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Long-Term Results of Charité Lumbar Disc Replacement: A 17-Year Follow-Up in a Workers' Compensation Cohort

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ABSTRACT

Background: Lumbar total disc replacement (TDR) is an alternative to lumbar fusion for the management of degenerative disc disease. This study aims to provide insight into the long-term clinical outcomes of lumbar TDR with a mean follow-up of 17.2 years in a group of workers' compensation patients.

Methods: A total of 26 workers' compensation patients with radiographically confirmed discogenic low back pain were treated with the Charité total lumbar disc replacement. Visual analog scale (VAS) scores were assessed before and after the surgery. At follow-up, patients were assessed on quality of life, employment, further lumbar spine surgeries, and associated complications. Simple nonparametric statistical analysis was performed by the first author using Microsoft Excel.

Results: Sixteen patients (62%) were able to be contacted with a mean follow-up time of 17.2 years. VAS scores at 17 years were significantly lower than their preoperation level. Of those 16 patients, 81% returned to work and worked for an average of 9.1 years after surgery. Additionally, 6 (38%) patients underwent further lumbar spinal surgery, of whom 4 underwent fusions of the adjacent segment. Nearly all patients (94%) were satisfied with the surgery.

Conclusion: This study suggests lumbar TDR may be a useful treatment for degenerative disc disease in select workers' compensation patients.

Clinical Relevance: Clinically relevant improvements in pain and employment can be achieved with the charite lumbar TDR in the treatment of degenerative disc disease in workers' compensation patients. These results are sustained over the long term.

Level of Evidence: 4.

TDR

Keywords: spine surgery, total disc replacement, low back pain, workers' compensation

INTRODUCTION

Chronic low back pain is the persistence of pain beyond 3 months and is often related to mechanical dysfunction.[1] Low back pain affects approximately 16% of the Australian population and is the most common musculoskeletal condition for which patients consult their general practitioners.[2] Low back pain is a significant cause of morbidity and loss of productivity and is one of the most common reasons for workers' compensation claims.[3,4] Low back pain costs the Australian Health system approximately $2.8 billion every year, representing 2.4% of total health expenditure.[3]

Traditionally, spinal fusion has been used for the treatment of low back pain unresponsive to conservative measures; however, for more than two decades now,[5] total disc replacement (TDR) has been offered as an alternative for select patients, but implementation rates of TDR have been relatively low.[6] Patients suitable for TDR typically have painful disc degeneration unresponsive to at least 6 months of nonoperative care with no obvious pathology on radiography or magnetic resonance imaging and a positive provocative discogram.[7,8] Given the risk of vertebral body fracture during implementation, TDR is generally reserved for younger patients with no evidence of osteopenia.[7]

Despite initial success with spinal arthrodesis improving quality of life and disability, recurrent chronic low back pain and the development of adjacent segment disease (ASD) have led to the development of the lumbar TDR in an attempt to maintain mobility and reduce the risk of ASD.[9] Harrop et al's systematic review reported a rate of ASD of 1% in patients who underwent TDR compared with a rate of 14% in the group of patients who underwent spinal arthrodesis; however, this effect was dampened by patient's age and increased follow-up time.[10] Despite promising early results, debate still exists as to whether lumbar TDR can reduce the rate of ASD in the long term.[10–12]

To date, the number of long-term studies on TDR remain small. Several studies have demonstrated similar results between spinal fusion and TDR surgery,[13–15] and more recent cohort studies have suggested high rates of

return to work (RTW) with good short-term to midterm clinical and radiological results in TDR patients.[16–19]

Workers' compensation status has always been thought to have a poor prognosis following surgery, especially surgery for low back pain alone.[20,21] In the early days of this study, patients were often advised that conservative treatment was the only form of management for low back pain. This study aimed to provide insight into the long-term clinical outcomes of lumbar TDR for low back pain in a workers' compensation cohort with a mean follow-up of 17.2 years. For this study, we measured the effect of surgery on pain, return to employment, and quality of life.

MATERIALS AND METHODS

Study Protocol and Patient Selection

A total of 26 workers' compensation patients with radiographically confirmed discogenic low back pain were treated with the Charité artificial disc replacement by the senior author between 2001 and 2007. All patients underwent a medical history and physical examination, lumbar radiography, and provocative discography to determine the diagnosis of discogenic back pain. Patients with radicular symptoms, abnormal endplate anatomy, spondylolisthesis, active facet disease, prior spinal surgery, osteoporosis, age 55 years or older, or infectious, or oncological etiologies were excluded from this study. Private patients were not included in this study. Inclusion criteria for this study were patients younger than 55 years who exhausted conservative management of lower back pain and had a positive provocative discogram.

