



Transpedicular Lumbar Fusion in Patients without Improvement of Low Back Pain Following Implantation of Disc Prostheses

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ABSTRACT

AIM: To evaluate the option of lumbar transpedicular fixation at the index level in patients who did not achieve adequate pain relief after lumbar total disc replacement (TDR) without evidence of device failure.

MATERIAL and METHODS: Four patients (mean age, 47 years) presented with persistent low back pain following lumbar TDR for 12–24 months (mean, 16.3). No device failures were observed. All patients underwent transpedicular fixation at the index level. Clinical outcome was assessed via the Oswestry disability index, a visual analog scale, and recording of the consumption of analgesics.

RESULTS: No postoperative complications were observed. The average follow-up after lumbar transpedicular fixation was 53.5 months (range, 43–80). Two patients considered the outcome as excellent, one as good, and one as poor. The mean visual analog scale pain score decreased from 7.8 (range, 7–8) to 4.3 (range, 2–8). The mean Oswestry disability index decreased from 43.5 (range, 39–47) to 27.5 (range, 14–47). At the last follow-up, one patient was without analgesic medication and substitution of opiates with non-opioid analgesics was possible in two patients.

CONCLUSION: In patients with persistent low back pain after TDR without device failure or adjacent segment pathologies, lumbar transpedicular fixation without removal of the disc prosthesis may be a useful therapeutic option.

KEYWORDS: Lumbar spine, Low back pain, Disc prosthesis, Lumbar fusion, Pedicle screws

ABBREVIATIONS: TDR: Total disc replacement, VAS: Visual analog scale, ODI: Oswestry disability index

INTRODUCTION

Several surgical options are available for the treatment of severe chronic low back pain secondary to degenerative disc disease (2,3,23). Rigid stabilization to promote osseous fusion has been considered the gold standard for many decades (2). However, since fusion may alter the biomechanical dynamics of adjacent segments (12,19), alternatives have been developed, including total disc replacement (TDR) with lumbar disc prostheses (3,8,21,22,33).

The safety and efficacy of TDR have been demonstrated in several studies, including pain relief in a large number of patients (17,24,27,36,38). Several underlying causes have been identified in patients who did not achieve long-term improvement with TDR, including technical errors, secondary device migration, or adjacent segment pathology (10,16,34). Nevertheless, there is also a subgroup of patients with well-placed prostheses and without progression of degenerative disease who do not benefit from TDR (1,11).

Re-operations after TDR have been reported to be necessary for a broad range from 0–33 % of patients in different studies (8,13,18,26,35,38). Limited data are available on the outcome in patients who underwent posterior fixation only after failed TDR with partially conflicting results (1,35). Here, we evaluated the option of secondary lumbar transpedicular fixation without revision of the lumbar prosthesis in patients who did not obtain appropriate benefit after lumbar TDR and had no evidence of device failure or adjacent segment morbidity.

■ MATERIAL and METHODS

Four patients with persistent low back pain after lumbar TDR were included in this study. The primary inclusion criteria were previous implantation of a lumbar disc prosthesis, persistent low back pain for more than 12 months after surgery, no adjacent level pathologies, and no device migration since implantation. The disc prostheses were all implanted in other hospitals and the patients were admitted to our department for revision surgery. The types of disc prostheses included the Maverick and Sofamor Danek systems.

Clinical presentation was evaluated using a visual analog scale (VAS) for low back pain and the Oswestry disability index (ODI) (9). For the VAS, the patients were asked to classify their pain intensity on an 11-point scale, where 0 indicates no pain and 10 indicates the worst imaginable pain. For the ODI, the patients assessed the level of pain impairment for different physical activities including sleep, self-care, sexual activity, social life, and traveling. Responses to all the questions were scored from 0 to 5. The scores of all sections were added and divided by 50 (corresponding to the total possible score). The result was multiplied by 100 to obtain the percentage score. Zero corresponds to no restriction, and 100 % corresponds to a maximal handicap (9).

