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Segmental Motion after Total Disc Replacement or Fusion for Discogenic Lumbar Back Pain

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Abstract

Objective: The postoperative goal of fusion is no segmental mobility, but treatment may induce degeneration in adjacent segments. Total Disc Replacement (TDR) aims to restore and maintain mobility by replacing a painful disc. The aim was to investigate whether the goals of treatment were reached and related to the clinical outcome.

Methods: A randomized controlled trial comparing fusion and TDR for Chronic Low Back Pain (CLBP) was undertaken (N=152 patients with CLBP; 72 in the fusion group and 80 in the TDR group). X-Ray measurements were compared and related to self-reported clinical results regarding back pain and disability. The primary outcome was Global Assessment of back pain; secondary outcomes were back and leg pain, Oswestry Disability Index, EQ5D, and SF-36 at 2 and 5 years (from SweSpine). Flexion-extension X-rays were analyzed preoperatively and at 2 and 5 years using distortion-compensated Roentgen analysis for treated and adjacent levels.

Results: Preoperative flexion-extension range of motion was similar in both groups. Sixty-four percent of patients who underwent fusion had no mobility in fused segments; 72% of patients who underwent TDR were mobile in operated levels. Fulfilment of surgical goals was correlated to improvement of back pain in the TDR group (mobility) but not in the fusion group (stiffness). There was more translation and flexion-extension at adjacent segments in the fusion group than in the TDR group.

Conclusions: The surgical goals were reached in most patients. Successful surgery correlated with clinical outcome in the TDR group but not in the fusion group.

Introduction

The most common surgical treatment for Chronic Low Back Pain (CLBP) has been fusion. However, fusion of a spinal segment may have negative effects on the normal physiologic and mechanical function of the neighboring segments and the rest of the spine [1]. Elimination of segmental mobility could lead to increased stress in adjacent segments and accelerate degeneration, known as Adjacent Segment Disease (ASD) [2,3]. A review of kinematic studies found that no overall kinematic changes at the cranial or caudal segments adjacent to a fusion occurred in most patients, but some (~20-30%) developed excessive kinematic changes (i.e., instability) at the cranial adjacent segment after lumbar fusion [4]. Thus, non-fusion, motion-restoring/-preserving techniques have been developed. Total disc replacement (TDR) was developed to avoid the problems of ASD by preserving motion at treated segments. Pain relief is thought to be achieved by a combination

of excision of the painful disc and restoration or improvement of load transfer [5,6]. A Cochrane review reported that TDR seems to be effective in treating low back pain in selected patients and is at least equivalent to fusion surgery in the short term [7]. The differences in clinical improvement were not out with the generally accepted boundaries for clinical relevance. The clinical results from a Randomized Controlled Trial (RCT) comparing fusion and TDR were better for TDR than for fusion surgery at both 2 and 5 years [8,9]. A higher number of patients in the TDR group reported that they were totally pain free.

Overall, lumbar Range of Motion (ROM) appears to decrease after spinal fusion. Studies have indicated that stress and changed mobility in adjacent segments are prevented when mobility is restored/maintained [10]. Several studies have reported on kinematics and load distribution after TDR, and close to normalized or normal motion has been reported [11,12]. However, one study reported that clinical outcome did not correlate to the degree of mobility in treated segments after TDR [13]. In a follow-up study of patients treated with an early version of the Charité prosthesis, 60% of the patients developed spontaneous fusion after 17 years but reported better clinical outcomes than the still-mobile group [14]. No signs of ASD were found in the still-mobile group. Others have reported even more promising results with this early version of a prosthesis [15,16]. Some studies have reported unchanged facet loads, whereas others claim support for increased facet joint loads after TDR [11,12,17].

A comparative mobility study from the above-mentioned RCT between fusion and TDR, based on measurements 2 years after surgery, has been presented [18]. Postoperative mobility changes at both treated and adjacent segments are expected to be time dependent; therefore, studies with longer follow-up are warranted [7].

The aim of this part of the RCT was to present the results from radiologic motion analysis after 5 years in patients treated with fusion or TDR. We examined whether the surgical goals for the treatments had been reached and related to the clinical outcome. We also examined whether there was a difference in disc height and motion in adjacent segments among patients operated on with each treatment option and compared the results from the 5-year follow-up with those from the 2-year follow-up.

