

Treatment of Lumbar Degenerative Disc Disease Using a Novel, Compressible Core Prosthesis: 24-Month Results

Ritter Lang K^{1*}, Dreßler N¹, Schätz C² and Gössel L²

¹Spezialpraxis für Wirbelsäulen Chirurgie, Potsdam, Germany

²Orthopädische Klinik Markgroningen gGmbH, Markgroningen, Germany

Abstract

Background: Low back pain is one of the most prevalent problems in industrialized countries and often results in decline in the quality of life of the affected individuals. There are a number of contributors to low back pain, one of which is Degenerative Disc Disease (DDD) of the spine. Although fusion has been well accepted for the treatment of DDD, high rates of complications and stress to adjacent segments remain a concern. Lumbar Total Disc Replacement (LTDR) is one technology that has become popular as an alternative to fusion. Artificial disc replacements were developed with a goal of preserving motion and avoiding various fusion-related complications.

Methods: This is a multi-center, single arm, prospective post-market registry of the M6[®]-L, a compressible core TDR, consisting of consecutive patients presenting with lumbar DDD who agreed to participate. Clinical outcome measures include the Oswestry Disability Index (ODI) and back and leg Visual Analogue Scales (VAS). Data was collected pre-operatively, peri-operatively and post-operatively at 6 weeks, 3, 6 and 12 months and yearly thereafter. AP, Lateral and flexion/extension x-rays were performed for radiographic analysis. Patients are monitored continuously to track complications.

Results: Results for 45 patients, (20 males, 25 females, mean age 44.6 years) are reported. Thirty-one patients were treated at 1 level, and 14 at multiple levels, between L3 and S1. Mean ODI has decreased significantly ($p < 0.001$) from $45.9 \pm 16.5\%$ at baseline to 19.7 ± 19.3 at 2 years post-implant. Low back pain has also decreased significantly ($p < 0.001$) from baseline with a preoperative back pain VAS of 7.0 and a 2 year value of 2.5. Physiologic range of motion was maintained from baseline through 2 years.

Conclusions: Two year results from the post-market registry suggest initial device safety and effectiveness when used for the treatment of lumbar degenerative disc disease.

Keywords: Total disc replacement; Degenerative disc disease; Low back pain

Introduction

Low back pain is one of the most prevalent problems in industrialized countries and often results in decline in the quality of life of the affected individuals. There are a number of contributors to low back pain, one of which is Degenerative Disc Disease (DDD) of the spine [1]. Degenerative disc disease can lead to chronic low back pain and is defined by a series of events which may cause inflammation, disc dehydration and restricted mobility of the spine [2]. In addition to non-operative management of the condition, patients who experience uncontrolled low back pain as a result of DDD may take advantage of numerous therapeutic techniques. Until the emergence of lumbar artificial discs, lumbar fusion surgery was considered to be the standard of care in such instances. Lumbar fusion is designed to eliminate the motion and instability of the affected vertebral region, thus decreasing low back pain. Unfortunately, fusion is associated with complications and intensifies the stress to adjacent levels resulting in loss of disc height, collapse, abnormal segment motion and degeneration. Total disc replacement surgery has emerged as a way to preserve motion of the affected segment and to potentially decrease the incidence of adjacent disc degeneration [2,3]. Previous clinical studies of lumbar artificial discs have shown non-inferiority to lumbar fusion at 2 years post-op in clinical and radiographic outcomes [4-7]. However, more recent publications have indicated sustained clinical and radiographic outcomes at 5 years in addition to re-analysis of original 2 year data resulting in possible clinical superiority to fusion for some clinical outcomes [8,9].

