A commentary by Daniel G. Tobert, MD, is linked to the online version of this article.

Clinical Outcomes After 1 and 2-Level Lumbar Total Disc Arthroplasty

1,187 Patients with 7 to 21-Year Follow-up

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Background: In this study, we expand the supportive evidence for total disc arthroplasty (TDA) with results up to 21 years in a large patient cohort who received a semiconstrained ball-and-socket lumbar prosthesis. The objectives of the study were to compare the results for 1 versus 2-level surgeries and to evaluate whether prior surgery at the index level(s) impacts clinical outcomes.

Methods: From 1999 to 2013, 1,187 patients with chronic lumbar degenerative disc disease (DDD) underwent lumbar TDA, of whom 772 underwent a 1-level procedure and 415 underwent a 2-level procedure. A total of 373 (31.4%) of the 1,187 patients had prior index-level surgery. Patients were evaluated preoperatively; at 3, 6, 12, 18, and 24 months postoperatively; and yearly thereafter. The follow-up duration ranged from 7 to 21 years (mean, 11 years and 8 months). Collected data included radiographic, neurological, and physical assessments, as well as self-evaluations using the Oswestry Disability Index (ODI) and visual analog scale (VAS) for back and leg pain. Perioperative data points, complication rates, and reoperation or revision rates were also assessed. Patients were divided into 4 groups: 1-level TDA with no prior surgery at the index level, 1-level TDA with prior surgery, 2-level TDA with no prior surgery, and 2-level TDA with prior surgery.

Results: All groups showed dramatic reduction in the ODI at 3 months postoperatively and maintained these scores over time. Although VAS pain did not diminish to its final level as rapidly for patients with prior surgery, there was no significant difference between the groups in terms of pain reduction at 24 months postoperatively. Of 1,187 patients, 49 (4.13%) required either a new surgery at another level or revision or reoperation at the index level. Rates were too low in all groups to compare them statistically. Total TDA revision and adjacent-level surgery rates over 7 to 21 years were very low (0.67% and 1.85%, respectively).

Conclusions: This study demonstrates the robust long-term clinical success of 1 and 2-level lumbar TDA as assessed at 7 to 21 years postoperatively in one of the largest evaluated cohorts of patients with TDA. Patients had dramatic and maintained reductions in disability and pain scores over time and low rates of index-level revision or reoperation and adjacent-level surgery relative to published long-term fusion data. Additionally, patients who underwent 1-level lumbar TDA and those who underwent 2-level TDA demonstrated equivalent improvement, as did patients with prior surgery at the index level and those with no prior surgery.

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

For decades, total joint arthroplasty has been the surgical standard of care for patients with chronic, debilitating joint disease. Surgical fusion of large joints is now rarely performed, being used only as a last alternative and never as the primary treatment choice. Total disc arthroplasty (TDA) for back pain associated with degenerative disc disease (DDD),

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however, lagged decades behind for reasons such as concerns over the safety and longevity of motion-restoring devices as well as a belief that the levels adjacent to the fusion site will compensate for the loss of motion at the fused level. Improvements in surgical techniques and implant design fueled the rapid expansion of fusion procedures for the treatment of DDD, including in patients with recurrent disc herniation, post-discectomy syndrome, and/or multilevel pathology.

However, less-than-perfect lumbar spinal fusion rates have been shown to contribute to poorer outcomes and relatively high rates of complications, including pseudarthrosis[1], device failure[2], and post-fusion comorbidities[3]. Research has shown that fusion also reduces spinal mobility and affects the natural instantaneous adaptation of the spine to position changes, including spinal balance[4-7]. Multiple studies have also clearly shown that fusion is associated with accelerated degeneration and symptomatic disease at adjacent levels, which ultimately leads to high reoperation rates[8-11]. These and other similar reports, however, did not slow the exponential growth of spinal fusion. Instead, what should have been a last-choice surgical treatment became a "gold standard" procedure.

Nevertheless, motion-preserving devices showed early success during this period[12], with the promise of mitigating the aforementioned key issues associated with fusion while enabling the restoration of lumbar mobility in flexion-extension, lateral bending, and axial rotation. In 2005, Tropiano et al. reported the 7 to 11-year outcomes of 64 patients who underwent first-generation lumbar disc replacement with the prodisc I (J.B.S., Troyes, France) between 1990 and 1993[13,14]. The authors demonstrated significant early and long-lasting reduction in disability and in back and leg pain and reported good or excellent results (using the modified Stauffer-Coventry score[15]) in 78% of patients, with no evidence of loosening, migration, or implant failure. In the same cohort, Huang et al. demonstrated the quality of long-term flexion-extension mobility at the operative levels and a clear relationship between motion restoration and preservation of the adjacent levels over an 8-year period[16,17]. The device was improved in 1999, although the mechanism of action—a semiconstrained ball-and-socket joint with a fixed polyethylene core and center of rotation—remained the same. The second-generation implant was released to expanded clinical usage, which allowed a new study by the Montpellier Spine Institute (Centre de Chirurgie Vertébrale de Montpellier)[18]. In 2001, the device was entered into U.S. Food and Drug Administration Investigational Device Exemption (IDE) studies comparing 1 and 2-level arthroplasty to 360° fusion.

The U.S. IDE studies showed excellent patient-reported outcomes and a lower reoperation rate at both the index and adjacent levels. Zigler et al. reported that the rate of adjacent segment degeneration at 5 years after TDA was dramatically lower than that after fusion[19-21]. Delamarter et al.[22] and Hannibal et al.[23] reported similar results for 2-level DDD and showed no significant difference between 1 and 2-level surgeries. Bertagnoli et al.[24] and Trincat et al.[25] confirmed the clinical success of 1 and 2-level TDA over 5 to 7 years of follow-up. Somewhat unexpectedly, many of these studies also showed that patients with a prior discectomy or post-discectomy syndrome had equivalent outcomes to patients without prior posterior discectomy[22-24].

The breadth of publications and the quality of the results provide strong evidence that lumbar TDA is superior to fusion for the treatment of lumbar degenerative disease[26], that it is as effective in treating 2-level disease as it is for 1-level disease, and that it is effective for patients with failed or repeated prior discectomy. However, long-term published data are limited, which has affected the wider acceptance of lumbar TDA. The present study was designed to present the clinical outcomes of patients with or without a prior discectomy at the index level(s) who underwent 1 or 2-level TDA for DDD and had long-term follow-up between 7 and 21 years. The objectives of this study were to determine if there were differences in outcomes between patients who underwent 1 versus 2-level TDA as well as between patients with no prior surgery versus those with a prior discectomy. This study of the data of 1,187 patients covered all eligible 1 and 2-level TDAs performed at a single institution.

