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Lumbar Total Disk Replacement Device Removals and Revisions Performed During a 20-Year Experience with 2141 Patients

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Study Design. This was a retrospective study with prospective patient contact attempted to collect current data.

Objective. The purpose was to investigate the incidence and reasons for lumbar total disk replacement (TDR) removal or revision.

Summary of Background Data. A concern regarding lumbar TDR was safety, particularly the need for device removal or revision. This may be particularly important considering removal/revision requires repeat anterior exposure with an increased risk of vascular injury.

Methods. Data were collected for a series of 2141 lumbar TDR patients, beginning with the first case experience in 2000. The mean follow-up was 78.6 months. For each case of device removal/revision, the reason, duration from index surgery, and procedure performed were recorded.

Results. Of 2141 patients, 27 (1.26%) underwent TDR removal or revision. Device removal was performed in 24 patients (1.12%), while three patients underwent revision (0.14%). Of the 24 removals, 12 were due to migration and/or loosening, three developed problems post-trauma, two developed lymphocytic reaction to device materials, two had ongoing pain, and there was one case of each: TDR was too large, vertebral body fracture (osteoporosis), lytic lesion, device subsidence and facet arthrosis, and infection seeded from a chest infection 146 months post-TDR. The three revisions were for Core repositioning (technique error), device repositioning after displacement, and core replacement due to wear/failure. With respect to timing, 37.0% of removals/revisions occurred within one-month post-implantation. Of note, 40.7% of removals/revisions occurred in the first 25 TDR cases performed by individual surgeons. There was one significant vascular complication occurring in a patient whose TDR was removed due to trauma. This was also the only patient among 258 with ≥15-year follow-up who underwent removal/revision.

Conclusion. In this large consecutive series, 1.26% of TDRs were removed/revised. The low rate over a 20 year period supports the safety of these devices.

Key words: disk replacement, lumbar spine, long-term follow-up, revision surgery, removal surgery, lumbar arthroplasty, anterior approach surgery

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Lumbar total disk replacement (TDR) is performed as an alternative to fusion for the treatment of painful disk degeneration unresponsive to nonoperative care. It was introduced with the goal of reducing pain while maintaining motion of the operated segment. There are multiple studies from multiple countries, including meta-analyses, reporting that TDR produces outcomes similar or superior to lumbar fusion.[1–9] Unlike fusion, TDR involves a motion-preserving implant, and therefore, concerns about durability and safety over time have been expressed. One measure of safety is the need for subsequent surgery. All reoperations are of interest with any spinal surgery; however, the reoperation types most indicative of problems with motion-preserving technology are revisions and removals of the implant. Motion-related problems may be reflected as device migration, device breakage, or implant wear. The need for removal/revision surgery may be of particular importance, considering such procedures after TDR generally require reoperation through the anterior approach with the corresponding increased risk of injury to vascular structures or possibly ureteral injury.[10] The risk is increased due to scarring near the vessels from the prior surgery. Also, the planes of dissection may be distorted from the previous anterior intervention.

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Using a state insurance database, a rate of mechanical complications leading to the reoperation of 4.2% of lumbar TDR procedures was reported.[11] The study suffered from the same challenges as other studies using this type of large database, in that while a large mixed sample is available, details of individual cases are not available. Also, the term "mechanical complication" was not defined as to whether this was migration, device breakage, lack of providing pain relief, subsidence, or other problems. Detailed patient-level data is needed to obtain insight into the mode of failure. The purpose of this study was to analyze the incidence of, and reasons for, lumbar TDR removal/revision in a large consecutive series of patients during a 20-year period at a single institution.

MATERIALS AND METHODS

Data were collected from a multi-site spine specialty practice in which 18 surgeons performed the TDR cases. A consecutive series of 2141 lumbar TDR patients, beginning with the first case in 2000, was reviewed to identify those undergoing reoperation for TDR removal or revision. A description of the study population is provided in Table 1. All patients were treated for symptomatic disk degeneration unresponsive to at least 6 months of nonoperative care. The revision or removal classification of a subsequent surgery was based on definitions provided by the Food and Drug Administration guidance document for spinal systems.[12] The procedure was classified as a revision if part of the implant was modified or removed, with or without replacement of a component, or the position of the original implant was adjusted. The reoperation was classified as a removal if all of the original system configuration was removed with or without replacement. Only patients who were at least 2 years postoperative were included. The study was reviewed by an Institutional Review Board. Data collected from the charts and surgery log included general descriptives (age, sex, height, weight), level(s) operated, surgeon, TDR *versus* hybrid, any subsequent surgery, and contact information. The study was retrospective, with attempted contact by mail and/or telephone phone calls to collect current data conducted for patients who did not have a recent office visit. The questionnaire specifically asked about any low back surgery since the TDR surgery, and if any such surgery had been performed, the patient was asked to provide more information, including the date, reason, level(s) operated, and procedure. The mean follow-up was 78.6 months (median 77 months, range 0–251 months). The follow-up rate was calculated using the Clark Completeness Index[13] and was 67.2%. For each case of device removal/revision, the reason, duration from index surgery, and procedure performed were recorded.

