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Single-Level Total Disc Replacement: Mid- to Long-Term Outcomes

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ABSTRACT

Background: Total disc replacement (TDR) has been shown to be effective for the treatment of lumbar degenerative disc disease (DDD) in carefully selected patients. Previous studies have demonstrated high rates of patient satisfaction and improvement in patient-reported outcome measures (PROMs) compared with preoperative status but most have short-term follow-up or small cohort sizes only.

Objective: The aim of this study is to report mid- to long-term PROMs from the treatment of symptomatic single-level lumbar DDD with TDR.

Methods: Data collected prospectively concerning single-level TDR performed via an anterior approach were included for analysis. A preoperative assessment was obtained followed by postoperative follow-up assessments at 3, 6, and 12 months, and yearly follow-up thereafter. PROMs included patient satisfaction, visual analog score back and leg, Oswestry Disability Index, and Roland-Morris Disability Questionnaire.

Results: A total of 211 patients (118 men, 93 women) operated on between June 1997 and July 2015 were included in this study. Minimum follow-up was 4 years. The average age was 42.2 (range 24–87) years and median follow-up 96 interquartile range 72–132, range 48–120) months. The operative levels were L5-S1 (160, 75.8%) and L4-L5 (61, 24.2%). Both statistically and clinically significant improvements observed postoperatively were maintained at 10 years. In addition, 92% of patients reported either good (n = 29) or excellent satisfaction (n = 155) with treatment at final review.

Conclusions: This study shows that single-level lumbar TDR used appropriately in selected patient results in clinically significant improvements in pain and function, well above the minimum clinically important difference, and good to excellent satisfaction in most patients. Further study to define long-term outcomes and survivorship is required.

Clinical Relevance: Statistically significant and clinically relevant improvements can be achieved by single-level lumbar TDR, in the treatment of single-level discogenic axial low back pain, with or without radiculopathy. These outcomes are sustained in the mid- to long-term followup periods.

Level of Evidence: 4.

Total Disc Replacement

Keywords: degenerative disc disease, total disc arthroplasty, single level, total disc replacement, back pain, motion preservation, lumbar spine, long-term outcomes

INTRODUCTION

Lumbar degenerative disc disease (DDD) is a common cause of low back pain (LBP) and is characterized by biomechanical, biochemical, and structural changes that affect the ability of the motion segment to resist physiological load without LBP.[1] Epidemiological studies have reported 70% to 80% of people in the Western world are afflicted by LBP at some stage and an estimated 15% to 20% develop chronic persistent LBP.[2] The socioeconomic implications of LBP are well documented.[2] Options reported for the management of appropriately diagnosed lumbar DDD include nonoperative management involving activity modification, medications, physiotherapy, and, when refractory, surgical intervention.

Historically, fusion for the treatment of lumbar DDD[3] was more commonly performed via a posterolateral, interbody, or combined technique. Fusion has been associated with donor site morbidity, pseudarthrosis, clinical and radiographic adjacent segment pathology, stenosis, and high rates of sagittal malalignment.[2,4] Total disc replacement (TDR), as an alternative treatment for lumbar DDD, with the goals being to alleviate pain while preserving range of motion and restoring stability, has been studied extensively.[5,6] TDR suitability is dependent on several considerations, including device design (particularly constraint), the type of spine,[7] the

anatomical level,[8] the bone quality, and the status of the facets.[9–11]

Over the decades, lumbar TDR for use in DDD has developed into a treatment that is no longer experimental or investigational and is supported by multiple favorable level I prospective randomized multicenter studies,[12–14] as well as long-term follow-up cohort studies.[15–17] The technology is maturing as implant designs continue to evolve, receive regulatory approval, and become available for clinical use.[4,18] One of the theoretical advantages of TDR over many fusion techniques is that the pain generator is removed completely and endplate distraction achieved with a concordant increase in disc height, lordosis, and neuroforaminal height. This is not uniformly performed in fusion techniques.[18] Unlike traditional fusion, where a rigid motionless segment is created,[4] motion is preserved, and the patient can "self-center" in their dynamic sagittal alignment,[19,20] thereby reducing shear stress transfer to adjacent segments. Accordingly, TDR has been shown to reduce the development of clinical and radiographic adjacent segment pathology when compared with fusion.[18,21–24] In addition, there is no donor site morbidity or risk of pseudarthrosis.

Recent literature demonstrates clinical equivalence with fusion,[25] with studies reporting superior clinical and radiological results, earlier return to and retention at work, superior function, and cost-effectiveness in the short- to midterm compared with fusion.[26–30] Clinical measures such as visual analog score for back (VAS-B) and leg (VAS-L) and the Oswestry Disability Index (ODI) have been shown to significantly decrease within 6 weeks after TDR, with maintenance of improvements at 5-year[31] and 10-year follow-up.[6,18] Patient-reported outcome measures (PROMs) in longer-term studies show clinical success in 79.6% to 87.5% of cases and satisfaction rates in the order of 82.1% to 93.3%.[18,22,32,33]

The scientific evidence supports the safety and efficacy of single-level lumbar TDR for patients meeting well-established selection criteria. The goal of this study is to augment the literature on the mid- to long-term follow-up of PROMs via analysis of a large prospective cohort of patients with single-level TDR for lumbar DDD.[6,25,30] The hypotheses were that TDR for DDD in our cohort would achieve clinically important pain relief and functional gains and that the results would be maintained over the course of follow-up.

MATERIALS AND METHODS

This study was approved by the Bond University Human Research Ethics Committee (0000015881) and involved 211 patients with a minimum of 4 years of follow-up, who underwent single-level TDR by the senior surgeon, using an unconstrained prosthesis. The prostheses used were Charité Artificial Disc (DePuy Spine, Raynham, MA, USA), InMotion (DePuy Spine, Raynham, MA, USA), and Prodisc L Total Disc Replacement (Synthes Spine, West Chester, PA, USA).

All participants had chronic LBP (>12 months) that was refractory to active nonoperative treatment, including physical therapy and rehabilitation programs. A diagnosis of single-level discogenic axial LBP, with or without radiculopathy, was established through history, examination, diagnostic imaging, and testing. The latter included a combination of standing lumbar radiographs, magnetic resonance imaging, and provocative discography with postdiscography fine cut computed tomography image.[34] Discography remains the gold standard for obtaining a diagnosis of discogenic pain[35] and is supported in the recently updated North American Spine Society guidelines.[36] The recommended technique has evolved over time,[34,37] and the most current guidelines are outlined by the Spine Intervention Society, as of 2019.[38] Electrophysiological studies (electromyography and nerve conduction studies) were performed to confirm the presence or absence of radiculopathy.