Materials and Methods

Between December 16, 1999, and December 16, 2013, a total of 2,251 patients received 3,763 TDAs with the prodisc L (Centinel Spine LLC, West Chester, PA; Fig. 1) at 1 to 5 levels. Those with chronic lumbar DDD who received a disc replacement at 1 or 2 levels (1,187 patients) were included in this retrospective study, comprising 772 patients who underwent 1-level TDA and 415 patients who underwent 2-level TDA (a total of 1,602 prostheses). The remaining 1,064 patients had >2-level TDA, prior fusion at an adjacent level, or other indications (stenosis, degenerative spondylolisthesis, hybrid constructs) and were excluded from the study.

In this cohort, TDA was a primary surgery for 550 patients undergoing 1-level TDA and for 264 patients undergoing 2-level TDA. Another 222 patients undergoing 1-level

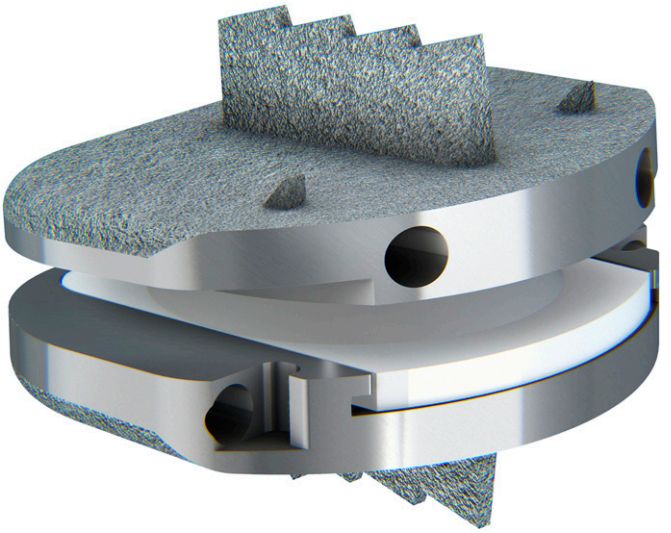

Fig. 1
Prodisc L. Reproduced with permission of Centinel Spine.

TABLE I Patient Demographics*

	Group 1 (1L/NPS)	Group 2 (1L/PS)	Group 3 (2L/NPS)	Group 4 (2L/PS)
Total no. of patients	550	222	264	151
Sex *(no. of patients)*				
Male	274	117	141	90
Female	276	105	123	61
Age *(yr)*				
Mean ± SD	42 ± 9.85	42 ± 8.66	45 ± 10.31	45 ± 9.67
Range	17-86	23-67	19-73	23-71
Weight *(kg)*				
Mean ± SD	71 ± 13.28	71 ± 13.2	74 ± 13.88	76 ± 13.96
Range	40-120	46-108	42-115	48-108
Height *(cm)*				
Mean ± SD	170 ± 9.11	171 ± 9.13	171 ± 8.56	173 ± 9.16
Range	147-203	150-193	153-198	153-193

*1L = 1-level, NPS = no prior surgery, PS = prior surgery (discectomy), 2L = 2-level, SD = standard deviation. All groups demonstrated equivalent demographic characteristics.

TDA and 151 patients undergoing 2-level TDA had previously undergone an operation and presented with recurrent disc herniation or post-discectomy syndrome. Patients were stratified into 1-level (1L) and 2-level (2L) groups and then divided into subgroups according to whether they had no prior surgery (NPS) or prior surgery (PS) at the index level (Table I). Patient demographics were comparable for all groups (Table I). Inclusion and exclusion criteria are presented in Table II; surgical inclusion and exclusion criteria remained the same throughout the study.

All patients who underwent 1 or 2-level TDA had had long-standing back pain (i.e., for a minimum of 2 years). Leg pain was more recent and was present with or without disc herniation. Patients in all groups had higher preoperative visual analog scale (VAS) scores for back pain than for leg pain. All patients had undergone a minimum of 6 months of conservative treatment without success. Patients included in the PS groups (Groups 2 and 4) had a medical history of a prior discectomy for disc herniation.

The indication for surgery was determined using clinical information, radiographs, magnetic resonance imaging (MRI), and, when necessary (for female patients ≥50 years old and male patients ≥60 years old), a bone density evaluation with a T-score cutoff of <−1 on dual x-ray absorptiometry (DXA) indicating the absence of osteopenia or osteoporosis. Radiographic assessment included full-length standing images and dynamic flexion-extension radiographs[27]. Figures 2 through 5 illustrate the radiographic assessments for Patient 1 (Group 1 [1L/NPS]) and Patient 2 (Group 4 [2L/PS]).

The TDA implantation statistics per year for all included patients with 1 or 2-level TDA are presented in Table III. All surgeries were performed with use of an anterior mini-open

TABLE II Inclusion and Exclusion Criteria*

Inclusion	Exclusion
DDD in 1 or 2 contiguous levels at L3-S1	DDD at >2 levels
Low back pain for >2 years	Prior fusion, below long fusion (scoliosis), hybrid construct
Failure of ≥6 months of conservative therapy	Prior laminectomy or complete facetectomy
ODI of ≥40%	Substantial facet degeneration, intracanal hypertrophy or osteophytes, or osseous stenosis
Back pain with or without leg pain	Degenerative spondylolisthesis >grade 1 or isthmic spondylolisthesis
Diagnosis confirmed radiographically	Osteoporosis or osteopenia (T-score <−1.0)
With or without prior discectomy and/or incomplete facetectomy	Metabolic disease, cancer, or infection
Anterior access possible (as shown on an angiogram)	Anterior access impossible

*DDD = degenerative disc disease, ODI = Oswestry Disability Index.

