J Neurosurg Spine 14:38–45, 2010

Lumbar total disc replacement from an extreme lateral approach: clinical experience with a minimum of 2 years' follow-up

Clinical article

Luiz Pimenta, M.D., Ph.D.,[1,2] Leonardo Oliveira, B.Sc.,[1] Thomas Schaffa, M.D.,[1] Etevaldo Coutinho, M.D.,[1] and Luis Marchi, M.Sc.[1]

[1]*Minimally Invasive and Reconstructive Spine Surgery, Instituto de Patologia da Coluna, São Paulo, Brazil; and* [2]*Department of Neurosurgery, University of California, San Diego, California*

Object. Current lumbar total disc replacement (TDR) devices require an anterior approach for implantation. This approach has inherent limitations, including risks to abdominal structures and the need for resection of the anterior longitudinal ligament (ALL). Placement of a TDR device from a true lateral (extreme lateral interbody fusion [XLIF]) approach is thought to offer a less invasive option to access the disc space, preserving the stabilizing ligaments and avoiding scarring of anterior vasculature. In this study, the authors attempted to quantify the clinical and radiographic outcomes of a lateral approach to lumbar TDR from a prospective, single-center experience.

Methods. A TDR device designed for implantation through a true lateral, retroperitoneal, transpsoas approach (XLIF) was implanted in 36 patients with discography-confirmed 1- or 2-level degenerative disc disease. Clinical (pain and function) and radiographic (range of motion [ROM]) data were prospectively collected preoperatively, postoperatively, and serially for a minimum of 24 months' follow-up.

Results. Thirty-six surgeries were performed in 16 men and 20 women (mean age 42.6 years). Surgeries included 15 single-level TDR procedures at L3–4 or L4–5, three 2-level TDR procedures spanning L3–4 and L4–5, and 18 hybrid procedures (anterior lumbar interbody fusion [ALIF]) at L5–S1 and TDR at L4–5 [17] or L3–4 [1]).

Operative time averaged 130 minutes, with an average blood loss of 60 ml and no intraoperative complications. Postoperative radiographs showed good device placement. All patients were walking within 12 hours of surgery and all but 9 were discharged the next day (7 of 9 had hybrid TDR/ALIF procedures).

Five patients (13.8%) had psoas weakness and 3 (8.3%) had anterior thigh numbness postoperatively, both resolving within 2 weeks. One patient (2.8%) demonstrated weakness of the leg ipsilateral to the approach side, which lasted through the 3-month visit but was resolved by the 6-month visit. One patient (2.8%) was found to have hypertrophy of the quadriceps contralateral to the approach side at the 12-month visit, which was resolved by the 2-year visit. Four patients (11%) had postoperative facet joint pain, all in hybrid cases.

All patients were 2 years or more postsurgery as of this writing, although 3 were lost to follow-up between the 1- and 2-year visits. In 2 cases (5.6%), removal of the TDR device and revision to fusion were required due to unresolved pain. At 2 years' follow-up, the average visual analog scale and Oswestry Disability Index scores had improved 69.6% and 61.4%, respectively, and ROM averaged 8.6°, well within physiological norms.

Conclusions. Long-term results of a laterally placed TDR device demonstrate maintenance of pain relief and functional improvement. The benefits of this technique—minimal morbidity, avoiding mobilization of the great vessels, preserving the ALL, biomechanically stable orientation, and broader revision options—suggest a promising new direction for TDR procedures. *(DOI: 10.3171/2010.9.SPINE09865)*

Key Words • **arthroplasty** • **total disc replacement** • **lateral approach** • **extreme lateral interbody fusion** • **minimally invasive surgery**

Lumbar TDR surgery has been proposed as an alternative to fusion procedures for the treatment of pain and instability associated with degenerative disc disease. To date, however, lumbar TDR surgery has been performed via anterior approaches only. The anterior approach to placement of lumbar TDR devices has inherent limitations, including considerable collateral damage to surrounding tissues and risk of vascular and visceral injuries. A complication rate of 38.3% has been reported in anterior fusion surgeries, with complications including sympathetic dysfunction, vascular injury, somatic neural injury, sexual dysfunction, prolonged ileus, wound incompetence, deep vein thrombosis, acute pan-

Abbreviations used in this paper: ALIF = anterior lumbar interbody fusion; ALL = anterior longitudinal ligament; BMI = body mass index; IDE = investigational device exemption; ODI = Oswestry Disability Index; ROM = range of motion; SF-36 = Short Form-36 Health Survey; TDR = total disc replacement; VAS = visual analog scale; XLIF = extreme lateral interbody fusion.

creatitis, and bowel injury.[24] Studies of anterior TDR surgeries have reported similar approach-related complications.[3] By approaching the spine laterally, many of these potential risks can be reduced or avoided.

