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The Fate of Facet Joint and Adjacent Level Disc Degeneration Following Total Lumbar Disc Replacement

A Prospective Clinical, X-Ray, and Magnetic Resonance Imaging Investigation

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Study Design. Prospective clinical, x-ray, and magnetic resonance imaging investigation following total lumbar disc replacement (TDR) with ProDisc II (Synthes, Paoli, PA).

Objective. To examine the progression of adjacent level degeneration (ALD), facet joint degeneration (FJD) as well as associated risk factors following TDR.

Summary of Background Data. Fusion procedures have been associated with adjacent level morbidities and facet joint pathologies in a considerable number of patients. Whether the incidence of these negative side effects can be reduced with TDR remains unestablished.

Methods. Clinical outcome scores Visual Analogue Scale (VAS), Oswestry Disability Index (ODI) and patient satisfaction rates were acquired within the framework of an ongoing prospective study with ProDisc II. The mean index-level ROM was established for every patient over the entire postoperative period from multiple flexion/extension x-ray images. The progression of ALD and FJD was evaluated from pre- and postoperative magnetic resonance images by 2 independent radiologists.

Results. Results from 93 patients with an average follow-up of 53.4 months (range, 24.1–98.7 months) were included in this study. The overall results revealed a significant improvement from preoperative VAS and ODI levels ($P < 0.0001$).

The incidence of ALD was 10.2% (n = 11/108 levels). The degenerative changes were mild and occurred late after surgery (mean, 65.2 months; range, 37.9–85.6 months). There was no significant correlation between index-level ROM and the occurrence of ALD ($P > 0.05$).

Progression of FJD was observed in 20.0% of all facet joints (n = 44/220). FJD occurred significantly more often following TDR at the lumbosacral junction in comparison to the level above the lumbosacral junction ($P < 0.02$) and was observed more frequently at index-levels than at nonindex levels ($P < 0.001$).

The degenerative changes were associated with a negative influence on postoperative outcome parameters VAS and ODI ($P < 0.03$) that were already detected early after surgery. The mean postoperative ROM was significantly lower in patients with progression of FJD in comparison to the remaining cohort ($P < 0.0001$).

Conclusion. TDR proved to have a beneficial effect with respect to adjacent level disc preservation. The degenerative changes were mild, occurred late after surgery and did not reveal a negative effect on postoperative clinical outcome. There was no significant correlation between index-level ROM and the occurrence of ALD ($P > 0.05$).

TDR was, however, associated with a progression of index-level FJD in a considerable number of patients, particularly at the lumbosacral junction. Lower segmental mobility and less favorable clinical results point to the fact that a particular cohort of patients may predominantly be affected in which TDR shows inferior compatibility with the index-segment's biomechanics.

Key words: total disc replacement, spine arthroplasty, facet arthrosis, adjacent level morbidity, adjacent disc degeneration, clinical results. **Spine 2010;35:1991–2003**

Lumbar degenerative disc disease (DDD) is a major cause of axial low back pain (LBP) in industrialized countries.[1,2] Over the past decades, fusion of lumbar motion segments has been established as a "gold-standard" for the treatment of DDD with true deformities and instabilities that have proved unresponsive to conservative treatment. Due to perceived disadvantages such as accelerated adjacent level degeneration (ALD), symptomatic facet/iliosacral joint complaints and hypertrophy of the facet joints with consecutive narrowing of the spinal canal, the role of lumbar fusion procedures remains controversially debated.[3–14]

In an attempt to avoid these fusion-related negative side affects, motion preserving technologies including total lumbar disc replacement procedures (TDR) have been pursued over the last decades. Their clinical efficacy has been demonstrated by a variety of class I to class IV studies.[15–28] Whether or not disc replacement technologies can, however, live up to their global expectation of adjacent level preservation still lacks evidence.[29–32]

Furthermore, a variety of clinical, radiologic, and biomechanical studies have suggested that TDR interferes with the highly sensitive biomechanics of the lumbar spine. Possible consequences may include excessive loads on the surrounding ligamentous structures and facet

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Table 1. Exclusion Criteria/Contraindications

Central or lateral spinal stenosis
Predominant radiculopathy
Facet joint arthrosis/symptomatic facet joint complaints
Spondylolysis/spondylolisthesis
Spinal instability (iatrogenic/altered posterior elements, *e.g.*, following laminectomy)
Major deformity/curvature deviations (*e.g.*, scoliosis)
Metabolic bone disease (*e.g.*, manifest osteoporosis/osteopenia)
Previous operation with severe scarring and radiculopathy
Compromised vertebral body (irregular endplate shape)
Previous/latent infection
Metal allergy
Spinal tumor
Post-traumatic segments

joints. Nevertheless, pathoanatomic and morphologic changes of the facet joints have, to date, not been investigated sufficiently. Only a very limited number of studies worldwide have focused specifically on these issues.

The purpose of this study was to investigate the incidence and progression of adjacent level degeneration (ALD) and facet joint degeneration (FJD) as well as associated risk factors following TDR. The primary working hypothesis was that motion preservation would reveal beneficial effects with regard to adjacent level preservation but that it might be disadvantageous with regard to the progression of the index-segment's facet joint degeneration.

Materials and Methods

Preoperative Diagnosis and Patient Selection

All patients included in this study are part of an ongoing prospective clinical trial with ProDisc II (Synthes, Paoli, PA). The minimum follow-up (FU) for inclusion in this study was 24 months. Disc replacement was performed for the treatment of patients with predominant axial low back pain originating from lumbar degenerative disc disease. The commonly agreed upon indications and contraindications for this procedure have been thoroughly outlined previously (Table 1).[15,26,28,33–36]

All patients were nonresponders to an intensive inpatient and outpatient conservative treatment program conducted over a minimum 6-month period. Low back pain (LBP) was clearly the predominant complaint (≥80% of overall complaints).

The preoperative diagnosis was based on lumbar x-rays taken in anterior-posterior and lateral view, functional flexion/extension images and preoperative magnetic resonance imaging (MRI) of the lumbar spine. Patients with previous discectomies were excluded if Gd-DTPA-MRI revealed notable scar tissue formation in the spinal canal.