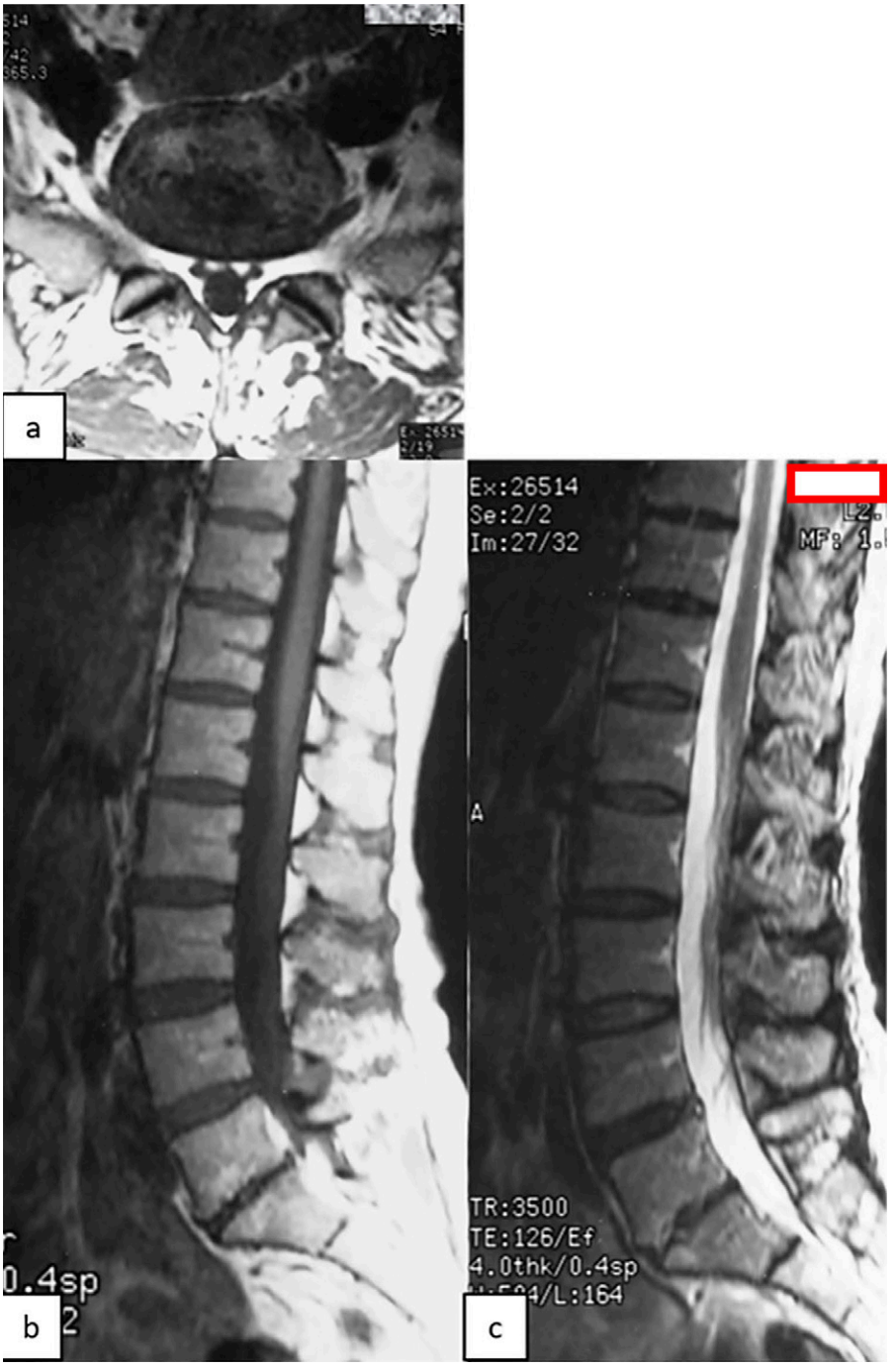

Fig. 2

Figs. 2-A, 2-B, and 2-C Patient 1. Female, 55 years of age, who underwent a 1-level disc replacement (Group 1: 1L/NPS) at L5-S1 in 1999. Preoperative T1 and T2-weighted MRI scans showing no root compression and no disc herniation, facets with limited degeneration, and no foraminal stenosis. The scans indicate L5-S1 collapse, cartilage damage, Modic type 2, retraction of the longitudinal ligament, and no bulging. A black disc can be seen at L4-L5.

retroperitoneal approach, as described by Tropiano et al.[14]. Postoperative management protocols evolved over 20 years following the global progress around surgical procedures (e.g., anesthesia, shorter hospital stay, pain management, faster return to activity).

Patients were evaluated preoperatively; at 3, 6, 12, 18, and 24 months postoperatively; and yearly thereafter. The follow-up duration ranged from 7 to 21 years (mean, 140 months; Table IV). Collected data included radiographic, neurological, and physical assessments, as well as self-evaluations using the