Materials and Methods

The study sample was taken from an RCT performed from 2003 to 2005 at the Stockholm Spine Centre in Stockholm, Sweden [8,9,18-21]. The study was approved by the Ethics Committee of the Karolinska Institute, Stockholm, Sweden, in 2003 (03-268). The study included 152 consecutive patients (90 women and 62 men; mean age 40 years; range, 21-55 years) who were considered to have symptomatic degenerative disc disease in one or two motion segments between L3 and S1 and who were diagnosed with CLBP as the predominant symptom with interspinous tenderness on examination, disc narrowing on radiographs, and signs of disc degeneration revealed by magnetic resonance imaging. Low-grade facet joint arthritis at the index segment and low-grade degeneration at other segments were accepted. The inclusion and exclusion criteria are shown in (Table 1).

Inclusion Criteria	Exclusion Criteria
LBP with or without leg pain for more than 1 year. If leg pain occurred, then LBP should dominate	Spinal stenosis requiring decompression
Conservative treatment scheduled for more than 3 months had failed	Moderate or worse facet joint arthritis
Confirmation of disc degeneration on magnetic resonance imaging	Three or more painful levels at clinical examination
Age 20-55 years	No obvious painful level, or levels, at diagnostic injection evaluation (if done)
Oswestry Disability Index over 30 or back pain (VAS) over 50/100 the week before inclusion	Isthmic spondylolysis/olisthesis
Signed informed consent	Degenerative spondylolisthesis >3 mm
Open mind to the two treatment options	Major deformity
	Manifest osteoporosis. If osteoporosis was suspected because of gender and age (women older than 50 years) and illness or medication, osteoporosis should be evaluated and excluded before inclusion
	Previous lumbar fusion or decompression with postoperative instability (e.g., facet joint damage or wide laminectomy)
	Compromised vertebral body
	Previous spinal infection or tumor
	Inability to understand information because of abuse, psychologic, or medical reasons
	Language difficulties with inability to understand follow-up instruments

	Pregnancy or other medical condition that would be a contraindication to surgery

Table 1: Inclusion and Exclusion Criteria.

Forty-one patients (27%) underwent preoperative diagnostic injection procedures, provocative discography, and disc block. These procedures were used to identify pain-generating level(s) when there was clinical uncertainty whether to treat one or two segments. After inclusion, patients were randomized to the fusion or TDR group using a closed envelope technique. Eighty patients were randomized to TDR and 72 to instrumented fusion. Patients in the TDR group were randomized to one of three devices available in Sweden at the time: Charité (Depuy Spine, Raynham, MA, USA), Prodisk (Synthes Spine, West Chester, PA, USA) or Maverick (Medtronic, Memphis, TN, USA). The randomization process was stratified by the number of segments to ensure an equal number of one- and two-segment procedures for each prosthesis device. The surgical approach for TDR was ventral extra-peritoneal. The fusion approach was posterior, and the fusion method was chosen according to the attending surgeon's preference. Instrumentation was performed with pedicle screws and rods or plates. All fusions were done with instrumentation and open technique. Only homologous bone transplants were used. Forty-four patients had posterolateral fusions, and 28 patients had posterior lumbar interbody fusions. Patients treated with TDR or fusion at an adjacent segment due to ASD were not included in this study.

Outcome Measures

All baseline data as well as 2- and 5-year follow-up data were extracted from answers to questionnaires collected in the Swedish Spine Register (Sweden, Spine) [22]. Back and leg pain were assessed separately using a visual analog scale. The Oswestry Disability Index (ODI) was used as a disease-specific questionnaire. Two generic questionnaires (Euro Qol 5D and 36-Item Short Form Health Survey [SF-36]) were used to assess quality of life and general health. There were no differences between the treatment groups with respect to age, gender, smoking status, baseline ODI, Euro Qol 5D, 36-SF, previous surgical treatment, back pain, and function scores [8,9,19]. Directly after surgery, the attending physician recorded the type of surgery and segments treated. At follow-up after 2 and 5 years, patients were asked if they were satisfied with their treatment. A Global Assessment (GA) score for back pain (total relief, much better, better, unchanged, or worse), which also constituted the primary clinical outcome variable at 2 and 5 years, was included. In the clinical study, the primary endpoint was total relief of back pain, whereas total relief or much better was considered a GA success. ODI success was described as greater than 25% improvement from the preoperative value. The follow-up rate for the SweSpine questionnaires was 100% at 2 years and 98% at 5 years. The primary outcome measure for this study was achievement of preoperative surgical goals, measured radiographically. For fusion, the primary surgical goal was the absence of mobility in all treated segments; for TDR, the goal was restored and maintained mobility in all treated segments. Secondary outcome measures included correlation between clinical outcomes and achievement of surgical goals, changes in mobility in adjacent segments, differences in disc height and anteroposterior displacement of treated and adjacent segments after surgery.