For disc replacements performed at the levels L4–L5 and above, diagnostics included a color-coded 3-dimensional-CT reconstruction of the prevertebral vessels as described and recommended previously.[28,37]

Women older than 45 and men older than 55 years of age received routine dual x-ray absorptiometry scans for bone density measurements. In accordance with the WHO definition of osteopenia, patients with a T-score ≤1.0 were not considered candidates for TDR.

Disc spaces were approached through means of a mini-open laparotomy, using a retroperitoneal approach as described previously.[38,39] Insertion of the ProDisc implant was performed according to the manufacturers guidelines.[40]

Study Documentation

All data were accumulated prospectively. Patients were examined before surgery and routine clinical and radiologic examinations were performed at 3, 6, and 12 months after surgery, annually from then. Study documentation was standardized and included the Visual-Analogue-Scale (VAS) and Oswestry Disability Index (ODI).[41] The subjective outcome evaluation of the disc replacement procedure was ranked on a 3-scale grading system according to the patients perception, namely, "highly satisfied," "satisfied," and "not satisfied."

At all pre- and postoperative FU examinations radiologic images were obtained which included standard anteroposterior, lateral, and functional images taken between maximum flexion and extension movements.

Study Cohort Definition and Inclusion Criteria

For the purpose of standardization of a homogenous study cohort, the following additional inclusion and exclusion criteria were defined:

- Minimum clinical and radiologic FU of 24 months.
- Only MR images without any significant distortion/artifacts from the implants which permitted a complete evaluation of the last 3 lumbar motion segments were employed.
- TDR limited to mono- and/or bisegmental interventions at the last 2 lumbar motion segments.
- Exclusion of patients with combined fusion and disc replacement procedures or patients who received TDR for the treatment of adjacent level pathologies following previous fusion.
- No history of previous TDR revision surgery, exclusion of previous adjacent level surgery.

Radiologic X-Ray Evaluation of Segmental Mobility

The hard copies of the radiographic x-ray films were scanned using a high-resolution scanner and a standard image-capture software program. The images were transferred to a computer station for further analysis. All measurements were performed with the aid of a custom-made medical image analysis software (Medimage V5.0, VEPRO AG, Pfungstadt, Germany) which was designed to determine angles and distances on the digital images.

The measurements were performed by 2 experienced and independent observers (P.Z.; J.C.S.B.), one neurosurgeon and one orthopedic surgeon. The observers were blinded to the clinical results and were not involved in the process of pre- or postoperative decision-making. The means from all measurements were calculated and incorporated into the final statistical analysis.

Radiologic measurements included the sagittal plane rotation (range of motion [ROM]) at the operated level which was represented as the difference between the measurements taken in maximum flexion and extension. Standard Cobb measurements were used to determine the preoperative ROM as described and recommended previously.[42] For postoperative ROM measurements, an improved precision and inter-/intraobserver reliability has been reported when the spikes of the upper and lower prosthesis-keels were used as radiologic landmarks.[43–45] This method was therefore applied to determine the postoperative segmental ROM.

Previous studies reported on motion preservation and ROM results of TDR procedures from images that were obtained at one particular point in time. With regard to potential avoidance of ALD, however, it is essential to establish whether segmental motion can be preserved over a considerable period of time. Therefore, all flexion/extension images from every single patient were included in the present study to establish the mean postoperative mobility at the index-segment over the entire postoperative course.

In summary, 1168 pre- and postoperative ROM measurements were performed by 2 independent observers overall. The means were established between both observers which resulted in 584 pre- and postoperative ROM measurement results that were eligible for the final statistical analysis.

MRI Investigation

One hundred eighty-six pre- and postoperative MRI images from 93 patients were available for final analysis. All images were evaluated by 2 trained and experienced skeletal radiologists specialized in the evaluation of spinal pathologies (U.S.; A.S.). Both radiologists were blinded to the clinical results and were not included in the process of pre- or postoperative decision-making.

The last 3 lumbar motion segments were evaluated on all MRI images with regard to the status of disc and facet joint degeneration. The degree of disc degeneration was classified on a 5-scale grading system as previously described by Pfirrmann *et al.*[46] The degree of facet joint degeneration (FJD) was classified on a 4-scale grading system according to the classification system introduced by Weishaupt *et al.*[47] Both classification systems have been widely used, validated, and recommended for application due to their high inter- and intraobserver reliability.[46–53] Bilateral facet joints were evaluated independently. In order to establish a progression of FJD or ALD, the deterioration of the degenerative condition of the facet-joints/adjacent level discs had to be confirmed by both radiologists independently.

Thus, the overall data that were acquired by both radiologists included the results of 2232 facet joint evaluations as well as the condition of 896 pre- and postoperative lumbar discs of the last 3 lumbar motion segments that were available for the final statistical analysis.

Statistical Analysis

The descriptive analysis of the results included means, standard deviations, medians as well as the first and the third quartiles. Boxplots and error bars were used for graphical illustration of metrically scaled values. Shapiro-Wilk tests and visualization *via* Q-Q plots were performed to test for normal distribution of variables. Pearson and Spearman correlation coefficients and corresponding P-values were used to quantify the degree of correlation among variables. Friedman tests, Wilcoxon matched pair tests, and 2-sided Student t tests for normally distributed data were performed to analyze VAS, ODI, and ROM variables over time. For the analysis of differences in groups (degeneration *vs.* nondegeneration) Kruskal-Wallis U tests together with Mann-Whitney U tests as *post hoc* tests were conducted. Fisher exact test was used to analyze the association of degenerations at different segments.

Results

Study Population and Cohort Definition

The clinical and radiologic data from 93 patients were included in this study overall. The mean FU was 53.4 months (range, 24.1–98.7 months). A FU of >4 years was available in 56 patients (60.2%), >5 years in 31 patients (33.3%), and >6 years in 14 patients (15.1%), respectively.

Of 93 patients, 34 were male (36.6%), 59 were female (63.4%). The average age was 43.5 years (range, 21.9–66.1 year).

The majority of disc replacements were performed as single level procedures (n = 76, 81.7%) at the levels L4/L5 (n = 13, 14.0%), L5/S1 (n = 59, 63.4%), L5/L6 (n = 2; 2.2%) and L4/S1 (n = 2; 2.2%). Seventeen TDRs (18.3%) were performed bisegmentally at the levels L4/L5/S1 (n = 16; 17.2%) and L5/L6/S1 (n = 1; 1.1%).