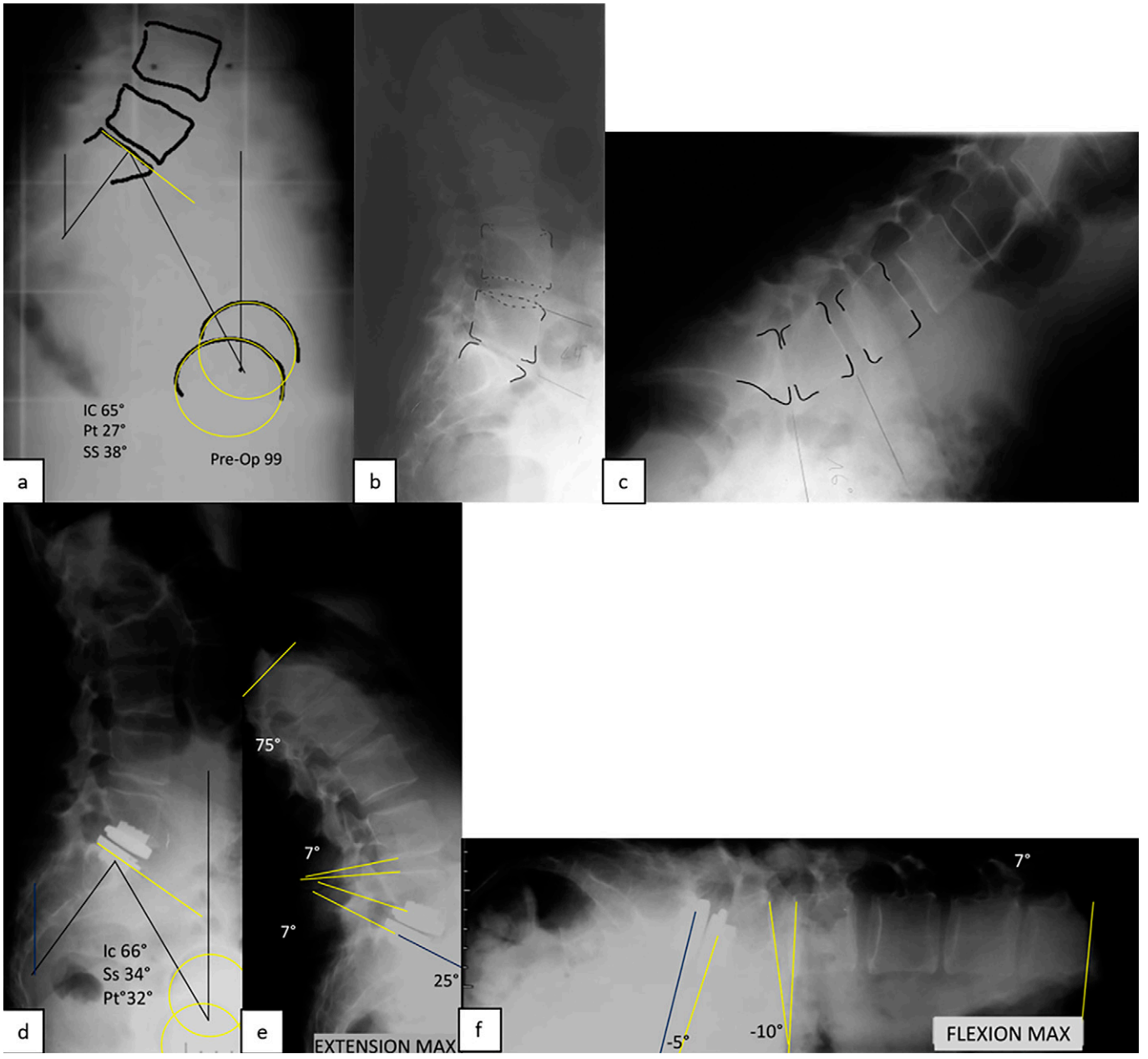

Fig. 3

Figs. 3-A through 3-F Patient 1. L5-S1 disc replacement (Group 1: 1L/NPS) with 21-year follow-up. Comparison of preoperative and 21-year postoperative motion. **Fig. 3-A** Preoperative pelvic parameters: incidence (IC), 65°; pelvic tilt (Pt), 27°; sacral slope (SS), 38°. **Figs. 3-B and 3-C** Preoperative extension: L4-L5, 8°; L5-S1, 2°; lordosis, 60°. Preoperative flexion: L4-L5, 5°; L5-S1, 2°; lordosis, 30°; sacral slope, 75°. Preoperative range of motion: L5-S1, 0°; L4-L5, 3°; lumbar, 30°; pelvic, 37°, L1 race (the angle between L1 extension and L1 flexion), 85°. **Fig. 3-D** Postoperative pelvic parameters: incidence (Ic), 66°, sacral slope (Ss), 34°; pelvic tilt (Pt), 32°. **Figs. 3-E and 3-F** Postoperative extension: L4-L5, 7°; L5-S1, 7°; lordosis, 75°; sacral slope, 25°. Postoperative flexion: L4-L5, −10°; L5-S1, −5°; lordosis, 7°; sacral slope, 104°. Postoperative range of motion: L4-L5, 17°; L5-S1, 12°; lumbar, 68°; pelvic (SS in flexion − SS in extension), 79°; L1 race, 135°.

Oswestry Disability Index (ODI) and VAS for back and leg pain. Perioperative data points, complication rates, and reoperation or revision rates were also assessed.

Statistical analysis was performed with use of the analysis of variance (ANOVA) homogeneity test to assess preoperative-to-postoperative evolution and to determine the potential differences ($p < 0.05$) or equivalences ($p > 0.05$) between the groups.

Results

The mean preoperative ODI was 48 in Group 1 (1L/NPS), 52 in Group 2 (1L/PS), 50 in Group 3 (2L/NPS), and 52 in

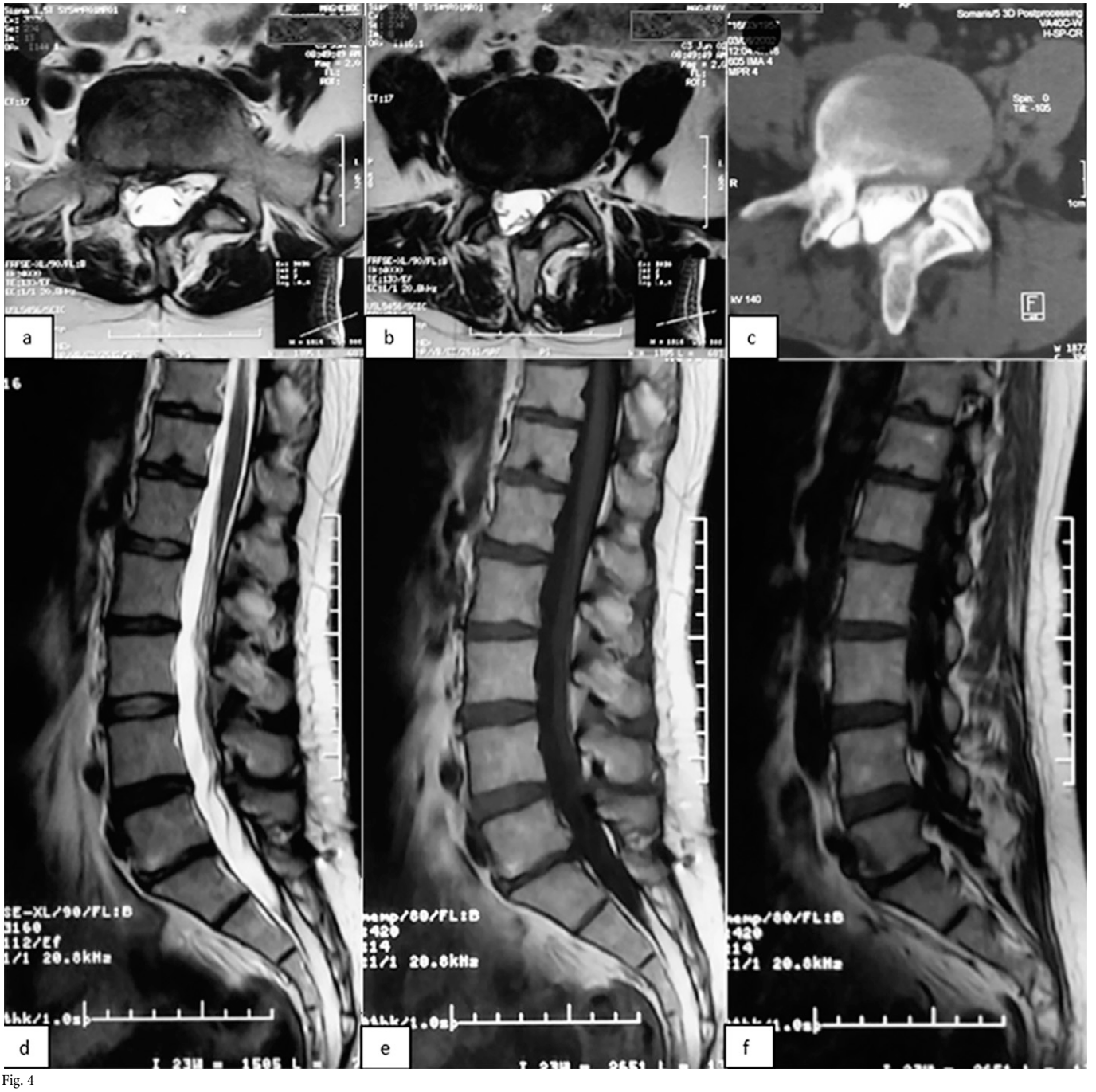

Fig. 4

Figs. 4-A through 4-F Patient 2. Female, 45 years of age, with a prior L5-S1 laminotomy who underwent 2-level surgery in the present study (Group 4: 2L/PS). The patient had had low back pain for 10 years and leg pain for 7 years. **Figs. 4-A, 4-B, 4-D, 4-E, and 4-F** Preoperative MRI scans showing compression on the right side, a black collapsed disc at L4-L5, and T1 and T2 signal hyperintensity (early Modic type 2). **Fig. 4-C** Preoperative computed tomography myelogram showing foraminal compression and a right-sided partial facet defect.

Group 4 (2L/PS). All groups experienced progressive improvement at 3 months postoperatively, with Group 1 demonstrating the fastest rate of decrease (i.e., improvement) in the ODI. Group 4 had the slowest rate of decrease. At 3 months, the percentage of reduction in the ODI was 45% in Group 1, 38% in Group 2, 36% in Group 3, and 31% in Group 4.