For a number of years the XLIF approach has been advocated for fusion of the anterior column. Studies on the XLIF approach report few approach-related complications, minimal morbidity, and rapid recovery.[20,25–28] Placement of a TDR device from an XLIF approach is thought to allow for easier, less-invasive access to the disc space, preservation of stabilizing ligaments, greater endplate support, and the opportunity for safer revision surgery. However, there have been no published studies on the outcomes of lateral TDR to date. The results of a prospective evaluation of the clinical and radiographic outcomes of a single-center series of lumbar TDR from a lateral approach are reported herein.

Methods

A prospective nonrandomized study was undertaken to evaluate the clinical and radiographic outcomes of a TDR procedure using a lateral approach. The study was approved by the Santa Rita Hospital Ethics Committee. All patients provided informed consent for participation. Inclusion/exclusion criteria (partially listed in Table 1) were similar to those previously cited for other lumbar TDR studies,[1,3,14,31,36] except that the L5–S1 disc level was excluded (due to inability to access that level laterally).

Surgical Technique

The approach technique does not differ significantly from the standard XLIF approach for fusion procedures,[20,23,26] with the added distinction that the exposure required for TDR device placement must extend more posteriorly than the exposure for an XLIF fusion procedure, making real-time stimulated EMG monitoring an especially important part of this procedure. Once the lateral aspect of the disc space is exposed, an annulotomy is created, and standard discectomy and endplate preparation are performed, while maintaining the integrity of both the anterior and posterior longitudinal ligaments.

A complete and thorough discectomy must be performed to the contralateral margin, and the contralateral anulus is released, ensuring parallel distraction and proper coronal alignment and permitting the placement of the device in its ideal position on both sides of the ring apophysis. Following sequential sizing of the device using trials, the lateral TDR device (XL TDR, NuVasive, Inc.) is inserted as a single assembly. The device (Fig. 1) consists of a superior endplate and an inferior endplate that mate to each other by means of a metal-on-metal (cobalt-chromium-molybdenum alloy) ball-and-socket articulation. The bone-contacting surfaces of the endplates have spikes to facilitate short-term fixation into the vertebral bone and are also coated with a dual-layer titanium plasma spray and hydroxyapatite plasma spray to facilitate bone on-growth for long-term fixation. The device, which provides surface area coverage of > 50% of the endplate area (Fig. 2), should span the ring apophysis on both sides for strong endplate support. The midline markers should align with the lateral center of the vertebral bodies in a lateral fluoroscopic view. Lateral insertion of the device in the midline provides ideal placement and rotation because the kinematic center of rotation is located posteriorly within the device.

TABLE 1: Selective list of some of the more relevant inclusion and exclusion criteria for the study

Inclusion Criteria
age: 18–60 yrs
symptomatic lumbar degenerative disease: MR imaging–confirmed disc desiccation, loss of disc height, bridging osteophytes
symptomatic level L1–2, L2–3, L3–4, or L4–5
preop ODI ≥30
unresponsive to conservative treatment for ≥6 mos or presence of progressive neurological symptoms
willing & able to comply w/ requirements defined in protocol for duration of study
signed & dated informed consent form
Exclusion Criteria
prior lumbar fusion surgery at the operative level
prior lumbar laminectomy at the operative level
prior complete lumbar facetectomy at the operative level
prior bilateral retroperitoneal surgery
radiographic signs of significant instability at operative level (>3 mm translation, >11° angulation different from adjacent level)
bridging osteophytes or absence of motion <2°
radiographic confirmation of significant facet joint disease or degeneration
pars defect, facet abnormality, or other compromise of the posterior elements
spondylolisthesis (>Grade 1)
osteopenia, osteoporosis, or osteomalacia to a degree that spinal instrumentation would be contraindicated
BMI >40
active local or systemic infection, including AIDS, hepatitis

