,12].

Decompression plus lumbar facet arthroplasty is an alternative treatment for LSS with DS. Lumbar facet arthroplasty allows for thorough decompression of the neural elements, stabilization of the spondylolisthesis, and preservation of motion, thereby limiting both the persistent instability that leads to recurrent stenosis following isolated decompression and the pathologic redistribution of motion that leads to adjacent segment degeneration following fusion. At present, there are no U.S. Food and Drug Administration (FDA)-approved lumbar facet arthroplasty devices. The Total Posterior Spine System (TOPS; Premia Spine) is a lumbar facet arthroplasty device that has been the subject of a recently concluded FDA Investigational Device Exemption (IDE) trial comparing the relative efficacy of lumbar facet arthroplasty versus fusion to treat lumbar grade-I DS with stenosis. Lumbar facet arthroplasty with the TOPS device has shown promise in retrospective clinical studies and in a single-arm interim review of the TOPS IDE trial[13-16].

The purpose of the present study is to report the results of the primary 2-year outcome of the TOPS IDE trial, as well as secondary outcomes including PROMs, radiographic parameters, and complications. We hypothesized that lumbar facet arthroplasty would outperform fusion in the primary composite outcome while successfully stabilizing the spondylolisthesis and maintaining motion at the surgical level.

Materials and Methods

Study Design and Oversight

In this randomized controlled IDE trial (IDE number G160168, ClinicalTrials.gov NCT03012776), patients were assessed for eligibility during the study period from July 17, 2017, to June 20, 2022, at 37 medical centers. The majority of patients were enrolled at 1 of 10 sites (see Appendix A,1). The primary outcome was the overall rate of composite clinical success at 24 months postoperatively. Data from a prior FDA IDE trial (G060063) provided the basis for the determination that 303 patients (202 arthroplasty, 101 fusion) would need to be randomized to provide 80% power to reject the null hypothesis of equality. Patients were randomized in a 2:1 ratio to either decompression plus lumbar facet arthroplasty or decompression plus fusion. Randomization was by blocks, with randomly varying block sizes to minimize the likelihood that a site would be able to infer the next randomization assignment in the sequence. Randomization schedules were maintained centrally by ProSoft Clinical, which utilized a secure software application to perform the randomization and transmit the treatment allocation directly to center-specific study personnel within 24 hours prior to surgery. Patients were blinded prior to surgery but were informed of their assignment postoperatively due to the impracticality of ensuring that they did not view their radiographs during follow-up appointments. Physicians and radiologists were not blinded to the treatment assignment. Appendix A,2 provides details regarding third-party data management, trial surveillance, independent review of indeterminate clinical events, and data transmission. Institutional review board approval was obtained at all participating sites prior to enrolling patients. All enrolled patients were counseled extensively regarding the surgical options and the ongoing clinical trial, and provided written informed consent.

Patients

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 >6 months of nonsurgical therapy that was unsuccessful. 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 >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

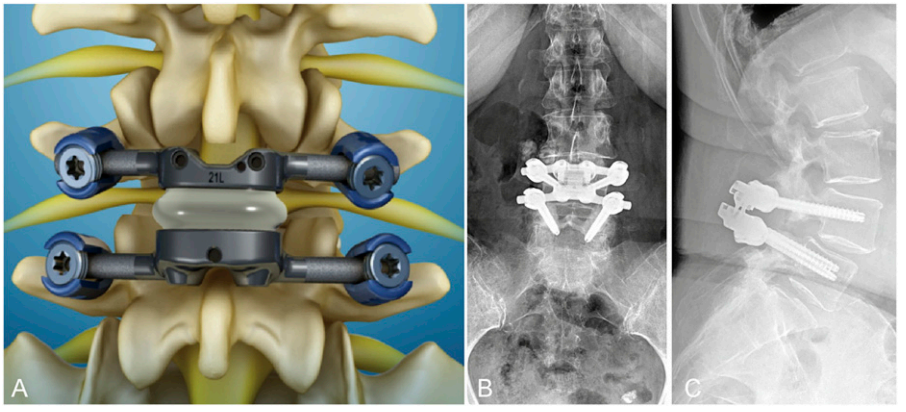

Fig. 1

Schematic (**Fig. 1-A**), anteroposterior radiograph (**Fig. 1-B**), and lateral radiograph (**Fig. 1-C**) demonstrating the TOPS device affixed to pedicle screws.