At the first postoperative evaluation, the difference in the ODI between Group 1 and Group 4 was significant ($p = 0.0148$, Fisher least significant difference test; Fig. 6). However, at 24 months postoperatively and thereafter, Groups 2, 3, and 4 had equivalent results to Group 1 (i.e., no significant difference; $p > 0.05$), demonstrating a delay in recovery for Group 4 (Table V).

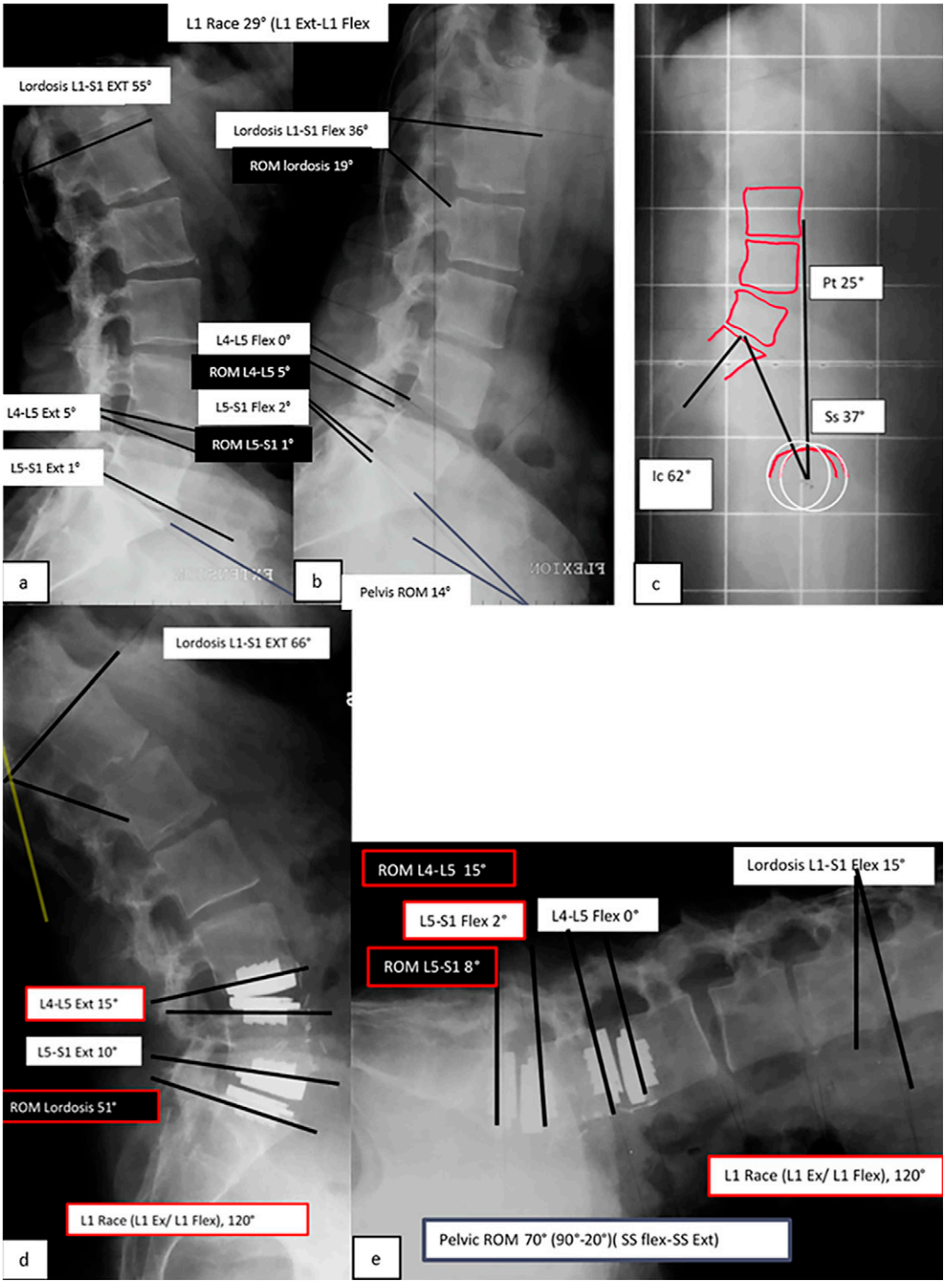

Fig. 5

Figs. 5-A through 5-E Patient 2. L5-S1 disc replacement (Group 4: 2L/PS) with 14-year follow-up. Comparison of preoperative and 14-year postoperative motion. Preoperative ODI and pain scores: ODI, 35; VAS back pain, 7.5; VAS leg pain, 4. Postoperative scores: ODI, 1; VAS back pain, 0; VAS leg pain, 0. **Figs. 5-A and 5-B** Preoperative extension (Ext): L5-S1, 1°; L4-L5, 5°; lordosis, 55°. Preoperative flexion (Flex): L5-S1, 2°; L4-L5, 0°; lordosis, 36°. Preoperative range of motion (ROM): L5-S1, 1°; L4-L5, 5°; lordosis, 19°; L1 race (the angle between L1 extension and L1 flexion), 29°. **Fig. 5-C** Preoperative pelvic parameters: incidence (Ic), 62°; sacral slope (Ss), 37°; pelvic tilt (Pt), 25°. **Figs. 5-D and 5-E** Postoperative extension: L5-S1, 10°; L4-L5, 15°; lordosis, 66°. Postoperative flexion: L5-S1, 2°; L4-L5, 0°; lordosis, 15°. Postoperative range of motion: L5-S1, 8°; L4-L5, 15°; lordosis, 51°; pelvic (SS [sacral slope] in flexion − SS in extension), 70°; L1 race, 120°.

TABLE III TDA Implantation Statistics per Year (1999 to 2013)*

	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	Total
Total patients																
1-level surgery†	1	10	29	35	49	49	40	55	67	69	52	52	47	84	133	772
2-level surgery‡	0	3	7	30	22	39	60	53	85	52	20	11	7	12	14	415
Total implants	1	16	43	95	93	127	160	161	237	173	92	74	61	108	161	1,602

*In 2009, the number of 2-level surgeries decreased due to reimbursement reasons. In 2012, the number of 1-level surgeries grew as a result of full 1-level reimbursement. Procedures were performed by 1 senior surgeon from 1999 to 2003, by 2 surgeons from 2004 to 2011, and by 3 surgeons from 2012 to 2013. †Comprises patients in Groups 1 and 2. ‡Comprises patients in Groups 3 and 4.

The percentage of improvement in the ODI between the preoperative evaluation and the last follow-up for each patient (ranging from 7 to 21 years) was 54% in Group 1, 57% in Group 2, 52% in Group 3, and 50% in Group 4. Improvement in the ODI (from the preoperative evaluation to the last follow-up) was 26 points in Groups 1, 2, and 3 and 24 points in Group 4.