To investigate a possible learning curve effect, cases for each surgeon were sequentially numbered based on the date of surgery. This provided a means to determine the rate of removal/revision in each surgeon's early *versus* late clinical experience with lumbar TDR.

TABLE 1. Overview of the Study Population

	Mean(SD)
Age (yr)	40.5 (9.25)
BMI (kg/m^2)	27.3 (4.62)
	N(%)
Sex:	
Female	909 (42.5)
Male	1,232 (57.5)
Procedure type:	
TDR only	1,769 (82.6)
Hybrid	372 (17.4)
Number of TDR levels:	
1 level	1,785 (83.4)
2 levels	340 (15.9)
3 levels	16 (0.7)

BMI indicates body mass index; TDR, total disk replacement.

Data Analysis

The primary data analysis was based on the calculations of the rates of TDR removals and revisions. A 95% confidence interval (CI) was calculated for the removal/revision rate. Forward stepwise logistic regression analysis was conducted to determine whether factors related to removal/revision surgery could be identified using age, gender, body mass index (BMI), number of levels operated, follow-up duration, and the surgeon's case series number (to assess the possible learning curve effect for each surgeon). To further investigate the possible learning curve, the removal/revision rate was compared for each surgeon's first 25 cases vs. subsequent cases using χ^2 analysis. Data were analyzed using SPSS Version 28 (IBM, Inc.).

The data were also analyzed with respect to the rate of removal/revision surgery in the subset of patients with a verified follow-up of 15 years or longer to determine if the rate was greater with long-term follow-up. The removal/revision rates in patients with greater than 15-year follow-up *versus* those with shorter duration were compared using χ^2 analysis. An additional analysis was performed to compare the rates of removal/revision surgery in patients who received the TDR as an investigational device in IDE trials, a control device in IDE trials, or post-approval. Chi-square was used to compare these subgroups.

RESULTS

In the series of 2141 patients, 27 (1.26%) underwent TDR removal or revision (95% CI: 0.09–1.80). Removal was performed in 24 patients (1.12%) and 3 patients underwent TDR revision (0.14%). There were 2513 devices implanted in the 2141 patients. A total of 25 devices were removed (0.99%) and 3 devices were revised (0.12%). All removal/revision procedures were carried out as planned with ALIF,

TABLE 2. Overview of the Removal/Revision Cases

Reason for removal	N	Time from implant date to re-op	Comments
Migration/loosening	12	13, 15, 15, 17, 25, 28 days; 7, 8, 14, 16, 30, 55 mo	
Posttrauma	3	5, 13, 185 mo	Two falls, one instability after MVA
Ongoing pain	2	9, 165 mo	165 mo remote
Lymphocytic reaction	2	12 mo, 20 mo	Reaction to metallic implant
TDR too large	1	16 days	Replaced with a smaller design of TDR
Vertebral body fracture	1	6 days	Related to poor bone quality (2-level)
Implant subsidence with facet arthrosis	1	129 mo	
Lytic lesion	1	72 mo	
Infection	1	146 mo	Seeded from the chest infection
Reasons for revision			
Repositioning the core	1	2 days	Due to technique error
Repositioning the device after displacement	1	3 days	
Replacement of the polyethylene core	1	18 mo	Due to wear/failure

MVA indicates motor vehicle accident; TDR, total disk replacement.

ALIF with supplemental posterior fixation, or TDR. There was only one patient in which more than one device was removed. This was a 2-level case who had a vertebral body fracture 6 days after the implantation. The patient had low bone density. The reasons for removal/revision and the timing of such are provided in Table 2. The most common reason for removal was device migration and/or loosening, which occurred in 12 patients. In two patients, there was not enough information available in the chart or patient report to determine the specific reasons for removal, but the patients did have ongoing pain. The three revisions consisted of repositioning the core (technique error), repositioning the implant after displacement, and core replacement due to wear/failure.

Significant vascular complication occurred during TDR removal in one patient whose removal was due to trauma, including spinal fracture, with the device displacing anteriorly. Although the patient required a transfusion, the removal was successfully completed. There were two patients with small tears. One was of the left iliac vein and was repaired without incident, and in the other patient, the small injury to the left common iliac artery was controlled with no formal repair needed.