Indications for disc replacement included DDD with (n = 37, 40.2%) and without Modic changes (n = 26, 28.3%) without any other accompanying pathologies. TDR was performed in 9 (9.8%) patients with DDD and an accompanying contained, central to mediolateral disc herniation with clinically predominant axial low back pain (≥80%). In 20 patients (21.7%), disc replacement was performed for the treatment of DDD following a previous discectomy.

Clinical Results

The combined data from the entire study cohort showed a highly significant improvement of VAS and ODI scores at all FU stages in comparison to baseline levels ($P < 0.0001$; Figure 1A, B). At the last FU examination, 63.4% (n = 59) of all patients were "highly satisfied," 28.0% (n = 26) were "satisfied," while 8.6% (n = 8) of all patients reported an "unsatisfactory" outcome.

Further analysis of the clinical outcome parameters revealed that satisfactory results were maintained for the parameters of ODI and patient satisfaction rates with no significant differences between various postoperative FU stages ($P > 0.05$). Conversely, VAS scores deteriorated throughout the postoperative course (Figure 1A). Although the improvement was still significant in comparison to preoperative levels, the data obtained from the 48 and 60 month FU examinations were significantly inferior when compared to the results that were observed early after surgery ($P < 0.01$).

X-Ray Results/ROM Analysis

Of 584 mean pre- and postoperative ROM measurements, 483 postoperative ROM measurement results were used to establish each patient's mean postoperative index-segment mobility which was observed over the entire postoperative course. These data were then analyzed with regard to their influence on and correlation with ALD and FJD. The overall results of all pre- and postoperative ROM measurements are outlined in Table 2.

MRI Investigation

A total of 110 disc replacements were performed in 93 patients. Before surgery, the vast majority of all discs (90.0%; n = 99/110) showed severe (≥fourth degree) degenerative changes at the index-levels. Of 110 levels

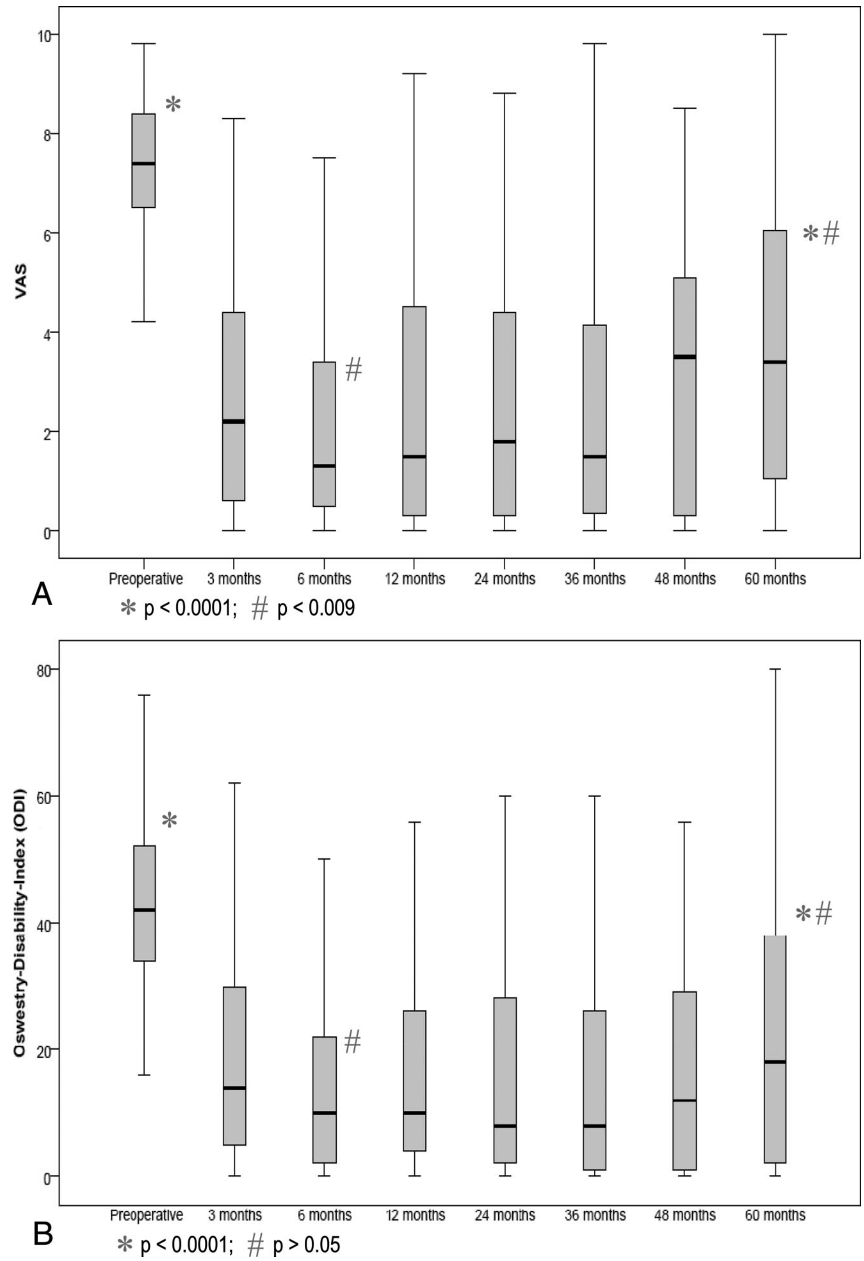

Figure 1. **A,** Mean pre- and postoperative Visual Analogue Scale (VAS, **A**) scores following total lumbar disc replacement. $*P < 0.0001$; $\#P < 0.009$. **B,** Mean pre- and postoperative Oswestry Disability Index (ODI, **B**) scores following total lumbar disc replacement. $*P < 0.0001$; $\#P > 0.05$.

treated with TDR, 11 (10.0%) were classified as Grade 3–4 disc degeneration.

Furthermore, 220 index-level facet joints were examined by both radiologists overall. Before surgery, 48.2% (n = 106/220) out of all index-level facet joints revealed minor, first degree degenerative changes. All remaining facet joints (51.8%, n = 114/220) were classified as <first degree FJD. There were no cases of advanced stages (≥second degree) of FJD before surgery.