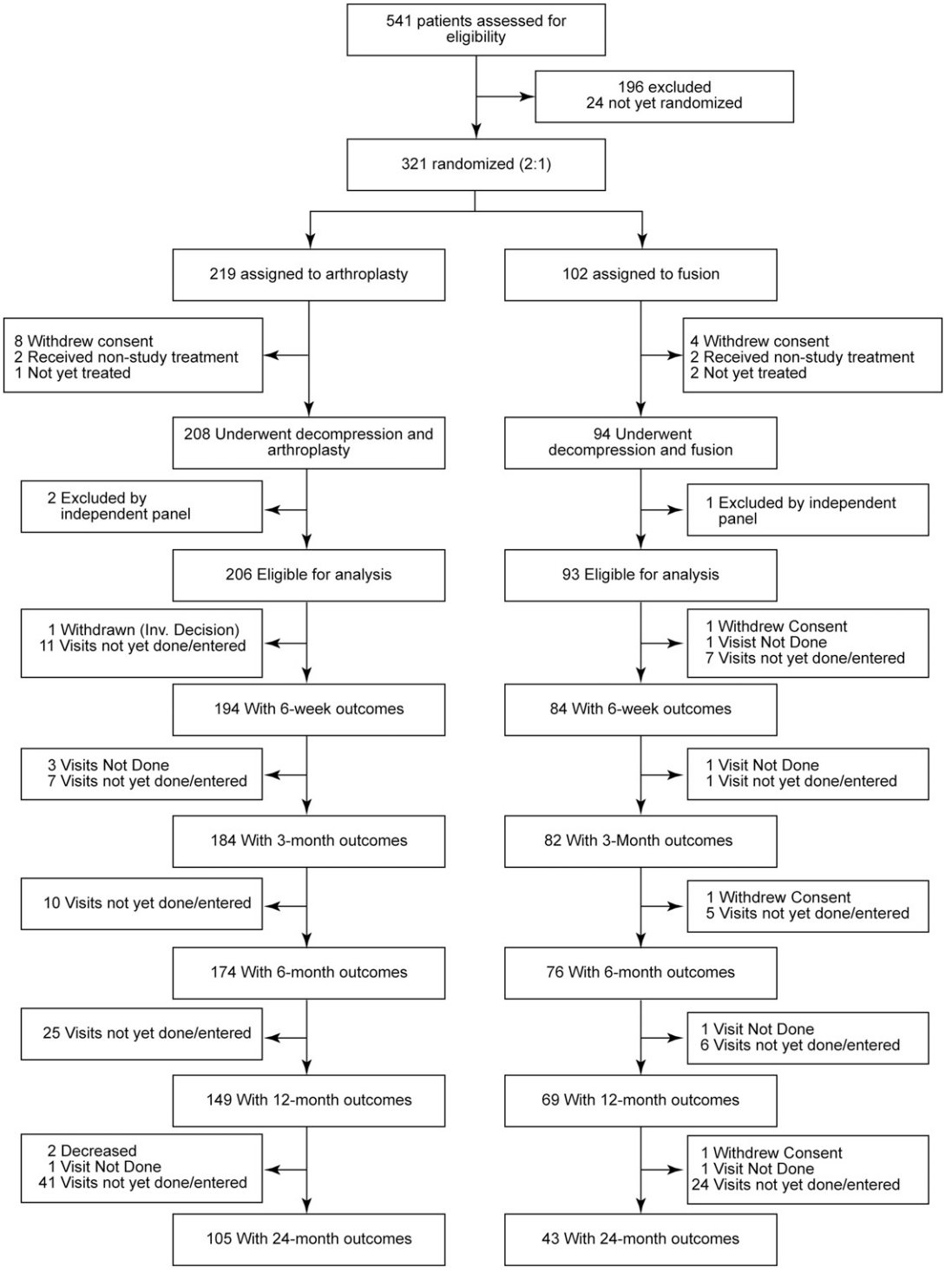

Fig. 2

Eligibility, randomization, and follow-up.

performed at the index level or an adjacent level (unless it involved only the posterior elements), or instrumented lumbar spine surgery had been performed at any level. A complete overview of inclusion and exclusion criteria is provided in Appendix A,3.

Trial coordinators at each site screened and enrolled patients. Radiographs and magnetic resonance imaging scans were reviewed centrally for each enrolled patient to verify the presence of LSS with grade-I DS without disc herniation.

TABLE I Baseline Characteristics of the Patients*

	Arthroplasty (N = 206)	Fusion (N = 93)	P Value
Demographics			
Age *(yr)*	63.3 ± 8.2	63.9 ± 8.6	0.53
BMI *(kg/m²)*	29.4 ± 4.9	29.9 ± 5.3	0.43
Female sex	116 (56.3%)	50 (53.8%)	0.71
Race			0.63
White	191 (92.7%)	86 (92.5%)	
Black	3 (1.5%)	3 (3.2%)	
Asian	3 (1.5%)	2 (2.2%)	
Other	9 (4.4%)	2 (2.2%)	
Medical comorbidities			
Congestive heart failure	0 (0.0%)	1 (1.1%)	0.74
Diabetes mellitus	6 (2.9%)	5 (5.4%)	0.11
Osteopenia	13 (6.3%)	6 (6.5%)	0.92
Depression	29 (14.1%)	13 (14.0%)	0.89
Chronic kidney disease	9 (4.4%)	2 (2.2%)	0.43
COPD	3 (1.5%)	2 (2.2%)	0.61
Use of nicotine products			0.97
No, never smoked	127 (61.7%)	59 (63.4%)	
No, but prior history	73 (35.4%)	32 (34.4%)	
Current smoker	6 (2.9%)	2 (2.2%)	
Prior lumbar surgery			0.80
Yes	12 (5.8%)	6 (6.5%)	
No	194 (94.2%)	87 (93.5%)	
Level implanted			0.59
L1-L2	0	0	
L2-L3	0	0	
L3-L4	10 (4.9%)	6 (6.5%)	
L4-L5	196 (95.1%)	87 (93.5%)	

*Group means of baseline patient-reported outcome measures are reported in Table III. Continuous variables are given as the mean ± standard deviation, and categorical variables are given as the number with the percentage in parentheses. BMI = body mass index, COPD = chronic obstructive pulmonary disease.

Interventions

Patients underwent either decompression plus transforaminal interbody fusion (fusion group) or decompression plus lumbar facet arthroplasty (arthroplasty group) at the single level of spondylolisthesis (Fig. 1). Appendix A,4 provides additional details regarding these 2 interventions.