Surgery was offered to patients whose clinical findings were consistent with both imaging and provocative tests and whose pain was interfering with their social, recreation, and employment opportunities. Contraindications to surgery included regional osteoporosis, active infection, tumors, significant scoliosis (>20° coronal malalignment), spondylolisthesis, grade II or greater facet arthropathy,[39] and pregnancy. Obesity and involvement in workers' compensation or litigation were relative contraindications.

Surgery was performed via a midline rectus split with a left- or right-sided retroperitoneal approach. All prostheses were confirmed to be within 3 mm of the midline clinically and on fluoroscopy and appropriately sized within the intervertebral space on lateral imaging. As unconstrained prostheses were used, an anterior longitudinal ligament repair or reconstruction with synthetic ligament was performed to reduce any segmental coronal or rotatory instability. Prescription of perioperative physiotherapy to condition the paraspinal and core muscles and facilitation of postural retraining was routine.[40,41]

Participants completed an ODI and Roland-Morris Disability Questionnaire (RMDQ) prior to and at regular intervals after surgery, along with VAS-B and VAS-L. Patient satisfaction was rated as excellent, good,

Table 1. Baseline characteristics of surgery patients (N = 211).

Characteristic	*n* (%)
Gender	
Female	93 (44.1)
Male	118 (55.9)
Age at time of surgery (y), mean (SD)	42.2 (11.1)
Age group	
<35 y	47 (22.3)
35–45 y	83 (39.3)
>45 y	81 (38.4)
Level	
L4-L5	51 (24.2)
L5-S1	160 (75.8)
Pain, median (IQR)	
VAS-back[a]	75.0 (55.0–89.0)
VAS-leg	60.0 (17.0–83.0)
Disability, median (IQR)	
ODI[b]	46.0 (34.0–56.0)
RMDQ[c]	16.0 (12.0–19.0)

Abbreviations: IQR, interquartile range; ODI, Oswestry Disability Index; RMDQ, Roland-Morris Disability Questionnaire; VAS, visual analog scale.
Note: Data are presented as *n* (%) unless otherwise indicated.
[a]The VAS is scored on a 0 (no pain) to 100 (worst pain) scale.
[b]The ODI is scored on a 0 (none) to 100 (worst) disability scale.
[c]The RMDQ is scored on a 0 (none) to 24 (worst) disability scale.

satisfactory, or poor. These outcomes were recorded postoperatively at 3, 6, and 12 months and yearly thereafter and were analyzed by an independent university research team. Radiographic analysis was undertaken to confirm movement, alignment, and lack of complication of the construct (eg, subsidence, migration, heterotopic ossification, and adjacent motion segment disease).

Statistical Methods

Baseline characteristics were expressed as mean (SD) or median (interquartile range [IQR]) depending on the distribution of the continuous variables. Categorical variables were summarized counts (%). Summary statistics were produced for the actual measurements at all individual timepoints but only the results for key timepoints are tabulated. Graphical representations of the mean change scores for all timepoints over 13 years were plotted along with 95% CI and the corresponding minimum clinically important difference (MCID) for each main outcome. Previous research has found the MCID for VAS-B to be 12,[42] VAS-L to be 16,[42] a 10-point change on the ODI,[30] and a change of 5 points on the RMDQ.[30]

Linear mixed-effects models were applied to the longitudinal data for each main outcome to model the trajectory of change scores over the 13-year period. All analyses were performed using R statistical software version 3.4.2, and the *nlme* package was used for the linear mixed-effects models.

RESULTS

Table 1 lists the baseline characteristics of the 211 surgery patients. Table 2 shows the summary statistics for VAS-B and VAS-L and the ODI and RMDQ disability scores. Figures 1 and 2 are graphical representations of the change scores for VAS-B, VAS-L, ODI, and RMDQ outcome measures over a 13-year period, with

Table 2. Summary statistics for VAS, ODI, and RMDQ outcomes over 13 y in 211 patients.

	VAS-Back			VAS-Leg		
Time After Surgery	***n***	**Median**	**IQR**	***n***	**Median**	**IQR**
0 (baseline)	211	75.0	55.0–89.0	211	60.0	17.0–83.0
6 mo	197	9.0	2.0–20.0	193	1.0	0.0–13.0
1 y	196	5.0	0.0–20.0	192	1.0	0.0–10.0
2 y	187	3.0	0.0–17.0	188	1.0	0.0–11.0
4 y	184	5.5	0.0–22.0	183	1.0	0.0–14.5
5 y	158	6.0	0.0–19.8	158	1.0	0.0–7.0
8 y	96	6.5	1.0–20.0	97	2.0	0.0–7.0
10 y	62	5.0	1.0–21.0	62	1.0	0.0–4.8
13 y	24	12.0	1.0–45.3	24	3.5	0.8–19.0
	ODI			**RMDQ**		
Time After Surgery	***n***	**Median**	**IQR**	***n***	**Median**	**IQR**
0 (baseline)	211	46.0	34.0–56.0	211	16.0	12.0–19.0
6 mo	198	6.0	0.0–18.0	193	1.0	0.0–3.0
1 y	197	4.0	0.0–14.0	195	0.0	0.0–2.0
2 y	188	2.0	0.0–14.0	186	0.0	0.0–2.0
4 y	182	6.0	0.0–14.0	182	0.0	0.0–3.0
5 y	157	4.0	0.0–14.0	157	0.0	0.0–4.0
8 y	97	4.0	0.0–14.0	95	0.0	0.0–3.0
10 y	62	4.0	0.0–13.5	62	0.0	0.0–3.0
13 y	24	4.0	0.0–19.0	23	0.0	0.0–4.5

Abbreviations: IQR, interquartile range; ODI, Oswestry Disability Index; RMDQ, Roland-Morris Disability Questionnaire; VAS, visual analog scale.

