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A Prognostic Evaluation of Back Pain Resolution Following Total Disc Replacement

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Abstract

Background: Spinal fusion is the traditional surgical treatment for chronic low back pain (CLBP), but loss of segmental motion may redistribute stress to adjacent levels and accelerate degenerative changes (adjacent segment disease (ASD)). Total disc replacement (TDR) was developed as a motion-sparing alternative, yet long-term evidence comparing surgical goal attainment with clinical outcome remains limited.

Objective: To evaluate the relationship between achievement of the surgical goal and clinical outcome following TDR versus instrumented fusion, and to characterize segmental and adjacent-level kinematic changes over time.

Methods: One hundred fifty consecutive patients (80 female, 70 male; mean age 42 years; range 22 - 60) with symptomatic degenerative disc disease at one or two segments between L1 and S1 and CLBP were randomized to TDR (n = 85) or instrumented fusion (n = 65). Outcomes were assessed using a visual analog scale (VAS) and a global assessment (GA) score for back pain. Segmental mobility was evaluated by means of dynamic conventional radiography (DCRA) preoperatively and at 2- and 5-year follow-up.

Results: The surgical goal was achieved in 72% of TDR patients (restored and sustained mobility) and 64% of fusion patients (complete absence of motion) (p = 0.31). 72% of TDR and 64% of fusion patients reported being pain-free or much improved; complete pain relief was reported by 37% versus 13%, respectively. A significant association between surgical goal achievement and clinical outcome was observed in the TDR group ($p < 0.02$), but not in the fusion group ($p = 0.46$). TDR patients meeting the surgical goal achieved significantly superior results across all outcome measures compared with fusion patients who attained arthrodesis. Fusion was associated with significantly greater anteroposterior displacement at the adjacent L4 - L5 segment ($p < 0.05$). Fourteen fusion patients required reoperation for implant removal, and seven TDR patients underwent secondary fusion for facet joint pain.

Conclusions: At 5-year follow-up, both surgical goal attainment and clinical outcomes were superior following TDR compared with fusion. These findings appear interrelated, as patients with mobile prostheses reported better results. Given the time-dependent nature of segmental mobility and ASD, a 10-year follow-up is planned.

Keywords: Total disc replacement, Back pain, Dynamic conventional radiography, Adjacent segment disease, Chronic low back pain

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Introduction

Spinal fusion has traditionally served as the primary surgical intervention for CLBP. Nevertheless, fusing a spinal segment can adversely affect the physiological and biomechanical function of adjacent segments and the spinal column as a whole [1]. The loss of motion at a fused level may redistribute stress to neighboring segments, potentially accelerating degenerative changes — a phenomenon termed ASD [2, 3]. A systematic review of kinematic investigations demonstrated that while most patients exhibited no generalized kinematic alterations at segments cranial or caudal to the fusion site, a subset (approximately 20 - 30%) developed pronounced kinematic instability at the cranial adjacent level following lumbar fusion [4]. These observations prompted the development of non-fusion, motion-sparing surgical techniques. TDR was introduced to mitigate the complications associated with ASD by maintaining mobility at the operated level. Symptom relief following TDR is believed to result from both the removal of the pathological disc and the restoration or enhancement of load transmission across the segment [5, 6]. A cochrane review concluded that TDR appears effective for managing low back pain in appropriately selected patients and yields outcomes at least comparable to fusion in the short term [7]. The observed differences in clinical improvement fell within generally accepted thresholds for clinical equivalence. Findings from a randomized controlled trial (RCT) directly comparing fusion and TDR favored TDR over fusion at both the 2- and 5-year follow-up intervals [8, 9]. Notably, a greater proportion of patients in the TDR cohort reported complete absence of pain. In general, lumbar range of motion (ROM) tends to diminish following spinal fusion.