Outcomes

The primary outcome was a study-specific composite clinical success measure determined at 2 years postoperatively. We defined clinical success as meeting all 5 of the following criteria: (1) the absence of reoperation, lumbar injection, or spinal cord stimulator implantation; (2) the absence of a major device adverse event; (3) a reduction in the ODI of ≥15 points; (4) the absence of a new or progressive neurologic deficit; and (5) the absence of fusion failure (pseudarthrosis in the fusion group or spontaneous fusion in the arthroplasty group)[17,18]. A major device adverse event was defined as device component degradation, breakage, separation, disassembly, or loosening (including screw loosening) or an increase in spondylolisthesis at the index level by at least 1 grade at any postoperative time point. These major adverse events were specifically device- or spine-related and did not include medical adverse events. An improvement in the ODI of ≥15 points has been determined to be the minimum clinically important difference (MCID) in multiple previous randomized controlled trials[17-19]. Appendix A,5 describes the definition of a neurologic deficit utilized in this study and limitations inherent to the neurologic examination. Appendix A,6 details the methodology used to assess fusion status with radiographs.

Patients were required to have reached 24 months of postoperative follow-up to be deemed a clinical success; however, a patient could be deemed an early clinical failure due to reoperation, lumbar injection, a major device adverse event, or development of a new neurologic deficit, or by the presence of a fusion in the

TABLE II Primary End Point: Composite Clinical Success

	Arthroplasty (N = 113*)		Fusion (N = 47*)		
	Rate†	%	Rate†	%	P Value
Composite clinical success					
Yes	83/113	73.5%	12/47	25.5%	<0.001
No†	30/113	26.5%	35/47	74.5%	<0.001
Reoperation, lumbar injection, or stimulator implantation	13/113	11.5%	5/47	10.6%	0.28
Major device adverse event	7/105	6.7%	2/41	4.9%	1.00
ODI reduction < 15 points§	6/96	6.3%	8/35	22.8%	0.01
Fusion failure#	1/104	1.0%	18/41	43.9%	<0.001
New or progressive neurologic deficit	3/107	2.8%	5/44	11.4%	0.047

*The number of patients in each treatment group represents all patients who reached 24 months of postoperative follow-up (105 arthroplasty, 43 fusion) plus those patients who had early treatment failure (8 arthroplasty, 4 fusion), defined as failure in ≥1 measure of the composite clinical success criteria prior to 24 months. †Number of patients who met the criterion in the row/number of patients available to be evaluated for the criterion in the row. ‡Some patients failed to achieve the primary end point for >1 reason. §The end point was censored if the patient underwent reoperation or lumbar injection prior to outcome measurement. #Defined as lack of fusion at 24 months postoperatively in the fusion group or the presence of spontaneous/unintended fusion in the arthroplasty group. The outcome was censored in patients who underwent reoperation prior to fusion assessment.

arthroplasty treatment group, prior to 24 months. Consequently, the number of patients analyzed for the primary outcome of composite clinical success was the sum of those patients who reached 24 months of clinical follow-up and those patients who were deemed early clinical failures.

Additional prespecified outcomes included mean ODI scores, VAS back and leg pain scores, Zurich Claudication Questionnaire (ZCQ) scores, Short Form (SF)-12 scores, surgical variables (estimated blood loss, length of stay, time in surgery), postoperative pain medication use, complications, reoperations, and radiographic alignment and motion parameters. Motion in both flexion-extension and lateral bending at the surgical level was measured in degrees on dynamic radiographs. Spondylolisthesis was graded according to the Meyerding classification and was determined to be stabilized if there was no postoperative increase in grade[20]. Reoperation was performed at the discretion of the treating surgeon. The proportion of patients achieving the MCID in the ODI (≥15-point improvement), VAS back pain (>10.5-point improvement), VAS leg pain (>10.5-point improvement), and ZCQ (>0.75-point improvement) was determined on the basis of established MCID values in the literature[21,22].

Enrollment, Randomization, and Statistical Analysis

Figure 2 shows the enrollment, randomization, and follow-up for the TOPS IDE trial. Overall, 541 patients were assessed for eligibility, of whom 196 were excluded on the basis of the trial inclusion and exclusion criteria and 24 had not yet been randomized to a treatment group at the time of this analysis. The remaining 321 patients were randomized, with 219 patients assigned to undergo facet arthroplasty and 102 patients assigned to undergo fusion. Of the 219 patients randomized to the arthroplasty group, 8 withdrew consent, 2 received a non-study treatment, 1 had not yet undergone surgery, and 2 were excluded by the independent review panel, leaving 206 patients eligible for analysis. Of the 102 patients assigned to the fusion group, 4 withdrew consent, 2 received a non-study treatment, 2 had not yet undergone surgery, and 1 was excluded by the independent review panel, leaving 93 patients eligible for analysis. No crossovers occurred from either treatment group.

In accordance with the predetermined statistical plan, an interim analysis of the primary outcome was performed when >300 patients were randomized, even though not all patients had reached 24 months of follow-up. Of the 206 arthroplasty group patients and 93 fusion group patients eligible for analysis, 105 patients (51.0%) in the arthroplasty group and 43 (46.2%) in the fusion group had reached 24 months of follow-up. An additional 8 patients (3.9%) in the arthroplasty group and 4 (4.3%) in the fusion group were deemed early clinical failures. Thus, a total of 160 patients were included in the primary outcome analysis, including 113 patients (54.9% of randomized patients) in the arthroplasty group and 47 patients (50.5% of randomized patients) in the fusion group. Although only approximately one-half of the randomized patients were analyzed for the primary outcome, the between-group difference in the primary outcome was sufficient to satisfy the predetermined criteria for concluding the clinical trial (see Appendix A,7). Although false-negative results can occur when a clinical trial is concluded or analyzed prematurely, a larger-than-expected between-group difference is an established precedent to conclude a clinical trial comparing 2 surgical interventions[23,24].

