

## Treatment of symptomatic adjacent-segment degeneration after lumbar fusion with total disc arthroplasty by using the ProDisc prosthesis: a prospective study with 2-year minimum follow up

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**Object.** The authors conducted a prospective longitudinal study to assess the efficacy of ProDisc arthroplasty in patients in whom symptomatic adjacent-segment degeneration has developed after remote lumbar fusion. The follow-up period was a minimum of 2 years.

**Methods.** The 20 patients in this study ranged in age from 18 to 67 years. They presented with disabling adjacent-level discogenic low-back pain with or without L1–S1 radicular pain. Patients with radiographic evidence of circumferential spinal stenosis or facet joint degeneration had been excluded. Patients were assessed preoperatively and postoperatively at 3, 6, 12, and 24 months.

Eighteen patients (90%) fulfilled all follow-up criteria. The median age of all patients was 50 years. Statistical improvements in visual analog scale, Oswestry Disability Index, and patient satisfaction scores were documented 3 months after arthroplasty. These improvements remained at the 24-month follow-up examinations. Patient satisfaction rates were 86% at 24 months. Radicular pain was also significantly decreased. No additional surgeries were necessary at affected or unaffected levels.

**Conclusions.** Analysis of early results indicates that ProDisc lumbar total disc arthroplasty is an efficacious treatment for symptomatic adjacent-segment lumbar discogenic low-back pain following remote fusion. Significant improvements in patient satisfaction and disability scores were observed by 3 months postoperatively and were maintained at the 2-year follow-up examination. No device-related complications occurred. Patients should be screened carefully for evidence of facet joint impingement/degeneration, hardware-induced pain, and/or nonunion at prior fusion levels before undergoing disc replacement surgery.

**KEY WORDS** • lumbar spine • adjacent-segment degeneration • arthroplasty • ProDisc • total disc replacement

APPROXIMATELY 185,000 spinal fusion procedures are performed annually in the US to treat various clinical conditions including trauma, spondylolisthesis, deformity correction, spinal stenosis, discogenic back pain, and adjacent-level disc disease following remote fusion.<sup>3</sup> The incidence and pathobiomechanics of adjacent-level disc disease have been extensively reported and studied.<sup>4,6–8, 11–13,15–20,23–26,28</sup> The clinical outcomes following adjacent-level fusion surgery have been reported to be excellent in a small subset of patients.<sup>5</sup>

Lumbar ADR has been proposed as an alternative to lumbar fusion in the treatment of certain cases of lumbar

spondylosis in the absence of significant facet joint degeneration.<sup>1,9,14,27,29</sup> To the best of our knowledge, the use of ADR in the treatment of adjacent-segment degeneration following remote fusion has not been prospectively studied. The goal of the present study was to assess the efficacy of ProDisc ADR in the treatment of adjacent-segment degeneration following remote lumbar fusion.

### Clinical Material and Methods

#### Patient Population

There were nine men and nine women. The median age for both sexes was 50 years (range 35–67 years). The median preoperative duration of pain was 104 months (mean 70, range 6–400 months).

#### Patient Evaluation

After institutional review board approval, prospective data were compiled for lumbar ProDisc procedures per-

Abbreviations used in this paper: ADL = activities of daily living; ADR = artificial disc replacement; ALIF = anterior lumbar interbody fusion; AP = anteroposterior; CT = computerized tomography; DDD = degenerative disc disease; MR = magnetic resonance; ODI = Oswestry Disability Index; PLF = posterolateral fusion; VAS = visual analog scale.



FIG. 1. Preoperative radiographs (*upper left and right*) obtained in a patient who had undergone a prior L3–5 fusion and preoperative MR images (*lower left and right*) revealing adjacent-level degeneration at L1–2 and L2–3.

formed at symptomatic levels adjacent to segments previously treated with lumbar fusion between December 2000 and December 2002. Patients ranging in age from 18 to 70 years were eligible for enrollment in this study. Patients suffered from disabling low-back pain with or without radicular symptoms resulting from L1–S1 DDD that was confirmed on MR imaging, CT scanning, and discography. Only cases with a minimum of 2-year follow-up data were included for analysis. All surgeries were performed by a single surgeon at a single center.