Research has shown that preserving or restoring segmental mobility helps avert abnormal stress and altered kinematics at adjacent levels [10]. Multiple investigations have characterized post-TDR kinematics and load distribution, with reports demonstrating near-normalized or fully normalized motion patterns [11, 12]. Conversely, one study found no association between clinical outcomes and the extent of segmental mobility following TDR [13]. In a long-term follow-up of patients implanted with an early-generation Charité prosthesis, 60% underwent spontaneous fusion over a 17-year period; paradoxically, these patients experienced superior clinical results compared with those whose segments remained mobile [14]. No radiographic evidence of ASD was detected among patients who retained mobility. Additional studies have documented even more favorable outcomes with this early prosthesis design [15, 16]. The literature remains divided regarding facet joint loading: some reports describe unchanged facet loads, while others provide evidence of increased facet joint forces following TDR [11, 12, 17].

A comparative analysis of segmental mobility derived from the aforementioned RCT, based on 2-year postoperative assessments, has been previously reported [18]. Because postoperative kinematic changes at both operated and adjacent segments are likely to evolve over time, investigations with extended follow-up periods are needed [7].

Methods

A total of 150 consecutive patients (80 female, 70 male; mean age 42 years; range 22 - 60 years) were enrolled. All participants presented with symptomatic degenerative disc disease affecting one or two motion segments between L1 and S1, with CLBP as the chief complaint. Clinical findings included interspinous tenderness on physical examination, radiographic evidence of disc space narrowing, and magnetic resonance imaging features consistent with disc degeneration. Patients exhibiting low-grade facet joint arthropathy at the target segment and low-grade degenerative changes at non-target segments were not excluded.

In 40 cases, preoperative diagnostic injections, provocative discography, and disc blocks were performed to pinpoint the pain-generating level(s) in situations where clinical uncertainty existed regarding whether one or two segments required treatment.

Following enrollment, patients were randomized to either the fusion or TDR arm using a sealed-envelope method. Eighty-five patients were allocated to TDR and 65 to instrumented fusion. TDR was performed through a ventral extraperitoneal approach. Fusion procedures employed a posterior approach, with the specific fusion technique selected at the discretion of the attending surgeon. Fixation was achieved using pedicle screws paired with rods or plates. All fusion surgeries were performed via an open instrumented technique. Homologous bone graft was used exclusively. Posterolateral fusion was performed in 40 patients, while posterior lumbar interbody fusion was carried out in 30 patients.

Back and leg pain were evaluated independently by means of a VAS. A GA score for back pain was also recorded, categorizing outcomes as total relief, much better, better, unchanged, or worse, which additionally served as a composite outcome measure.

Statistics

Disc height, translational motion, and sagittal alignment were expressed as deviations from sex-, age-, and segment-matched normative reference values, as previously described. These deviations were quantified in standard deviation units from the normative mean. Statistical comparisons employed the student t-test, chi-squared test, Fisher exact test, Mann-Whitney U test, Pearson product-moment correlation, and Spearman rank correlation. Statistical significance was defined $p < 0.05$.

Results

A statistically significant difference between the two groups was observed with respect to GA scores and the degree of low back pain improvement. No substantial intergroup differences in comparative outcomes were identified, partly because of patient attrition during radiologic follow-up in the TDR cohort.

Achievement of surgical goals

Flexion-extension radiographs were obtained both preoperatively and at the postoperative mark for 25 patients in the fusion arm and 35 patients in the TDR arm. Baseline ROM was comparable between the two groups (Figure 1). At the follow-up, flexion-extension ROM at the treated segments in the TDR group had increased relative to preoperative measurements. Within the TDR group, ROM at the L5-S1 level declined ($p < 0.01$). Regarding L5 - S1 segments treated with TDR

Figure 1: Surgical goal achievement rate — TDR 72% vs fusion 64% ($p = 0.31$).

demonstrated increased extension compared with baseline values ($p < 0.001$). Among fusion patients with radiographic evidence of successful arthrodesis, extension decreased at both L4 - L5 ($p < 0.001$) and L5 - S1 ($p < 0.001$). For TDR patients meeting the surgical success criterion, postural changes at L4 - L5 were not significant, whereas extension increased at L5 - S1 ($p < 0.001$).