Adjacent Level Disc Degeneration

The overall results delineating the progression of adjacent level disc degeneration (ALD) are outlined in Table 3. A total of 108 adjacent levels were independently evaluated by the 2 radiologists: 93 cranial adjacent levels in all patients and 15 caudal levels following monosegmental TDR at the level above the lumbosacral junction.

The overall incidence of ALD was 10.2% (n = 11/108 adjacent segments). In 7 of 11 cases, both observers confirmed a progression of ALD by 1°. In 3 of 11 patients, the deterioration was recorded as first degree by one radiologist and as second degree by the other. A progression of ALD by 2° was only observed once overall (0.9%; n = 1/108).

There was no significant difference between the incidence of cranial (10.8%; n = 10/93) and caudal (6.7%; n = 1/15) adjacent level disc degeneration ($P > 0.05$).

In 11 patients, the signs of ALD were observed after a mean FU of 62.5 months (range, 37.9–85.6 months). The progressive degenerative changes occurred after 48 to 60 months FU in 4 patients, after 60 to 72 months FU

Table 2. Range of Motion (ROM) Following Total Lumbar Disc Replacement (TDR)

	Preoperative Range of Motion	Mean Postoperative Range of Motion
Group 1: 1-level TDR at L5/S1	6.6° (0.4°–19.0°) SD: ±4.6 n = 57	5.7° (0.1°–15.6°) SD: ±3.9 n = 248
Group 2: 1-level TDR at L4/L5	10.3° (0.9°–22.4°) SD: ±6.0 n = 14	6.3° (0.2°–16.8°) SD: ±4.6 n = 67
Group 3: 2-level TDR, caudal segment (L5/S1)	8.4° (1.0°–19.6°) SD: ±5.6 n = 15	5.3° (0.3°–14.3°) SD: ±3.2 n = 84
Group 4: 2-level TDR, cranial segment (L4/L5)	8.5° (1.3°–20.2°) SD: ±5.8 n = 15	7.6° (0.6°–15.8°) SD: ±4.0 n = 84

Postoperative results refer to the average data from all available x-ray measurements over the entire postoperative course. Values include means, range, ±SD as well as the overall no. of pre- and postoperative measurements.

in 4 patients, and later than 72 months FU in another 2 patients, respectively. Only one patient showed signs of progression of ALD at the 37.9-month FU.

All levels with progression of ALD already showed minor pre-existing degenerative changes before surgery. There was no case of improvement of an adjacent level disc in comparison to preoperatively.

Facet Joint Degeneration

As outlined in Table 4, the overall rate of progression of FJD was 20.0% (n = 44/220). In 33 cases, both observers confirmed a progression of the FJD by 1°. In another 11 facet joints, the deterioration was recorded as first degree by one radiologist and second degree by the other. There was no case with an advanced deterioration of FJD by ≥2 classes.

Following monosegmental interventions, the majority of FJDs occurred at the lumbosacral junction (23.0%; n = 28/122). Conversely, the incidence of FJD was only 3.3% (n = 1/30) when TDR was performed monosegmentally at the level above the lumbosacral junction. The difference in the rate of progressive FJD between the 2 different levels was statistically significant ($P < 0.02$).

After bisegmental disc replacements, a progression of FJD was similarly observed more frequently at the lumbosacral junction (37.5%, n = 12/32) in comparison to the level above the lumbosacral junction (9.4%, n = 3/32). This difference was statistically significant ($P < 0.02$).

The incidence of FJD at the index-level increased for 2-level TDRs when compared with the results of monosegmental disc replacements performed at the same levels: 3.3% (n = 1/30) *versus* 8.8%. (n = 3/34) at the level above the lumbosacral junction and 23% (n = 28/122) *versus* 35.3% (n = 12/34) at the lumbosacral junction, respectively. Although this increased incidence of FJD was considerable and noteworthy, the difference was not statistically significant ($P > 0.05$).

Comparison of Facet Joint Degeneration at Index-Levels **Versus** *Nonindex Levels*

The progression of FJD was compared between index segments and nonindex segments at the last 2 lumbar motion segments following monosegmental TDRs. At the level above the lumbosacral junction, the observed progression rates of FJD was 3.3% (n = 1/30) at index-segments and 6.6% (n = 8/122) at nonindex segments. This difference was not statistically significant ($P > 0.05$).

At the lumbosacral junction, however, the corresponding rates were 23.0% (n = 28/122) incidence of

Table 3. Adjacent Level Disc Degeneration (ALD) Following Total Lumbar Disc Replacement (TDR)

	No. Patients	Incidence of Cranial ALD	Incidence of Caudal ALD	Total Incidence of ALD
Incidence of ALD (overall results)	n = 93 patients; (n = 108 adjacent levels)	10.8% (n = 10/93)	6.7% (n = 1/15)	10.2% (n = 11/108)
Incidence of cranial ALD (overall results)	n = 93	10.8% (n = 10/93)	—	10.8% (n = 10/93)
Incidence of caudal ALD (overall results)	n = 15	—	6.7% (n = 1/15)	6.7% (n = 1/15)
TDR at L5–S1	n = 59	10.2% (n = 6)	—	10.2% (n = 6)
TDR at L4–S1	n = 2	50% (n = 1)	—	50% (n = 1)
Total incidence of ALD following 1-level TDR at the lumbosacral junction (TDR at L5/S1 or L4/S1)	n = 61	11.5% (n = 7/61)	—	11.5% (n = 7/61)
TDR at L4/L5	n = 13	15.4% (n = 2)	7.7% (n = 1)	11.5% (n = 3/26)
TDR at L5/L6	n = 2	0% (n = 0)	0% (n = 0)	0% (n = 0)
Total incidence of ALD following TDR at the level above the lumbosacral junction (TDR at L4/L5, L5/L6)	n = 15	13.3% (n = 2/15)	6.7% (n = 1/15)	10% (n = 3/30)
Total incidence of ALD following mono-segmental TDR (TDR at L5/S1, L4/S1, L4/L5 and L5/L6)	n = 76 patients (n = 91 adjacent levels)	11.8% (n = 9/76)	6.7% (n = 1/15)	11.0% (n = 10/91)
TDR at L4/L5/S1	n = 16	6.3% (n = 1/16)	—	6.3% (n = 1/16)
TDR at L5/L6/S1	n = 1	0% (n = 0/1)	—	0% (n = 0/1)
Total incidence of ALD following bisegmental TDR (TDR at L4/L5/S1 and L5/L6/S1)	n = 17	5.9% (n = 1/17)	—	5.9% (n = 1)