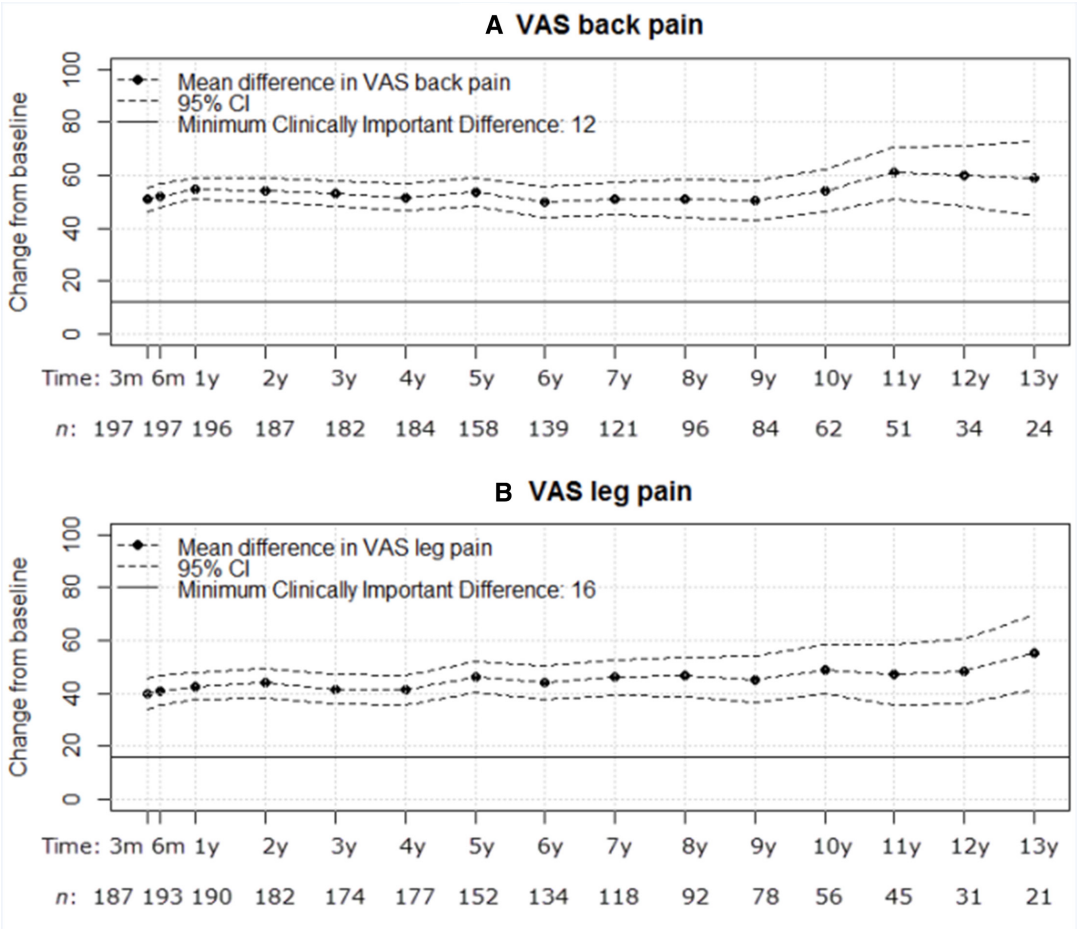

Figure 1. Profile of the mean reduction from baseline and 95% CIs for visual analog scale (VAS) back and leg pain scores. All improvements from baseline were statistically significant ($P < 0.001$).

a reference line plotted for the relevant MCID for each outcome. All the profiles showed an improvement in pain or function that was well above the corresponding MCID and was also statistically significant ($P < 0.001$). Six patients received index-level revision spine surgery, and 12 patients received adjacent-level revision spine surgery.

Mixed-effects regression analysis was used to model the longitudinal data for each outcome to assess the effect of time, adjusted for baseline and several covariates (age, gender, and level group). The unconditional models that assessed the outcomes with only random intercepts for patients already account for most of the variation: VAS-B (75.1%), VAS-L (83.1%), ODI (83.2%), and RMDQ (81.3%), indicating that the change scores for individual patients tend to remain constant over time, and that there were more differences among individuals than within individuals.

A summary of the most suitable conditional models that included time is shown in Table 3. Gender and level group were not statistically significant. All models were adjusted for baseline score which was significant. For a patient with a baseline of 46.0 and 16.0, respectively, for ODI and RMDQ, the estimated mean change scores at year 1 postsurgery were 35.0 and 13.7, respectively. The effect of time was not statistically significant for the disability outcomes. Variation in the VAS-B score can also be explained by a statistically significant mean reduction of 0.6 point per year in the improvement postsurgery over time ($P = 0.002$). However, over a 13-year period, this only constitutes a difference of less than 8 points, that is, within the MCID of 12. VAS-L pain change scores appear to be relatively constant over time ($P = 0.27$). There was evidence that the improvement in leg pain for older adults (>45 years) was on average slightly lower than for the youngest group (<35 years) by a mean difference of 7/100 points ($P = 0.007$).

An exploratory analysis was performed on a subgroup of patients ($n = 10$) who had the longest follow-up (from 13 to 15 years) and the most complete data, including baseline scores for all 4 outcomes. Profile plots were produced, fitted with individual regression lines to