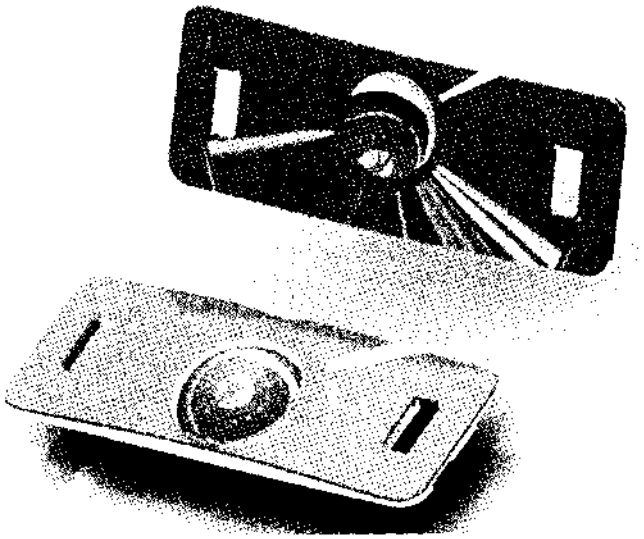

Fig. 1. Photograph showing the XL TDR device—a metal-on-metal, ball-in-socket articulation with a dual-layer titanium plasma spray and hydroxyapatite plasma spray coating.

Clinical and Radiographic Evaluations

Patients were evaluated clinically and radiographically before surgery; immediately after surgery; 6 weeks and 3, 6, and 12 months postoperatively; and annually thereafter. At every visit, patients provided a self-reported measure of pain via a VAS for both back and leg symptoms, function via the ODI, and quality of life via the SF-36. Surgeon-reported clinical measures included the results of a physical examination to measure motor and sensory function in the lower limbs at each visit, as well as a surgeon-reported measure of overall outcome (Odom criteria: excellent, good, fair, poor). Radiographic evaluations included ROM measurements from flexion/extension radiographs obtained at each follow-up visit. Surgical details, including operative time, blood loss, complications, and length of hospital stay were recorded. Descriptive statistics were used to characterize the patient population and results. Paired and unpaired Student t-tests, chi-square tests, and ANOVA were used, where appropriate, to compare results over time or between groups.

Results

Demographic Characteristics

Thirty-six patients with discography-confirmed 1- or 2-level degenerative disc disease underwent TDR through an XLIF approach. The patient group included 16 men and 20 women with an average age of 42.6 years (range 22–60 years). Although the BMI was not calculated for all patients, the rate of obesity tends to be lower in Brazilians than in the US population, and the average BMI found in those reported was 26.1, with a maximum of 33.9. Three patients (8.3%) reported that they were tobacco users. Patients presented predominantly with back pain, with or without leg pain and/or motor or sensory deficits.

Surgeries included 14 single-level TDR procedures at L4–5 and 1 single-level procedure at L3–4. Three procedures included 2 levels of TDR spanning L3–4 and L4–5.

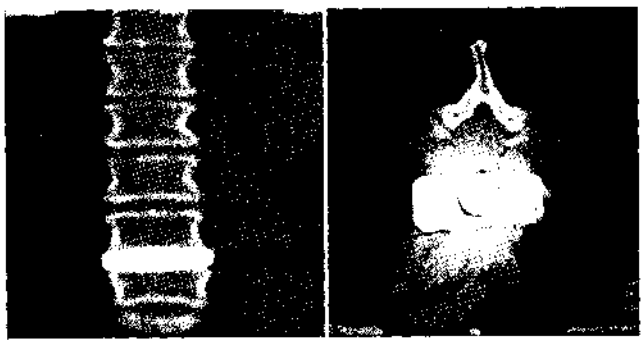

Fig. 2. Coronal (**left**) and axial (**right**) CT image of the XL TDR device seated across the ring apophyses of the L4–5 disc space, with significant endplate area coverage.