Duration From Implantation

The mean duration from TDR implantation to removal/revision was 33.7 months (median 9.4 mo). With respect to timing, 37.0% of removals/revisions occurred within one month after the index implantation. To investigate removal/revisions occurring in long-term follow-up, a subset of 258 patients with removal/revision status verified by recent office visits or mailing/telephone contact with a minimum of 15-year follow-up was reviewed. Within this subset, the mean follow-up was 201.7 months, and the median was 197 months (range 180–264 mo). Only one patient underwent removal/revision surgery 15 or more years postimplant. This occurred at 15.4 years post-TDR and was related to a traumatic fracture of the vertebral body and coccyx.

Factors Related to TDR Removal/revision

Results of conditional forward regression analysis found that the factor most significantly related to removal/revision surgery was the patient's sex ($P < 0.016$). After this factor was accounted for in the analysis, the factor of being a patient in the individual surgeon's first 25 lumbar TDR cases was also significantly related to the removal/revision rate ($P < 0.024$). None of the remaining variables of age, BMI, number of levels operated, or follow-up duration were related to the occurrence of TDR removal/revision (Table 3).

TABLE 3. Results of the Forward Conditional Regression Analysis

	P
Variables in the equation	
Sex	$P < 0.03$
Case series number	$P < 0.03$
Variable not in the equation	
Age (years)	$P > 0.70$
BMI (kg/m^2)	$P > 0.30$
Number of levels operated	$P > 0.80$
Follow-up duration (mo)	$P > 0.15$

BMI indicates body mass index.

Sex

The regression analysis found that the factor most strongly related to TDR removal/revision was sex. This was analyzed in greater detail. Among females, the rate of removal/revision surgery was 1.9%, which was significantly greater than the rate of 0.8% in males ($P < 0.030$; χ^2).

Learning Curve

Based on the results of the regression analysis, the learning curve was investigated further. It was found that 40.7% of removals/revisions occurred in the first 25 TDR cases performed by individual surgeons. When comparing the removal/revision rates for early *versus* later cases in each surgeon's series, the rate was significantly greater in the early cases (3.1% vs. 0.9%; $P < 0.01$, χ^2).

Additional Analyses

An additional analysis was performed to investigate the possible impact of using the device post-approval when surgeons could expand indications to off-label use beyond the rigidly defined patient selection criteria required in IDE trials, including hybrid surgery. The rate of TDR removal/revision was significantly greater ($P < 0.015$) in the investigational group (2.5%) compared with the TDR as a control group (0.0%) or post-approval (0.9%). This suggests that the higher rate in the investigational group may be related to the learning curve impact.

The rate of removal/revision was calculated for each TDR level. There were no removals/revisions at L2-3, L3-4, or L5-6. Among the 1,015 TDRs implanted at L4-5, 7 (0.7%) were removed/revised. At L5-S1, 1290 TDRs were implanted, and 21 (1.6%) were removed/revised (not statistically significantly different, $P > 0.05$).

DISCUSSION

In this large consecutive patient series, 1.26% of lumbar TDRs were removed or revised, resulting in repeat anterior approach surgery at the index level. This rate was similar to that reported in FDA IDE trials evaluating lumbar TDR during two to five-year follow-up.[14–17] In these studies, the reported rates ranged from 1.0% to 2.8%.

As lumbar arthroplasty was introduced, one of the primary concerns was the need for a repeat anterior approach to remove or revise these devices. In the current series, the rate for such surgery was low at 1.26%. Due to the risks of repeat lumbar anterior approach surgery, alternative strategies have been described. Some authors suggested that posterior instrumented fusion can address failed TDR while avoiding the risks associated with repeat anterior lumbar exposure.[18,19] Similarly, the use of a lateral approach to remove a TDR has also been described.[20] While these strategies may be appropriate in some cases, in many, they are not, such as in cases of device migration, lymphocytic reaction, allergy, or infection, where the implant needs to be removed. A lateral approach may be feasible for some patients, but not for L5-S1 (the level most commonly replaced), and may be challenging for cases with keeled implants. The safety of repeat anterior approach surgery has been investigated.[21–24] These authors report that repeat anterior approach surgery can be performed safely when needed, but great care must be used.

In 2003, van Ooij *et al.* reported on a series of 27 complications related to lumbar TDR occurring with a mean duration from TDR to presentation of 53 months and a maximum of 127 months.[25] They warned to expect late-onset problems related to TDR in many patients. Fortunately, the results of the current study, as well as others with long-term follow-up,[26–28] have not fulfilled this prediction. In fact, there was only one removal occurring in the subset of 258 patients with a minimum 15-year follow-up, and this occurred in a patient whose subsequent surgery was due to trauma.