Exclusionary criteria included the following: spinal stenosis, osteoporosis, chronic infections, metal allergies, pregnancy, facet joint arthrosis, inadequate vertebral endplate size, Workers' compensation, spinal litigation, body mass index greater than 35, and/or any isthmic or degener-

ative spondylolisthesis greater than Grade 1. In all cases a minimum 9-month course of conservative treatment had failed. This conservative management included physical therapy, medication usage, and appropriate interventional pain management.

Magnetic resonance images had been obtained in all patients at the time of their initial fusion surgeries. All of these MR imaging studies, as well as repeated studies acquired within 6 months of the index ADR surgery, were analyzed for the presence of DDD at the adjacent levels. In our cohort of patients, there was no evidence of adjacent-level DDD at the time of fusion surgery.

Surgery was performed after a complete radiographic/neuroimaging assessment in all patients including AP lateral flexion–extension, lateral bending radiography, CT, and MR imaging. All patients underwent discography/CT scanning to evaluate discogenic sources of pain and the degree of facet joint degenerative changes. Patients with evidence of intraarticular facet degeneration, specifically that of joint space narrowing with or without cystic changes, were excluded from the study. Patients in whom we observed minimal extraarticular facet joint changes (calcifications) were not excluded. Positive discography was defined as concordant pain with at least a VAS score of 6 of 10 and an abnormal postdiscography CT scan contrast pattern (that is, annular tear, disc extrusion). All procedures were performed by the senior author at a single tertiary care Level-1 institution. Twenty-five percent of our patients experienced only discogenic low-back pain without radicular and/or neurogenic symptoms; 75% had either intermittent (25%) or persistent (50%) leg pain as well.

An outcome bias was avoided by using primary outcome measurements determined by patient responses to questionnaires. Secondary parameters requiring measurements such as disc height of the affected level, adjacent-level disc height, and motion were performed by a trained technician. The data were collected and compiled by an independent technician. After the aforementioned data had been compiled, they were analyzed by an independent examiner who had no interaction with the patients or involvement with the surgical procedures at any time during this study.

#### *Surgical Technique*

The surgical approach was consistent in all cases as follows. The patient was placed supine on a fluoroscopic imaging table, with his/her legs and arms abducted, and with the surgeon working between the patient's legs. Fluoroscopy images were obtained in the AP and lateral planes to determine the level of diseased disc and obliquity of lordosis prior to incision. A transverse incision in cases for L5–S1 treatment, or a longitudinal incision for all other levels, was then made at the marked level of diseased disc. A standard right-sided median retroperitoneal approach to L5–S1, or a left-sided median retroperitoneal approach for all other levels, was then undertaken by the senior author to expose the level of disease.

Using lateral fluoroscopy, trialing was performed to make the assessment of appropriate size of the artificial disc with regard to height and AP diameter. Adequate central/midline location of prosthesis was confirmed on AP fluoroscopy prior to the making of keel cuts. After the midline was determined, keel cuts were made using the keel

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cutting chisel guided over the prosthesis trial. The endplates were then distracted, and the polyethylene implant was inserted. Anteroposterior and lateral fluoroscopy was performed to confirm the appropriate prosthesis positioning and size. No other procedures were performed at that time of the index procedure.

### Outcome Measurement

Patients were assessed preoperatively and 3, 6, 12, and 24 months postoperatively. The primary functional measures were disability (the ODI) and pain (the VAS).<sup>10</sup> Additional clinical parameters included analysis of pre- and postoperative patient satisfaction, general back pain, radicular pain, medication usage, and complications. Patient satisfaction was rated as completely satisfied (pain absent at all times and unimpaired employment and ADL), satisfied (slight pain that requires no medication and that occurs no more than once per day, minimal impairment in employment or ADL; and unsatisfied (pain that occurs more than one time per day, requires medication, and results in changes in ADL and employment). Back pain, radicular pain, and medication usage were rated none (1), occasional ( $\leq$  once per day; 2), and regular ( $>$  once per day; 3).

### Radiographic Assessment

Postoperative radiographs (standing AP, lateral, flexion-extension, and lateral bending films) were obtained at 3, 6, 12, and 24 months in all patients (Figs. 1 and 2). The patient represented in Fig. 1 underwent preoperative discography that revealed positive findings at L1–2 and L2–3. Detailed measurements of intervertebral disc heights of affected and adjacent levels, angular intervertebral disc motion, subsidence, pelvic tilt and incidence, and sacral slope were obtained using digitized images and appropriate computer software (Medimage Software; Vepro Computersysteme GmbH, Pfungstadt, Germany). To measure the angular motion, the Cobb method was calculated using the prosthetic endplates as references. Measurements were performed three times by a single reviewer, and a mean score was obtained for angular and length measurements. Two separate reviewers (the attending spine surgeon not involved in surgery and an attending radiologist) reviewed all pertinent radiographs for signs of device-related loosening, dislodgment, and/or subsidence.