Of the patients not assessed for the primary outcome, 4 patients in each group were lost to follow-up, and the remaining patients are being followed prospectively but have not yet reached 24 months of postoperative follow-up. Patients

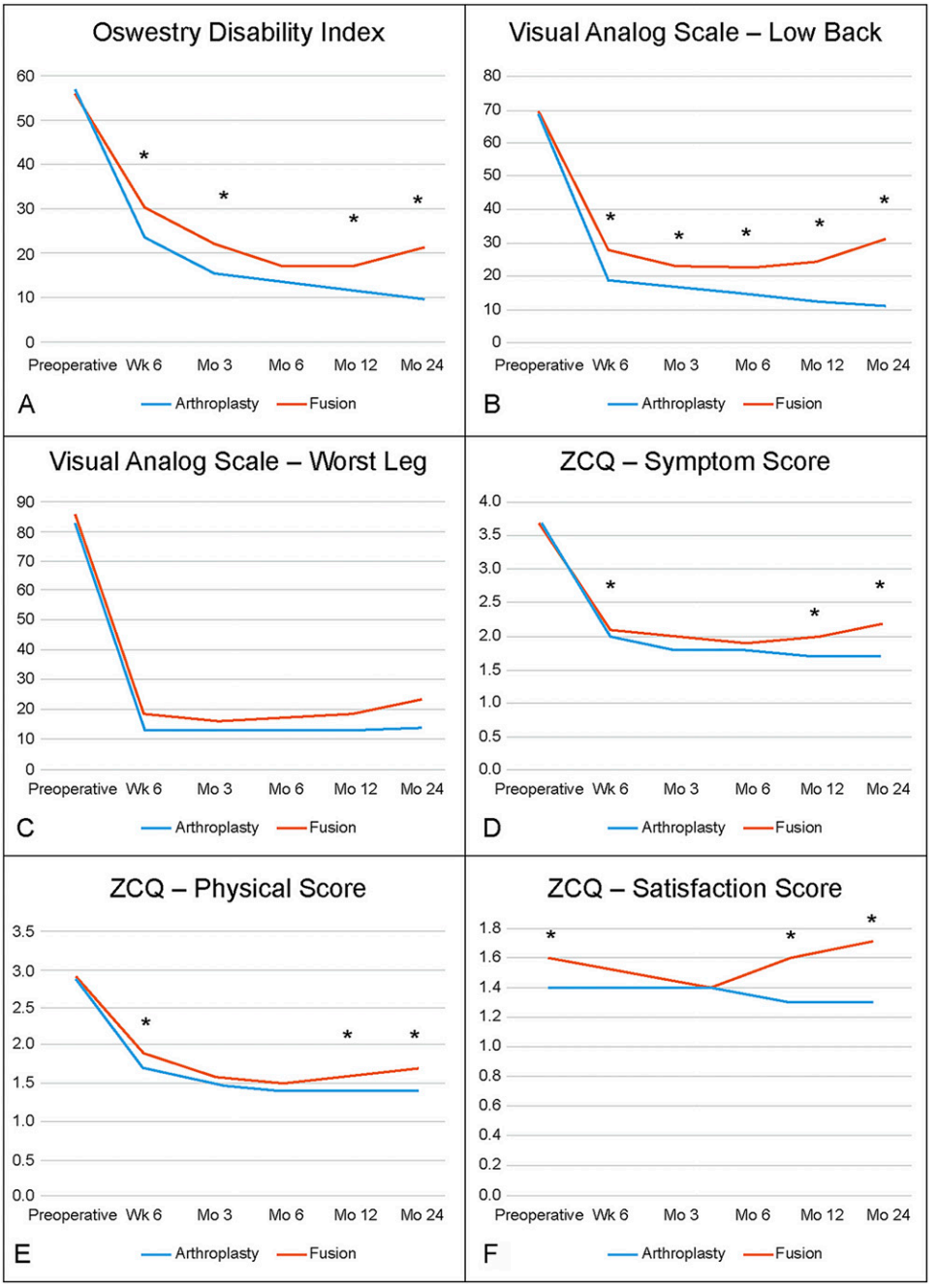

Fig. 3

Mean scores on the Oswestry Disability Index (scores range from 0 to 100, with higher scores indicating more disability related to back pain) (**Fig. 3-A**), visual analog scale for low back pain (**Fig. 3-B**) and worst leg pain (**Fig. 3-C**) (scores range from 0 to 100, with higher scores indicating more pain in the specified anatomic region), and each component of the Zurich Claudication Questionnaire (ZCQ; scores range from 1 to 5 on the symptom score and from 1 to 4 on the physical and satisfaction scores, with lower numbers representing less severe symptoms related to neurogenic claudication, greater physical function, and greater satisfaction, respectively) (**Figs. 3-D, 3-E, and 3-F**), before and after surgery, among patients who were randomly assigned to undergo decompression plus lumbar facet arthroplasty or decompression plus fusion. *A significant difference ($p < 0.05$) between groups at the indicated time point.

who underwent reoperation and thus had treatment failure according to the composite end point were included in the primary analyses, but their PROMs were censored at reoperation to avoid confounding the results of the primary treatment by including those of successful secondary treatment following a failed primary treatment[25].