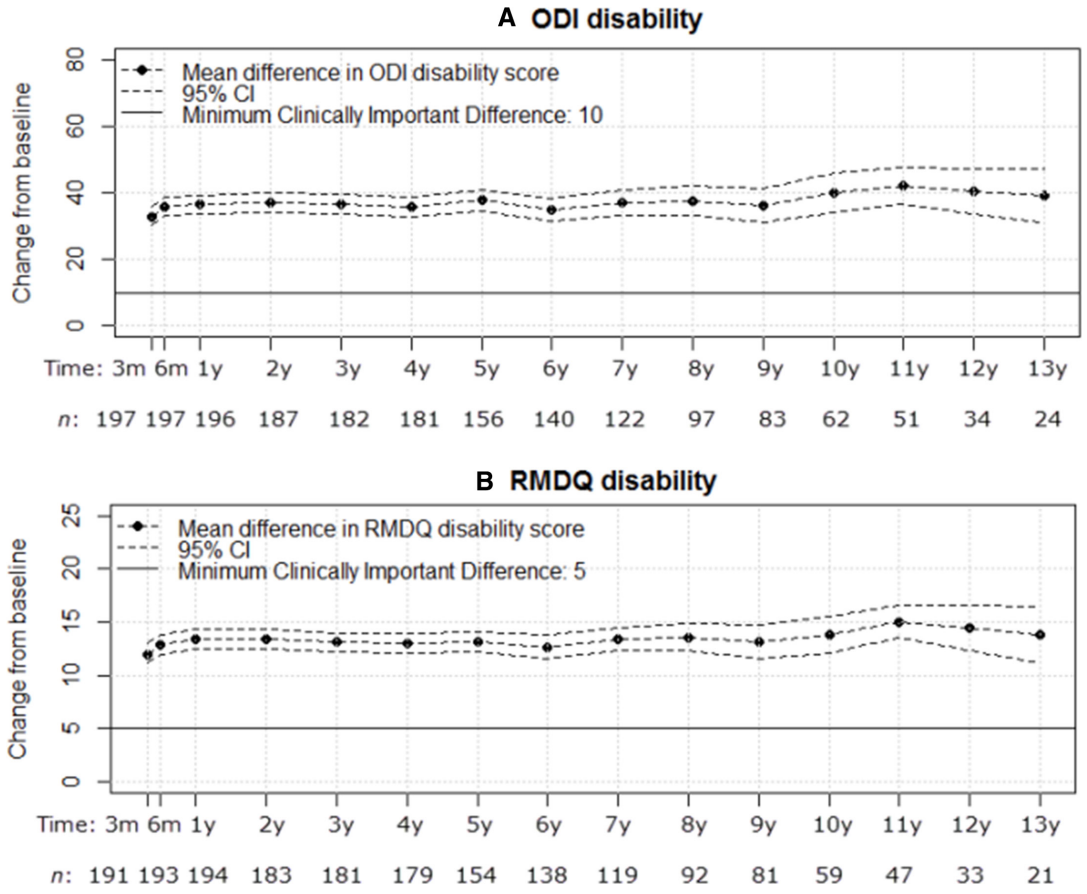

Figure 2. Profile of the mean reduction from baseline and 95% CIs for Oswestry Disability Index (ODI) and Roland-Morris Disability Questionnaire (RMDQ) disability scores. All improvements from baseline were statistically significant ($P < 0.001$).

assess change over time. The results showed slopes near 0 for the change scores for most individuals; all but 1 patient apart maintained the improvement experienced after surgery. Figure 3 shows x-ray images for a patient with a Charité Artificial Disc at 183 months postoperatively.

Table 3. Estimates of the fixed effects in the mixed-effects regression modeling of pain and disability change scores over 13 y.

Parameter	Coefficient β	95% CI	*P* Value
VAS-B			
Intercept	60.3	(58.3, 62.3)	<0.001[b]
Baseline score (centered on 75)	0.9	(0.9, 1.0)	<0.001[b]
Time, y	−0.6	(−1.0, −0.2)	0.002[b]
VAS-L			
Intercept	53.1	(49.0, 57.3)	<0.001[b]
Baseline score (centered on 60)	0.9	(0.9, 1.0)	**<0.001[b]**
Time, y	−0.2	(−0.5, 0.1)	0.27
Age group[a] coded 1 (35–45 y)	−3.1	(−8.3, 2.1)	0.24
Age group[a] coded 2 (>45 y)	−7.2	(−12.3, −2.0)	0.007[b]
ODI			
Intercept	35.0	(33.5, 36.5)	<0.001[b]
Baseline score (centered on 46)	0.9	(0.8, 1.0)	<0.001[b]
Time, y	0.1	(−0.1, 0.4)	0.22
RMDQ			
Intercept	13.7	(13.2, 14.1)	<0.001[b]
Baseline score (centered on 16)	1.0	(0.9, 1.1)	<0.001[b]
Time, y	−0.03	(−0.11, 0.05)	0.45

Abbreviations: ODI, Oswestry Disability Index; RMDQ, Roland-Morris Disability Questionnaire; VAS-B, visual analog scale for back pain; VAS-L, visual analog scale for leg pain.

[a]Reference age group coded 0: <35 y.

[b]Statistically significant $P < 0.0125$. A negative coefficient signifies a decrease in improvement. The intercept coefficient represents the mean change score at year 1 for patients with median baseline for VAS-B, ODI, and RMDQ and for the <35 y age group for VAS-L.

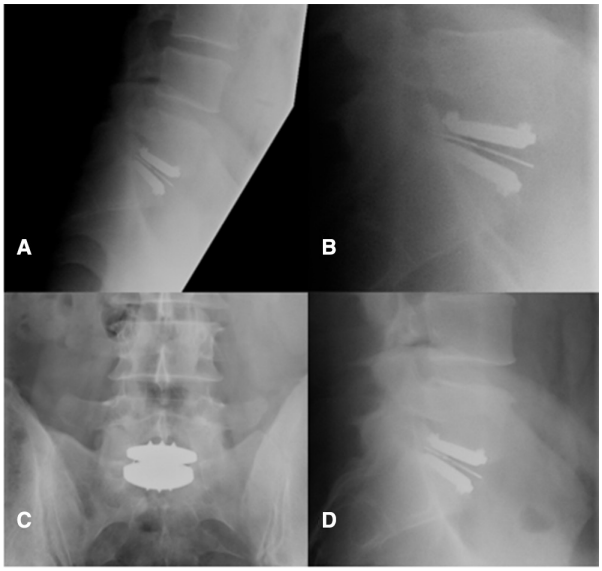

Figure 3. X-ray images of a Charité Artificial Disc at 183 mo after surgery: (a) flexion, (b) extension, (c) anteroposterior, and (d) lateral.

Further tests on all available data for the main outcomes (n = 205–211) showed that there were statistically significant differences ($P < 0.001$) between baseline and final value (measured between 4 and 15 years postsurgery); these improvements from initial pain and disability function were also clinically significant.

Results of the pooled patient satisfaction levels for the entire 10-year follow-up period are displayed in Table 4 below. Patient satisfaction was rated good or excellent in over 90% of cases throughout the follow-up period, with only about 2% expressing a poor level of satisfaction (Figure 4).

DISCUSSION

The aim of this study was to report the prospective PROMs at medium- to long-term follow-up of a large patient cohort who underwent single-level lumbar TDR for DDD. There is recognition of the significance of PROMs, as health care providers and government agencies prioritize the distribution of monies from limited health care resources based upon the cost-value analysis of treatments. The return to and maintenance of functionality, and reduced disability, in the patient cohort (often of working age) from treatment with TDR are apparent when observing cohort outcome scores at each timepoint. A small number of patients provided PROMs showing that these improvements were maintained even 13 years and longer postsurgery.