Table 4. Progression of Index-Level Facet Joint Degeneration (FJD) Following Total Lumbar Disc Replacement (TDR)

	No. Patients (No. Index-Level Facet-Joints)	Facet Joint Degeneration (1-Level TDR)	Cranial Index Segment Facet Joint Degeneration (2-Level TDR)	Caudal Index Segment Facet Joint Degeneration (2-Level TDR)	Total Incidence of Facet Joint Degeneration
Incidence of FJD (overall results)	n = 93 (n = 220)	19.1% (n = 29/152)	8.8% (n = 3/34)	35.3% (n = 12/34)	20.0% (n = 44/220)
FJD at L5–S1	n = 59 (n = 118)	22.9% (n = 27/118)	—	—	22.9% (n = 27/118)
FJD at L4–S1	n = 2 (n = 4)	25.0% (n = 1/4)	—	—	25.0% (n = 1/4)
Total incidence of FJD following 1-level TDR at the lumbosacral junction (TDR at L5/S1, L4/S1)	n = 61 (n = 122)	23.0% (n = 28/122)	—	—	23.0% (n = 28/122)
TDR at L4/L5	n = 13 (n = 26)	3.8% (n = 1/26)	—	—	3.8% (n = 1/26)
TDR at L5/L6	n = 2 (n = 4)	0% (n = 0)	—	—	0% (n = 0)
Total incidence of FJD following 1-level TDR at the level above the lumbosacral junction (TDR at L4/L5, L5/L6)	n = 15 (n = 30)	3.3% (n = 1/30)	—	—	3.3% (n = 1/30)
Total incidence of FJD following 1-level TDR (TDR at L5/S1, L4/S1, L4/L5 and L5/L6)	n = 76 (n = 152)	19.1% (n = 29/152)	—	—	19.1% (n = 29/152)
TDR at L4/L5/S1	n = 16 (n = 64)	—	9.4% (n = 3/32)	37.5% (n = 12/32)	23.4% (n = 15/64)
TDR at L5/L6/S1	n = 1 (n = 4)	—	0% (n = 0)	0% (n = 0)	0% (n = 0)
Total incidence of FJD following 2-level TDR at the last 2 motion segments (TDR at L4/L5/S1 and L5/L6/S1)	n = 17 (n = 68)	—	8.8% (n = 3/34)	35.3% (n = 12/34)	22.1% (n = 15/68)

FJD for index-segments whereas no advanced FJD was observed at nonindex segments (0%; n = 0/30). This difference was highly significant ($P < 0.001$).

Correlation Between ALD and Clinical Outcome Parameters

A comparison of the clinical results between the cohort of patients with and those without signs of ALD did not reveal any significant difference between both groups at any one of the FU stages in terms of VAS/ODI scores or the subjective patient satisfaction rates ($P > 0.05$). Furthermore, there was no significant deterioration of the clinical symptomatology in patients with signs of ALD throughout the postoperative course ($P > 0.05$).

Correlation Between FJD and Clinical Outcome Parameters

Conversely, the occurrence of FJD was associated with a negative effect on the patients symptomatology with significantly inferior VAS and ODI scores in comparison to the cohort of patients without progression of FJD ($P < 0.02$; Figure 2). In spite of the fact that morphologic signs of FJD were observed at later postoperative stages, significantly inferior VAS and ODI scores in this cohort were already detectable at an early postoperative stage at the 3 ($P < 0.03$), 6 ($P < 0.002$), and 12 ($P < 0.002$) month FU examination, respectively. There was no significant influence of FJD on the patient reported subjective satisfaction rates ($P > 0.05$).

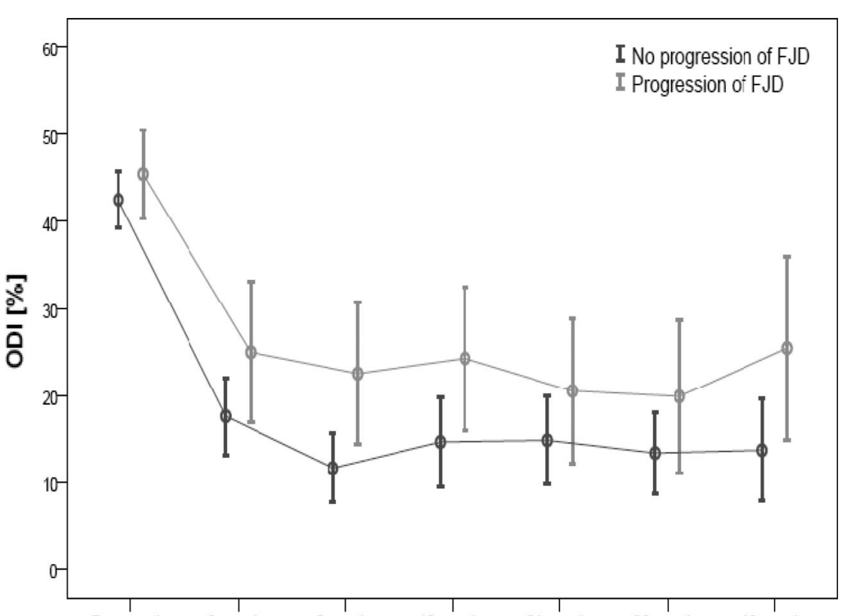

Figure 2. Influence of facet joint degeneration (FJD) on the clinical results as outlined by pre- and postoperative Oswestry Disability Index (ODI) scores following total lumbar disc replacement. Comparison between both groups revealed significantly inferior results for patients with progression of FJD which were already detectable at an early postoperative stage at the 3 ($P < 0.03$), 6 ($P < 0.002$), and 12 ($P < 0.002$) month FU examination, respectively.