All patients underwent standard imaging examinations, including myelography and postmyelo-computed tomography (CT) with flexion-extension X-rays. Secondary lumbar transpedicular fixation was performed with polyaxial titanium screws (Expedium DePuy Synthes; Warsaw, Indiana, USA) and autologous bone was used for fusion. Follow-up was assessed in an outpatient setting and the last follow-up information was obtained through telephone interviews.

Statistical analysis included descriptive statistics. A paired t-test was used to assess the statistical significance of the

improvement before and after surgery. Alpha was set to 0.05. Statistical analyses were performed using JMP® 14 Pro 14.3.0 (SAS Institute Inc., Cary, NC, USA).

■ RESULTS

The mean age was 47 years (range, 30–58 years) at the time of the second surgery (Table I). Two patients were women and two were men. The average time from lumbar TDR surgery to lumbar transpedicular fixation was 16.3 months (range, 12–24 months). Primary surgeries were performed in other hospitals and all patients were referred for evaluation of additional treatment. Lumbar TDR was performed for severe refractory chronic back pain in all instances. Two patients presented with degenerative disc disease at level L5/S1 without previous surgery, one patient had persistent pain after three disc surgeries at level L4/5, and one patient had chronic pain after four disc surgeries at levels L4/5 and L5/S1.

Myelography and postmyelo-CT showed facet joint arthrosis at the level of the implanted disc prosthesis in all patients. An example of this is shown in Figure 1A, B. There was no osteochondrosis or facet joint arthrosis of the adjacent segments. There was a slight axial prosthesis displacement that had been present since the initial surgery in patients 1 and 2 (Figure 2A-H), whereas disc spaces were unremarkable in patients 3 and 4.

There were no neurological deficits or signs of neuropathic pain syndromes. All patients received opioids at the time of presentation at various dosages. The mean VAS score was 7.8 (range, 7–8), and the mean ODI was 43.5 (range, 39–47) (Table I).

Lumbar transpedicular fixation was performed only at the level of the implanted prostheses. Pedicle screws were inserted using fluoroscopy. Autologous bone fragments obtained from dorsal decompression at the index level were added as posterolateral grafts to prompt fusion. No additional segments were fused. Each secondary lumbar transpedicular fixation surgery was uneventful. Postoperatively, no new neurological deficits were observed. The average follow-up after lumbar transpedicular fixation was 53.5 months (range, 43–80 months). At the latest follow-up, two patients considered their outcome as excellent, one as good, and one as poor (patient with bisegmental procedure). There were long-term decreases in both VAS and ODI. At the last follow-up, the mean VAS score

Table I: Visual Analog Scale (VAS) and Oswestry Disability Index (ODI) Scores in Four Patients With Previous Disc Replacement Surgery for Chronic Back Pain, Prior to Transpedicular Fixation and at the Last Available Follow-Up

Patients	Age	Gender	Visual analogue scale (back pain)		Oswestry Disability Index	
			Before lumbar transpedicular fixation	Last follow-up	Before lumbar transpedicular fixation	Last follow-up
1	42	M	7	2	39	14
2	58	F	8	5	46	33
3	30	F	8	8	47	47
4	58	M	8	2	42	16