Visual analog scale (VAS) scores were assessed preoperatively for every patient as a standard of care. Unfortunately, 7 patients' preoperative VAS scores were lost to our data set due to a system error. These patients were contacted by phone as part of the follow-up and asked to recall their VAS scores from before the operation with the knowledge that the operating surgeon declined to operate on patients whose VAS scores were below a score of 7 out of 10.

Patient Follow-Up

Patients were contacted by mail and phone for consent to have their medical records assessed and for further participation in this survey. Prior to surgery, patients were asked to complete a VAS for pain. At follow-up, patients were asked to complete a further VAS score for pain, a EuroQol 5-Dimension 5-level (EQ-5D-5L) quality-of-life index, and further questions related to subsequent lumbar spine surgeries, complications from those surgeries, and employment outcomes, including the return to employment, the duration of return, and level of activities they returned to work under. Patients were also asked if they would repeat the surgery given the same circumstances.

Surgical Technique

The patient was positioned in the French position, and the procedure was performed as described in the literature. Particular attention, however, was taken to elements of the procedure.

All levels above L5-S1 were approached via a longitudinal incision and a left retroperitoneal approach. The L5-S1 level was approached through a Pfannenstiel incision, and the disc space was explored from a right retroperitoneal approach, keeping the left side free for further surgery.

In preparation of the disc, the entire endplate cartilage was removed, and attention was taken to not penetrate the endplate or rupture the lateral annulus. To prevent adherence to the disc space, a gortex graft was applied at the end of the procedure. Postoperatively, core stability exercises were instituted by the hospital physiotherapist once pain settled. Patients were advised to avoid heavy lifting or repetitive bending for 2 months.

Statistical Analysis

Statistical analysis was performed by the first author using Microsoft Excel 365 Version 2201 (14931.20120). The Mann-Whitney *U* test was used to determine differences in age, preoperative VAS scores, and quality-of-life scores between patients who were lost to follow-up and those who were followed up as well as those with further surgery compared with no further surgery. Fisher exact test was used to determine differences in gender distribution between groups that were lost to follow-up as well as opioid use between those requiring further surgery and those who did not. The Wilcoxon signed rank test was used to assess the difference between preoperative and postoperative VAS scores. Significance was accepted to be at the $P < 0.05$ level.

RESULTS

Patient Demographics

A total of 16 patients responded to the follow-up phone interview in late 2020. The mean follow-up duration was 17.2 years (range 12.5–19.5). All patients included in this study were workers' compensation

Table 1. Mann-Whitney *U* test (lost vs found preoperative VAS and age at surgery) and Fisher exact test (lost vs found gender).

Patient Characteristics	Patients Followed Up (n = 16)	Patients Lost to Follow Up (n = 10)	P Value
Preoperative VAS scores, mean	9.5	7.5	**0.001**
Age at surgery, mean	42.0	37.4	0.16
Gender, male:female	8:8	7:3	0.28
Workers' compensation, *n*	16	10	

Abbreviation: VAS, visual analog scale.
Note: Boldface indicates statistically significant findings.

patients. A summary of patient demographics is provided in Table 1.

Patients who were lost to follow-up had less pain preoperatively compared with those who responded to follow-up (P = 0.001). There was no significant gap in age or gender between the 2 groups. All 7 patients who lost their preoperative VAS scores (due to system error) belonged to the group that was followed up and were subsequently asked to recall their VAS score as they remembered it before the surgery. These 7 patients reported a mean preoperative VAS score of 9.7 compared with the preoperative VAS scores of 9.4 in the other 9 patients who were followed up.

Pain Relief and Quality of Life

The mean preoperative VAS score for the 16 patients analyzed in this study was 9.5 (SD 0.6). At follow-up 17.2 years later, VAS scores were significantly lower at 3.1 (SD 2.4) (P < 0.001). The 10 patients lost to follow-up had a mean preoperative VAS score of 7.5.

VAS scores for those who required further surgery averaged 5.3 at follow-up (Table 2), compared with VAS scores of 1.8 in patients who did not require further surgery (P = 0.004). Of the 16 patients who were followed up, 5 (31%) had undergone further lumbar spine surgery and were on prescription opioid pain medication to manage their lower back pain. Patients who did not require further surgery did not require opioids for pain management. The mean EQ-5D-5L score for quality of life for the entire cohort was 0.68 (SD 0.2). Patients who underwent further surgery had a lower quality of life at follow-up of 0.45 (SD 0.2) compared with patients who did not require further surgery 0.81 (SD 0.1) (P = 0.002). Out of the 16 patients, 15 (94%) reported they would repeat the surgery given similar circumstances.