Distortion-Compensated Roentgen Analysis

Distortion-Compensated Roentgen Analysis (DCRA) was used to measure ROM and disc height [23,24], including vertebrae L1 to S1. When radiographs did not cover the entire lumbar spine, the identical number of vertebrae were mapped and digitized from the preoperative and postoperative radiographs. For DCRA, disc height and anteroposterior displacement (sagittal alignment) were corrected to standard angles of lordosis. For the purpose of quality control in this study, the height of the cranial and caudal vertebrae of the operated segments, measured from the preoperative and postoperative pairs of radiographs, was compared. For each vertebra, the four height values determined preoperatively and postoperatively in extension and flexion should coincide within the limits of the measurement error. Using this method, we measured the position in extension and flexion for each segment to calculate the ROM. Disc height, translation, and anteroposterior displacement of spinal segments were also measured. The precision of the DCRA protocol has been validated by specimen experiments and comparison with the gold standard Roentgen stereophotogrammetrical analysis [25]. This has established the Standard Deviation (SD) for DCRA measurement error when measuring flexion-extension ROM. The SD ranges between 1° and 2.3°, the largest error occurring at L5-S1 [23-25]. Thus, the confidence interval for the measurement error is ±1.96 SD. For the fusion group, the absence of mobility was defined as an ROM at the treated segment less than the confidence interval for the measurement error of the method, which is 1.96 times the SD from the specimen experiments. For a given case, the absence of mobility was defined as ROM at the treated segment of no greater than 2° at the L3-L4 and L4-L5 segments and no greater than 4.5° at the L5-S1 segment. For the TDR group, mobility was defined as ROM that exceeded 1.96 SD at the respective segment. By this definition, mobility in L5-S1 and in L3-L4/L4-L5 should be greater than 4.5° and 2°, respectively. DCRA was used to measure the achievement of the outcome measures. Flexion-extension radiographs of the lumbar spine were taken preoperatively and 2 and 5 years postoperatively and analyzed using DCRA at treated and adjacent segments.

Preoperative and 2-year examinations were available for 85% of the patients; [18] preoperative, 2-year and 5-year examinations were available for 72% of the patients. ROM, disc height (the

height of the intervertebral space postoperatively), translation, and anteroposterior displacement were determined from the preoperative and 2- and 5-year postoperative pairs of flexion-extension radiographs. These preoperative and postoperative measurements were compared with normative data as described previously [23-25]. Because the amount of translational motion depends linearly on the extent of the ROM, actual translational motion for a given patient was compared with translational motion predicted for a normal individual based on the observed extent of ROM for the patient. Thus, the comparison between actual and predicted translational motion was independent of the extent of the actual ROM for the patient. Changes in mobility in adjacent segments were compared between both groups. Mobility is presented in degrees; disc height and translation are presented in units of the standard deviation of the normal population, thus not in millimeters.

Statistics

The Lehr formula was used to provide crude estimates of sample size (Lehr 1992). With 80% power at 5% significance level, the size of each group was estimated at 64 patients. The sample size was increased to 72 to allow for potential dropouts. Disc height, translation motion, and sagittal alignment were calculated by their deviation from the sex-, age-, and segment-appropriate normative values as described previously [23-25]. Deviation was measured in units of the SD from the norm. For example, a value of -1.0 denotes that the respective parameter assumes a value of 1 SD below the norm. Deviations of preoperative values from normative data were compared with deviations of postoperative values from normative data. For comparison of flexion-extension ROM, the actual measured degrees were recorded, and differences calculated. For these calculations, the Student t test, chi-squared test, Fisher exact test, Mann-Whitney U test, Pearson product moment correlation, and Spearman rank correlation were used. Alpha (p value) was set to 0.05.