Additionally, 18 surgeries included hybrid procedures of ALIF at L5–S1 and TDR at L4–5 (16 surgeries) or L3–4 (2 surgeries). Representative cases are shown in Figs. 3 and 4. Overall operative time (inclusive of all levels treated) averaged 130 minutes (range 90–300 minutes; 112 minutes in single-level, 147 minutes in 2-level, and 141 minutes in hybrid procedures), and blood loss averaged 60 ml (range 30–150 ml). There were no intraoperative complications. Patients were up and walking within an average of 8.2 hours postoperatively (range 4–12 hours) and were discharged in an average of 1.36 days (26 patients in 1 day, 7 in 2 days, and 3 in 3 days). In the postoperative neurological examinations, 5 patients (13.8%) had psoas weakness (that is, weakness in hip flexion) and 3 (8.3%) had anterior thigh numbness postoperatively, both conditions resolving within 2 weeks in all cases. Four patients (11%) had postoperative facet joint pain, all in hybrid cases. One patient demonstrated a weakness of the leg ipsilateral to the approach side, which lasted through the 3-month visit, but was resolved by the 6-month visit. One patient was found to have hypertrophy of the quadriceps contralateral to the approach side at the 12-month visit, which was resolved by the 2-year visit. This was believed to be an effect of compensation for ipsilateral hip flexion weakness. There were no lasting neurological symptoms at the 2-year follow-up.

At the time of this report, all patients are 2 years or more postsurgery, although 3 of the 36 patients were lost to follow-up between the 1- and 2-year visits; in another 4

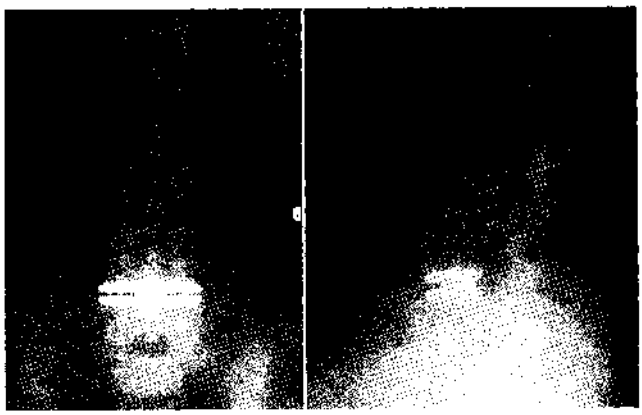

Fig. 3. Anteroposterior and lateral radiographs showing single-level placement of the XL TDR device at the L4–5 disc level.