TABLE III Patient-Reported Outcome Measures*

	Arthroplasty (N = 206)		Fusion (N = 93)			MCID Achievement		
	N	Value†	N	Value†	P Value	Arthroplasty	Fusion	P Value
ODI								
Preop.	206	56.5 ± 12.1	93	55.8 ± 13.1	0.75			
Week 6	194	23.5 ± 16.4	84	30.2 ± 17.0	0.001	84.0%	73.8%	0.07
Month 3	183	15.7 ± 16.5	82	22.1 ± 17.8	0.02	89.1%	84.1%	0.31
Month 6	171	13.4 ± 15.5	74	16.9 ± 15.9	0.01	91.8%	90.5%	0.81
Month 12	143	11.6 ± 13.7	65	16.9 ± 17.2	<0.001	94.4%	89.2%	0.25
Month 24	105	9.4 ± 14.5	43	21.1 ± 22.3	<0.001	93.7%	77.2%	0.01
P value†		<0.001		<0.001				
VAS, low back pain								
Preop.	206	68.6 ± 23.3	93	69.5 ± 22.2	0.75			
Week 6	194	18.5 ± 18.0	83	27.7 ± 25.3	0.001	83.5%	68.7%	0.009
Month 3	183	16.2 ± 21.3	82	23.1 ± 24.5	0.02	83.6%	79.3%	0.39
Month 6	171	14.7 ± 21.1	74	22.7 ± 24.8	0.01	86.0%	79.7%	0.26
Month 12	143	12.4 ± 19.6	65	24.5 ± 27.6	<0.001	86.0%	76.9%	0.11
Month 24	105	11.1 ± 18.1	43	30.9 ± 33.1	<0.001	84.4%	61.8%	0.01
P value†		<0.001		<0.001				
VAS, worst leg pain								
Preop.	206	82.7 ± 13.5	93	85.1 ± 10.8	0.13			
Week 6	194	12.9 ± 20.5	84	17.9 ± 25.2	0.09	92.8%	92.8%	1.00
Month 3	182	13.3 ± 22.5	82	15.9 ± 23.7	0.38	94.5%	92.7%	0.58
Month 6	171	12.9 ± 22.7	74	17.0 ± 24.9	0.21	92.4%	91.9%	1.00
Month 12	143	12.8 ± 22.0	65	18.7 ± 27.8	0.10	94.4%	90.8%	0.38
Month 24	105	13.7 ± 24.2	43	23.3 ± 33.8	0.08	90.6%	88.2%	0.74
P value†		<0.001		<0.001				
ZCQ, symptom								
Preop.	206	3.7 ± 0.6	93	3.7 ± 0.6	0.63			
Week 6	194	2.0 ± 0.7	84	2.1 ± 0.8	0.04	93.8%	90.5%	0.32
Month 3	180	1.8 ± 0.7	81	2.0 ± 0.7	0.09	95.6%	96.3%	1.00
Month 6	169	1.8 ± 0.7	74	1.9 ± 0.7	0.22	95.9%	93.2%	0.36
Month 12	141	1.7 ± 0.7	63	2.0 ± 0.8	0.04	96.5%	92.3%	0.29
Month 24	103	1.7 ± 0.8	41	2.2 ± 1.0	0.01	93.8%	85.7%	0.16
P value†		<0.001		<0.001				
ZCQ, physical								
Preop.	206	2.9 ± 0.4	93	2.9 ± 0.4	0.50			
Week 6	194	1.7 ± 0.6	84	1.9 ± 0.6	0.01	86.7%	76.2%	0.04
Month 3	180	1.5 ± 0.6	81	1.6 ± 0.6	0.11	91.2%	91.5%	1.00
Month 6	169	1.4 ± 0.6	74	1.5 ± 0.5	0.26	90.6%	91.9%	1.00
Month 12	141	1.4 ± 0.5	63	1.6 ± 0.7	0.001	96.5%	84.6%	0.01
Month 24	103	1.4 ± 0.6	41	1.7 ± 0.8	0.02	92.7%	82.9%	0.11
P value†		<0.001		<0.001				
ZCQ, satisfaction								
Week 6	194	1.4 ± 0.5	84	1.6 ± 0.6	0.02	96.4%	95.2%	0.74
Month 3	180	1.4 ± 0.6	81	1.5 ± 0.6	0.08	94.0%	95.1%	1.00
Month 6	169	1.4 ± 0.6	74	1.4 ± 0.6	0.30	94.7%	95.9%	1.00
Month 12	141	1.3 ± 0.5	63	1.6 ± 0.8	0.002	94.4%	86.2%	0.06
Month 24	103	1.3 ± 0.6	41	1.7 ± 0.8	0.01	92.7%	88.6%	0.48

*Continuous variables are given as the mean ± standard deviation. MCID = minimum clinically important difference, ODI = Oxford Disability Index, VAS = visual analog scale, ZCQ = Zurich Claudication Questionnaire. †Values are given as the mean ± standard deviation unless otherwise noted. ‡Within-group comparison between preoperatively and 24 months postoperatively.