Table 2. Mann-Whitney *U* test (further surgery vs no further surgery age, VAS preoperative, VAS postoperative, EQ-5D-5L) and Fisher exact test (further surgery vs no further surgery gender and opioid use).

Patient Characteristics	No Further Surgery (n = 10)	Further Surgery (n = 6)	P Value
Gender, male:female	4:6	4:2	0.94
Age at surgery, y, mean	41	44	0.91
VAS preoperative, mean	9.6	9.5	1.0
VAS postoperative, mean	1.8	5.3	**0.004**
Postoperative opioid use, %	0%	83%	**0.042**
Quality of life, mean	0.81	0.45	**0.002**

Abbreviations: EQ-5D-5L, EuroQol 5-Dimension 5-level instument; VAS, visual analog scale.
Note: Boldface indicates statistically significant findings.

Employment Outcomes

Out of the 16 patients, 13 (81%) who followed up at 17 years returned to work after the Charité disc replacement for some period. Of those 13, 7 (54%) returned to preinjury duties (PID), and 6 (46%) returned to light duties. Patients who returned to work worked on average for 9.1 years (SD 7.04). Six patients were still working at the time of follow-up with the longest duration of employment being over 18 years. Of the remaining 8 patients, 6 cited back pain as the main contributor to their retirement while the other 2 retired for other reasons. Of the 6 patients who required further surgery, 5 returned to work after the initial TDR. After reoperation (Table 3), 2 of these 5 patients returned to work and worked an additional 10 and 7 years, respectively.

Complications and Further Surgery

Out of the 16 patients, 3 (19%) reported complications from the index procedure, including 2 medical complications (hypotension and anaphylaxis) and 1 surgical complication (ilioinguinal nerve damage).

Out of the 16 patients, 6 (38%) underwent further lumbar spinal surgery, of whom 4 underwent fusions of the adjacent segment. The average time to reoperation was 6.5 years after the index surgery, with 2 patients requiring second surgery more than 13 years after their index surgery. Two patients required further surgery at the level of the original TDR. A summary of the further surgeries required after TDR is shown in Table 4.

DISCUSSION

Despite enthusiasm for alternative surgical treatment for lower back pain, implementation rates of TDR have been relatively low. Thus, there is a paucity of evidence as to the long-term efficacy of lumbar TDR for the treatment of degenerative disc disease beyond 10 years, let alone in a group of workers' compensation patients.[16,18,22] Previous systematic reviews suggest that

Table 3. Further surgeries required after TDR.

Index TDR Site	Reoperation	Duration Between Surgeries
L5-S1 TDR (2003)	L4-L5 fusion (2016) L3-L4 TDR (2016)	13 y
L5-S1 TDR (2004)	L3-L4 fusion (2009)	5 y
L3-L4-L5 TDR (2003)	L5-S1 fusion (2016)	13 y
L5-S1 TDR (2002)	Foraminotomy (2003)	1 y
L4-L5-S1 TDR (2003)	L3-L4 fusion (2010) L4-L5 fusion (2018)[a] L5-S1 fusion (2019)[a]	7 y
L4-L5 TDR (2003)	Discectomy (2004) L4-L5-S1 fusion (2005)[a]	1 y

Abbreviation: TDR, total disc replacement.
[a]Denotes further surgery at the index (operated) level.

lumbar TDR provides improvements to quality-of-life measures in the medium to long term and substantial pain relief in the short to medium term with pain relief documented as long as 12 years.[16,18,22–24] Our study reports improved pain and quality-of-life measures after 17 years in a group of workers' compensation patients. In this study, 15 of 16 patients (94%) would repeat the surgery given similar circumstances, which reinforces international data that TDR is a popular surgery among patients.[16,18,23,25] Bai et al's meta-analysis reported TDR as superior to spinal fusion in single-level patients using similar metrics of VAS, patient satisfaction, reoperation rates, and quality of life.[26]