VAS back pain scores decreased in all groups. The percentage of improvement at 24 months was high: 60% in Group 1, 58% in Group 2, 59% in Group 3, and 52% in Group 4 (Fig. 7). Mean preoperative (baseline) VAS values for leg pain (Fig. 8) were not as high as those for back pain because radicular compression or irritation, while present, was not the primary source of pain. The highest baseline score was 6.5, in Group 2, and took 12 months to drop to a final score of 2.6, at which point it reached equivalence with the scores in the other groups ($p > 0.05$). The percentage of improvement between the preoperative time point and the 24-month follow-up remained superior, in the range of 50% to 60%, in all groups for all measures until the last follow-up (Fig. 9).

The rates of revision or reoperation and new surgery were low (and too low for statistical comparisons) and involved only 49 (4.13%) of the 1,187 patients (Table VI). Ten patients required posterior decompression. Nine patients underwent reoperation for hematoma or surgical wound complication. Eight patients (0.67%) required revision of the implant at the index level: 1 underwent posterior fusion, 4 underwent a new disc implantation, and 3 underwent anterior lumbar interbody fusion. Most of the revisions at the index level were in Group 1 and occurred during the earliest part of the clinical series due to mis-centering, vertebral body fracture, or an unlocked polyethylene core. Twenty-two (1.85%) of the 1,187 patients had undergone a new surgery at the adjacent level by the time of the last follow-up.

Discussion

The surgical treatment of intractable back pain associated with lumbar DDD took a revolutionary turn in 1990 with the introduction of TDA. At that time, there were several unanswered questions regarding TDA, specifically in terms of device and surgical safety, the efficacy of TDA in treating low back pain, the capacity of TDA to treat associated leg pain, the value of the procedure for not only 1 level but also multiple levels, and the effectiveness of TDA after an unsuccessful discectomy. As a total joint replacement procedure, the longevity of both the device and the clinical results was also an essential question. Preservation of the adjacent levels after TDA also had yet to be proven through a long-term follow-up study.

The first medium-term follow-up analysis by Tropiano et al.[13] and the radiographic results reported by Huang et al.[16] answered the first question, demonstrating that the device and the procedure are safe and effective. Multiple studies have confirmed these findings[24,28,29]. For the remaining questions, Huang et al. demonstrated that restoring mobility has a direct correlation with the quality of the clinical outcomes and protection of the adjacent levels[17]. Zigler et al. confirmed that the adjacent levels were protected after TDA at 5 years of follow-up[21]. During the last 20 years, Delamarter et al.[22] and Trincat et al.[25] demonstrated that the results of 2-level TDA were superior to those of 2-level fusion. These studies also demonstrated equivalent results between 1 and 2-level TDA.

TABLE IV Follow-up Rates from 3 to 84 Months and in the Long Term (Up to 252 Months)

	Postop. Follow-up in Months						
	3	6	12	24	84	140*	252
Patient cohort	1,187	1,187	1,187	1,187	1,187	890	14
Patients with completed follow-up	1,172	1,162	1,112	1,068	992	644	9
Percent follow-up	98.7	97.9	93.7	90.0	83.6	72.4	64.3

*Mean follow-up (11 years and 8 months).

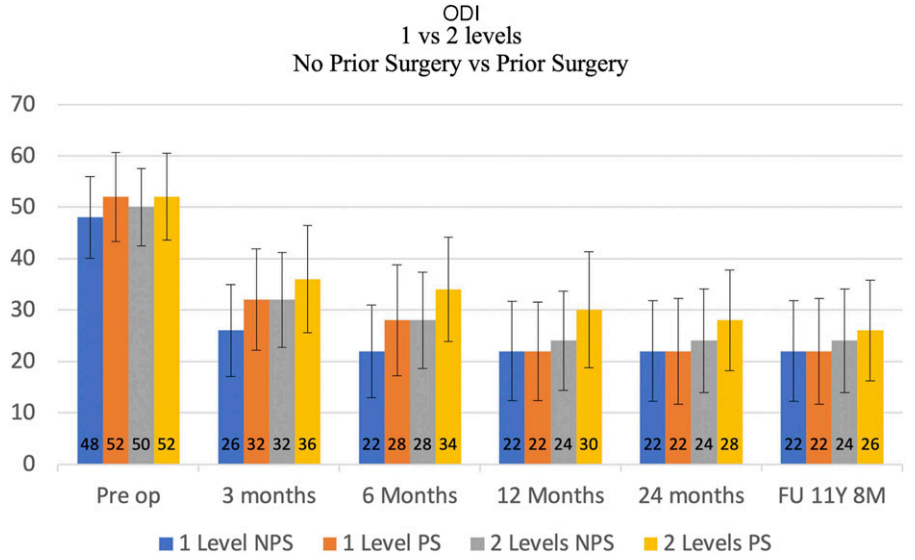

Fig. 6

Bar graph showing the preoperative and postoperative ODI values in each group. The bar represents the mean and the whiskers represent the standard deviation. The graph shows the evolution of the difference in scores between Group 1 (1L/NPS) and Group 4 (2L/PS): their scores were significantly different from 3 to <24 months and equivalent thereafter. FU = follow-up.

TABLE V Preoperative and Postoperative ODI and VAS Pain Scores*

	Preop.	Postop.				
		3 Months	6 Months	12 Months	24 Months	Mean 11 Years 8 Months
ODI						
Group 1 (1L/NPS)	48 ± 8.0	26 ± 8.9	22 ± 9.0	22 ± 9.7	22 ± 9.7	22 ± 9.7
Group 2 (1L/PS)	52 ± 8.7	32 ± 9.8	28 ± 10.8	22 ± 9.6	22 ± 10.3	22 ± 10.3
Group 3 (2L/NPS)	50 ± 7.6	32 ± 9.2	28 ± 9.4	24 ± 9.6	24 ± 10.0	24 ± 10.0
Group 4 (2L/PS)	52 ± 8.4	36 ± 10.4	34 ± 10.2	30 ± 11.3	28 ± 9.8	26 ± 9.8
P value†		0.37†	0.27†	0.94†	0.52	0.45
VAS back pain						
Group 1 (1L/NPS)	6.8 ± 2.3	2.7 ± 2.5	2.6 ± 2.5	2.6 ± 2.6	2.7 ± 2.7	2.5 ± 2.5
Group 2 (1L/PS)	6.7 ± 2.6	3.0 ± 2.6	3.2 ± 2.8	2.4 ± 2.4	2.8 ± 2.8	2.6 ± 2.6
Group 3 (2L/NPS)	7.0 ± 2.2	2.8 ± 2.3	3.0 ± 2.3	2.7 ± 2.6	2.9 ± 2.6	2.8 ± 2.6
Group 4 (2L/PS)	6.9 ± 2.1	2.7 ± 2.5	3.0 ± 2.6	2.5 ± 2.5	3.3 ± 2.9	3.1 ± 2.9
P value†		0.22	0.29	0.44	0.97	0.82
VAS leg pain						
Group 1 (1L/NPS)	5.4 ± 3.1	2.4 ± 2.4	2.1 ± 2.1	2.3 ± 2.3	2.3 ± 2.3	2.2 ± 2.2
Group 2 (1L/PS)	6.5 ± 3.0	3.9 ± 3	3.2 ± 3.1	2.5 ± 2.5	2.7 ± 2.6	2.6 ± 2.5
Group 3 (2L/NPS)	5.4 ± 3.1	3.2 ± 2.9	2.6 ± 2.6	2.6 ± 2.6	2.6 ± 2.5	2.5 ± 2.5
Group 4 (2L/PS)	5.8 ± 2.9	3.2 ± 2.8	3.3 ± 3.1	3.0 ± 2.8	3.0 ± 2.9	2.9 ± 2.8
P value†		0.87†	0.91†	0.99†	0.94	0.92