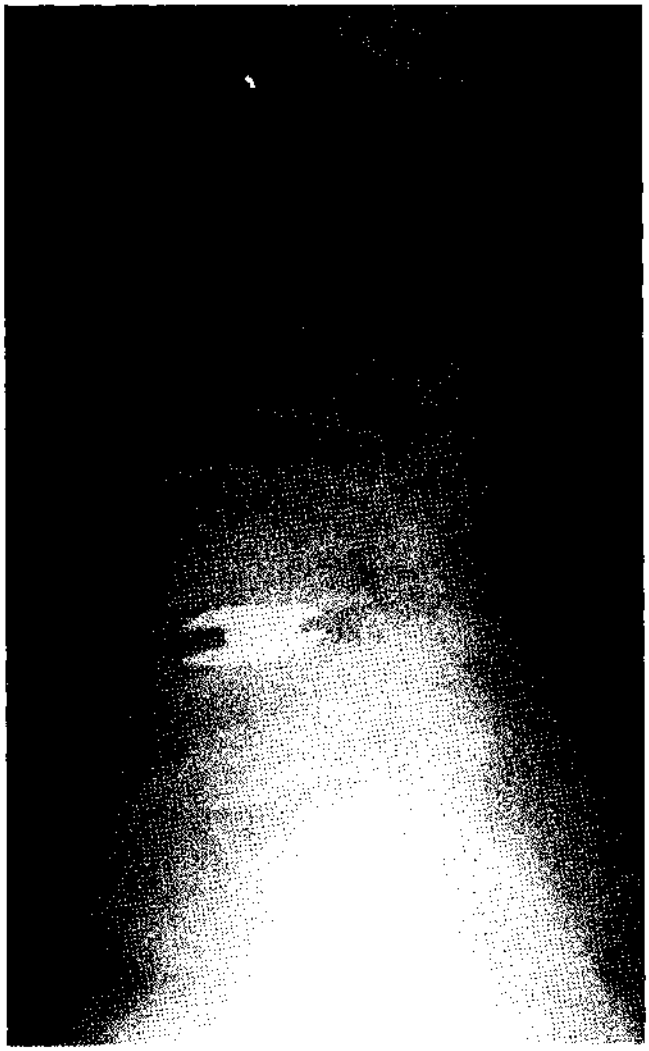

Fig. 4. Lateral radiograph showing a hybrid construct with XL TDR at the L4–5 level and ALIF at L5–S1.

cases, the patients were seen and radiographs were evaluated, but questionnaires were not completed at the 2-year visit.

Clinical Outcomes

Longitudinal outcomes scores are graphically displayed in Fig. 5. The VAS pain scores improved from an average of 92.5 preoperatively to 39.6 at 6 weeks postoperatively. The average was 28.4 at 2 years, a statistically significant change from baseline ($p < 0.0001$). The ODI scores improved from an average of 57.3 at preoperative to 29.8 at 6 weeks and 22.1.0 at 2 years (a 61.4% improvement from baseline [statistically significant, $p < 0.0001$]). Based on a commonly used definition of ODI success of an improvement of at least 15 points from baseline, the clinical success rate was 82.8% at 2 years. The SF-36 scores improved from an average of 34.8 preoperatively to 53.8 at 6 weeks, with continued improvement to 68.6 at 6 months and maintenance to 2 years, with a final score of 66.5, a statistically significant change from baseline ($p < 0.0001$). Per the Odom criteria, 80.0% of patients were rated to have "good" or "excellent" results at 2 years.

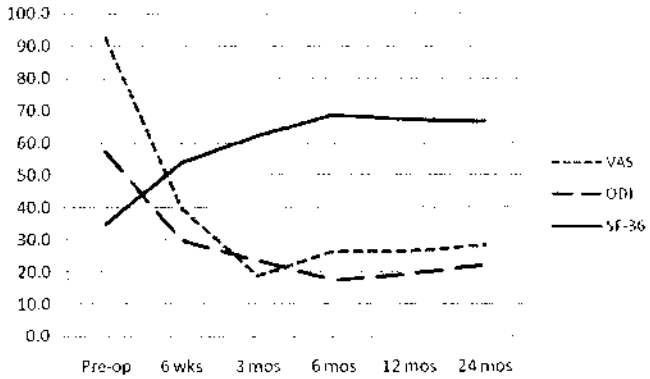

Fig. 5. Longitudinal progression of mean clinical outcome scores. The 24-month outcomes exclude 3 patients lost to follow-up.

Clinical success rates did not differ with patient age ($p = 0.6120$), sex ($p = 0.1186$), level treated ($p = 0.6543$), or whether the construct was single-level, 2-level, or hybrid ($p = 0.7989$).

Revision Rate

Two patients (5.6%) required removal of the TDR device and revision to fusion. The first patient was a 33-year-old woman whose primary surgery was a hybrid XL TDR at L4–5 and ALIF at L5–S1. Her pain and function appeared to improve in the short-term after surgery, although it was noted on postoperative imaging that the caudal endplate of the TDR device was somewhat oblique. The patient reported at the 6-month postoperative visit that her back and leg pain had returned significantly. After several months of nonsurgical therapy, the patient opted to have the device removed 1 year after her primary procedure. She underwent a second XLIF approach ipsilateral to the primary TDR approach. No scar tissue was encountered in the retroperitoneal space, and the disc space was easily accessible from the side. The TDR device was removed without difficulty, and the level was revised to fusion with supplemental bilateral pedicle screws (Fig. 6).

The second patient was a 22-year-old woman whose primary surgery was a single-level XL TDR at L4–5. Although her pain and function improved postoperatively and through the 3-month postoperative visit, she reported increased back pain and decreased function at the 6-month visit. Radiographs obtained at this time showed axial rotation of one of the device endplates and slight subsidence of the TDR device. Symptoms continued beyond the 1-year postoperative visit, and the patient opted to revise the TDR to fusion via XLIF 20 months after the primary procedure. At the most recent follow-up visits postrevision, neither of these patients has reported significant improvement in symptoms, despite radiographic fusion.