### Statistical Analysis

Two primary research questions are of interest: 1) whether significant improvement occurred between baseline and the 3-month postsurgery examination (proximal effect); and 2) whether improvement was maintained from 3 months to 2 years postsurgery. Because of the size and observational nature of the study, we limited our analysis to several simple tests (t-tests for the continuous VAS and ODI scores, and nonparametric sign tests for back and leg pain scores) combined with careful exploratory data analysis.

## Results

### Demographic Data

Eighteen of 20 patients fulfilled all follow-up criteria. Two patients could not be examined postoperatively be-



FIG. 2. Postoperative AP (left) and lateral (right) radiographs showing L1–2 and L2–3 ADR above a previous L3–5 fusion site.

cause they moved. Questionnaires regarding ODI, VAS, satisfaction, medication usage, and back pain rating were sent to these two patients. No adverse events occurred nor were additional procedures necessary in these patients. The median follow-up period was 27 months (range 24–48 months). The mean interval between the prior fusion surgery and ProDisc ADR was 4.5 years (median 3 years, standard deviation 51.8 months, range 6–216 months).

Fifty-six percent of the patients had undergone prior two-level (eight cases [44%]) or three-level (two cases [11%]) fusion (Table 1). The remaining 45% of patients had undergone single-level fusion. In one case, a ProDisc was placed into a prior nonunion and an additional level of ADR was performed. In our study, 16 patients underwent one-level ADR and two patients underwent two-level ADR. Two patients had previously undergone ALIF. In these two patients, a standard retroperitoneal exposure was performed. The median blood loss was 100 ml (range 40–300 ml). One patient required a blood transfusion.

The median operative time was 152 minutes (range 70–280 minutes). The duration of hospital stays ranged from 6 to 14 days (mean 12 days). Note that surgeries were performed at a German facility where hospital stays are regulated according to diagnosis and German national patients are required to stay in the hospital based on diagnosis codes for at least 10 days following ADR surgery.

### Clinical Outcomes

The graphs in Fig. 3 show individual patient measurements for the continuous variables, ODI and VAS. An improvement in VAS-documented pain failed to occur in only two patients between the baseline and 24-month measurements, and some improvement in ODI scores were observed in both. Furthermore, one of these two patients was the only patient who did not report an immediate reduction in VAS score by 3 months (there was no change in this patient's VAS score during this period). In all patients, an immediate improvement in ODI scores was documented at

TABLE 1

Summary of data pertaining to previous fusion and current ADR\*

Case No.	Prior Fusion		ADR	
	Level	Type	Implant Level(s)	No. of Levels
1	L2-5	IPLF	L5-S1	1
2	L4-S1	IPLF	L3-4	1
3	L4-S1	IPLF	L3-4	1
4	L4-S1	IPLF	L3-4	1
5	L4-S1	IPLF	L3-4	1
6	L5-S1	ALIF & IPLF	L4-5	1
7	L4-S1	IPLF	L3-4	1
8	L4-S1	IPLF	L3-5	2
9	L5-S1	PLF	L4-5	1
10	L5-S1	IPLF	L4-5	1
11	L5-S1	IPLF	L4-5	1
12	L2-5	IPLF	L5-S1	1
13	L3-4	IPLF	L4-5, L5-S1	2
14	L4-5	ALIF & IPLF	L5-S1	1
15	L2-3	PLF	L3-4	1
16	L3-5	IPLF	L2-3	1
17	L3-5	IPLF	L1-2, L2-3	2
18	L5-S1	PLIF	L4-5	1

\* IPLF = instrumented PLF; IPLIF = instrumented posterior lumbar interbody fusion.

3 months, and all demonstrated some improvement at the 24-month examination compared with the presurgery examination. In only three patients did ODI scores not continue to improve between 3 and 24 months. The mean trend is represented by the line segments connecting the points in the center of the clusters in Fig. 3. Decreases in medication usage were also noted at 24 months compared with preoperative values (Table 4).