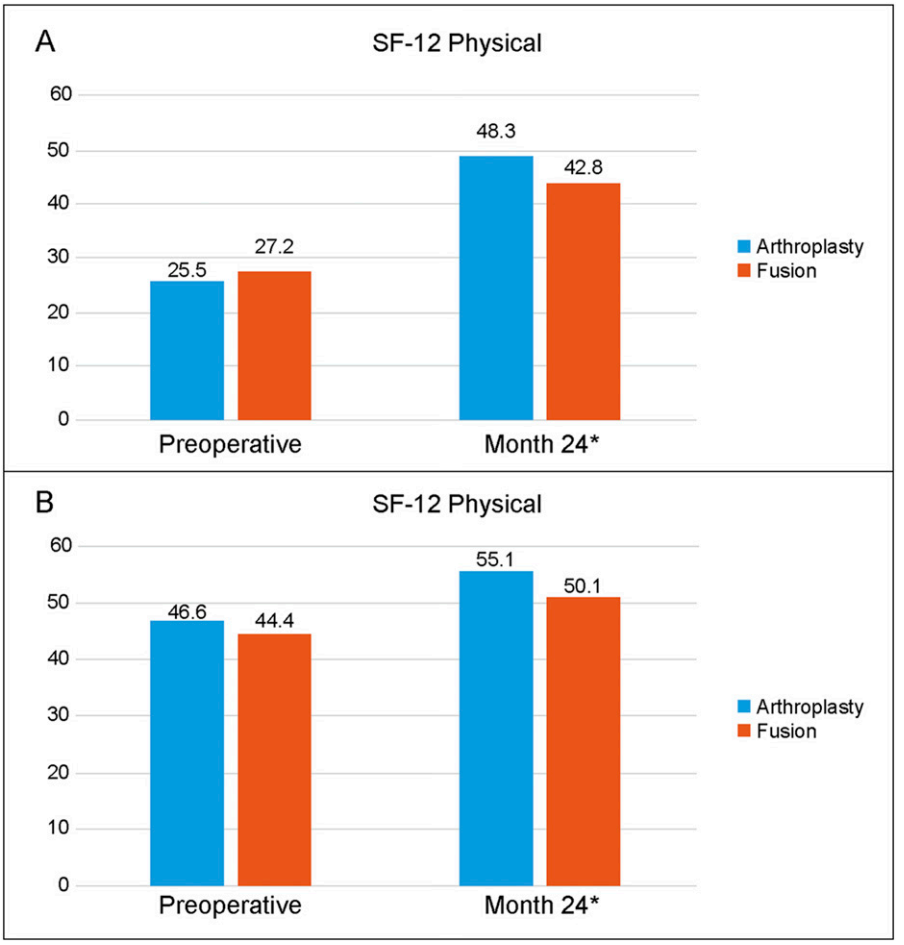

Fig. 4

Mean scores on the physical (**Fig. 4-A**) and mental (**Fig. 4-B**) component summary scores of the Short Form-12 Health Survey (SF-12; scores range from 0 to 100, with higher scores indicating better quality of life), before and 24 months after surgery, among patients who were randomly assigned to undergo decompression plus lumbar facet arthroplasty or decompression plus fusion. *A significant difference ($p < 0.05$) between groups at the indicated time point.

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 exact tests for categorical variables (see Appendix B).

Results

Patients

Baseline characteristics of the patients assigned to the arthroplasty and fusion treatment groups are shown in Table I. No differences between treatment groups, including in baseline PROMs, were identified.

Primary Outcome

At 24 months after surgery, a significantly greater proportion of patients achieved composite clinical success in the arthroplasty group than in the fusion group (83 patients [73.5%] versus 12 patients [25.5%]; $p < 0.001$), equating to a between-group difference of 47.9% (95% CI, 33.0% to 62.8%) (Table II). Consequently, the null hypothesis was rejected, and it can be concluded that facet arthroplasty is superior to fusion in terms of the primary outcome. The fusion group demonstrated higher rates of developing a new or progressive neurologic deficit (11.4% versus 2.8%; $p = 0.047$) and fusion failure (43.9% versus 1.0%; $p < 0.001$) at 24 months postoperatively. Appendix A,8 provides additional details regarding between-group differences in the various components of the primary outcome.

Secondary Outcomes

The arthroplasty group demonstrated significantly lower VAS back pain at all postoperative time points, and the magnitude of the difference in treatment effect grew from 6 to 24 months postoperatively (Fig. 3, Table III). A greater proportion of patients in the arthroplasty group achieved the MCID in the ODI (93.8% versus 77.1%, $p = 0.01$) and in VAS back pain (84.4 versus 61.8%, $p = 0.01$) at 24 months postoperatively. The arthroplasty group demonstrated superior SF-12 physical

TABLE IV Surgical Complications

	Arthroplasty (N = 206)	Fusion (N = 93)	P Value
Dural tear	14 (6.8%)	2 (2.2%)	0.16
Infection	1 (0.5%)	0 (0.0%)	1.00
Seroma	1 (0.5%)	0 (0.0%)	1.00
Hematoma	1 (0.5%)	0 (0.0%)	1.00
Adjacent segment degeneration*	0 (0.0%)	5 (5.4%)	0.003
Retained drains	2 (1.0%)	0 (0.0%)	1.00
Reoperation†	11 (5.3%)	8 (8.6%)	0.31

*Defined as symptomatic stenosis at a motion segment adjacent to the index surgical level requiring reoperation for symptom relief.
†The 11 arthroplasty patients underwent a total of 15 reoperations. The 8 fusion patients underwent a total of 10 reoperations.

(mean and standard deviation, 48.3 ± 11.2 versus 42.8 ± 13.6; p = 0.02) and mental (55.1 ± 8.2 versus 50.1 ± 10.2; p = 0.005) component summary scores at 24 months postoperatively (Fig. 4; see also Appendix A,9).