It should be noted that in both cases, the laterally placed TDR devices were removed without significant effort or bony violation in detaching them from the endplates. The surface coatings of TDR devices allow for on-growth, or bony attachment, rather than in-growth. Although on-growth was noted in these cases, and it was sufficient for internal fixation of the devices, it was not a significant hindrance in retrieval. This endplate fixation effect has been consistent with our experience with all TDR devices.[22]

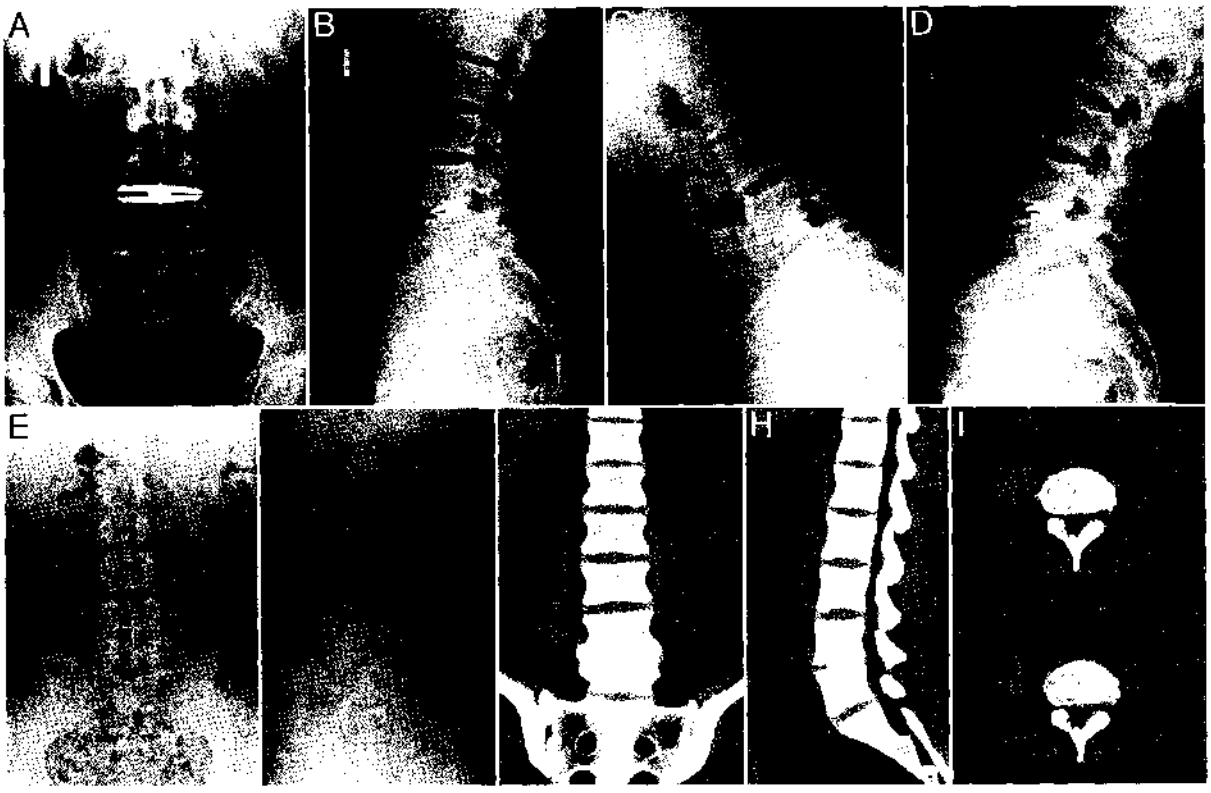

Fig. 6. Radiographs obtained pre- and postrevision of 1 of the XL TDR devices to an XLIF fusion. **A–D:** Radiographs obtained 20 months after TDR. **E–I:** Radiographs obtained 6 months following revision to XLIF.