Table 2 provides a summary of the ODI and VAS scores, including the means and standard errors of the means presurgery and at 3, 6, 12, and 24 months postsurgery, as

well as two measures of improvements (presurgery-3 months and 3-24 months). The improvements observed during the interval between pretreatment and 3 months post-treatment were statistically significant in both measures (in each case,  $p < 0.0001$ ).

Although 3- to 24-month follow-up ODI improvements were of statistical significance ( $p = 0.002$ ), the corresponding improvement in VAS score was not significant; however, the improvements in VAS score achieved at the 3-month examination appear to be well sustained to 24 months. Finally, it is interesting to note that in 11 of the 20 patients a reduction in ODI score greater than 50% was present at 24 months, and in 17 the reduction was greater than 20%. Similarly, in 16 of 20 more than a 20% reduction in VAS score was documented, whereas in 12 at least a 50% reduction in VAS score was observed at the 24-month examination. Two patients with initial improvements in VAS and ODI scores experienced a return of some pain and disability at 6 months. Both of these patients had previously undergone posterior instrumented PLF and removal of previous instrumentation was required. After the hardware was removed, disability and pain improved.

Back pain, leg pain, and satisfaction scores were ordinal (completely satisfied [1], satisfied [2], unsatisfied [3]; Table 3). Figure 4 shows a graphic representation of the mean score at each follow-up interval, although no measure of patient satisfaction was available at baseline. A delayed onset in reduction of back pain was evident; improvement at 3 months was rare, with only three patients experiencing any improvement compared with their baseline status. In contrast, improvement in leg pain appeared immediately, but with little continued improvement on average throughout the follow-up period. In fact, examination of individual leg pain scores showed that the leg pain measurements were far more variable (and fewer clear trends by individual) than any of the other measures considered. It is interesting to note that of the four patients with moderate baseline back pain (pain Grade 2), none claimed any im-

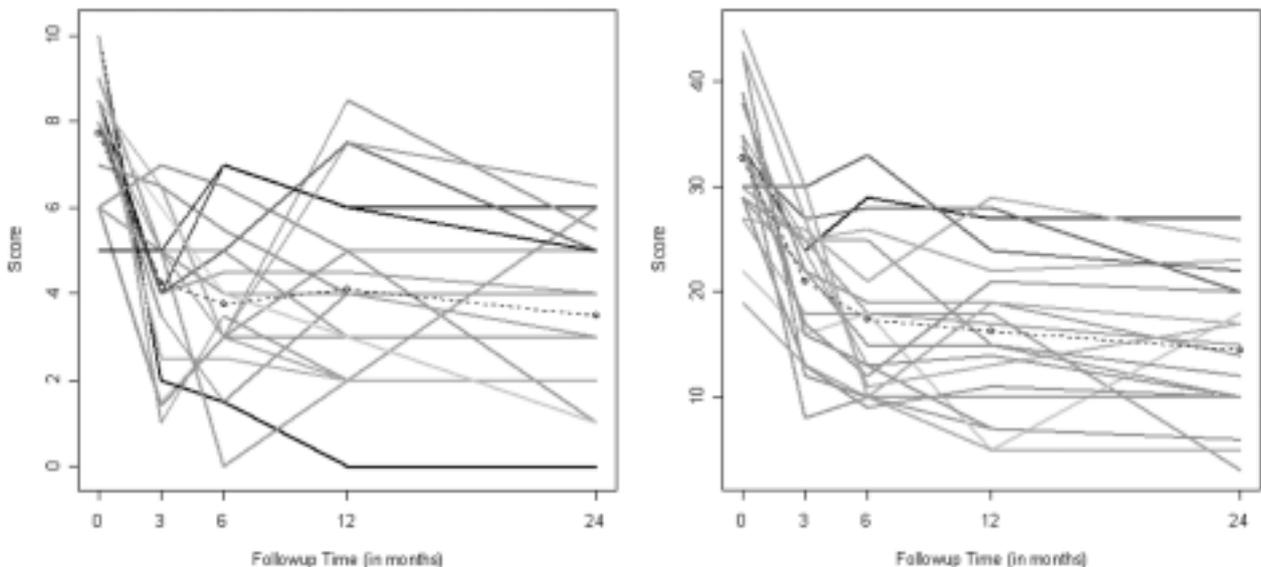


FIG. 3. Raw VAS (left) and ODI (right) scores obtained in each of the 20 patients.