The literature reports a medium- to long-term reoperation rate of TDRs ranging between 0 and 39% with a mean reoperation rate of 12% in studies that follow patients for longer than 3 years.[22] In that systematic review, the mean reoperation time was 0.8–6.9 years after TDR surgery, which is similar to our reported reoperation time of 6.5 years.[22] Our reoperation rate of 38% and reoperation time of 6.5 years may reflect 2 late reoperations approximately 13 years after the original TDR. These late reoperations of the adjacent segment may not have been captured in studies of shorter follow-up time. Our study found reoperation to be associated with poorer outcomes in VAS scores, opioid use, and quality of life. Similarly, poorer long-term results with further spinal surgery after TDR have been demonstrated in other studies.[27] However, despite this comparatively high reoperation rate and associated poorer outcomes in those who required further surgery, it is worth noting that these poorer outcomes were still an improvement compared with the reported preoperative VAS scores. While patients were selected according to the Charité implementation guidelines, further identification and selection of patients with isolated single-level disc disease with minimal psychosocial risk factors may further improve patient outcomes.[7,17,28,29]

The rate of opioid prescription for patients with TDR has been reported as high as 71.2% at 24 months postoperation.[30] This study reports that 5 of 16 (31%) patients required opioids for the management of their low back pain 17 years after TDR. All patients in this study had previously exhausted conservative management before surgery was offered, with many patients requiring opioid-based analgesia for pain management before surgery. It is interesting to note that the only patients who required opioids at follow-up were those who had further lumbar spinal surgery; 4 had undergone further spinal fusion surgery, while the fifth patient underwent a foraminotomy a year after surgery. This patient reported a good initial response to the TDR but unfortunately developed diffuse idiopathic skeletal hyperostosis syndrome more than a decade later.

All patients in our study were workers' compensation patients. The RTW rate of 81% and the return to PID of 54% in workers' compensation cohorts are considerably higher than the RTW and PID rates of 40 and 11%, respectively, previously described in the Australian literature.[30] Their study indicated poor RTW and high rates of ongoing opioid management (71%) at 24 months, leading the authors to conclude "along with the poor evidence base for these procedures … [this result] forces us to question the role of fusion and TDR surgeries in a workers' compensation population."[30] We believe that the patient's RTW is based on several factors. First, the recovery and rehabilitation for TDR are faster than they are for spinal fusion.[14,31] Second, we believe patients' and employers' expectations for recovery are greater, as they tend to compare TDR with other orthopedic joint replacements with good clinical outcomes.

Table 4. Wilcoxon signed rank test (preoperative vs postoperative VAS).

Patient population	VAS Preoperative	VAS 17.2 y	*P* Value
Total patients	8.8 (n = 26)	3.1 (n = 16)	**<0.001**
Followed up	9.5 (n = 16)	3.1 (n = 16)	
Lost to follow-up	7.5 (n = 10)	N/A	

Abbreviations: N/A, not applicable; VAS, visual analog scale.
Note: Boldface indicates statistically significant findings.

Limitations

There were several limitations to this study. The first limitation is the small sample size of 26 patients with a follow-up rate of 62%. This follow-up rate is perhaps a reflection of the extended follow-up time, with many patients uncontactable via phone or mail and some patients who died in that time. This follow-up rate is

consistent with other long-term studies of TDR and represents difficulties in studying patients over long periods.[32] The second notable limitation is the retrospectivity of 7 patients who lost their preoperative VAS scores due to a computer system malfunction. These patients were asked to recall their preoperative VAS scores at follow-up. This introduces a potential element of recall bias, as they may have recalled their pain being more severe than it in fact was at the time. However, when compared with the preoperative VAS scores of the patients who did follow-up with the study, we note that the scores are similarly high around 9.4/10 and 9.7/10, respectively. Furthermore, the primary surgeon did not operate on any patient with a VAS score less than 7/10 at the time of surgery. A further limitation of this study is that we did not gather radiologic data and compare outcomes in those with low VAS scores compared with high VAS scores, nor did we assess ASD. Body mass index has been shown to be a potential outcome predictor in other studies; however, body mass index was not assessed in this study.[33]

The literature currently suggests that due to the mobility characteristics of TDR, ASD is not as common in patients undergoing TDR, compared with arthrodesis in the short to medium term. A systematic review by Wang and Arnold reported that patients who underwent arthrodesis for lumbar degenerative disc disease were 6 times more likely to require surgical treatment for ASD than those who underwent TDR.[34] ASD, however, was not assessed in this study.

CONCLUSION

This study presents the outcomes of 16 patients treated with the Charité TDR with a mean follow-up of 17 years, in a workers' compensation cohort. An RTW was achieved in 81% of cases, and they were employed for an average of more than 9 years, with many still employed at the time of follow-up. Pain was significantly reduced at 17 years, and many patients did not require opioid analgesia for pain relief. These results demonstrate that satisfactory long-term clinical results can be achieved for workers' compensation patients using the Charité TDR.

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