*1L = 1-level, NPS = no prior surgery, PS = prior surgery (discectomy), 2L = 2-level. Values are given as the mean ± standard deviation. †ANOVA using several mean independent samples. For the postoperative scores, an intergroup ANOVA (1L/NPS versus 1L/PS versus 2L/NPS versus 2L/PS) was performed. ‡Differences were found in ODI and VAS leg pain only between Group 1 (1L/NPS) and Group 4 (2L/PS) from 3 to 12 months of follow-up (as shown by the Fisher least significant difference test at 3 months; $p = 0.0148$), but these differences disappeared at 24 months, at which point all groups had equivalent results ($p > 0.05$).

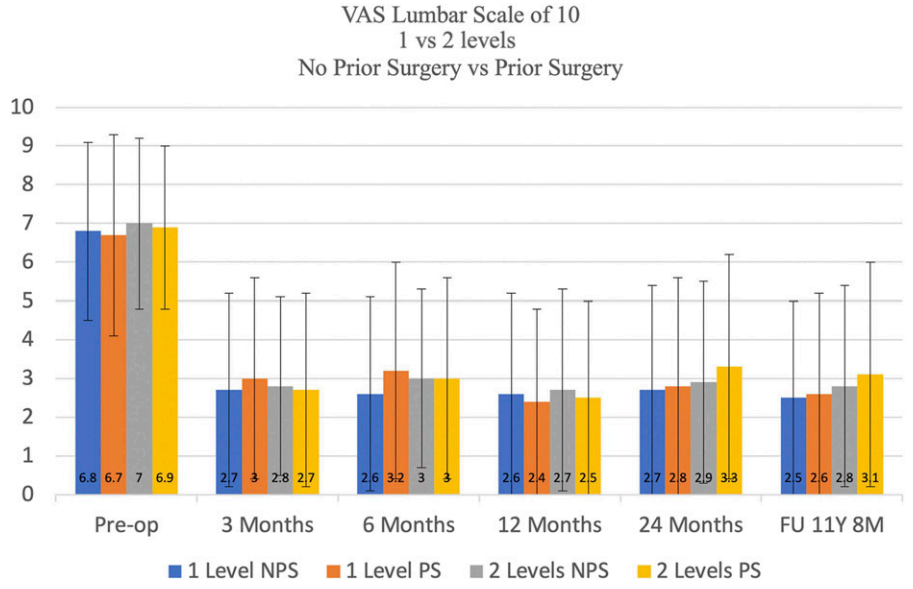

Fig. 7

Bar graph showing the preoperative and postoperative VAS back pain scores in each group. The bar represents the mean and the whiskers represent the standard deviation. A dramatic and immediate reduction in VAS back pain scores was demonstrated at 3 months postoperatively. FU = follow-up.

In cases of recurrent disc herniation, anterior transdiscal decompression is a true salvage procedure; unlike posterior decompression, the anterior approach enables decompression of the nerve without traction and thus avoids causing additional surgical injury. Further, removing all of the degenerated disc material avoids chemical toxicity in the roots from acidic disc degeneration, cytokines, and prostaglandin-B toxicity. These advantages point to the efficacy of the transdiscal approach for recurrent decompression.

In the IDE studies of 1 and 2-level TDA with prodisc[21,22], a positive result with respect to ODI improvement was considered to be a change of ≥15%. Those studies led the U.S. Food and Drug Administration to approve prodisc for 1 and 2-level surgery. In the present study, the mean percentage of improvement was between 50% and 60% in all groups for each of the 3 criteria (ODI, VAS back pain, and VAS leg pain), which is comparable with the IDE study.

The other goal of the present study was to compare the results between patients with or without disc herniation who had not previously undergone surgery and patients who had previously undergone surgery and presented with recurrent

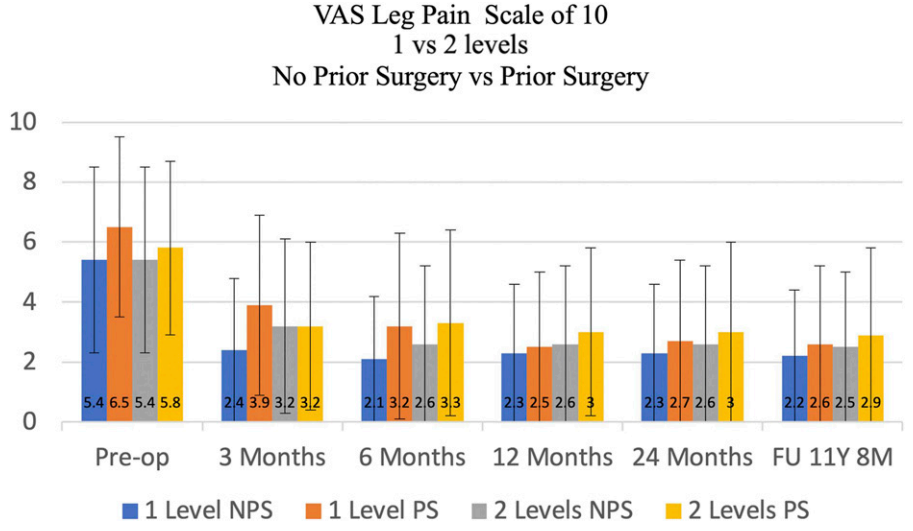

Fig. 8

Bar graph showing the preoperative and postoperative VAS leg pain scores in each group. The bar represents the mean and the whiskers represent the standard deviation. VAS leg pain scores were reduced immediately (at 3 months postoperatively), especially in Group 1, thereby confirming the efficacy of TDA as a primary procedure for 1-level DDD with disc herniation. Neurological compression after prior discectomy delays recovery. FU = follow-up.