The M6[®]-L Artificial Lumbar Disc System (Spinal Kinetics, Inc., Sunnyvale, CA) is an advanced generation intervertebral

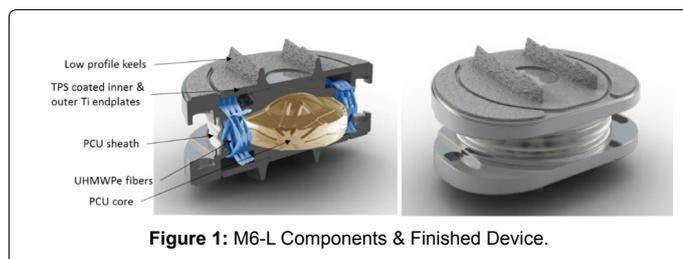
disc designed to maintain motion of a functional spinal unit by replicating anatomic, physiologic and biomechanical characteristics of the native disc. The device is comprised of an assembly of high-tensile strength, Ultra-High-Molecular-Weight Polyethylene (UHMWPE) fibers wound in multiple redundant layers around a Polycarbonate Urethane Polymer (PCU) core and through titanium alloy endplates. The polymer core is designed to simulate the structure of the nucleus and the fibers are designed to simulate the annulus. This unique design provides a progressive resistance to motion and enables the device to have all six degrees of freedom. The disc also has a polycarbonate urethane polymer sheath surrounding the core and fiber construct to minimize tissue in growth as well as the migration of wear debris. Serrated keels located on the exterior surfaces of the device provide acute fixation to the superior and inferior vertebral bodies. Both the endplates and keels are coated with porous titanium to increase bone contact surface area and promote osseointegration (Figure 1). The device is intended to replace the degenerative disc, restore and maintain

***Corresponding author:** Karsten Ritter-Lang, Spezialpraxis für Wirbelsäulen Chirurgie Rudolf-Strasse 22 Breitscheid 14482 Potsdam Brandenburg Germany, Tel: +49 (0)331-7409700, Email: k.ritter-lang@wirbelsaeule-potsdam.de, lbeeman@austin.r.com

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normal segmental motion without affecting adjacent segments, and achieve a good clinical outcome.

Materials and Methods

This is an ongoing multi-center, single arm, prospective post-market registry. Consecutive patients presenting for surgery with lumbar degenerative disc disease, who gave consent to participate, were enrolled. The Investigators were instructed to select patients according to the Instructions For Use (IFU) and perform the surgery according to the Surgical Technique Manual. The key inclusion/exclusion criteria are presented in Table 1.

This study presents data obtained from all patients enrolled during the first year of the registry from February 2010 to March 2011 who have completed the 24 month follow-up visit.

Patient history, neurological examination specific to low back pain, the Oswestry Disability Index [10,11] (ODI) questionnaire, back and leg pain Visual Analogue Scales [12] (VAS) and incidence and severity of complications were collected and evaluated. Study visits consisted of pre-operative and post-operative visits at 4-6 weeks, 3,6,12 and 24 months after surgery. Additional long-term follow-up will continue.

The Oswestry Disability Index (ODI) is one of the most commonly used outcome measures for spinal disabilities [10,11]. It is designed to give information as to how back pain has affected patient's ability to manage everyday life. It consists of 10 different categories ranging from pain intensity and personal care to walking, lifting and standing. Each of these categories has a total of five possible answers; the higher the score, the higher the disability. The ODI has been subjected to numerous reviews and still remains a valid measure of various spine-related disabilities [10]. Because the questionnaire is self-administered and lacks any open-ended questions, it safeguards against any interviewer bias thus leading to reliability and uniformity of presentation [11].

The Visual Analogue Scale (VAS) is a measurement instrument consisting of a 10 cm continuous line anchored on one end with "no pain" and on the other end with "worst pain ever" [12]. Patients can indicate their response by placing a vertical mark on the continuous scale designating their pain level. For the purpose of this study the VAS was used to measure back and leg pain. Scores are reported out of 10 possible points. A high score indicates higher pain intensity. A major advantage of VAS is its ratio scale properties which allows for easy comparison between percentage differences in various points in time [12].

Neutral Antero Posterior (AP), neutral lateral, and Flexion/Extension (F/E) x-rays were performed pre-operatively, immediately post-operatively (neutral AP and lateral only) and were to be performed at each follow-up visit thereafter. In an effort to minimize patient radiation exposure, the investigators were permitted to bypass the early post-op x-rays if it was outside of their standard of care x-ray protocol. Qualitative (e.g. device migration, subsidence) and quantitative (e.g.

range of motion, disc height, disc angle) outcomes were assessed by a core laboratory (Medical Metrics, Inc., Houston, TX). Flexion/Extension x-ray images were used to derive Range of Motion (ROM) in degrees. Longitudinal changes in disc height and disc angle were reported.