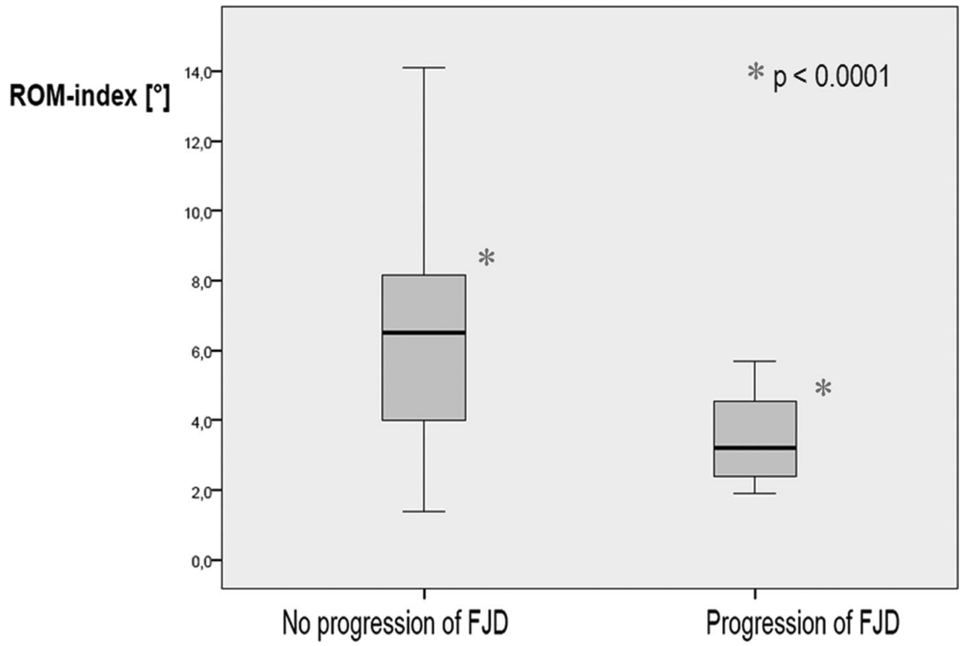

Figure 3. Correlation between the mean postoperative range of motion (ROM) following monosegmental disc replacement procedures in patients with and without progression of facet joint degeneration (FJD). Inferior index-level mobility was observed in patients with progression of FJD, statistical analysis revealed highly significant differences between both groups (*$P < 0.0001$).

Correlation Between ROM and ALD/FJD

There was no significant threshold value of segmental ROM associated with the progression of ALD. Although 5 of 11 patients with ALD had a mean postoperative ROM of ≤4.3°, ALD was similarly observed in 6 of 11 patients with ROM ≥6.5°. Thus, there was no statistically significant correlation between the mean postoperative index level mobility on one hand and the development of ALD on the other hand ($P > 0.05$).

Conversely, Figure 3 demonstrates that lower ROM values were observed in the cohort of patients with progression of FJD in comparison to the group of patients without any advancement of the degenerative changes. The difference in the mean ROM values between both groups was highly significant ($P < 0.0001$).

■ Discussion

The fusion of lumbar motion segments for the treatment of patients with discogenic low back pain resulting from DDD without any true deformities or instabilities remains controversially debated. Perceived disadvantages such as accelerated adjacent level morbidities, iatrogenic superior segment facet joint violation, symptomatic complaints from facet or sacroiliac joints or facet joint hypertrophy with consecutive narrowing of the spinal canal have been previously reported.[3–14] In a literature review, Park *et al* outlined previously published rates of adjacent segment degeneration following lumbar fusion procedures.[7] While the radiographic signs of adjacent level degeneration varied substantially between 5.2% and 100% (FU intervals between 36 and 369 months), the rate of clinically relevant symptomatic adjacent segment disease was considerably lower, ranging from 5.2% to 18.5% at FU intervals between 44.8 and 164 months.

Since the introduction of new motion preserving technologies such as total lumbar disc replacement (TDR), expectations have been high to reduce the above-mentioned fusion-related negative side effects. Whether or not disc replacement technologies can, however, live up to their global expectations is still yet to be proven.[29–32]

Adjacent Level Degeneration

Only a very limited number of studies have specifically evaluated the incidence of ALD following TDR as outlined in Table 5. To date, this study represents the largest published evaluation of adjacent level and facet joint degeneration following TDR.

Huang *et al*[54] reported a 23.8% incidence (n = 10/42 segments) of ALD following TDR with ProDisc I after a mean FU of 8.7 years. Access to MRI was not available in the study setting and the authors therefore had to rely on radiographic alterations on x-ray images such as loss of disc space height or anterior osteophyte formation. Since the initial stages of DDD are primarily characterized by a loss of fluid content as seen on MRI images, the evaluation of x-ray images will, however, only detect advanced stages of disc degeneration.[2,55–59]

In a retrospective MRI and CT study, Park *et al* published a 4.3% progression rate of ALD in a cohort of 32 patients after a mean FU of 32.2 months following TDR with ProDisc II.[49] Conversely, Shim *et al* reported a 19.4% to 28.6% incidence of ALD in a retrospective MRI investigation of 57 patients after a mean FU of 38 to 41 months.[50] While Park *et al* interpreted their results of the degenerative changes in the discs and the facet joints at the adjacent segments to be minimal, Shim *et al* concluded that the aggravation of the degenerative process within the facet joints and ALD raised concerns about the late consequences of TDR.

Table 5. Previously Published Data on Adjacent Level Degeneration (ALD) and Facet Joint Degeneration (FJD) Following Total Lumbar Disc Replacement (TDR)