In the fusion group, the surgical objective — defined as complete absence of segmental motion — was (64%). This rate was consistent across both fusion techniques. In the TDR group, the surgical goal — defined as restored and sustained mobility exceeding measurement error thresholds — was (72%). ROM values increased significantly relative to pre-treatment measurements ($p < 0.02$). The frequency of achieving the respective surgical goal was comparable between the two groups ($p = 0.31$).

No differences in surgical goal achievement were observed between single- and two-segment procedures in either treatment arm, nor were there any differences attributable to the various prosthesis brands utilized.

Relationship between surgical results and clinical outcome

At the follow-up, (72%) in the TDR group and (64%) in the fusion group reported being completely pain free. When complete pain relief alone was used as the criterion for success (Figure 2). A significant association between GA and surgical outcome was detected in the TDR group when a composite definition of clinical success — encompassing pain free, totally pain free, and much improved categories — was applied ($p < 0.02$). All remaining outcome measures likewise demonstrated significant differences within the TDR group. In contrast, no correlation between surgical and clinical results was found for any outcome measure in the fusion group. Patients in the TDR group who met the surgical goal achieved significantly superior results across all outcome measures compared with fusion patients who attained their respective surgical goal.

Adjacent segment

Absolute lordosis values were significantly greater in the TDR group than in the fusion group at both L4 - L5 and L5 - S1. This indicates that fused spines exhibited reduced lordosis relative to their preoperative state, whereas TDR augmentation resulted in increased lordotic curvature (Figure 3).

Disc height changes between baseline and the evaluation did not differ significantly between groups (Figure 4). A reduction in disc

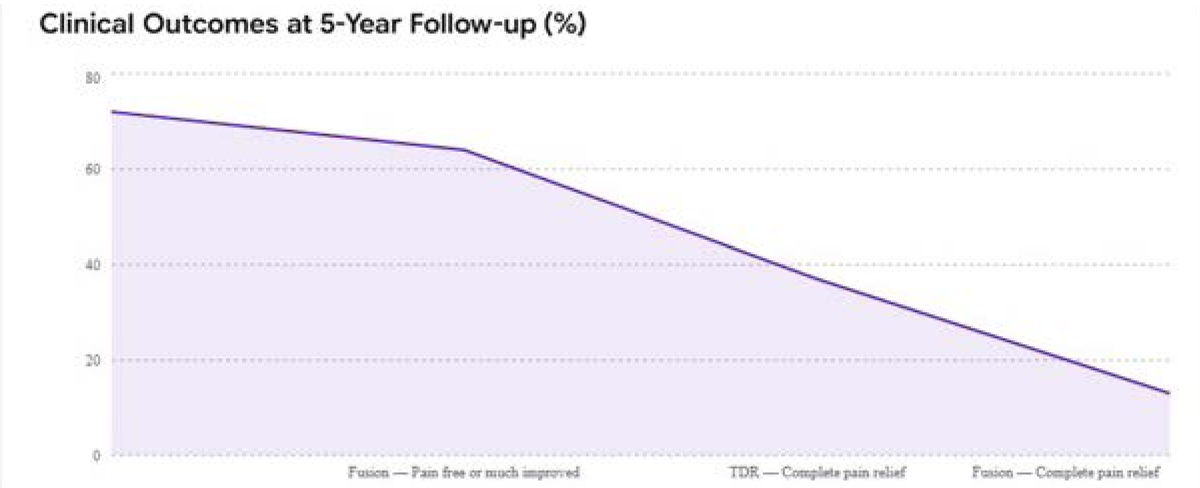

Figure 2: Clinical outcomes at follow-up (highlights the striking gap: 37% vs 13% for complete relief).