Surgical technique

Implantation was accomplished through an anterior transperitoneal or retroperitoneal abdominal approach. In this technique, following the approach and identification of the target disc space, the midline is determined and marked. A complete discectomy is performed and the disc space prepared by removal of cartilaginous material, preserving the bony endplates. Posterior mobilization and restoration of posterior height is accomplished with an intervertebral distractor. The endplate size is determined. A Trial Implant of appropriate footprint, posterior height and lordosis angle is inserted into the disc space under close fluoroscopic control and referenced to the midline marker. Upon fluoroscopic verification of correct Trial Implant location, Chisels are used to create keel tracks into the superior and inferior endplates while the Trial remains as a guide. The Trial and Chisels are removed and the artificial disc is implanted using an Implant Inserter under fluoroscopic visualization.

Statistical methods

Clinical statistical analyses were performed utilizing Predictive Analytics Software (v.18, SPSS Inc., Chicago, IL) and were based on all available data for all patients who had completed 24 month visits as of February 2013. Descriptive statistics (mean and standard deviation) were employed to characterize results for continuous variables and their differences. Categorical variables were reported with frequencies or percentages as appropriate. Longitudinal change between pre-operative and post-operative visits was calculated and statistical significance value (p-value) was determined using the paired t-test based on the differences. Radiographic statistical analyses were performed using a paired t-test.

To further evaluate the effectiveness of the surgery, the minimum clinically important difference or the smallest differences that the patient considers beneficial for both ODI and back pain VAS were determined [13,14]. The incidence and status of any complication was documented at each follow-up visit. Adverse events related to device safety such as subsidence, migration or expulsion, which may require additional surgical intervention, were recorded. Success was assessed using a composite measure defined as (i) increase in function reflected by a 10 percent point decrease in ODI; (ii) decrease of back pain VAS by 1.8 cm; (iii) no complications, defined as re-operations, revisions, device removals or device-related serious adverse events.

Results

Seventy five (75) patients were enrolled in the first year of the study and 45 had completed their 24 month follow-up visits by February 2013. There were 20 males and 25 females with a mean age of 44.6 years. The mean height and weight were 172.1cm and 76.7kg, respectively. Average BMI for the study patients was 25.8 (Table 2). Thirty-one (31) patients were treated at 1 level, and 14 at multiple levels, between L3 and S1 (Table 3). The average surgery time for all patients in the registry was 84.4 ± 36.9 minutes for single level cases and 111.2 ± 44.5 for multiple level cases. Blood loss during surgery was 201.7 cc (median 155.0 cc). The overall mean hospital stay duration was 6.2 days (median 6.0), which is longer than one might expect to see in some markets, but is consistent with standard local healthcare practices.

Inclusion Criteria:	Exclusion Criteria:
Between 18 and 75 years of age	Osteopenia or osteoporosis
Treatment at one or two adjacent levels between L3 and S1	Have a history of endocrine or metabolic disorders. Have rheumatoid arthritis or other autoimmune disease or a systemic disorder such as HIV or active hepatitis.
Have not responded to at least 6 months of non-operative, conservative management	Prior intra-abdominal or retroperitoneal surgery that would make the approach prohibitively dangerous, or prior anterior surgery at the same level
Have symptomatic degenerative disc disease (DDD) demonstrated by signs and/or symptoms of disc herniation, osteophyte formation, or loss of disc height	Have uncontrolled insulin dependent type 1 or type 2 diabetes
	Require a treatment (e.g., posterior element decompression) that destabilizes the spine.
	Isolated radicular compression syndromes, especially due to disc herniation
	Bony lumbar stenosis, pars defect, increased segmental instability, spinal deformities, spondylolisthesis above 3mm at the involved level(s)
	Radiological confirmation of severe facet joint disease or degeneration

Table 1: Inclusion/Exclusion criteria.

Gender:		
	Female	25 (45%)
	Male	20 (55%)
Age in years	(Mean ± SD)	44.6 ± 8.2
Height in cm	(Mean ± SD)	172.1 ± 10.1
Weight in kg	(Mean ± SD)	76.7 ± 14.9
BMI	(Mean ± SD)	25.8 ± 3.7

Table 2: Baseline Characteristics.