	Current Study	Shim *et al*[50]	Park *et al*[49]	Huang *et al*[54]
Implant	ProDisc II	33× Charité III 24× ProDisc II	ProDisc II	ProDisc I
No. patients	n = 93	n = 57 (MRI FU available in 52 patients)	n = 32	n = 42
No. disc replacements	n = 108 (15× bisegmental)	Charité: n = 35 (2× bisegmental) ProDisc: n = 29 (5× bisegmental)	n = 41 (9× bisegmental)	n = 60 (27× 1-level, 12× 2-level, 3× 3-level)
Follow-up	53.4 mo (range, 24.1–98.7 mo)	Charité: 41 mo (range, 36–48 mo) ProDisc: 38 mo (range, 36–40 mo)	32.2 mo (range, 26–42 mo)	8.7 yr (range, 6.9–10.7 yr)
Study design	Prospective; MRI investigation	Retrospective; MRI investigation	Retrospective; MRI and CT investigation	Retrospective; radiographic x-ray investigation
No. observers	2 independent skeletal radiologists	2 independent neurosurgeons	1 independent skeletal radiologist	Single observer
Range of motion (overall results)				3.8° ± 2.0°
ROM at L4/L5	6.3° ± 4.6°	Charité: 11.7° (2.6°–23.8°) ProDisc: 11.9° (3.3°–21.8°)	6.5° ± 4.0°	
ROM at L5–S1	5.7° ± 3.9°	Charité: 11.2° (4.2°–20°) ProDisc: 5.6° (0.3°–11.5°)	3.0° ± 1.6°	
Adjacent level disc degeneration				
Classification system for evaluation of disc degeneration	Pfirrmann *et al*[46]	Pfirrmann *et al*[46]	Pfirrmann *et al*[46]	(Loss of cranial disc space height >2 mm; anterior osteophyte formation >3 mm, flexion/extension instability >3.5 mm)
Mode of evaluation	Discs cranial and caudal of TDR	Discs above TDR	Discs cranial and caudal of TDR	Discs above TDR
Incidence of adjacent level degeneration (ALD)	10.2% (n = 11/108 segments)	Charité: 19.4% (n = 6/31 segments) ProDisc II: 28.6% (n = 6/21 segments)	4.3% (n = 2/47 segments)	23.8% (n = 10/42)
Facet joint degeneration				n.a.
Classification system for evaluation of facet joint degeneration	Weishaupt *et al*[47]	Modified from Fujiwara *et al*[51]	Weishaupt *et al*[47]	n.a.
Mode of evaluation	Each facet joint evaluated and scored separately; degeneration confirmed by both observers	Bilateral facet joints evaluated, joint that showed worst grade was scored	—	n.a.
Incidence of index segment facet joint degeneration (FJD)	20.0% (n = 44/220 facet joints)	Charité: 36.4% (n = 12/33 segments) ProDisc II: 32.0% (n = 8/25 segments)	29.3% (n = 12/41 segments)	n.a.

n.a. indicates not applicable.

The data from this study reveal a low incidence of ALD observed at 10.2% (n = 11/108) of all adjacent levels. Signs of ALD occurred late postoperatively after an average FU of 62.5 months. The degenerative changes were mild, a second degree ALD was only observed once overall (n = 1/108, 0.9%). Finally, the occurrence of ALD did not negatively affect the clinical symptomatology in terms of inferior VAS or ODI scores ($P > 0.05$).

In a 5-year prospective longitudinal MRI study in asymptomatic individuals, 20 to 50 years of age, Elfering *et al* reported a deterioration of the disc status in 41% (n = 17/41) of all individuals.[60] In another 5-year FU study of 116 adult male monozygotic twin pairs, Videman *et al* published a progression rate of the degenerative changes in approximately 10% of the Th12–S1 discs examined.[61] In light of these studies, the current data highlight that the incidence of ALD following TDR does not exceed previously published rates of the natural progression of DDD in asymptomatic individuals.

Therefore, our results are in congruence with findings that have previously been published in a variety of independent biomechanical and radiologic studies which demonstrated an unloading effect of TDR on adjacent levels in comparison to fusion procedures.[62–65]

Mechanisms of Adjacent Segment Preservation

The precise mechanism of adjacent level preservation following TDR remains unknown. The primary working hypothesis in this particular study was that motion preservation and increased index-level mobility would reveal beneficial effects with regard to adjacent level preservation but that it might be disadvantageous with regard to the progression of the degenerative changes at the index-segment's facet joints.

Huang *et al* previously published that 5° ROM at the index level may possibly be a protective threshold against the development of ALD.[54,66] Nevertheless, the exact quality and quantity of ROM required for preservation of the adjacent segments remains unknown. This was similarly outlined in a biomechanical study performed by Nunley *et al.*[67] The authors compared pressure effects on adjacent level discs after 2-level constructs, *i.e.*, fusion, hybrid, and TDR. No significant differences were found between the different stabilization procedures. In a comment on this study, Benzel therefore concluded that the range or extent of motion is much more than likely overrated, and less range of motion in exchange for better quality of motion would be a highly satisfactory trade-off.

In contradiction with our primary working hypothesis, our own data did not confirm a significant correlation or relevant threshold value of the index-segment ROM on one hand and the progression of the degenerative changes observed at adjacent segments on the other hand ($P > 0.05$).

Thus, it may be assumed that other additional protective factors may come into play. As opposed to lumbar fusion procedures for which a sagittal malalignment has been held responsible for the development of ALD in a considerable number of patients,[7,8,68,69] previous studies have reported a maintained physiologic sagittal alignment following TDR with possible advantageous effects on the adjacent segments.[70–73]

Finally, the anterior approach avoids iatrogenic adjacent level weakening resulting from superior segment facet joint violation which has similarly been reported for pedicle screw based instrumentation systems.[12–14]

Facet Joint Degeneration

In a study with CT osteoabsorptiometry, Trouillier *et al* reported morphologic findings following TDR with SB Charité (Depuy Spine, Raynham, MA). The authors suggested that there was not only an absence of facet joint degeneration but also possibly a reversal of an already existing facet osteoarthritis due to "improved segmental kinematics and restored disc space height with unloading of the facet joints."[74] The fact that these data have, to date, not been confirmed by other study groups raises doubts on the interpretation of the results.

Conversely, a variety of biomechanical studies have demonstrated increased facet pressures, segmental instability at the index level and altered load patterns with sudden rather than gradual load increase in the facet joints.[63,75–85] Radiologic studies have demonstrated an increased segmental hyperlordosis with the potential of subluxation of the facet joints.[70,73,86–89] It has also been shown that TDR with Charité III did not restore the physiologic segmental rotational stability with additive destabilizing effects for multilevel *versus* monosegmental TDRs.[80,90] Leivseth *et al* highlighted the disparity between the prosthesis and the anatomic center of rotation in patients treated with ProDisc II, particularly at the lumbosacral junction.[91] Similarly, Rousseau *et al* highlighted aberrant centers of rotation following TDR, and the authors also published possible consequences on facet joint contact forces.[82,92] The clinical implications include post-TDR facet joint complaints as has been published previously.[27,93]

In spite of these well justified concerns, the currently available data on pathoanatomic morphologic changes of lumbar facet joints following TDR is scarce. Shim *et al* reported a 32% to 36.4% rate of degeneration of the facet joints following TDR with Charité III and ProDisc II (Table 5).[50] According to the authors, the high incidence of facet joint degeneration after an average FU of 38 to 41 months appeared to be too short to be explained by the natural course of degeneration. Park *et al* observed progression of FJD in 29.3% of TDR segments at a FU of 32.2 months from grade 1 to grade 2, predominantly in women and 2-level TDR.[49]

In accordance with the above mentioned studies by Shim *et al* and Park *et al*,[49,50] our own data similarly reveal a progression rate of FJD in a considerable number of patients (20%, n = 44/220 facet joints). The severity of FJD was, however, less than expected. There was no case of a deterioration by ≥2 classes.