No significant differences were identified between the fusion and arthroplasty groups in terms of surgical variables (see Appendix A,10). Complications did not differ between groups except that the fusion group demonstrated higher rates of symptomatic adjacent segment degeneration (5.4% versus 0.0%; p = 0.003) (Table IV). Two reoperations in the arthroplasty group were performed for pedicle screw loosening, and 6 reoperations were performed in 5 patients in the fusion group for symptomatic adjacent segment degeneration (Table V). Both treatment groups demonstrated adequate stabilization of the spondylolisthesis, and the arthroplasty group maintained motion at the index level (Table VI). The overall rate of pedicle screw loosening in the arthroplasty group was 8.0% (9 of 113 patients) at 24 months postoperatively (see Appendix A,8).

Discussion

In the present study comparing lumbar facet arthroplasty versus fusion to treat LSS with grade-I DS, the lumbar facet arthroplasty treatment group achieved a significantly higher rate of composite clinical success, which was predominantly driven by higher rates of fusion failure, new or progressive neurologic deficit, and failure to achieve sufficient reduction in low back disability (as measured by the ODI) in the fusion group. Although both treatments successfully stabilized the spondylolisthesis, the arthroplasty group did so while maintaining motion at the index level at 24 months postoperatively, as evidenced by preserved range of motion in both the sagittal and coronal planes. There were no significant differences in demographics or other secondary outcomes between groups, including surgical variables, complications, reoperations, and lumbar lordosis, at 24 months postoperatively, except that the fusion group demonstrated a higher rate of developing adjacent segment degeneration. The present study included younger patients (≥35 years) than prior studies of patients with DS, but this younger age cutoff is consistent with previous studies comparing motion-preserving versus spinal fusion surgery, and the mean age in the present study (63 years) is comparable with that in previous studies involving similar populations of patients[4-6,18].

There is general consensus in the literature that lumbar fusion surgery stabilizes a mobile spondylolisthesis, but likely at the expense of accelerating adjacent segment degeneration[9]. In the present trial, both lumbar facet arthroplasty and fusion led to a reduction in the magnitude of spondylolisthesis, which was maintained longitudinally at 24 months postoperatively. Furthermore, both groups experienced a substantial improvement in all PROMs from baseline to 6 months postoperatively, consistent with a positive response to decompression of the neural elements during the index operation. However, although the arthroplasty group continued to demonstrate ongoing improvement in almost all PROMs from 6 to 24 months postoperatively, the fusion group demonstrated worsening in the ODI, VAS back pain, VAS leg pain, and all ZCQ component scores from 6 to 24 months postoperatively.

Previous attempts to address LSS with DS by decompression plus implantation of a motion-preserving dynamic stabilization device have been unsuccessful due to high rates of major adverse device events, pedicle screw loosening, and reoperation[26,27]. In the present trial, the rate of pedicle screw loosening was similar to reported rates of pedicle screw loosening in the literature following single-level lumbar fusion surgery[28,29]. No patient in the arthroplasty group experienced device breakage or disassembly during the study period. Small series of patients who underwent lumbar facet arthroplasty with the TOPS device in Europe have yet to demonstrate an instance of device breakage or disassembly up to 11 years postoperatively[16,30]. The long-term durability of lumbar facet arthroplasty devices remains unknown.

Limitations

The primary limitation of this study is the relatively short postoperative follow-up, which precludes evaluation of the long-term durability of lumbar facet arthroplasty. A second limitation is that industry funding was utilized to perform this study. Third, this study was unable to blind surgeons, patients, or radiologists to the patients' treatment allocation postoperatively. Therefore, detection bias is a distinct possibility. Fourth, the trial utilized strict inclusion and exclusion criteria to mitigate the impact of confounding variables on the outcomes reported; however, these strict criteria inadvertently narrow the applicability of these results in the broader cohort of patients with LSS. Fifth, fusion was assessed using radiographs rather than computed tomography, which may limit the sensitivity of fusion assessments. Finally, this study reports the primary outcome in only approximately one-half of the randomized sample; however, this is consistent with both the predetermined statistical plan and previous randomized controlled trials when there is a sufficiently large between-group difference at a preplanned interim analysis[24].

TABLE V Reoperations*

Patient ID	Surgery	Index Level	Adverse Event	Time from Index Surgery to Reoperation *(mo)*	Arthroplasty Device Removal	Surgical Outcome
1	Arthroplasty	L4-5	Retained drain	1.7	No	Removal of retained drain
2	Arthroplasty	L4-5	Worse LBP	6.6	Yes	Removal of TOPS and conversion to single-level posterolateral fusion
3	Arthroplasty	L4-5	Seroma	2.5	Yes	Wound exploration and TOPS removal
4	Arthroplasty	L4-5	Dural tear	0.6	Yes (replaced)	Removal of TOPS, dural repair, placement of new TOPS
			Persistent CSF leak	11.1	Yes (fusion)	Removal of TOPS, dural repair, conversion to single-level posterolateral fusion
			Persistent CSF leak, severe leg pain	11.5	NA	Wound exploration
			Pseudomeningocele	17.4	NA	Wound exploration and shunt implantation
5	Arthroplasty	L4-5	Unresolved pain	31.4	No	Spinal cord stimulator placement at T12-L2
6	Arthroplasty	L4-5	Bilateral pedicle screw loosening at L5	17.2	Yes	2-stage revision including removal of TOPS followed by ALIF at L4-5
7	Arthroplasty	L3-4	Wound infection	0.4	No	Irrigation and debridement
			Dural tear	0.9	Yes	Removal of TOPS, dural repair (with subsequent ALIF at L3-4)
8	Arthroplasty	L3-4	Hematoma	0.4	No	Hematoma evacuation
9	Arthroplasty	L4-5	Retained drain	0.1	No	Removal of retained drain
10	Arthroplasty	L4-5	Bilateral pedicle screw loosening at L4	13.8	Yes	Removal of TOPS, conversion to posterolateral fusion at L4-5
11	Arthroplasty	L4-5	Pedicle screw misplacement	0.2	No	Revision of L4 pedicle screws
12	Fusion	L4-5	Adjacent segment degeneration	10.0	–	Decompression at L3-4, extension of fusion to L3-5
			Pseudarthrosis at L3-4	25.3	–	Revision decompression and fusion at L3-5
13	Fusion	L4-5	Persistent neurologic symptoms	0.9	–	Revision decompression
14	Fusion	L4-5	Adjacent segment degeneration	20.4	–	Decompression at L5-S1, extension of fusion to L4-S1
			Adjacent segment degeneration	23.3	–	Decompression at L3-4, extension of fusion to L3-S1
15	Fusion	L4-5	Dural tear	0.4	–	Dural repair
16	Fusion	L4-5	Adjacent segment degeneration	4.5	–	Decompression at L5-S1, extension of fusion to L4-S1
17	Fusion	L4-5	Adjacent segment degeneration	23.0	–	Discectomy/decompression at L3-4
18	Fusion	L4-5	Adjacent segment degeneration	30.2	–	Decompression at L3-4, extension of fusion to L3-5
19	Fusion	L4-5	Interbody cage displacement	1.1	–	Revision interbody cage