Index Level(s)	n (%) of pts
L4/L5	8(-17.8%)
L5/S1	23(-51.1%)
L3/L4; L4/L5	3(-6.7%)
L4/L5; L5/S1	10(-22.2%)
L3/L4; L4/L5; L5/S1*	1(-2.2%)

*Although the IFU for the M6 -L device indicates implantation of the device at 1 or 2 levels from L3 – S1, the decision to implant the device at 3 levels was made for one patient

Table 3: Surgery Levels.

Clinical outcomes

The mean ODI was $45.9 \pm 16.5\%$ at baseline, and had improved by 57% at 24 months (Figure 2). This was a highly significant improvement in overall mean ODI ($p < 0.001$). According to the literature, a 10-point improvement in ODI is considered the Minimum Clinically Important Difference (MCID) [14]. In this study, 78% of the patients achieved MCID at 24 months. The mean ODI improvement from baseline to 24 months follow-up was 26 percentage points.

According to ODI criteria, 93.3% ($n=42$) of the study population had a disability of moderate to bed-bound pre-operatively, with only 6.7% reporting minimal disability. At the 24-month follow-up, 62.2% of the patients reported minimal disability. The level of patient disability pre-operatively and at 24 months is shown in Figure 3.

Back pain was 7.0 ± 2.0 pre-operatively on the visual analogue scale. Mean right and left leg pain scores were 3.5 ± 3.2 and 3.9 ± 3.1 , respectively (Figure 4). At 24 months follow-up mean pain VAS decreased significantly for all 3 measures with back pain score averaging 2.5 ± 2.6 , right leg pain 1.1 ± 1.9 and left leg pain 1.7 ± 2.7 . Back pain decreased by 64%, right leg pain by 68%, and left leg pain by 56% at 24 months.

It has been reported that an improvement of 1.8-1.9 cm in VAS back pain can be equivalent to the minimum clinically important difference [14]. In this cohort, 77.8% of the patients achieved MCID based on 1.8 cm improvement in back pain VAS.

Thirty-four (34) patients, or 76% of the patient population, completed a patient satisfaction survey at 24 months post-op. Eighty eight percent (30 patients) responded that their condition was greatly improved and 97% (32 of 33) reported willingness to undergo surgery again under the same circumstances.

Radiographic outcomes

Radiographic outcomes were derived from longitudinal data on disc angle, anterior and posterior disc height, index and global range of motion analysis. Due to concerns about the effects of x-ray radiation, not all study participants completed all radiographic analyses at each time point; all available data were included in the analyses. At 24 month follow-up, thirty-seven (37) study participants completed the neutral radiographs required to assess disc angle, anterior and posterior disc height; eighteen (18) and nineteen (19) completed the flexion/extension radiographs required to assess global and index range of motion, respectively. Figures 5 and 6 show a comparison of pre and post-operative lateral x-rays over time for a single level disc replacement at L5/S1. Both anterior and posterior mean disc height increased significantly over the course of the study (Figure 7). At baseline, anterior disc height was 10.2 ± 3.1 mm and increased to 17.7 ± 2.9 mm at 24 months follow-up ($p < 0.0001$). Posterior disc height increased significantly from 3.9 ± 1.6 mm pre-operatively to 7.6 ± 1.9 mm at 24 months follow-up ($p < 0.0001$).

An increase in average disc angle was also observed at all follow-

up time points compared to baseline (Figure 8). At the immediate post-operative visit, the disc angle had increased by more than 60% and this increase was maintained throughout all follow-up time points ($p < 0.0001$).

Global range of motion for this group was maintained throughout the follow-up time period with a slight increase from 38.0° pre-operatively to 40.6° at 24 months. Index level range of motion was also maintained from baseline through the 24 month follow-up (Figure 9).

Clinical success and patient safety

As indicated previously, individual patient success was assessed using a composite measure encompassing changes in ODI and VAS and lack of relevant complications. According to the composite



Figure 5: Lateral radiographs of the lumbar spine including the index level, for single level disc replacement at L5/S1.