Results

The clinical results for the 5-year follow-up of the RCT have been reported previously [9]. Both groups showed clinical improvement at 5-year follow-up. We have recalculated the results for the two groups because they did not include the same number of patients. Sixty-five of 80 in the TDR group (81%) and 55 of 71 in the fusion group (77%) are included in the radiologic follow-up. There was a significant difference between the groups concerning GA and improvement of low back pain (Table 2).

	The Original Group (TDR n=80, fusion n=71)			The Group Evaluated Radiologically Preoperatively and at 5 Years		
	TDR (n=80)	Fusion (n=71)	p	TDR (n=65)	Fusion (n=55)	p
GA totally pain free	30 (38%)	11 (15 %)	0.002	24 (65%)	7 (13%)	0.003
VAS back pain	23±30	31±32	0.09	22±29	33±27	0.04
Difference pre- to postoperatively	40±32	28±32	0.02	38±31	23±30	0.008
EQ5D	0.76±0.30	0.69±0.30	0.13	0.34±0.31	0.67±0.30	0.18
Difference pre- to postoperatively	0.34±0.35	0.32±0.39	0.71	0.33±0.37	0.27±0.38	0.42
ODI	17±19	22±17	0.08	17±19	22±16	0.16
Difference pre- to postoperatively	25±18	18±19	0.04	24±18	17±18	0.04
ODI success	77%	65%	0.08	78%	64%	0.07

GA, global assessment; VAS, visual analog scale; EQ-5D, EuroQol; ODI, Oswestry Disability Index.

Table 2: Outcome 5 Years After Surgery.

There were no major differences in the outcome comparison between groups due to loss of patients for radiologic follow-up for the TDR group. However, in the fusion group, those patients who chose not to take part in the radiologic examination after 5 years showed better improvement due to surgery than patients who chose to be examined (visual analog scale improvement 43±35 compared with 23±31, p=0.03).

Achievement of Surgical Goals

X-Ray films with flexion and extension were available preoperatively and 5 years after treatment for 55/72 patients in the fusion group and 65/80 patients in the TDR group. Preoperative ROM was similar between both groups (Table 3).

	L3-L4			L4-L5			L5-S1		
	Pre	Post 2	Post 5	Pre	Post 2	Post5	Pre	Post 2	Post 5
Fusion	6.0±3.6	1.2±1.1	3.3±3.5	8.0±4.9	1.3±2.9	0.9±2.3	6.9±2.5	0.7±2.5	0.3±2.4
TDR	3.9±4.1	8.0±2.5	6.9±6.5	7.3±4.3	10.3±4.8	10.7±4.0	6.0±5.0	9.0±4.8	6.3±4.7

TDR, total disc replacement.

Table 3: Range of motion (degrees) for operated segments, preoperatively (Pre) and at 2 years (Post 2) and 5 years (Post 5) follow-up.

At the 5-year postoperative follow-up, flexion-extension ROM in treated segments in the TDR group had increased compared with preoperative values (Table 3). ROM had decreased by 2.8±5.5° (p<0.01) in the TDR group with surgery at the L5-S1 disc level from the 2- to 5-year follow-up. The differences concerning ROM between the 2- and 5-year follow-up were non-significant for all other levels in the TDR and for all operated levels in the fusion group. With regard to stature, there was an increase in extension for L5-S1 segments operated with TDR at 5 years compared with preoperative values (6.0±7.3, p<0.001). For the fusion group with surgical success (those with a healed fusion), there was a decrease in extension at the L4-L5 level (6.4±4.3°, p<0.001) and the L5-S1 level (5.8±7.5°, p<0.001). For the TDR group with surgical success, there was no change in posture at the L4-L5 level (-2.2±6.4, p<0.08) but an increase in extension at L5-S1 (8.1±7.2°, p<0.001). The absolute values show that patients in the TDR group had higher lordosis than patients in the fusion group at L4-L5 (17.25±5.3 vs 11.4±4.5, p<0.001) and L5-S1 (29.2±5.5 vs 15.9±6.3, p<0.001). This means that the spine was fused with less lordosis than preoperatively but, on the other hand, TDR increases lordosis.