Table 4. Patient satisfaction ratings (excellent/good) over a postsurgical period of 10 y.

Time After Surgery (in mo)	Total n	Excellent/Good, n (%)
3	184	171 (92.9)
6	180	169 (93.9)
12	178	164 (92.1)
24	179	167 (93.3)
36	174	161 (92.5)
48	181	165 (91.2)
60	157	146 (93.0)
72	138	129 (93.5)
84	121	115 (95.0)
96	92	89 (96.7)
108	81	75 (92.6)
120	61	59 (96.7)

While the advantages of lumbar TDR over fusion have been reported in short- to midterm studies,[21,28,29] a lack of literature concerning long-term data and implant survival, along with payer restrictions, have been reasons for the perceived slow adoption of TDR compared with the incumbent "gold standard" of fusion for lumbar DDD.[43–46] The results of this study show that single-level TDR for DDD reliably achieves improvement in PROMs that exceed the MCIDs for both pain and disability in the midterm to long term. In addition, patient satisfaction is maintained at an excellent/good rating in above 90% of cases up to 10 years follow-up.

Regarding pain scores, significant reductions were seen. At 24 months, the median scores in VAS-B had improved by 96% (from 75.0 to 3.0) while the VAS-L scores improved 98.3% in the same time frame (from 60.0 to 1.0). Existing literature has reported changes in VAS-B (49.9%–89%)[5,8,21,47,48] and VAS-L (42%–56.2%),[5,6,21] respectively. Regarding longevity of the results, Zigler reported sustained VAS-B changes when comparing 2 to 5 years postoperatively with the VAS-B reduction at 2 years of 49.9% (75.9–36.6) maintained at 5 years (48.7% improvement) in the cohort.[21] More recent positive results with respect to outcomes of TDR may be reflective of the learning curve and evolution of indications associated with adoption of evolving surgical techniques.[8]

Changes in ODI scores in our cohort compare favorably to the existing literature and, importantly, demonstrate a cohort of patients moving from severe to minimal disability following treatment. The mean difference in ODI scores is above the MCID at all timepoints and representative of minimal disability. Other authors report comparable ODI improvements of anywhere from 45.7% to 76% depending on the time period studied.[8,21,49]

The RMDQ is the most validated and second most widely used of the many LBP disability questionnaires and has been suggested as a core outcome measure for LBP. Despite data being presented on the RMDQ in

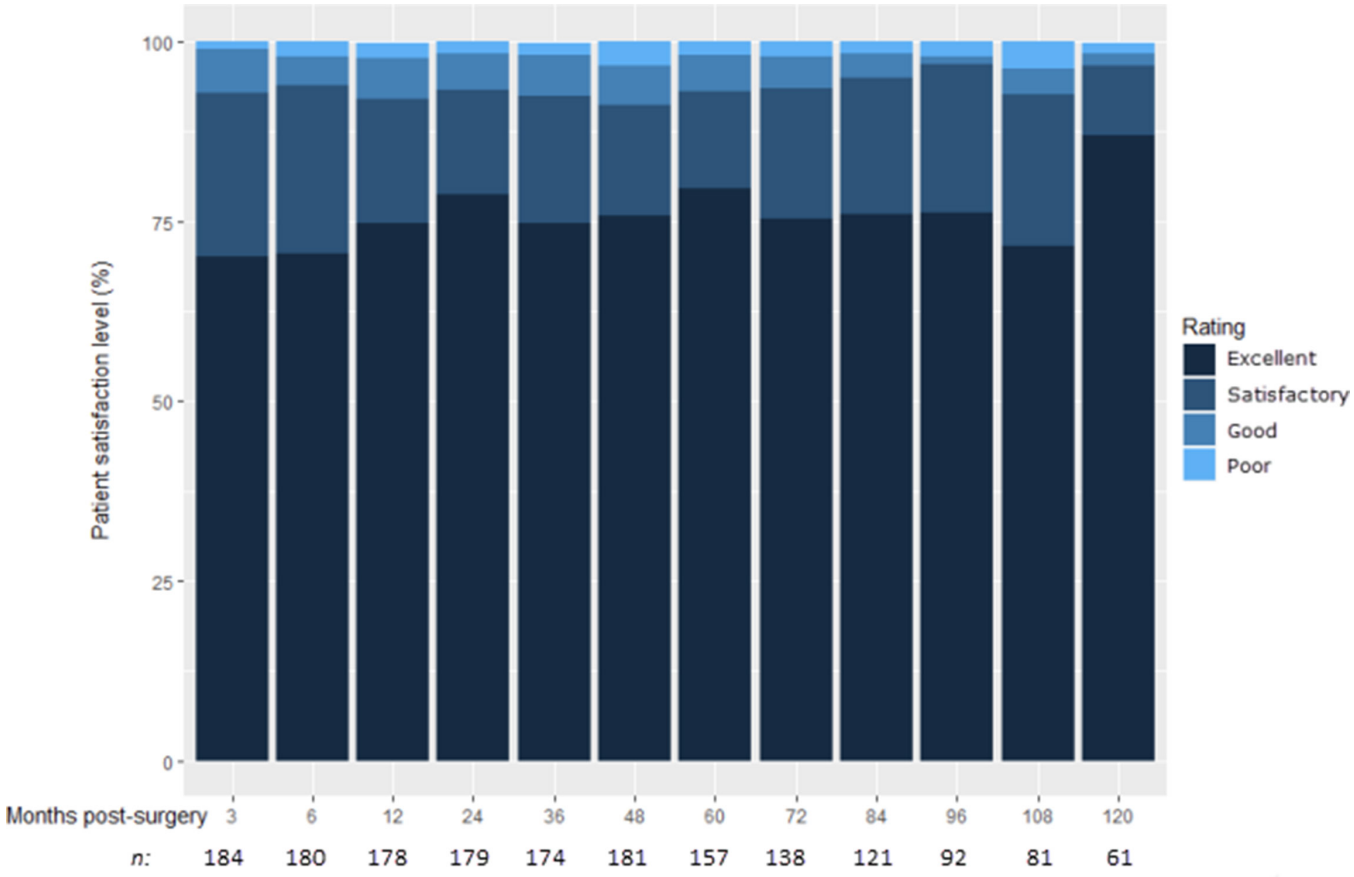

Figure 4. Patient satisfaction levels over the duration of postsurgery follow-up (*N* = 211).

this study that showed significant improvements in the cohort, few other studies have utilized it when evaluating lumbar TDR outcomes. Possible reasons for this may be the fact that it is purported to be more sensitive in assessing mild to moderate disability, and the ODI is more suitable in evaluating persistent severe disability.[50]

Patient satisfaction outcomes in this study are comparable with the existing literature with satisfaction rates ranging from 82.1% to 90%.[8,22,32,51] The clinical outcomes of this study are notable, given it is generally accepted that longer follow-up may result in decay of the clinical results due to age-related degeneration. Over the entire follow-up period in our study, 98.1% of patients reported their satisfaction as excellent, good, or satisfactory.