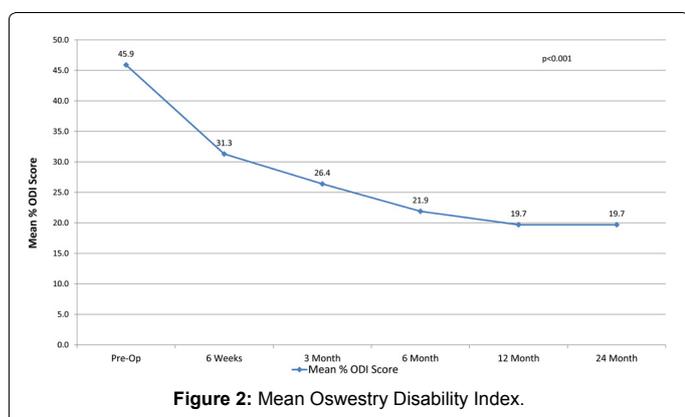


Figure 2: Mean Oswestry Disability Index.

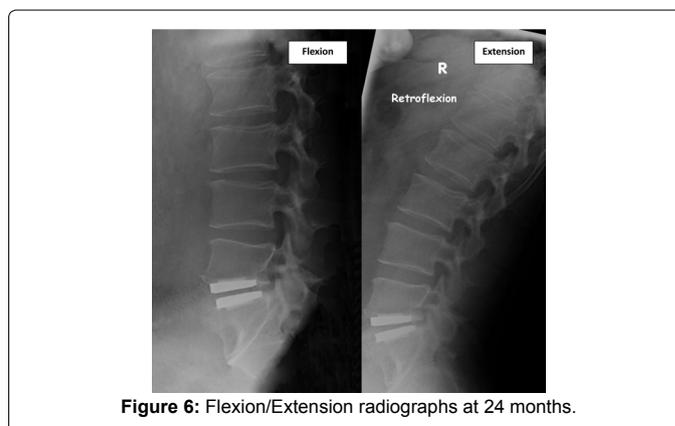


Figure 6: Flexion/Extension radiographs at 24 months.

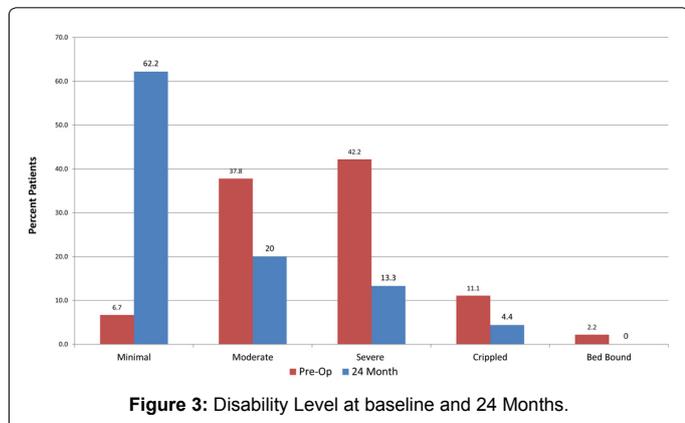


Figure 3: Disability Level at baseline and 24 Months.

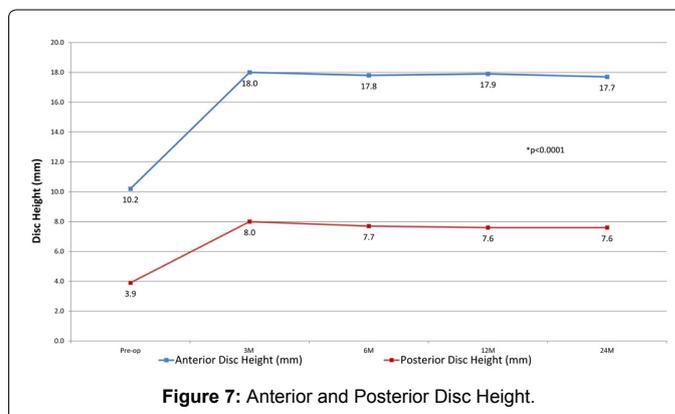


Figure 7: Anterior and Posterior Disc Height.