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TABLE 2

Summary of pre- and postoperative ODI and VAS scores\*

Interval	Mean Score ± SEM	
	ODI	VAS
preop	65.40 ± 1.51	7.73 ± 0.33
postop		
3 mos	42.00 ± 1.43	4.25 ± 0.40
6 mos	34.80 ± 1.66	3.78 ± 0.41
12 mos	32.60 ± 1.67	4.10 ± 0.49
24 mos	29.00 ± 1.57	3.50 ± 0.42
3-mo improvement	23.40 ± 1.87	3.48 ± 0.56
24-mo improvement†	13.00 ± 1.82	0.75 ± 0.53

\* SEM = standard error of the mean.

† Indicates a continued improvement from 3 to 24 months postoperatively.

provement (to a grade of 1) at 24 months and one reported increased back pain (to a grade of 3); the other three reported no change (Grade 2). Of the 16 patients who presented with severe pain (Grade 3), pain in eight decreased to the lowest level (Grade 1), it improved somewhat in five (to a grade of 2), and it continued to be severe in three patients.

Preoperatively, 23% of the patients worked part time and 13% worked full time; these rates increased to 38 and 27%, respectively. Thirty-five percent of the patients remained unemployed postoperatively.

### Radiographic Analysis

The median preoperative affected posterior disc height was 3.7 mm; postoperatively, it increased 11 mm ( $p < 0.001$ ). Motion of the affected discs was increased on average from 3° preoperatively to 6° postoperatively ( $p < 0.004$ ). The adjacent-level disc height was not significantly changed. There were no cases of hardware subsidence, loosening, dislocation, or failure of metallic or polyethylene components.

### Summary of Complications

**Device-Related Complications.** We observed no device-related complications. There were no cases of hardware loosening, subsidence, migration, metallic or polyethylene failure, allergic rejection/reaction, visceral or neurological injuries caused by the implant components, and/or infection.

**Approach-Related Complications.** There were no approach-related complications.

**Other.** A single patient experienced delayed-onset elevated liver function parameters and jaundice. The cause was thought to be secondary to a transfusion reaction. No viral origin was identified, and recovery was spontaneous.

### Discussion

Adjacent-level disc degeneration following lumbar fusion has been well documented and little controversy exists as to the additional disability resulting from this proximate degenerative process.<sup>7,11,12,18,20,24</sup> Ghiselli, et al.,<sup>11</sup> have reported the incidence of postoperative adjacent-segment degeneration (defined by instability) to be 16.5% at 5 years and 36.1% at 10 years.<sup>11</sup> Although Chen, et al.,<sup>4</sup> reported

TABLE 3

Patient satisfaction, back pain, leg pain, and work rate data\*

Outcome Variable	Preop (%)	Postop Interval (%)			
		3 Mos	6 Mos	12 Mos	24 Mos
patient satisfaction					
overall	NA	84	87	87	88
satisfied	NA	67	60	40	53
completely satisfied	27	27	47	33	
back pain					
overall	100	100	93	87	69
intermittent	25	25	68	68	44
persistent	75	75	25	19	25
leg pain					
overall	75	49	60	47	44
intermittent	25	43	47	40	44
persistent	50	6	13	7	0
full- & part-time employment	38	20	65	80	87

\* NA = not applicable.

a 94.9% fusion rate in patients with adjacent-level degeneration, their combined excellent and good clinical rate was only 76.4%. The optimal treatment method for adjacent-segment degeneration, thus, has yet to be defined. Although renewed pain is often a clinical indicator of symptomatic adjacent-segment degeneration, the disease process at the adjacent segment can often be distinct from the initial triggering process at the proximate level of disease.<sup>25</sup> Schlegel, et al.,<sup>25</sup> conducted a longitudinal study in 58 patients with symptomatic abnormalities adjacent to previously fused segments. The patients were symptom free for a mean of 13 years. Although spinal stenosis was the most common diagnosis, adjacent-segment abnormalities also included prolapsed disc and listhesis. Interestingly, the authors also found that 58% of the levels contiguous with the adjacent levels were also abnormal. Therefore, diagnos-