The improvements in all clinical measures may be reflective of appropriate patient selection for specific procedures and an attempt at precision diagnosis through a suggestive history and examination, supported by concordant discography and electromyography and nerve conduction studies. Indeed, studies have highlighted that patients selected with such an approach are more likely to have improved clinical outcomes.[6,52–54] The high patient numbers and accompanying favorable results seen in this study are not readily reproducible by the occasional arthroplasty surgeon, and it is well documented that outcomes are correlated with a volume-performance threshold.[55,56] Additional factors likely contributing to the results include meticulous surgical technique and routine structured postoperative rehabilitation. The latter is critical, as poor paraspinal musculature has been shown to impair proprioception and postural control, which can influence motion segment kinematics[57,58] and has associated poorer outcomes after TDR compared with patients with satisfactory musculature.[10,11]

The strengths of this study lie in the follow-up period achieved and the high number of patients available for analysis. Direct comparison to other long-term studies remains difficult due to the inclusion of multilevel TDR surgery in the results of other studies.[8,18,59] Limitations may also relate to some patients presenting without leg pain, leaving the change in this outcome postoperatively at 0. The IQR may instead provide useful information for this outcome. Another difficulty in comparison with other studies is patient selection and preoperative assessment. There is heterogeneity among studies with

the use of provocative discography and defining contraindications. Sagittal alignment and spinal subtype[7] were not uniformly assessed in those patients enrolled earlier in the study but have since become common in the literature[20] and routine in the authors' institution, and this would be expected to affect outcomes. Finally, there is the question of the ideal PROMs to use in a spinal surgery study. Some PROMs lack sensitivity in measuring subtleties of function, making it difficult to accurately define their utility. Furthermore, they do not define important economic outcomes of treatment such as health care provider use, employment, and related indices.

CONCLUSION

This study involves a large cohort with symptomatic single-level lumbar DDD and suggests that single-level TDR in carefully selected patients results in improved PROMs well above the MCID and good or excellent satisfaction in most patients at mid- to long-term follow-up. Most patients reach maximum improvement in all measured outcomes by 12-months postoperative follow-up. These outcomes are sustained at mid- to long-term follow-up. Further studies defining long-term outcomes and survivorship are required.

REFERENCES

1. Adams MA. Biomechanics of back pain. *Acupunct Med*. 2004;22(4):178–188. doi:10.1136/aim.22.4.178

2. Bertagnoli R, Zigler J, Karg A, Voigt S. Complications and strategies for revision surgery in total disc replacement. *Orthop Clin North Am*. 2005;36(3):389–395. doi:10.1016/j.ocl.2005.03.003

3. Yoshihara H, Yoneoka D. National trends in the surgical treatment for lumbar degenerative disc disease: United States, 2000 to 2009. *Spine J*. 2015;15(2):265–271. doi:10.1016/j.spinee.2014.09.026

4. Young JM, Feldman RA, Auerbach SM, et al. Tadalafil improved erectile function at twenty-four and thirty-six hours after dosing in men with erectile dysfunction: Us trial. *J Androl*. 2005;26(3):310–318. doi:10.2164/jandrol.04126

5. Garcia R, Yue JJ, Blumenthal S, et al. Lumbar total disc replacement for discogenic low back pain: Two-year outcomes of the activl multicenter randomized controlled IDE clinical trial. *Spine (Phila Pa 1976)*. 2015;40(24):1873–1881. doi:10.1097/BRS.0000000000001245

6. Scott-Young MN, Lee MJ, Nielsen DEA, Magno CL, Kimlin KR, Mitchell EO. Clinical and radiological mid-term outcomes of lumbar single-level total disc replacement. *Spine (Phila Pa 1976)*. 2018;43(2):105–113. doi:10.1097/BRS.0b013e3182345aa2

7. Roussouly P, Gollogly S, Berthonnaud E, Dimnet J. Classification of the normal variation in the sagittal alignment of the human lumbar spine and pelvis in the standing position. *Spine (Phila Pa 1976)*. 2005;30(3):346–353. doi:10.1097/01.brs.0000152379.54463.65

8. Siepe CJ, Heider F, Wiechert K, Hitzl W, Ishak B, Mayer MH. Mid- to long-term results of total lumbar disc replacement: A prospective analysis with 5- to 10-year follow-up. *Spine J*. 2014;14(8):1417–1431. doi:10.1016/j.spinee.2013.08.028

9. Gornet MF, Schranck F, Wharton ND, et al. Optimizing success with lumbar disc arthroplasty. *Eur Spine J*. 2014;23(10):2127–2135. doi:10.1007/s00586-014-3309-8

10. Le Huec J-C, Basso Y, Aunoble S, Friesem T, Bruno MB. Influence of facet and posterior muscle degeneration on clinical results of lumbar total disc replacement: Two-year follow-up. *J Spinal Disord Tech*. 2005;18(3):219–223. doi:10.1016/j.ocl.2005.02.001

11. Storheim K, Berg L, Hellum C, et al. Fat in the lumbar multifidus muscles - predictive value and change following disc prosthesis surgery and multidisciplinary rehabilitation in patients with chronic low back pain and degenerative disc: 2-year follow-up of a randomized trial. *BMC Musculoskelet Disord*. 2017;18(1):1–11. doi:10.1186/s12891-017-1505-5

12. Sköld C, Tropp H, Berg S. Five-year follow-up of total disc replacement compared to fusion: a randomized controlled trial. *Eur Spine J*. 2013;22(10):2288–2295. doi:10.1007/s00586-013-2926-y

13. Zigler J, Delamarter R, Spivak JM, et al. Results of the prospective, randomized, multicenter food and drug administration investigational device exemption study of the prodisc-L total disc replacement versus circumferential fusion for the treatment of 1-level degenerative disc disease. *Spine (Phila Pa 1976)*. 2007;32(11):1155–1162. doi:10.1097/BRS.0b013e318054e377

14. Gornet MF, Burkus JK, Dryer RF, et al. Lumbar disc arthroplasty with MAVERICK disc versus stand-alone interbody fusion: a prospective, randomized, controlled, multicenter investigational device exemption trial. *Spine (Phila Pa 1976)*. 2011;36:1600–1611.