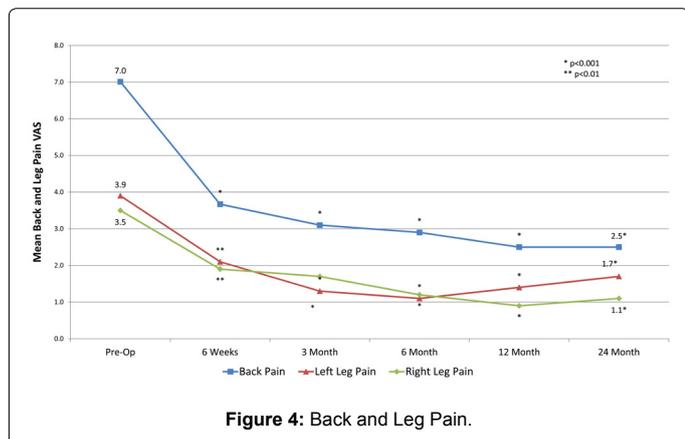


Figure 4: Back and Leg Pain.

measure for success, at 24 months overall clinical success was attained for 73.3% ($n = 33$) of the patients. There were no reported procedural complications, revisions, device removals or device-related serious adverse events, nor were there any other reported unanticipated or serious adverse device effects.

Discussion

Low back pain is one of the most prevalent problems in industrialized countries and often results in decline in the quality of life of the affected individuals. There are a number of contributors to low back pain, one of which is degenerative disc disease of the spine [1]. Although fusion has been well accepted for the treatment of DDD, high rates of complications and stress to adjacent segments remain a major concern. It has been reported that up to 20% of fusion patients have required

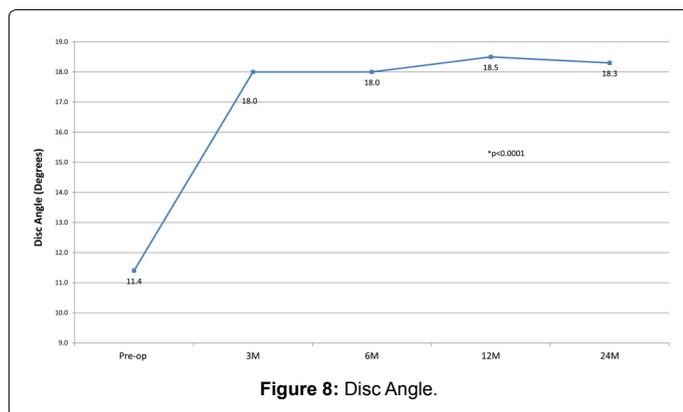


Figure 8: Disc Angle.

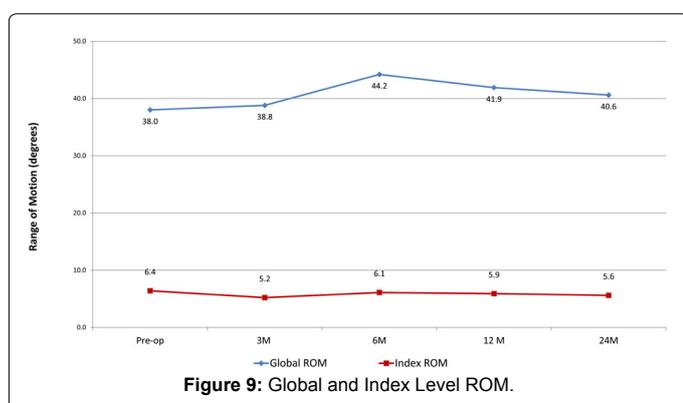


Figure 9: Global and Index Level ROM.

surgery at an adjacent level [15]. This increased risk associated with fusion led to a paradigm shift towards innovative technologies that aim to preserve motion and reduce adjacent level disc degeneration [15,16]. Total Lumbar Disc Replacement (TDR) is one such technology that has since become more popular as an alternative to fusion. Artificial disc replacement devices were developed with a goal of preserving motion and avoiding various fusion-related complications [3]. The compressible core device studied herein is intended to further mimic the natural function of the lumbar disc in an attempt to better preserve the kinematics and biomechanics of the affected spinal segment.