The surgical goal in the fusion group (absence of mobility) was achieved in 35/55 patients (64%). The results were the same for both fusion methods. The surgical goal in the TDR group (restoring and maintaining mobility that exceeded measurement error) was achieved in 47/65 patients (72%). ROM increased compared with pretreatment values (p<0.02). The surgical goal was reached with a similar frequency in both groups (p=0.31).

There was no difference between one- and two-segment treatments in either of the groups regarding achievement of surgical goals and no difference between the different brands of prostheses.

Relationship Between Surgical Results and Clinical Outcome

Forty-seven of 65 patients (72%) in the TDR group and 35/55 (64%) in the fusion group reported that they were totally pain free or much better at the 5-year follow-up. If totally pain free is taken as success, the figures are 24/65 (37%) and 7/55 (13%), respectively (Tables 2 and 4).

	Totally Pain Free	Very Improved	Quite Improved	No Difference	Impaired	Row Total
Global assessment for the TDR group (n=65)						
Surgical failure	3	6	4	1	4	18
Surgical success	21	17	7	1	1	47
Total	24	23	11	2	5	65
Global assessment for the fusion group (n=55)						
Surgical failure	3	11	3	2	1	20
Surgical success	4	17	10	2	2	35
Total	7	28	13	4	3	55

Table 4: The Relationship Between the Clinical Result (Global Assessment, GA) and the Surgical Result in the Two Groups.

There was a significant association between GA and the surgical result in the TDR group if pain free/totally pain free together with much improved were used as a measure for clinical success ($p<0.02$). All other outcome measures also showed this significant difference for the TDR group. In the fusion group, there was no correlation between surgical and clinical results for any of the outcome measures ($p=0.46$). Those in the TDR group who reached the surgical goal had significantly better results for all outcome measures than those in the fusion group who reached the surgical goal.

Adjacent Segment

No difference between the groups for disc height changes was seen between baseline and 5 years (Table 5).

	L3-L4			L4-L5			L5-S1		
	Pre	Post 2	Post 5	Pre	Post 2	Post 5	Pre	Post 2	Post 5
Fusion	-0.01±1.02	-0.03±0.96	-0.09±0.89	0.27±1.17	0.59±1.11	0.26±0.96	-0.27±1.37	-0.06±1.58	-1.34±1.46
TDR	-0.04±0.95	-0.39±1.10	-0.57±1.2	0.58±1.05	0.48±0.97	0.33±1.06	-0.61±1.42	-1.18±1.36	-0.43±1.56
Pre, preoperatively; post 2, at 2-year follow-up; post 5, at 5-year follow-up; TDR, total disc replacement. There was no difference between the two groups concerning changes.									

Table 5: Disc Height for Adjacent Levels.

There was a loss of disc height for L3-L4 discs if they were adjacent to a TDR. The loss appeared at 2 years and was unchanged at 5 years. There was no difference if the L3-L4 disc was adjacent to a fused level. ROM for all non-operated segments as well as for all adjacent segments was calculated preoperatively and at 2- and 5 years (Table 6).

	L3-L4			L4-L5			L5-S1		
	Pre	Post 2	Post 5	Pre	Post 2	Post5	Pre	Post 2	Post 5
Mobility (ROM) at different adjacent segments compared with preoperative values and between treatment groups									
Fusion	6.1±3.8	10.7±3.7	10.4±2.6	8.9±5.5	14.7±5.5	12.6±4.2	8.0±3.5	8.3±6.6	5.2±5.1
TDR	7.8±3.8	10.2±2.8	10.3±3.5	9.5±4.9	12.1±5.1	12.3±3.5	8.2±3.2	7.2±5.5	9.4±5.3
Mobility (ROM) at non-operated segments compared with preoperative values and between treatment groups									
Fusion	6.2±3.5	10.6±3.4	9.7±3.9	8.6±5.7	14.7±5.5	12.7±4.1	7.8±4.3	7.0±5.2	5.2±5.1
TDR	6.7±3.9	9.8±3.4	9.3±4.9	10.1±5.3	12.1±5.2	12.5±3.7	8.2±3.2	7.2±5.5	9.2±6.5
TDR, total disc replacement. There was a significant increase in ROM for L3-L4 discs for both methods after 2 years. There was a significant increase for L4-L5 after 2 years in the fusion group. However, the ROM decreased in patients in the fusion group between 2 and 5 years.									

