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ProDisc-L learning curve: 24-Month clinical and radiographic outcomes in 44 consecutive cases

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Abstract

Background: Total disc replacement (TDR) promises preservation of spine biomechanics in the treatment of degenerative disc disease but requires more careful device placement than tradition fusion and potentially has a more challenging learning curve.

Methods: A cohort of 44 consecutive patients had 1-level lumbar disc replacement surgery at a single institution by a single surgeon. Patients were followed up clinically and radiographically for 24 months. Patients were divided into 2 groups of 22 sequential cases each. Clinically, preoperative and postoperative Oswestry Disability Index, visual analog scale, Short Form 12 (SF-12) Mental and Physical Components, and postoperative satisfaction were measured. Radiographically, preoperative and postoperative range of motion (ROM) dimensions, prosthesis deviation from the midline, and disc height were measured. TDR-related complications were noted. Logarithmic curve–fit regression analysis was used to assess the learning curve.

Results: Operative time decreased as cases progressed, with an asymptote after 22 cases. The operative time for the later group was significantly lower ($P < .0005$), but hospital stay was significantly longer ($P = .03$). There was no significant difference in amount of blood loss ($P = .10$) or prosthesis midline deviation ($P = .86$). Clinically, there was no significant difference in postoperative scores between groups in Oswestry Disability Index ($P = .63$), visual analog scale ($P = .45$), SF-12 Mental Component ($P = .66$), SF-12 Physical Component ($P = .75$), or postoperative satisfaction ($P = .92$) at 24 months. Radiographically, there was no significant difference in improvement between groups in ROM ($P = .67$) or disc height ($P = .87$ for anterior and $P = .13$ for posterior) at 24 months. For both groups, there was significant improvement for all clinical outcomes and disc height over preoperative values. One patient in the later group had device failure with subluxation of the polyethylene, which required revision.

Conclusions/level of evidence: Early experience can quickly reduce operative time but does not affect clinical outcomes or ROM significantly (level IV case series).

Clinical relevance: Lumbar TDR is a rapidly learnable technique in treatment of degenerative disc disease.

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Keywords: Learning curve; ProDisc-L; Total disc replacement

Degenerative disc disease (DDD) is a common cause of chronic low-back pain, a major health problem in Western countries.[1–4] If extended conservative treatment fails to alleviate symptoms, patients and physicians may consider surgical intervention. Lumbar fusion (arthrodesis) remains the most commonly accepted surgical treatment for DDD.[5,6] However, successful fusion results in restricted mobility of the treated segments, which may increase the risk of degeneration of adjacent discs.[7–10] These factors may contribute to the modality's poor long-term outcomes and significant rate of complications.[5]

Total disc replacement (TDR) has emerged as an increasingly popular alternative to lumbar fusion that attempts to re-create disc biomechanics and address the perceived shortcomings of arthrodesis.[11,12] TDR has shown significantly better patient satisfaction when compared with fusion at the 24-month follow-up point.[6]

Still, correct positioning of TDR prostheses is more technically challenging than fusion cage placement.[13] Exact positioning is essential to preserving disc biomechanics and optimal performance. Ideal implant position is perfectly midline on the antero-posterior view and slightly posterior to the midpoint of the end-plate on the lateral view.[13–15] The surgeon must focus on exacting standards of positioning while also familiarizing himself or herself with proper prosthesis size selection and new tools.

The learning curve describes the rate of improvement in mastering a task and is an important marker in the adoption

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of new techniques. Recent studies have described the learning curve for several spinal procedures.[16–21] No studies have evaluated the learning curve associated with TDR. In this study we evaluate the learning curve associated with TDR with the ProDisc-L (Synthes, West Chester, Pennsylvania) by a single surgeon at a single institution analyzing operative time, blood loss, clinical outcome markers, range of motion, prosthesis placement, and complications.

Methods

Patients and data collection

This study was approved by our institutional review board. Forty-four consecutive patients with lumbar DDD received single-level ProDisc-L insertions from a single surgeon at a single institution as part of the Food and Drug Administration Investigational Device Exemption study for the evaluation of the ProDisc-L.[22] Inclusion criteria included patients aged between 18 and 60 years, in whom conservative treatment for more than 6 months failed, who did not have diabetes, who did not smoke or had quit smoking, and who had a minimum Oswestry Disability Index (ODI) of 40. These criteria were consistent with on-label indications for the ProDisc-L as specified by the US Investigational Device Exemption clinical trial.