The clinical outcomes of total disc replacement reported in this study for the compressible core device are consistent with those reported for other arthroplasty devices. At two years, 78% of the study population in this limited study reported clinical success as measured by ODI scores, with an average improvement of 57% from baseline. Data from the literature were comparable, with reports of ODI success ranging from 73 to 77% of the study population for both single-level and two-level ProDisc implantations at 2 to 5 years (improvement of 44-66% from baseline) [3,5,17-19]; improvements of 47-51% in ODI at 2 to 5 years after implantation with the Charite disc [4,8,20]; 47-63% improvements after 2 years of implantation of a Maverick disc [6,21]; and 52-62% improvements in ODI in studies examining more than one type of TDR [22,23]. VAS scores in the present study indicated an improvement of 64% in back pain and 56% in leg pain at two years. While reports in the literature varied in the VAS measure reported, VAS score improvement was similar, ranging from 41-79% when a general VAS pain score was reported [4,5,8,17-20,23]; from 58-75% for back pain VAS [3,6,21,22]; and 46 to 64% for leg pain VAS [3,6,21,22]. Individual patient success is an even more difficult measure to assess among studies, as the measures utilized by different authors varied. In

this study, individual patient success was defined using a composite measure and was found to be 73%, which is comparable to reported overall patient success in the TDR literature [24].

The disc angle and disc height at the index level were found to have increased after TDR. The observed increases in disc angle of about 6° are consistent with the observations of several investigators who have examined the effect of lumbar TDR on sagittal balance and found that the overall lordosis is either unchanged or improved, while the index segmental lordosis is increased. For example, LeHuec et al. [25] measured the segmental and overall lordosis of 35 patients who received single-level Maverick TDRs and reported that the segmental lordosis increased significantly at the index level (5.1° at L4-L5, 4.9° at L5-S1). Cakir et al. [26] studied segmental and overall lordosis after implantation of the ProDisc in 29 patients and similarly found an increase (average of 8.4°) in segmental lordosis. Several other authors, reporting on clinical or biomechanical studies of segmental lordosis changes after TDR with a variety of implants [27-31], similarly found significant increases in segmental lordosis. Since the sagittal balance is either unchanged or improved, the increase in angle after TDR is likely restorative. Likewise, disc height restoration been observed after TDR with several different prostheses [31,32] and is in fact often a stated goal of the procedure. Siepe et al. [31] reported anterior height increases of an average of 6.9 mm anteriorly, and 3.4 mm posteriorly, after implantation of a ProDisc II. As noted by the authors of this study, this relatively larger increase in the anterior height relative to the posterior height is directly related to an increase in the disc angle.

Both the global and segmental range of motion remained relatively unchanged from pre-op through 24 months; there was no statistically significant difference between the preoperative ROM and that at any other time point for either measure. Reports from the literature reflect a lack of consistency in the ROM achieved at the index level after TDR with a variety of articulating prostheses [6,27,31,33-35]. One possible reason for this variation could be varying surgical procedures and the degree to which the PLL is resected. Since all anterior TDR procedures sacrifice the ALL, there can be an imbalance in the forces permitting flexion and extension motion. The M6-L, which provides a progressive resistance to motion in both flexion and extension, may permit a more natural or balanced range of motion, particularly if the PLL is fully resected.

This study reports results from forty-five patients followed in a post-market registry. Despite the limitations imposed by the sample size and study type, a registry is an effective tool that allows for data to be collected on patients treated according to standard of care and demonstrates the results of the treatment in a real-life setting. The data from the registry indicate that the compressible core device behavior and results are promising and are consistent with that observed in other TDRs.

Conclusion

The purpose of a TDR is to provide improved, physiologic disc height and range of motion, which in turn may lead to less wear and stress on adjacent vertebral levels and have a positive effect on clinical outcomes. The improvements in clinical outcomes reported in this registry study, such as disability and pain relief, and the radiographic outcomes, including maintenance of range of motion and physiologic disc height and disc angle at the affected level, suggest that the compressible core device behaves as intended, with an adequate initial safety and effectiveness profile at the two year time point. As in the case of other lumbar artificial discs, a larger sample size and extended

follow-up are necessary; the post-market registry continues for this purpose.

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