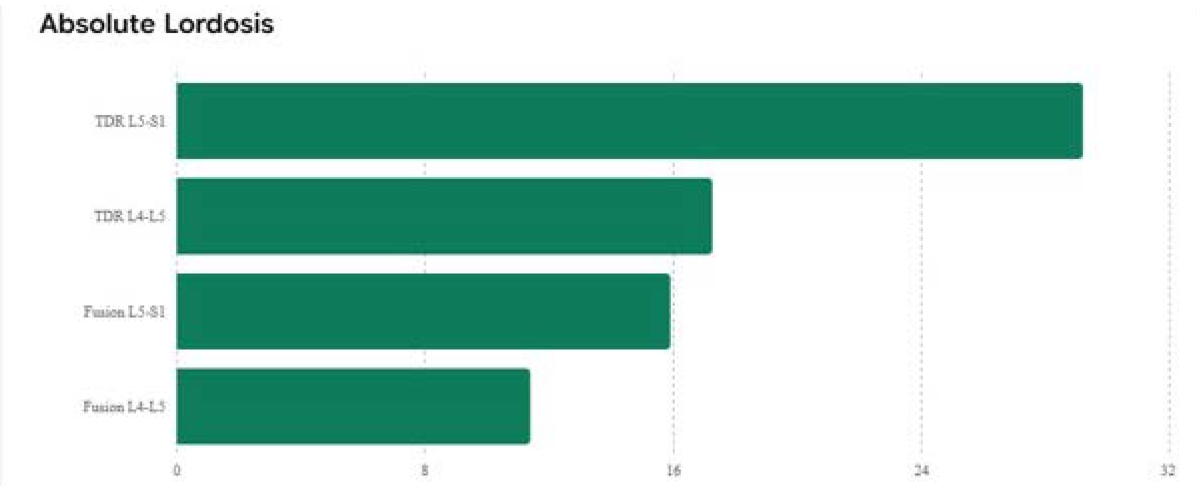

Figure 3: Absolute lordosis — TDR shows significantly greater lordotic curvature at both L4 - L5 and L5 - S1 ($p < 0.001$).

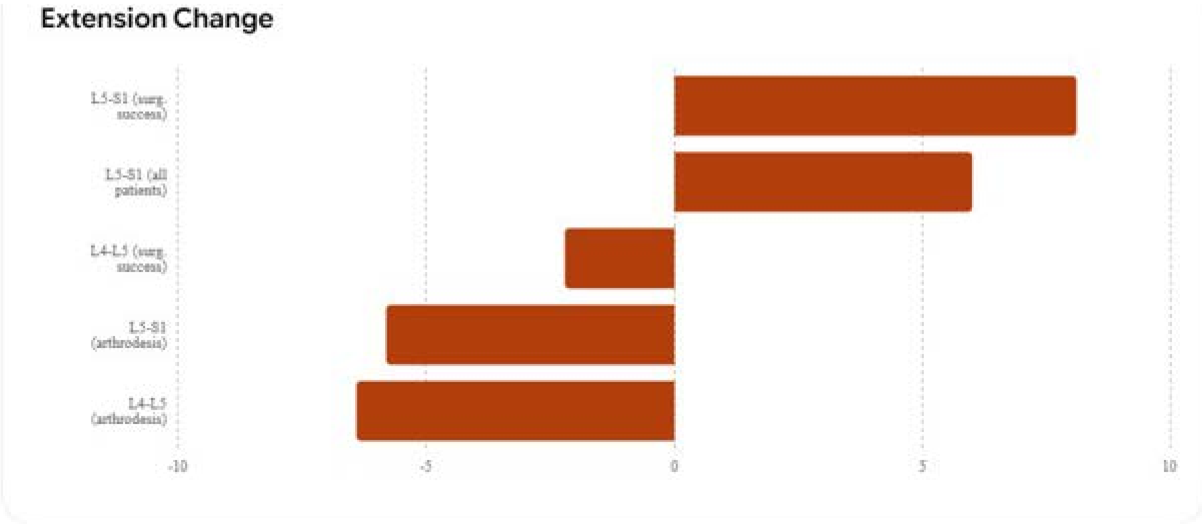

Figure 4: Extension change from baseline — positive bars for TDR L5 - S1 (+6.0° all patients, +8.1° surgical-success subset) vs negative bars for fusion (–6.4° L4 - L5, –5.8° L5 - S1), illustrating the opposite biomechanical effects.