The mean patient age at the time of surgery was 37 years (range, 25–59 years). The study included 29 men and 15 women, and the mean body mass index was 26.7 ± 3.7. Two cases were performed at L3-4, 13 cases were performed at L4-5, and 29 cases were performed at L5-S1.

Of the 44 patients, 40 were followed up for 24 months (91% follow-up rate). Clinical factors evaluated included ODI (0–50), visual analog scale (VAS) (0–10), and Short Form 12 (SF-12) Physical Component (PC) (0–100) and Mental Component (MC) (0–100).[23,24] Preoperative and follow-up questionnaires at 3 weeks, 3 months, 6 months, 12 months, and 24 months were administered during in-office appointments. Radiographic factors evaluated included anterior and posterior disc height, range of motion, and deviation from the midline. Radiographs were acquired immediately postoperatively and at 3 months, 6 months, 12 months, and 24 months.

Surgical procedure

The access-surgery portion of each case was performed by a single fellowship-trained vascular surgeon who, at the time of the initial surgical procedures, had performed approximately 20 vascular access surgeries. Since 2002, this same vascular surgeon has performed over 1000 access surgeries. Exposure of L4-5 is different from and more difficult than exposure of L5-S1. The L4-5 level is approached uniquely in the sense that the ascending lumbar vein must be exposed and in some instances ligated after mobilization of the vena cava is assessed. If safe mobilization of the vena cava can be performed with limited tension on the as-

cending lumbar vein, the vein is not ligated. In those cases in which the vein appears to be under unsafe tension, the vein is ligated. The use of Thompson blade retractors (Thompson Surgical, Inc., Traverse City, Michigan) is advised to adequately retract the vessels to the right. The use of Hohmann-type retractors (Innomed, Inc., Savannah, Georgia) fixed to the vertebrae is discouraged unless absolutely necessary because of the potential vascular and viscous injury.

The surgical technique for the ProDisc-L has been previously described.[25] We elaborate on our technique used for achieving midline positioning: The patient is placed supine on a fluoroscopic table with a pillow behind the knees and arms abducted 90° to the torso. Anteroposterior C-arm fluoroscopic imaging with the C-arm at 0° is then performed. Midline positioning is performed by rotating the patient's buttocks and lumbar spine such that the spinous processes are equidistant from the medial border of each pedicle. Intraoperatively, any superior metallic retractor is removed, and the soft tissues are protected using a plastic sucker with a large sucker tip. By use of a long-tip Bovie, a small cautery mark is made on the vertebral body in the midline. A small osteotome is then used to etch a small groove in the bone to mark the midline.

Possible perioperative complications include retrograde ejaculation, vascular lacerations and other complications with exposure, and neurologic injury.[26]

Study design

Patients were arranged in order of surgery. In terms of demographic data and preoperative parameters, the groups did not differ significantly (Table 1). The mean operative time was 171 ± 41 minutes. Patients' operative times were arranged in order of surgery, and changes were evaluated. Patients were then divided into 2 equivalent groups comprising the first 22 patients (group A) and later 22 patients (group B), and parameters were compared. Operative time, intraoperative blood loss, and prosthetic deviation from the

Table 1
Comparison of demographics and preoperative clinical and radiographic parameters between groups A and B

	Group A	Group B	P value
No. of patients	22	22	—
Mean age (y)	35.2 ± 7.7	37.7 ± 7.8	.29
No. of male patients	15	14	—
No. female patients	7	8	—
Preoperative ODI (0–50)	33.6 ± 6.4	32.1 ± 6.3	.44
Preoperative VAS (0–10)	7.2 ± 1.7	7.9 ± 1.9	.21
Preoperative SF-12 PC (0–100)	29.2 ± 5.2	27.7 ± 4.5	.31
Preoperative SF-12 MC (0–100)	42.8 ± 10.4	41.4 ± 12.7	.70
Preoperative anterior disc height (mm)	15.7 ± 5.8	14.4 ± 5.2	.47
Preoperative posterior disc height (mm)	6.8 ± 2.3	6.9 ± 2.5	.93
Preoperative range of motion (°)	9.7 ± 5.9	6.2 ± 5.8	.07