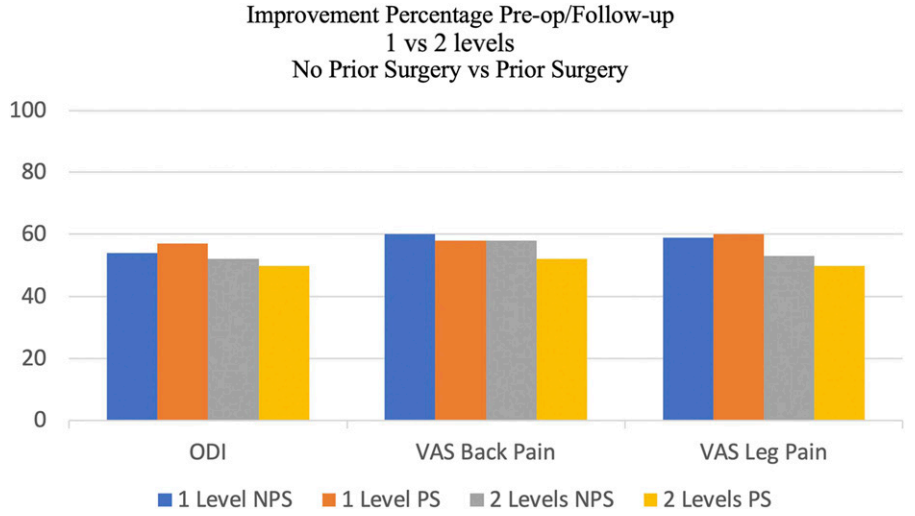

Fig. 9

Bar graph showing the percentage of improvement in the ODI, VAS back pain, and VAS leg pain between the preoperative time point and 24-month follow-up for each group. All groups had improvement of between 50% and 60%.

disc herniation and/or post-discectomy syndrome. As stated in the Results section, we found no difference at the time of the last follow-up between Groups 1, 2, and 3 and a small, non-significant difference between Groups 1 and 4 ($p > 0.05$).

We also confirmed that restoring mobility protects the adjacent levels, as there were only 22 new, adjacent-level surgeries by the time of the final follow-up (1.85% of patients). This finding, the lowest rate published, strengthens previously published evidence[29] and is comparable with the 5-year results of the pivotal IDE study, which demonstrated that the rate of adjacent-level surgery in a fusion cohort was twice that of a TDA cohort[21].

Markwalder et al.[30] reported the long-term results of TDA as a primary treatment for patients with combined long-standing DDD and recent disc herniation without an intermediate posterior discectomy. Our study data for Groups 1 and 3, who presented with herniation without prior surgery, conform with the statement by Markwalder et al. that "patients with long history of discogenic LBP [low back pain] and recent disc herniation have a better result with TDA."[30]

There were preconceived ideas regarding TDA and specifically the prodisc L implant that were debunked in the present study. First, we found that the fixed-core design of the disc provided long-term implant survivorship, as was also noted by Park et al.[31], who reported no device failure over a 10-year period. Second, this design and the mobility that it provided protected the adjacent levels in the long term, which contrasts with the findings reported for fusion in the literature as was described by Zigler et al. in their 5-year follow-up study[28]. TDA at 2 levels had equivalent results to TDA at 1 level over the long term, confirming the results of the 1 and 2-level IDE studies already published[17,20]. TDA may be safely and effectively utilized in patients with recurrent disc herniation or post-discectomy syndrome: the long-term results for both 1 and 2-level procedures in these patients were equivalent to those in patients who did not have a prior surgery. On this point, we found that

TABLE VI Revisions and New Surgeries*

Surgery Type	Group 1 (1L/NPS) (N = 550)	Group 2 (1L/PS) (N = 222)	Group 3 (2L/NPS) (N = 264)	Group 4 (2L/PS) (N = 151)	Total
Laminectomy/posterior decompression	1 (0.18%)	0 (0.00%)	5 (1.89%)	4 (2.65%)	10
Revision TDA, same level	6 (1.09%)	1 (0.45%)	0 (0.00%)	1 (0.66%)	8
Surgical wound complication or hematoma	1 (0.18%)	1 (0.45%)	5 (1.89%)	2 (1.32%)	9
New surgery, adjacent level†	7 (1.27%)	8 (3.60%)	3 (1.09%)	4 (2.65%)	22

*1L = 1-level, NPS = no prior surgery, PS = prior surgery (discectomy), 2L = 2-level. Values are given as the number of patients, with the percentage of patients in parentheses. Percentages are expressed relative to the subgroup population. †Adjacent-level degeneration requiring surgery occurred at a higher rate in the PS groups (Groups 2 and 4) than in the NPS groups (Groups 1 and 3).

patients in the PS groups had a longer delay in recovery with respect to leg pain but still achieved a similar, reduced level of pain as patients in the NPS groups at 12 months. The percentage of patients who underwent index-level revision was 0.67%, the lowest rate published, with most of those patients undergoing revision during the first years of the study.

We defined 5 fundamental technical rules that align with the conclusions of Park et al.[31], who experienced a challenging learning curve (an implant-related complication rate of 9.3%): (1) adequate bone quality (DXA T-score ≥−1.0) is important, (2) the implant must be carefully centered, (3) the anterior release must be meticulously performed, (4) keel-cut chiseling should be monitored under lateral fluoroscopy to ensure that the superior vertebral body cut is as deep as the inferior cut, and (5) polyethylene inlay locking should be confirmed both tactilely and visually. In our study, following these rules, revisions occurred in only 0.49% of implants (Table VI).

As noted previously, adjacent-level degeneration is one of the critical points to study for any lumbar surgery, as it determines the long-term efficacy of the surgery. The adjacent-level degeneration rate in the present study was higher in the groups with prior surgery (Groups 2 and 4) than in the groups without. This difference can be explained by the long delay (the time from the initial signs to the first discectomy to the TDA) before the restoration of mobility at the index level in Groups 2 and 4. When following these recommendations regarding the type of access, careful selection of patients, and the technical rules for implantation, it is obvious that, as in all surgery, training and experienced mentors are key to a low complication rate.

Limitations

This was a retrospective study. Patients were selected for TDA by experienced anterior lumbar spine surgeons according to the indications and contraindications mentioned above. We analyzed a large cohort of 1,187 patients at up to 21-year follow-up. Our follow-up rate at 84 months (83.6% [992 of 1,187 patients]) is higher than that in prior long-term studies. However, later follow-up rates declined for the usual or natural reasons (e.g., no response, moved without providing the new address, deceased, not interested in being contacted). Theoretically, those patients who were lost to longer-term follow-up might have had poorer results than the rest of the group; however, it is just as likely that they did not return because they were experiencing satisfactory results.

The natural history (aging process) of the joints, especially in the spine, should also be taken into consideration in the analysis of the patient-reported outcomes. Despite these limitations, the present study is the first of its kind in the literature to evaluate such a large cohort of patients who underwent lumbar TDA with such a long duration of follow-up.

Conclusions

In a study of one of the largest TDA cohorts to date, we found equivalent improvement between patients who underwent 1-level lumbar TDA and those who underwent 2-level TDA, as well as between patients with prior surgery at the index level and patients with no prior surgery. This study also demonstrated the robust long-term clinical success and durability of 1 and 2-level lumbar TDA, as assessed at 7 to 21 years postoperatively. Patients had dramatic and maintained reductions in disability and pain scores over time and low rates of index-level revision or reoperation and adjacent-level surgery. ■

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