Figure 5: Reoperations — 14 in the fusion arm vs 7 in TDR.

height was observed at L3 - L4 when this level was adjacent to a TDR. No such height loss was detected when the L3 - L4 disc was adjacent to a fused segment. A significant increase in motion at L3 - L4 was observed for both treatment modalities. In the fusion group, L4 - L5 motion also increased significantly; however, ROM subsequently declined. No significant intergroup difference was found for translational movement, though anteroposterior displacement at L4 - L5, when functioning as an adjacent segment, was significantly greater in the fusion group than in the TDR group postoperatively ($p < 0.05$).

Reoperations

Among patients monitored with dynamic radiography, 14 individuals who had undergone instrumented fusion required reoperation with implant removal due to persistent localized pain. Ten of these 14 patients had achieved surgical success (i.e., absence of segmental motion). Within the TDR group, seven patients underwent secondary segmental fusion for facet joint pain. Of these seven, two retained residual motion at the operated segment despite the secondary fusion procedure (Figure 5).

Discussion

Based on the DCRA findings, the surgical objective was achieved in 64% of fusion patients and 72% of TDR patients. The high proportion of TDR patients who retained mobility is encouraging, particularly given that these mobile patients demonstrated superior clinical outcomes at both the 2- and 5-year follow-ups compared with fusion patients who met their surgical endpoint. The observed postoperative mobility fell below the range permitted by the prosthesis design. These findings may reflect favorable advances in both implant technology and surgical technique since the early Charité era [14-16]. A recent computed tomography (CT)-based method for assessing mobility in TDR patients reported a median sagittal vertebral rotation at the operated level of 5.4° (±2.3°) preoperatively and 6.8° (±1.7°) postoperatively. The higher mobility values in our study may be attributable to the fact that CT imaging is performed in the supine position, whereas DCRA evaluations are conducted in the standing posture. Our findings contrast with those of Pinto et al. [13], who found no association between clinical outcome and surgical goal achievement in their TDR cohort.

Published reports describing the onset of facet joint arthropathy following TDR have raised concerns regarding both surgical methodology and implant dimensions and design [19, 20]. These refinements seek to position the prosthesis precisely at the midline to prevent asymmetric loading and irregular motion patterns between the facet joints, with the objective of placing the implant flush against the posterior longitudinal ligament. Such concerns have also prompted manufacturers to design lower-profile implants, thereby preventing the treated segment from being forced into hyperlordosis by an excessively tall prosthesis. These procedural and implant modifications were introduced after the patients in this trial received treatment; consequently, the rate of surgical goal achievement with current techniques remains uncertain. In the 2-year follow-up report from this RCT, non-physiologic disc height was observed following TDR, attributable to implants of excessive height. Whether a greater proportion of mobile TDRs would have been achieved with lower-profile implants cannot be confirmed, though it remains a plausible hypothesis.

The fusion group developed significantly greater anteroposterior displacement at the nearest adjacent segment relative to the TDR group. Nevertheless, overall lumbar flexion-extension mobility declined in the fusion group, despite the increased motion observed at the adjacent L4 - L5 level. Whether these findings represent early manifestations — or indeed the underlying cause — of ASD requires further investigation. The absence of clinical outcome differences between patients with stiff and non-stiff fusions may be explained by the possibility that incompletely stiffened segments impose less mechanical burden on adjacent levels. A limitation of this study is that the fusion group experienced dropout among patients with more favorable clinical outcomes. Had these patients been retained, a correlation between surgical success (solid arthrodesis) and clinical outcome might have been demonstrated.

Conclusion

In this RCT follow-up, both surgical goal attainment and clinical outcomes were superior following TDR compared with fusion. These two findings are likely interrelated, as patients with mobile prostheses reported better results than those whose prosthesis mobility was uncertain. Given that segmental mobility following TDR and the potential development of ASD after fusion may be time-dependent processes, a 10-year follow-up of this cohort is planned.

Acknowledgements

None.

Conflict of Interest

None.

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