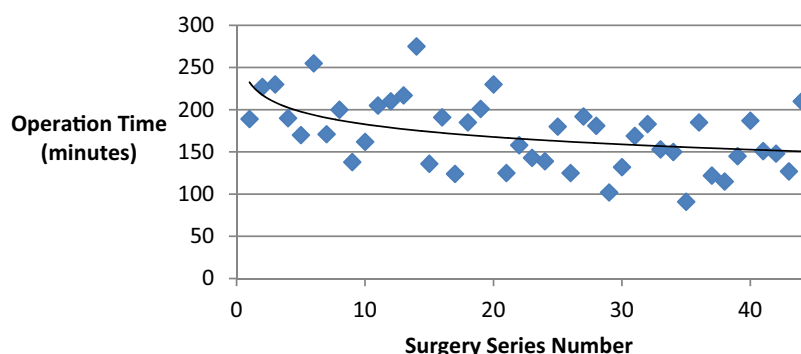## Operation Time as a function of Surgery Series Number

Fig. 1. Learning curve as shown by logarithmic correlation between surgery series and operative time.

midline were compared between groups. Prosthetic deviation from the midline was calculated by use of the spinal process as described by Bendo et al.[27] Intraoperative complications were noted. ODI, VAS, SF-12 PC and MC questionnaires, and patient satisfaction on a 10-point scale were used to assess clinical results. Anterior and posterior disc height and range of motion were used to assess radiographic results. Total range of motion was calculated by measuring the amount of flexion and extension as separate measurements from the neutral position and then adding the absolute values of these 2 total measurements. This range-of-motion measurement is termed total excursion of the implant in flexion and extension. Differences in clinical and radiographic parameters between the early and later groups were evaluated. Differences in these parameters between the preoperative evaluation and final postoperative evaluation were also evaluated. Postoperative complications were noted.

Statistical methods

The change in operative time over the series of surgeries was correlated by use of a logarithmic curve–fit regression analysis. The first derivative of this regression was used to determine the change in operative time for each successive surgery. Unpaired 2-tailed Student *t* tests were used to compare all parameters evaluated. Interobserver reliability for prosthetic midline deviation was evaluated with a Pearson product-moment correlation test, and the average between both observers was used for statistical analysis. $P < .05$ was considered statistically significant. SPSS 20.0.0 statistical software (SPSS, Chicago, Illinois) was used for analysis. The plus/minus symbol indicates 1 SD above and below the mean.

Results

Changes in operative time over series of surgeries

Operative time decreased progressively as case number progressed. The equation of the logarithmic regression curve is $y = -21.62\ln(x) + 232.5$, where *x* is the case

number and *y* is operative time in minutes (Fig. 1). This was statistically significant ($P = .001$), and a moderate correlation coefficient was obtained ($R = 0.47$). By use of the first derivative of this regression curve, which determines the change in operative time for each successive surgery, it was determined that there was a reduction of less than 1 minute by the 22nd surgery in the series.

Comparison of parameters

When we compared group A (earlier group) and group B (later group), operative time decreased significantly from 190 ± 40 minutes to 151 ± 31 minutes ($P = .001$) (Table 2). Intraoperative blood loss decreased from 244 ± 151 mL to 182 ± 87 mL. However, this decrease was not significant ($P = .102$). Hospital time for group B was significantly longer than that for group A ($P = .03$). The mean prosthetic deviation from the midline decreased from 2.81 ± 2.40 mm in group A to 2.67 ± 1.56 mm in group B. However, this decrease was not significant ($P = .86$).

Overall, all clinical parameters evaluated showed statistically significant improvement from preoperatively to 24 months postoperatively. ODI values decreased from a mean of 32.8 ± 6.3 preoperatively to 15.6 ± 11 ($P < .001$). VAS values decreased from a mean of 7.5 ± 1.8 preoperatively to 4.0 ± 2.9 ($P < .001$). SF-12 PC increased from 28.5 ± 11.5 to 39.7 ± 13.0 ($P < .001$), and SF-12 MC increased from 42.1 ± 11.5 to 48.2 ± 11.5 ($P < .05$). Most radiographic factors also showed statistically significant improvement from preoperatively to postoperatively. Anterior disc height increased from 15.1 ± 5.5 mm to 18.6 ± 4.1 mm ($P = .003$), and posterior disc height increased from 6.9 ± 2.4

Table 2
Comparison of intraoperative parameters between groups A and B

	Group A	Group B	*P* value
Operative time (min)	190.4 ± 40.5	151.4 ± 31.4	$<.01$
Blood loss (mL)	244.3 ± 150.8	182.3 ± 86.8	$.10$