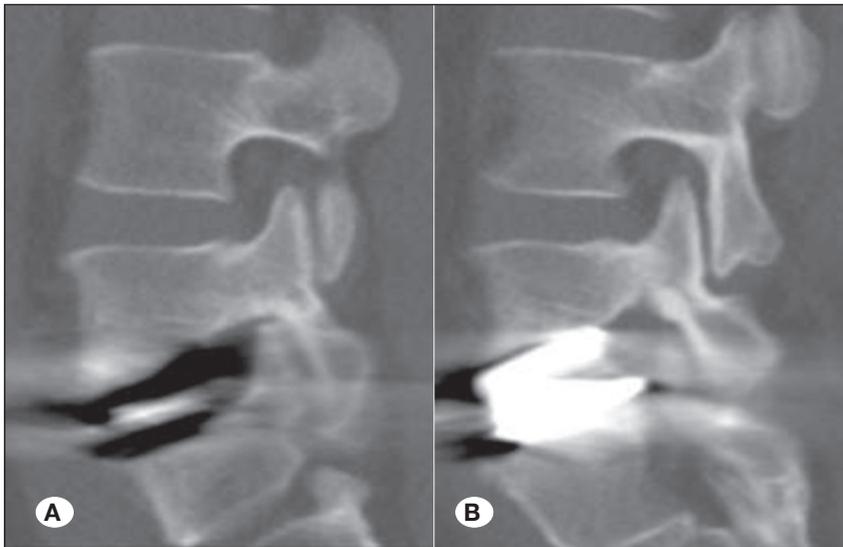


Figure 1: Sagittal reconstructions of computed tomography scans in the bone window mode (**A:** right side, **B:** left side) of patient 1 show marked degeneration of the facet joints at the index level after total disc replacement before transpedicular fixation, more pronounced in the right side.