One of the concerns about the need for removal/revision was related to the wear of the polyethylene core during long-term use. There are very few reports of removal/revision surgery for wear-related problems. A study involving 4 cases of wear analysis after TDR removal found wear was associated with what the authors described as an unfavorable biomechanical environment (e.g., subsidence, migration, undersized prosthesis, and adjacent segment fusion).[29] Their study described mechanisms of wear as adhesive/abrasive wear of the domed region of the core, as well as rim impingement, resulting in rim fatigue and fracture. David reported a case of TDR removal and replacement with another TDR performed 9.5 years after implantation due to wear of the polyethylene core.[30] The authors attributed the wear to high oxidation related to the sterilization process used at the time of the initial surgery but no longer used at the time of the second surgery. In the current study, only one patient underwent TDR revision to replace the polyethylene core. The reason for the failure of the core could not be discerned.

In the current study, two factors were identified as related to a significantly greater rate of TDR removal/revision surgery. The first was the female sex versus the male sex. The reason for this could not be clearly determined. It may be speculated that body size may be a factor related to device sizing and/or placement. The second factor was patients receiving TDR in the subgroup derived from each surgeon's first 25 lumbar TDR cases. While a learning curve is sometimes described for new procedures, it may not be as anticipated when the approach is very similar to a traditional procedure. Most of these surgeons were highly experienced with ALIF, which is performed using the same approach as for lumbar TDR.

The observed learning curve for TDR may have been related, at least in part, to technical aspects of TDR, such as fine points of soft tissue release and balancing, selecting the appropriate implant size and endplate angulation, correct implant positioning, and factors related to the shape of the vertebral body endplates. As other authors have stated, the best strategy to reduce the rate of revision TDR surgery is to use appropriate indications and surgical techniques.[23,24,31] Aspects of surgical technique noted to be related to TDR

removal/revision include the use of too small of an implant, too great of an implant height resulting in overdistraction, failure to perform an adequate discectomy, inappropriate implant positioning within the disk space, and fracturing an endplate during device implantation.

Of note, there was a significant difference in the removal/revision rates of patients enrolled in FDA IDE trials as receiving the investigation device, the TDR control device, or post-approval, including off-label use for 2-level and hybrid procedures. The higher rate of removals/revisions in the FDA investigational group might not be expected due to the rigorous selection criteria employed in the trials; however, this is likely related to the early learning curve data that was significantly related to the revision/removal rate. However, for multiple surgeons, their TDR experience was post-approval. The lack of increased removals/revisions as the surgical group moved from FDA trials to post-approval use was possibly reflective of expanded indications being appropriately applied, such as use at more than 1-level, hybrids, and implantation next to a prior fusion or prior TDR while complying with selection criteria of not using TDR in patients with significant facet joint degeneration, osteoporotic bone, significant instability, or anatomy that may compromise implant performance. In a study investigating specifically when TDR specialists performed fusion instead of lumbar TDR, it was found fusion was undertaken in 34.6% of patients.[32] The most common reason for performing fusion rather than TDR was combined degenerative pathology. Other reasons included greater than Grade I spondylolisthesis, osteoporosis, spinal deformity, bridging osteophytes, and significant scarring from prior discectomy.

This study had limitations commonly encountered with retrospective studies. Some patients did not have complete data sets, and there was a great variation in the follow-up duration. As may be expected, there were patients who were deceased (none related to the TDR surgery), could not be located, or who declined to participate in follow-up. This study had the strengths of a large number of patients and a long follow-up duration for many of them. The subgroup analysis comparing patients with follow-up of 15 or more years to those of shorter duration found no difference in the removal/revision rates. One unique aspect of the study was that there was an attempt to contact patients to collect current long-term follow-up data rather than depending on chart review alone. This provided a collection of input from patients treated at other facilities after their TDR surgery at our clinic.

The low rate of removals/revisions in this large series, many with long-term follow-up, should provide surgeons and patients reassurance that these implants are durable in the long term. Future research incorporating clinical and radiographic assessment would be interesting in similar patients.

CONCLUSION

In this large consecutive series of more than 2000 patients undergoing lumbar TDR during a 20-year experience, the rate of removal/revision was 1.26%. There was no indication of an increasing rate of removals/revisions with increasing follow-up duration. This supports the safety and durability of these implants. The low rate of removal/revision in this large institutional experience over a 20-year period provides reassurance in the safety of arthroplasty technology in appropriately selected patients.

➢ Key Points

- ❑ In a consecutive series of 2141 patients who underwent lumbar total disk replacement, the rate of device removal or revision surgery was 1.26%.
- ❑ With respect to timing, 37.0% of removals/revisions occurred within one month postimplantation.
- ❑ There was a suggestion of a learning curve, as 40.7% of removals/revisions occurred in the first 25 TDR cases performed by individual surgeons.

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