15. Plais N, Thevenot X, Cogniet A, Rigal J, Le Huec JC. Maverick total disc arthroplasty performs well at 10 years follow-up: a prospective study with HRQL and balance analysis. *Eur Spine J*. 2018;27(3):720–727. doi:10.1007/s00586-017-5065-z

16. Laugesen LA, Paulsen RT, Carreon L, Ernst C, Andersen MØ. Patient-reported outcomes and revision rates at a mean follow-up of 10 years after lumbar total disc replacement. *Spine (Phila Pa 1976)*. 2017;42(21):1657–1663. doi:10.1097/BRS.0000000000002174

17. Lu S, Sun S, Kong C, et al. Long-term clinical results following charite III lumbar total disc replacement. *Spine J*. 2018;18(6):917–925. doi:10.1016/j.spinee.2017.08.252

18. Park S-J, Lee C-S, Chung S-S, Lee K-H, Kim W-S, Lee J-Y. Long-term outcomes following lumbar total disc replacement using prodisc-ii. *Spine*. 2016;41(11):971–977. doi:10.1097/BRS.0000000000001527

19. Tournier C, Aunoble S, Le Huec JC, et al. Total disc arthroplasty: consequences for sagittal balance and lumbar spine movement. *Eur Spine J*. 2007;16(3):411–421. doi:10.1007/s00586-006-0208-7

20. Wuertinger C, Annes RDÀ, Hitzl W, Siepe CJ. Motion preservation following total lumbar disc replacement at the lumbosacral junction: a prospective long-term clinical and radiographic investigation. *Spine J*. 2018;18(1):72–80. doi:10.1016/j.spinee.2017.06.035

21. Zigler JE. Five-year results of the prodisc-L multicenter, prospective, randomized, controlled trial comparing prodisc-L with circumferential spinal fusion for single-level disabling degenerative disk disease. *Semin Spine Surg*. 2012;24(1):25–31. doi:10.1053/j.semss.2011.11.006

22. David T. Long-term results of one-level lumbar arthroplasty: minimum 10-year follow-up of the charite artificial disc in 106 patients. *Spine (Phila Pa 1976)*. 2007;32(6):661–666. doi:10.1097/01.brs.0000257554.67505.45

23. Ren C, Song Y, Liu L, Xue Y. Adjacent segment degeneration and disease after lumbar fusion compared with motion-preserving procedures: a meta-analysis. *Eur J Orthop Surg Traumatol*. 2014;24 Suppl 1:S245-53. doi:10.1007/s00590-014-1445-9

24. Schätz C, Ritter-lang K, Gössel L, et al. Comparison of single-level and multiple-level outcomes of total disc arthroplasty: 24-month results. *Int J Spine Surg*. 2015:1–11.

25. Vital J-M, Boissière L. Total disc replacement. *Orthop Traumatol Surg Res*. 2014;100(1 Suppl):S1-14. doi:10.1016/j.otsr.2013.06.018

26. Rihn JA, Radcliff K, Norvell DC, et al. Comparative effectiveness of treatments for chronic low back pain: a multiple treatment comparison analysis. *Clin Spine Surg*. 2017;30(5):204–225. doi:10.1097/BSD.0000000000000410

27. Stubig T, Ahmed M, Ghasemi A, Nasto LA, Grevitt M. Total disc replacement versus anterior-posterior interbody fusion in the lumbar spine and lumbosacral junction: a cost analysis. *Global Spine J*. 2018;8(2):129–136. doi:10.1177/2192568217713009

28. Zigler J, Gornet MF, Ferko N, Cameron C, Schranck FW, Patel L. Comparison of lumbar total disc replacement with surgical spinal fusion for the treatment of single-level degenerative disc disease: a meta-analysis of 5-year outcomes from randomized controlled trials. *Global Spine J*. 2018;8(4):413–423. doi:10.1177/2192568217737317

29. Mattei TA, Beer J, Teles AR, Rehman AA, Aldag J, Dinh D. Clinical outcomes of total disc replacement versus anterior lumbar interbody fusion for surgical treatment of lumbar degenerative disc disease. *Global Spine J*. 2017;7(5):452–459. doi:10.1177/2192568217712714

30. Jacobs W, Van der Gaag NA, Tuschel A, et al. Total disc replacement for chronic back pain in the presence of disc degeneration. *Cochrane Database Syst Rev*. 2012:Art No.:CD008326. doi:10.1002/14651858.CD008326.pub2

31. Guyer RD, Pettine K, Roh JS, et al. Five-year follow-up of a prospective, randomized trial comparing two lumbar total disc replacements. *Spine (Phila Pa 1976)*. 2016;41(1):3–8. doi:10.1097/BRS.0000000000001168

32. Lemaire J-P, Carrier H, Sariali E, Sari Ali E-H, Skalli W, Lavaste F. Clinical and radiological outcomes with the charité artificial disc: a 10-year minimum follow-up. *J Spinal Disord Tech*. 2005;18(4):353–359. doi:10.1097/01.bsd.0000172361.07479.6b

33. Lu S, Hai Y, Kong C, et al. An 11-year minimum follow-up of the charite III lumbar disc replacement for the treatment of symptomatic degenerative disc disease. *Eur Spine J*. 2015;24(9):2056–2064. doi:10.1007/s00586-015-3939-5

34. Sachs BL, Vanharanta H, Spivey MA, et al. Dallas discogram description. A new classification of CT/discography in low-back disorders. *Spine (Phila Pa 1976)*. 1987;12(3):287–294. doi:10.1097/00007632-198704000-00018

35. Bogduk N, Aprill C, Derby R. Lumbar discogenic pain: state-of-the-art review. *Pain Med*. 2013;14(6):813–836. doi:10.1111/pme.12082

36. Kreiner DS, Matz P, Bono CM, et al. Guideline summary review: an evidence-based clinical guideline for the diagnosis and treatment of low back pain. *Spine J*. 2020;20(7):998–1024. doi:10.1016/j.spinee.2020.04.006

37. Anderson SR, Flanagan B. Discography. *Current Review of Pain*. 2000;4(5):345–352. doi:10.1007/s11916-000-0017-3

38. Spine Intervention Society. *Safety Practices for Interventional Pain Procedures. 2nd Ed San Fr CAInternational Spine Interv Soc 2013 – Updat 2019*. www.spineintervention.org/resource/resmgr/patient_safety/safety_practices/safetypractices_module5_prov.pdf. Accessed September 10, 2019.