Table 6: Range of Motion (ROM, degrees) for All Non-Operated Segments and for All Adjacent Segments, Preoperatively (Pre) and at 2 Years (Post 2) and 5 Years (Post 5) Follow-Up.

There was a significant increase in motion for the L3-L4 disc for both methods after 2 years. There was a significant increase in motion for L4-L5 after 2 years in the fusion group. However, ROM decreased for patients in the fusion group between 2 and 5 years. There was no difference between the groups concerning translational movement ($p<0.61$), but anteroposterior displacement at L4-L5 as an adjacent segment was larger postoperatively in the fusion group than in the TDR group ($p<0.05$).

Reoperations

Among those patients followed by motion X-ray, we identified 14 patients operated on with instrumented fusion who had been re-operated with extraction of implants because of local pain. Ten of the 14 reached surgical success (thus there was no motion in the segment). In the TDR group, seven patients were operated on with segmental fusion because of facet joint pain. Two of these seven patients still had motion in the operated segment after fusion.

Discussion

Surgical goals were achieved for 64% of the fusion group and 72% of the TDR group based on the DCRA results. It is promising that mobility was achieved in such a high percentage in the TDR group, especially considering that these mobile patients had better clinical outcomes than those in the fusion group who reached their surgical goal at the 2- and 5-year follow-ups. The postoperative mobility was less than that allowed by the design of the prostheses. The results of this study may indicate that there have been positive developments in implants and surgical methods since the early Charité phase [14-16]. Recently, a Computed Tomography (CT)-based method used for mobility measurements in patients undergoing TDR showed that the median vertebral rotation in the sagittal plane at the operated level was 5.4° (±2.3°) before surgery and 6.8° (±1.7°) after. Our results show higher mobility, probably because CT is done in the supine position and DCRA in the standing position. Our results are in contrast to the study by Johnsen et al.; [13] that showed that no correlation was seen between clinical outcome and achievement of the surgical goal in their TDR group. Their results are based on a 2-year follow-up, whereas this present study presents 5-year follow-up.

Reports on the development of facet joint arthritis after TDR surgery have led to concerns about the surgical method as well as implant size and design [26,27]. The surgical method has developed greatly since this RCT was performed (2003-2005) to avoid increased loads on the facets. The aim of such developments is to place the prosthesis at the absolute midline to avoid unequal loads and motion patterns between the facet joints, with a clear goal to place the implant all the way to the posterior longitudinal ligament. These concerns have led the manufacturers to develop lower implants to avoid the treated segment being shifted over into hyper lordosis due to a too high implant. These procedural and implant changes were implemented after the patients in this study were treated, so we do not know how often the surgical goal would be reached with today's technique. In the report on the 2-year follow-up from this RCT, we found non-physiologic disc height after TDR surgery due to too high implants. Whether an even higher frequency of mobile TDRs would have been achieved if the implants were lower remains unknown, but it is definitely a possibility.

Significantly higher anteroposterior displacement at the closest adjacent segment developed in the fusion group compared with the TDR group. Even so, lumbar spine mobility in flexion-extension was lost in the fusion group between 2 and 5 years despite the increased mobility at adjacent L4-L5 segments in the fusion group. Whether these findings are early signs or even the cause of ASD is still to be investigated. The absence of differences in clinical outcome, whether stiff or not in the fusion group, may be due to the not fully stiff segment being less of a strain on the adjacent segment. One weakness of the study is the fact that the fusion group had dropouts with a better clinical outcome. If they had been included, surgical success (healed fusion) may have been shown to correlate to clinical outcome.

Conclusions

Achievement of the surgical goal and clinical outcome were better after TDR treatment than after fusion in the 5-year follow-up of this RCT. These results are probably related because patients with mobile prostheses reported better outcomes than those with questionable mobility in their prostheses. Because mobility in a patient treated with TDR and the development of ASD in a patient treated with fusion are possibly time dependent, a 10-year follow-up of this study is planned.

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