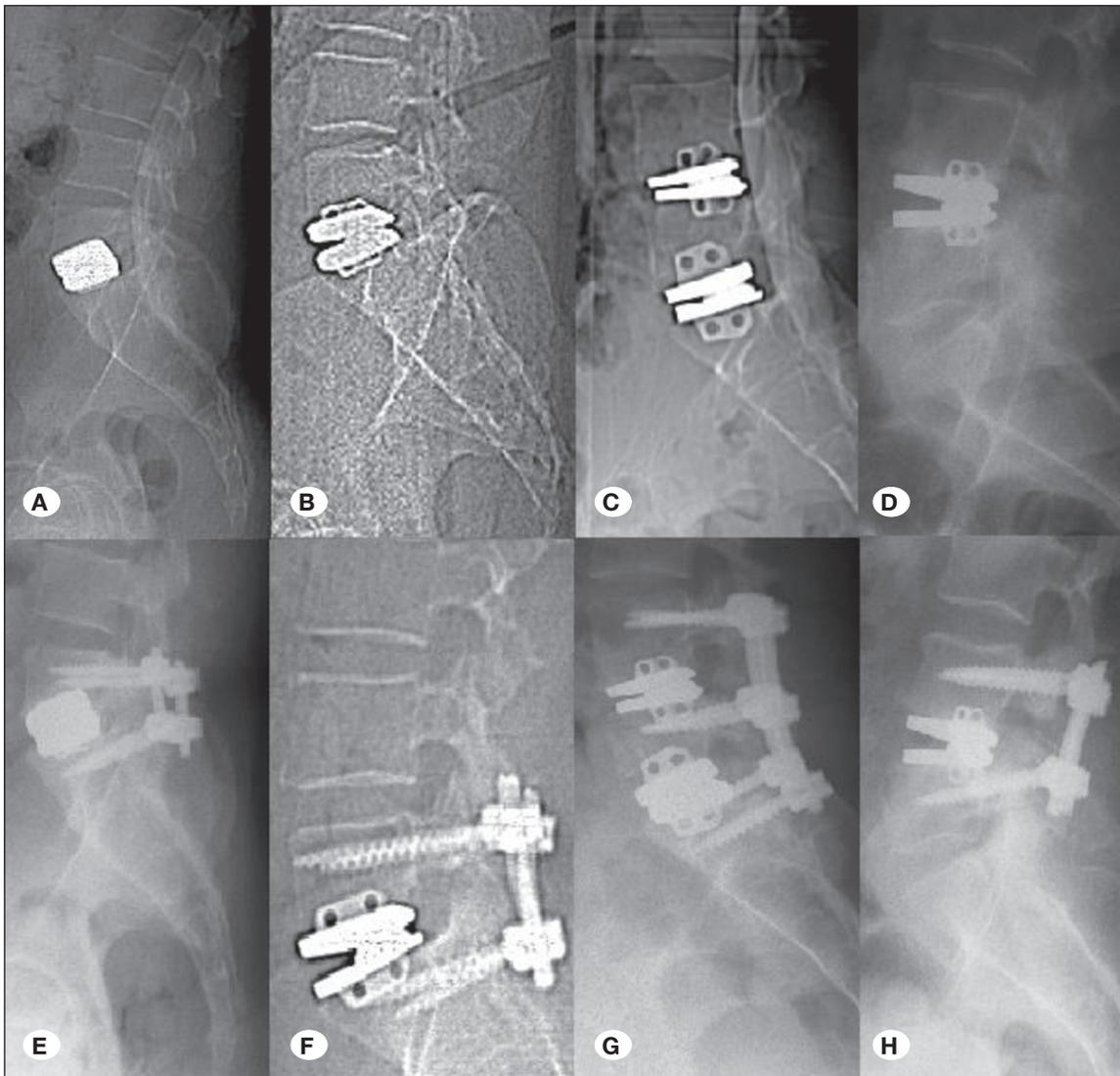


Figure 2: A–H: Lateral X-rays before (A–D) and after (E–H) lumbar transpedicular fixation in four patients with an implanted lumbar total disc replacement.

was 4.25 (range, 2–8) and the average ODI was 27.5 (range, 14–47) (Table I). The paired-differences statistics in VAS and ODI revealed statistically significant mean differences (\pm 95 % confidence intervals of -3.5 ± 4.21 ($p=0.0386$), and -16 ± 19.4 ($p=0.0393$) for VAS and ODI, respectively (one-sided alternative hypothesis: mean < 0 , $df=3$)).

The patient with a previous bisegmental procedure who did not benefit from lumbar transpedicular fixation could not reduce the analgesic medication because of substance dependence. In two patients it was possible to replace opioids with non-steroidal analgesics. One patient did not take any medications at all anymore.

Postoperative lumbar radiography showed a regular position of the pedicle screws and the same position of the lumbar TDR without dislocation. Follow-up imaging studies did not reveal signs of screw loosening in any patient.

■ DISCUSSION

Although TDR has attracted considerable attention in recent years and randomized studies comparing TDR with fusion surgery have proven TDR to be non-inferior, the definite role of TDR still needs to be defined and it also remains to be determined whether TDR indeed avoids adjacent segment morbidity (3,6,10,24,30,33). Interestingly, meta-analyses on the subject have conflicting results (6). More recently, studies have shown consistently greater improvement with TDR than with arthrodesis using new prosthesis technology (13,39).

There are multiple causes for unsatisfactory results after TDR, including wrong indications, poor implantation technique, and improper positioning of the implant on one hand, but also device-related complications such as subsidence, vertebral body fractures, polyethylene extrusion, and problems due to polyethylene wear on the other hand (4,35). In a series of 75 patients with persistent low back pain after insertion of SB Charite lumbar disc prostheses, disc prosthesis subsidence was noted in 39 instances, adjacent disc degeneration in 36, facet joint degeneration in 25, inappropriate size of disc prosthesis in 24, lumbar scoliosis in 11, breakage of the metal wire around the core in 10, disc prosthesis migration in 8, wear of the disc prosthesis in 5, and subluxation of the polyethylene core and severe osteolysis in one patient (29).

The causes for the lack of improvement with well-placed prostheses in a subset of patients after TDR remains unclear (1), but facet joint degeneration has been suggested as a major possible cause (35). Remarkably, facet joint degeneration was also present in all patients in our series. In this regard, it has been proposed to use test infiltration of the corresponding facet joint to select patients for surgery (31).

The exact causes why the four patients in our study did not have long-term benefits from TDR surgery remain unknown. A common finding, however, was facet joint arthrosis at the level of the surgery. Remarkably, facet joint degeneration at the index segment was also considered as the main cause for TDR failure in a previous study (37).

The incidence of index level facet joint degeneration after TDR at two-year follow-up was 29% in another study (25).