These data should, however, be adequately placed into perspective. Previous studies have shown that the degenerative cascade within a lumbar disc, which will alter segmental kinematics and which will finally result in degenerative changes in the facet joints at the index- and adjacent levels, can already be initiated following a mere needle puncture or a standard stab incision into the disc.[2,51,55,56,58,59,92,94–101] From this point of view, it does not seem surprising that the complete removal of a disc and replacement with an artificial implant, which is associated with all of the above mentioned potential biomechanical pitfalls, will ultimately result in secondary degenerative changes in the facet joints.

However, these data should also be interpreted in light of previously published high rates of adjacent level arthropathies which can be observed following so-called "gold-standard" fusion procedures, which have been reported either as secondary degenerative changes or as a direct result of cranial segment facet joint violation.[6,12–14]

Kalichman *et al* previously published the prevalence of FJD in a community-based population.[52] The authors found a significant increase in FJD with age. The prevalence of FJD was 24.0% in patients below the age of 40. This number increased to 44.7% for patients between 40 and 49 years of age, which resembles the mean age group examined in the current study. These data highlight the difficulties to differentiate between the progression of FJD that may be attributed to either a normal aging process on the one hand or possible late consequences following TDR on the other hand.

Factors Influencing the Progression of Facet Joint Degeneration

However, a variety of factors indicate that biomechanical alterations may at least be partially responsible for the development and progression of FJD following TDR. The data from the current study revealed that the incidence of FJD was significantly higher at index-levels in comparison to nonindex levels following TDR at the lumbosacral junction ($P < 0.001$). Furthermore, previous studies have shown that the highest prevalence of FJD in the general population can be found at the level L4/L5.[102,103] Following TDR, however, the occurrence of FJD seems to shift to the lumbosacral junction, while TDRs that were performed at the level above the lumbosacral junction did not significantly alter the incidence of FJD (Table 4).

In opposition with our primary working hypothesis, the current data revealed significantly lower ROM values in segments with progression of FJD in comparison to the group of patients that were not affected by any progression of the degenerative facet joint condition ($P < 0.0001$; Figure 3). Thus, locked-in facet joints which are exposed to persistent stress may predispose the segment to progressive degenerative changes in the facet joints as opposed to levels with potentially more physiologic motion patterns following TDR.

Finally, the progression of FJD was associated with a negative influence on the patient's clinical symptomatology as reflected in significantly inferior VAS and ODI scores ($P < 0.02$; Figure 2). Despite the fact that the morphologic changes within the facet joints occurred at later FU stages, it was interesting to observe that the inferior VAS and ODI scores were already detected at an early postoperative stage at the 3 and 6 month FU examination.

In summary, our findings indicate that progressive degenerative changes in the facet joints may affect a particular cohort of patients, namely, the one which demonstrates inferior compatibility between the prosthesis' and the physiologic index-segment's biomechanical properties. This phenomenon is outlined by significantly lower ROM values which could possibly be attributed to locked-in facet joints, coupled with inferior clinical results that were already detected at an early postoperative stage.

Future studies will have to investigate whether the progressive degenerative changes will predominantly be limited to this particular cohort of patients with unfavorable biomechanical compatibility, or whether the overall patient population will be affected, which may have consequences for the long-term clinical results of lumbar disc replacement procedures.

■ Conclusion

The data obtained from this study reveal a low incidence of ALD following TDR with ProDisc II after a mean FU of 53.4 months. The degenerative changes were mild, occurred late after surgery and did not reveal a negative influence on the patient's clinical symptomatology. There was no significant correlation between the index-level mobility and the progression of ALD which suggests that other concomitant factors contribute to adjacent level preservation.

Conversely, progressive index-level FJD was observed in a considerable number of patients (20%, n = 44/220), particularly at the lumbosacral junction. With the majority of cases being classified by a deterioration of 1°, the severity of FJD was, however, less than expected. The progressive degenerative changes in the facet joints were associated with a negative influence on the clinical outcome in terms of inferior VAS and ODI scores which were already detectable at an early postoperative stage ($P < 0.03$). In opposition with our primary working hypothesis, the progression of FJD was observed in segments that were significantly less-mobile ($P < 0.0001$), possibly attributed to locked-in facet joints.

A variety of factors indicate that biomechanical alterations are responsible for the degenerative changes in patients with potential discrepancies between the prosthesis and the physiologic index-segment's biomechanical properties. Future studies will have to investigate whether the progressive degenerative changes will predominantly be limited to this particular cohort of patients with unfavorable biomechanical compatibility or if the overall patient population will be affected which may have consequences for the long-term clinical results of lumbar disc replacement procedures.

■ Key Points

- After a mean FU of 53.4 months the observed incidence of ALD following TDR was low (10.2%; n = 11/108 levels). The degenerative changes were mild, occurred late after surgery and did not reveal a negative effect on postoperative clinical outcome. There was no significant correlation between index-level ROM and the occurrence of ALD ($P > 0.05$).
- Degenerative changes in the facet joints were observed in a considerable number of patients (20.0%; n = 44/220 index level facet joints). FJD occurred significantly more often following TDR at the lumbosacral junction in comparison with the level above the lumbosacral junction ($P < 0.02$), and was observed more frequently at index-levels in comparison to nonindex levels ($P < 0.001$).

- Progression of FJD revealed a negative influence on the postoperative clinical outcome. Although the degenerative morphologic changes were observed at later stages, significantly inferior outcome parameters VAS and ODI were already detected early after surgery at the 3- and 6-month FU examination ($P < 0.03$).
- The mean postoperative ROM was significantly lower in patients with progression of FJD in comparison to the remaining cohort without signs of FJD ($P < 0.0001$).

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