39. Weishaupt D, Zanetti M, Boos N, Hodler J. MR imaging and CT in osteoarthritis of the lumbar facet joints. *Skeletal Radiol*. 1999;28(4):215–219. doi:10.1007/s002560050503

40. Canbulat N, Sasani M, Ataker Y, et al. A rehabilitation protocol for patients with lumbar degenerative disk disease treated with lumbar total disk replacement. *Arch Phys Med Rehabil*. 2011;92(4):670–676. doi:10.1016/j.apmr.2010.10.037

41. Green A, Gilbert P, Scott-Young M, Abbott A. Physiotherapeutic rehabilitation following lumbar total disc replacement: a retrospective study. *Physiother Res Int*. 2016;21(3):155–163. doi:10.1002/pri.1630

42. Copay AG, Glassman SD, Subach BR, Berven S, Schuler TC, Carreon LY. Minimum clinically important difference in lumbar spine surgery patients: a choice of methods using the oswestry disability index, medical outcomes study questionnaire short form 36, and pain scales. *Spine J*. 2008;8(6):968–974. doi:10.1016/j.spinee.2007.11.006

43. Salzmann SN, Plais N, Shue J, Girardi FP. Lumbar disc replacement surgery-successes and obstacles to widespread adoption. *Curr Rev Musculoskelet Med*. 2017;10(2):153–159. doi:10.1007/s12178-017-9397-4

44. Sandhu F, Blumenthal S, Grunch B, Kimball B, Ferko N, Hollmann S. Barriers to and budget impact of lumbar total disc replacement utilization. *Spine (Phila Pa 1976)*. 2017;42 Suppl 24:S112–S114. doi:10.1097/BRS.0000000000002455

45. Janssen M, Garcia R, Miller L, et al. Challenges and solutions for lumbar total disc replacement implantation. *Spine*. 2017;42(24):S108–S111. doi:10.1097/BRS.0000000000002454

46. Scott-Young M, McEntee L, Schram B, et al. Concurrent use of lumbar total disc arthroplasty and anterior lumbar interbody fusion. *Spine (Phila Pa 1976)*. 2018;43:E75–E81. doi:10.1097/BRS.0000000000002263

47. Boss OL, Tomasi SO, Bäurle B, Sgier F, Hausmann ON. Lumbar total disc replacement: correlation of clinical outcome and radiological parameters. *Acta Neurochir (Wien)*. 2013;155(10):1923–1930. doi:10.1007/s00701-013-1774-1

48. Yue JJ, Garcia R, Miller LE. The activl(®) artificial disc: a next-generation motion-preserving implant for chronic lumbar discogenic pain. *Med Devices (Auckl)*. 2016;9:75–84. doi:10.2147/MDER.S102949

49. Yue J, Zhang K, Bai HX, et al. A comparison of patients who have undergone 1-level versus 2-level prodisc arthroplasty: a prospective study with minimum of 5-year follow-up. *Spine (Phila Pa 1976)*. 2013;38(14):1194–1198. doi:10.1097/BRS.0b013e31828b31e8

50. Roland M, Fairbank J. The roland-morris disability questionnaire and the oswestry disability questionnaire. *Spine (Phila Pa 1976)*. 2000;25(24):3115–3124. doi:10.1097/00007632-200012150-00006

51. Lu S, Hai Y, Kong C, et al. An 11-year minimum follow-up of the charite iii lumbar disc replacement for the treatment of symptomatic degenerative disc disease. *Eur Spine J*. 2015;24(9):2056–2064. doi:10.1007/s00586-015-3939-5

52. Colhoun E, McCall IW, Williams L, Cassar Pullicino VN. Provocation discography as a guide to planning operations on the spine. *J Bone Joint Surg Br*. 1988;70(2):267–271. doi:10.1302/0301-620X.70B2.2964449

53. Margetic P, Pavic R, Stancic MF. Provocative discography screening improves surgical outcome. *Wien Klin Wochenschr*. 2013;125(19–20):600–610. doi:10.1007/s00508-013-0404-5

54. Xi MA, Tong HC, Fahim DK, Perez-Cruet M. Using provocative discography and computed tomography to select patients with refractory discogenic low back pain for lumbar fusion surgery. *Cureus*. 2016;8(2):e514. doi:10.7759/cureus.514

55. Birkmeyer JD, Stukel TA, Siewers AE, Goodney PP, Wennberg DE, Lucas FL. Surgeon volume and operative mortality in the united states. *N Engl J Med*. 2003;349(22):2117–2127. doi:10.1056/NEJMsa035205

56. Regan JJ, McAfee PC, Blumenthal SL, et al. Evaluation of surgical volume and the early experience with lumbar total disc replacement as part of the investigational device exemption study of the charité artificial disc. *Spine (Phila Pa 1976)*. 2006;31(19):2270–2276. doi:10.1097/01.brs.0000234726.55383.0c

57. Willigenburg NW, Kingma I, Hoozemans MJM, van Dieën JH. Precision control of trunk movement in low back pain patients. *Hum Mov Sci*. 2013;32(1):228–239. doi:10.1016/j.humov.2012.12.007

58. du Rose A, Breen A. Relationships between paraspinal muscle activity and lumbar inter-vertebral range of motion. *Healthcare (Basel)*. 2016;4(1):E4. doi:10.3390/healthcare4010004

59. Tropiano P, Huang R, Girardi F, et al. Lumbar total disc replacement. seven to eleven-year follow-up. *J Bone Jt Surg*. 2005;87:490–496. doi:10.2106/JBJS.C.01345

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