Inadequate restoration of physiological kinematics with an increased load of the facet joints at the index level may be a major factor (36). Biomechanical studies have shown that disc prostheses result in an increased static load of the facet joint at the index level even in well-placed prostheses (7). The abnormal sagittal balance after TDR may lead to an increase in facet load (32). To unload the index facet joints and to achieve sagittal balance, some authors recommended more posterior positioning of the disc prostheses. Particularly, lateral displacement of the disc prosthesis with abnormal coronal balance may lead to an increase in index facet load, even if there is only a slight lateral displacement.

Different concepts of disc prostheses may also influence the facet load. Disc prostheses are constructed as constrained devices with low ranges of motion or as unconstrained prostheses with larger ranges of motion. During movement, unconstrained prostheses share more load with the surrounding structures. Thus, unconstrained prostheses may increase the index facet joint load (18,20). Constrained prostheses, however, with low ranges of motion can unload the index facet joints which may increase the risk of adjacent level degeneration.

There is no agreement about the best option for the treatment of unsatisfactory results after TDR. While there is a need to replace the prosthesis in patients with device failures and anterior or posterior displacements, cases with subsidence or unremarkable findings might also be suitable for posterior stabilization. There is great variability in the proportion of patients who undergo either treatment in different studies (4,5,18,28,29). Selection criteria specifying which approach should be favored upon revision surgery have been only partially outlined, and the follow-up reporting on outcomes after salvage surgery is limited (13).

Overall, the results of revision surgery after failed TDR surgery have been very variable, with some studies reporting large improvements in several scores (31), while poor clinical outcomes have been described in other studies (11). In addition, the type of revision surgery has not been specified in several studies (18). In general, most groups favor an anterior approach for revision surgery (5,28,29). It has been speculated that anterior approaches with removal of the disc prosthesis would be superior to posterior lumbar fusion only, since it was hypothesized that it would be advantageous to remove the periprosthetic tissue (29). However, there are no comparative studies that support this concept.

Revision surgery via anterior or lateral approaches can be complicated by scar tissue and adhesions of previously mobilized abdominal vessels during the index procedure. The lumbar TDR has to be removed completely and is usually replaced by a bone graft. It is associated with a higher approach-related complication rate (4,14,15,35), including intraoperative vascular injury, retrograde ejaculation, impotence, retroperitoneal fibrosis, muscle hematoma, pancreatitis, femoral nerve palsy, pseudomeningocele, and latissimus dorsi rupture.

There is a lack of long-term follow-up data of salvage surgery via lumbar transpedicular fixation without removal of the lumbar disc prosthesis (1,27,29,35). In one of the few studies

providing detailed individual clinical outcomes after posterior fixation without TDR replacement as a salvage procedure for failed TDR, no improvement was achieved in three patients (1). In a series of 37 patients who underwent repeat surgery after failed TDR, 15 patients underwent lumbar transpedicular fixation only without removal of the TDR. In 22 patients, disc prostheses were removed via an anterior approach and the gap between the vertebral bodies was filled with an autologous strut graft, often supplemented by posterior fixation (29). Changes in the VAS and ODI were comparable within groups, although the results after disc removal were considered slightly better. Only patients with a follow-up period of at least one year were included but the exact length of follow-up was not stated. In a study on long-term follow-up for five to ten years after TDR, re-operations were performed in 16 % of patients of an initial cohort of 201 patients (35). Posterior instrumentation for fusion was used in a larger proportion of patients than anterior revision surgery. However, the differences in surgical outcomes and the length of follow-up after revision surgery were not outlined in detail.

Our study shows that patients with unsatisfactory results after TDR may achieve additional long-term benefit after secondary posterior stabilization and fusion. It also demonstrates that even in patients with suboptimal TDR placement there is no need to replace the prosthesis.

■ CONCLUSION

Although the number of patients in our study was small, it shows that fusion is superior to TDR in some patients. A subset of patients, who do not achieve appropriate relief of low back pain after TDR despite seemingly well-placed disc prostheses and who have no signs of adjacent segment pathology, may benefit from salvage surgery via posterior transpedicular fixation without anterior disc replacement. This strategy has a lower risk of side effects. However, comparative studies and more evaluations of long-term outcomes are needed to confirm these findings.

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