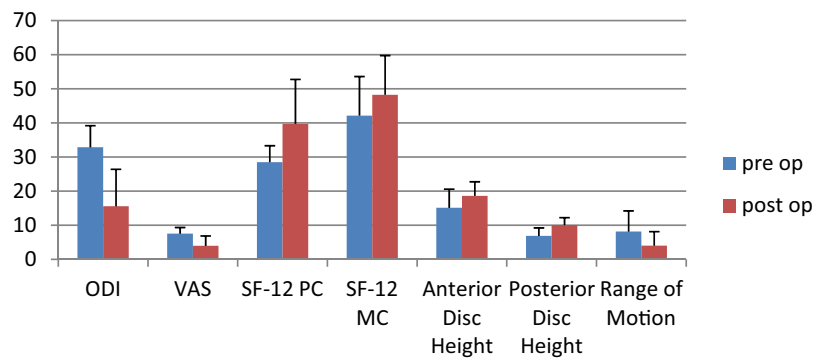## Pre-op vs. 24 Month Clinical and Radiographic Parameters

Fig. 2. Twenty-four–month follow-up parameters versus preoperative measurements. ODI, VAS, SF-12 PC, SF-12 MC, and satisfaction are graded on their respective scales. Disc heights are given in millimeters. Range of motion is given in degrees. (post op, postoperative; pre op, preoperative.)

mm to 10.0 ± 2.2 mm ($P < .001$). Range of motion decreased significantly from 8.1 ± 6.1 mm to 4.0 ± 4.1 mm ($P = .048$) (Fig. 2). There was not a statistically significant difference in any of the parameters when we compared the 24-month postoperative values between groups A and B (Table 3, Fig. 3).

Complications

One incidence of a major long-term complication occurred in group A. Between 3 and 6 months' follow-up, there was a malfunction of the ProDisc-L with radiographic evidence of subluxation of the polyethylene component. The patient elected to undergo a replacement ProDisc-L procedure, after which no notable complications occurred. Two complications occurred in group B. One incidence involved abdominal swelling, and the other involved urinary tract infection. However, the rate of the incidence of complications between the 2 groups was not significant ($P = .56$) (Table 3).

Discussion

Lumbar fusion is the accepted gold-standard surgical intervention for DDD, with many new approaches and techniques having been developed over the past several decades. However, in eliminating segment mobility to treat symptomatic levels, the procedure may induce compensatory changes to spinal biomechanics, which accelerate the degeneration of adjacent discs.[7–10] TDR was developed to mitigate these drawbacks by trying to preserve spinal biomechanics at the symptomatic segment. From their first description in the 1950s, artificial discs have undergone many iterations, and many are now available for the European market.[28] Two products, Charité (DePuy Spine, Raynham, Massachusetts) and ProDisc-L (Synthes), are currently Food and Drug Administration approved and available on the US market.

A learning curve represents the acquisition of skill in a task over time. Usually, skill progress is made more quickly in early stages, with diminishing returns over time.[16] Benzel and Orr[29] emphasize the importance of a "steep" learning curve, where one gains proficiency very quickly before finding it increasingly difficult to make gains. In introducing a new technique, ideally, surgeon skill would be built very quickly to avoid the necessity of "warm-up" patients who are exposed to increased risk while the surgeon becomes comfortable with the technique. Although TDR offers some promising theoretic and short-term advantages over the gold standard of fusion, enthusiasm and speed of adoption must be informed by the risks borne by patients in the surgeon learning period, especially given the scarcity of long-term data showing superiority to the accepted standard.[5,6]

Operative time is the most widely used measure for learning curve because it tends to trend downward with increasing surgical skill and comfort with the procedure.[21] We find that TDR shows a learning curve characteristic of quick improvement in initial surgeries followed by steady but diminishing improvements in operative time. Mathematical analysis produced a logarithmic curve with surgery

Table 3

Comparison of 24-month clinical and radiographic outcomes between groups A and B

	Group A	Group B	*P* value
ODI (0–50)	14.7 ± 10.0	16.4 ± 11.8	.63
VAS (1–10)	3.6 ± 2.9	4.3 ± 2.9	.45
SF-12 PC (1–100)	40.4 ± 13.3	39.0 ± 13.1	.75
SF-12 MC (1–100)	47.4 ± 11.5	49.1 ± 11.7	.66
Patient satisfaction (0–10)	6.9 ± 3.7	7.0 ± 2.9	.92
Disc height anterior (mm)	18.5 ± 4.5	18.7 ± 3.5	.87
Disc height posterior (mm)	9.6 ± 2.0	10.7 ± 2.2	.13
Range of motion (°)	4.6 ± 5.5	3.4 ± 2.7	.67
Deviation from midline (mm)	2.81 ± 2.40	2.67 ± 1.56	.86
Rate of complications	1	2	.56