*LBP = low back pain, TOPS = Total Posterior Spine System, NA = not applicable, CSF = cerebrospinal fluid, ALIF = anterior lumbar interbody fusion.

TABLE VI Radiographic Parameters*

	Arthroplasty		Fusion		
	N	Value	N	Value	P Value
Flexion-extension ROM *(deg)*					
Preop.	206	4.1 ± 3.1	92	4.5 ± 3.4	0.41
Month 12	149	3.9 ± 2.8	69	1.4 ± 0.8	<0.001
Month 24	105	3.9 ± 2.9	43	1.2 ± 0.8	<0.001
Δ, preop. to 12 months		−0.1 ± 3.4		−2.9 ± 2.9	<0.001
Δ, preop. to 24 months		0.0 ± 3.3		−3.0 ± 2.9	<0.001
P value†		0.93		<0.001	
Flexion-extension translation *(mm)*					
Preop.	206	1.0 ± 0.8	91	1.2 ± 1.2	0.10
Month 12	148	0.9 ± 0.9	68	0.3 ± 0.3	<0.001
Month 24	105	0.9 ± 1.0	43	0.2 ± 0.3	<0.001
Δ, preop. to 12 months		−0.1 ± 1.1		−0.9 ± 1.2	<0.001
Δ, preop. to 24 months		−0.1 ± 1.2		−0.8 ± 0.7	<0.001
P value†		0.28		<0.001	
Lateral bending ROM *(deg)*					
Preop.	206	3.2 ± 2.6	90	3.5 ± 2.8	0.43
Month 12	148	3.5 ± 2.4	66	1.1 ± 1.1	<0.001
Month 24	102	3.5 ± 2.8	40	0.8 ± 0.9	<0.001
Δ, preop. to 12 months		0.4 ± 2.9		−2.2 ± 1.9	<0.001
Δ, preop. to 24 months		0.3 ± 3.5		−2.2 ± 1.8	<0.001
P value†		0.41		<0.001	
Lumbar lordosis *(deg)*					
Preop.	206	40.8 ± 9.7	92	38.7 ± 8.6	0.08
Month 12	148	38.9 ± 9.9	69	37.4 ± 9.4	0.24
Month 24	105	45.2 ± 8.6	43	40.8 ± 8.4	0.01
Δ, preop. to 12 months		−1.7 ± 5.4		−1.3 ± 6.3	0.64
Δ, preop. to 24 months		5.9 ± 5.6		5.6 ± 5.6	0.78
P value†		<0.001		<0.001	
Spondylolisthesis‡ *(mm)*					
Preop.	206	−4.8 ± 2.4	92	−4.0 ± 2.6	0.007
Postop.§	148	−3.2 ± 2.6	69	−1.7 ± 2.3	<0.001
Month 24	105	−3.8 ± 3.1	43	−2.5 ± 2.6	0.02
Δ, preop. to postop.		1.6 ± 2.0		2.1 ± 1.9	0.07
Δ, preop. to 24 months		0.8 ± 2.2		1.4 ± 2.0	0.17
P value†		<0.001		<0.001	

*Values are given as the mean ± standard deviation unless otherwise noted. ROM = range of motion, Δ = change. †Within-group comparison between preoperatively and 24 months postoperatively. ‡Anterolisthesis is denoted by negative values; retrolisthesis and reduction in anterolisthesis are denoted by positive values. §Postoperative radiographs were obtained during the index hospitalization.

Conclusions

The present study demonstrated that decompression plus lumbar facet arthroplasty was associated with superior PROMs across multiple metrics, lower rates of new or progressive neurologic symptoms, and lower rates of symptomatic adjacent segment degeneration, equating to higher rates of composite clinical success, compared with decompression plus fusion, at 24 months postoperatively. Long-term follow-up will be necessary to determine differences in implant longevity, PROMs, and radiographic parameters such as stability of the spondylolisthesis and maintenance of motion beyond 2 years. A future randomized controlled trial may be considered to compare lumbar facet arthroplasty versus decompression alone in a broader sample of patients.

Appendix

eA Supporting material provided by the authors is posted with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJS/H985, http://links.lww.com/JBJS/H986). ■

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