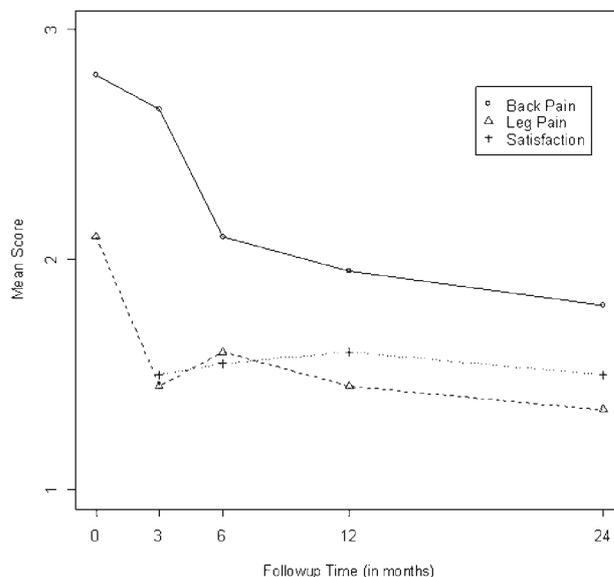


FIG. 4. Graph demonstrating the mean back and leg pain scores and patient satisfaction at each follow-up interval.

TABLE 4  
Summary of medication usage stratified  
by regularity of consumption\*

Drug Usage	NSAIDs (%)		Narcotics (%)		Tramadol (%)	
	Preop	24 mos	Preop	24 mos	Preop	24 mos
never	31.2	64.2	68.7	92.8	37.5	42.8
occasionally	0	14.2	0	7.1	0	14.3
regularly	68.8	20.0	31.2	0	62.5	42.8

\* NSAIDs = nonsteroidal antiinflammatory drugs.

tically, adjacent-segment degeneration can be a daunting clinical challenge.

In early in vitro biomechanical studies, Lee and Langrana<sup>21</sup> found that posterior fusion produced the greatest stress on adjacent motion segments. In a clinical study, Lee<sup>20</sup> further characterized adjacent-level disease including facet joint degeneration, disc degeneration, acquired spondylolysis, and spinal stenosis. In in vitro studies conducted by Weinhoffer, et al.,<sup>28</sup> and others,<sup>4</sup> increased intradiscal pressure has also been demonstrated in adjacent-level discs. Finite analysis demonstrated that fusion increased stress on the vertebral endplate and annulus fibrosus, suggesting that adjacent-level disease may begin with damage to these two motion segment components.<sup>13</sup> Similar stresses were found in finite analysis of cervical fusion.<sup>22</sup> Histological analysis of adjacent-level specimens obtained in a canine model implicated the facet joints in the degenerative process.<sup>16</sup>

Due to the varying clinical presentations and degrees of adjacent-segment degeneration, a single optimal treatment modality will not likely be found; however, as illustrated in our early findings, ADR appears to offer an effective option for those patients with adjacent-segment degeneration in the setting of primarily axial back pain with or without radicular symptoms, in the absence of facet joint degeneration. Compared with our analysis of multilevel ADR in which we observed a 93.4% clinical success rate,<sup>2</sup> the use of ADR to treat adjacent-segment degeneration appears to offer a reasonable alternative. Although a randomized prospective comparison of ADR and fusion may theoretically yield superior Level-1 data, analysis of our data provides initial feasibility and clinical support for the use of ADR as a treatment alternative. We concede that long-term follow-up evaluation will be necessary before ADR can be considered a general recommendation for the treatment of adjacent-segment degeneration.

We recommend strict adherence to traditional inclusion and exclusion criteria for ADR and that all patients undergo CT scanning to assess for facet joint degeneration. The presence of facet joint impingement secondary to posterior fixation used for prior fusion should be excluded. The pain-inducing hardware should be removed prior to ADR. If necessary, myelography should be undertaken to exclude advanced cases of spinal stenosis. Circumferential spinal stenosis present at the adjacent-level segment should be considered a relative contraindication to ADR because of the potential of decreasing the spinal canal volume as a result of the lordotic enhancement.

## Conclusions

In conclusion, analysis of our early results indicated that ProDisc lumbar total disc arthroplasty is an effective treatment alternative for symptomatic adjacent-segment lumbar DDD following remote fusion. Significant improvements in patient satisfaction and disability scores were observed 3 months after surgery and were maintained throughout the 2-year follow-up period. No hardware-related complications occurred and revision surgery was not necessary.

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