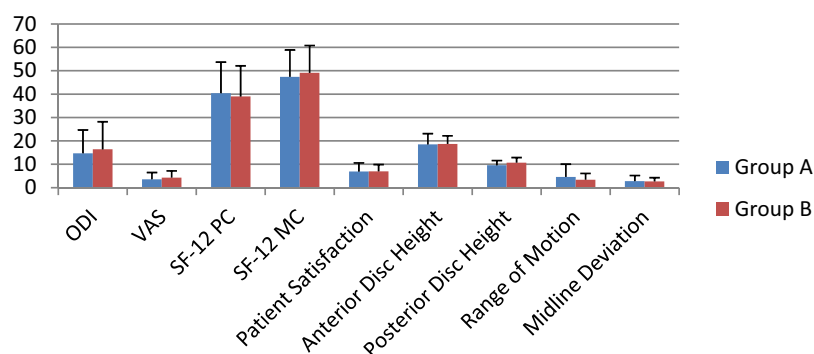## 24 Month Follow-up Parameters of Early and Later Stage Groups

Fig. 3. Comparison of 24-month follow-up parameter values for early and later groups. ODI, VAS, SF-12 PC, SF-12 MC, and satisfaction are graded on their respective scales. Disc heights are given in millimeters. Range of motion is given in degrees.

times gradually approaching an asymptote near 150 minutes (Fig. 1). Operative time reductions were found to be statistically significant between the first 22 patients and last 22 patients in the series. By the 22nd case, successive operations reduced operative time by less than 1 minute, showing a relatively fast approach to maximized efficiency.

Although the later group showed a lower mean blood loss than the early group, this difference was not statistically significant. Within the groups, there was wide variation in blood loss, which may have reduced the power of this study to resolve a statistically significant difference in blood loss between the 2 groups. Deviation from the midline provides a relevant marker of surgeon skill in prosthesis placement that has been previously correlated with clinical outcomes.[15] The later group showed a lower mean deviation from midline for the prosthesis than the early group, but this difference was not statistically significant. In both groups the mean deviation from the midline was less than 3 mm, which has previously been correlated with better ODI and VAS than greater deviations.[27,30] There was high variability in prosthetic midline deviation as well, which may have reduced the power of this study to resolve a statistically significant difference between the groups. The insignificant difference between early and later patients in these criteria suggests that proficiency with the technique is gained relatively quickly with minimum blood loss risk. On the other hand, this could also suggest that improvement of proficiency is difficult to achieve and blood loss risk is difficult to reduce.

Patients showed statistically significant improvements in all clinical measures including ODI, VAS, SF-12 PC, and SF-12 MC from preoperatively to postoperative follow-up points. Radiographic measures of flexion and anterior and posterior disc height also improved significantly from preoperatively to postoperatively. Still, none of these measures showed significant differences between the early and later groups. Again, this seems promising because the decreases in surgical time did not lead to compromised clinical out-

comes during the learning period. This suggests that the reduction in operative time represented increased skill with the procedure rather than reckless increases in surgical speed. However, this might also signify that it is also very difficult to improve clinical and radiographic outcomes in such a limited number of cases.

Complications are a serious concern in the learning period, and 1 major long-term complication did occur in the early group with prosthesis failure requiring subsequent revision. Although small numbers prevent us from drawing the conclusion that significant differences in complication rate exist between early and later cases, an early complication here does inject caution into early cases where surgeons must familiarize themselves with new techniques and technology. A limitation of the study is that operative times of different phases of the procedure were not individually evaluated. This may identify steps of the operation that limit the operative time or are highly variable. Identification of these particular steps of the operation may help surgeons exercise more caution or obtain extra training to better develop their technique. It is also important to note that this study reports the experiences of 1 surgeon whose foundational experience may not be representative. Lumbar TDR is still a relatively novel and more technically challenging technique compared with interbody fusion. Despite the technical challenges of lumbar TDR, our study suggests that the procedure is quickly learnable without affecting clinical outcome in the learning period. Therefore lumbar TDR warrants attention for the improvements it offers over traditional fusion.

Conclusion

Proficiency was quickly achieved with the lumbar TDR technique in initial cases, with good long-term clinical and radiographic outcomes for both early and later patients. Operative time rapidly approached its asymptote without

compromise in quality of the operation. Thus lumbar TDR is a quickly learned technique in the treatment of DDD.

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