Radiographic Outcomes

Postoperative radiographs showed good device placement, with restoration of disc height, foraminal volume, and sagittal balance. The average sagittal-plane ROM at 24 months (Fig. 7) was 8.6°, which was not significantly different from preoperative values ($p = 0.6859$). The ROM was not statistically different between TDR-treated L3–4 or L4–5 levels ($p = 0.4680$). A significant effect was, however, associated with treatment groups: single-level (mean ROM 12.8°), 2-level (mean ROM 5.3°), and hybrid (mean ROM 7.3°) constructs ($p = 0.0181$). Range of motion was not a statistically significant factor in clinical success ($p = 0.6730$).

Discussion

The indications for lateral TDR are not different from those considered standard for anteriorly placed TDR devices—in general, degenerative disc disease without facet degeneration. However, lateral placement of a TDR device is limited to levels above L5–S1 due to obstruction by the iliac crest at that level. In our experience, multilevel pathologies that include L5–S1 have been treated using a hybrid construct of lateral TDR at upper levels and ALIF fusion at L5–S1. The clinical and radiographic results in the current study did not differ between hybrid and nonhybrid constructs, consistent with prior reports and assumptions based on kinematic testing.[2,7] Given the relatively low mobility of the L5–S1 disc space when treated with TDR,[12,16] the benefits of treating that level with TDR do not seem to outweigh the risks.

In a series of 60 patients treated by means of anterior-approach fusion, Rajaraman et al.[24] reported a complication rate of 38.3%, with complications including sympathetic dysfunction, vascular injury, somatic neural injury, sexual dysfunction, prolonged ileus, wound incompetence, deep venous thrombosis, acute pancreatitis, and bowel injury. The results of the US FDA IDE trial of the Charité (Depuy Spine) anterior TDR reported similar approach-related complications, with a rate of 9.8% in the investigational group and 10.1% in the anterior fusion control group.[3] Many of these inherent risks can be avoided by approaching the spine laterally, as shown

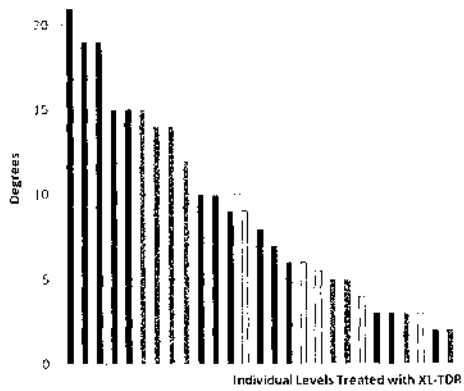

Fig. 7. Histogram showing the range of motion, in degrees, of each level of XL TDR 2 years postoperatively. Not all levels had available data. *Black bars* represent L4–5 levels, *white* L3–4 levels, and *gray* the TDR levels in a hybrid construct.

through the minimal blood loss, short hospital stay, and low complication rate in the current study.

The major concern in a lateral approach is risk of injury to the nerves of the lumbar plexus within the psoas muscle lateral to the spine. Indeed, because the approach for TDR is more posterior on the lateral border than it is even for fusion, the risk would seem that much higher. However, the experience detailed herein, which was with the use of real-time, stimulus-evoked discrete-threshold electromyography to help identify nerves during the approach, resulted in 1 case (2.8%) of lower-extremity weakness attributable to neural injury, which resolved within 6 months.

Neurological deficits have been reported in anterior-approach TDR surgery as well. Neurological success at 2 years was unmet for 17.6% of the Charité IDE study patients;[3] major neurological events were reported to have occurred in 4.9% of patients in that study,[8] and 2.2% in European Charité studies.[35] The ProDisc-L (Synthes Spine) IDE study reported an 8.8% neurological failure rate at 2 years.[36] Studies using the Maverick device (Medtronic Sofamor Danek) have reported neurological symptoms in 6.2% of patients.[14] The results of the current study do not support the assumption that the incidence of injury from a lateral approach is higher than that from an anterior approach.

The lateral approach has also been used as a revision strategy for primary anterior TDR surgery.[21,22] Anterior retrieval of a TDR device and revision to an anterior lumbar interbody fusion is difficult, particularly after the 1st 2 weeks postoperatively, due to scar formation and elevated risk of vascular injury, particularly at the level of the vascular bifurcation at L4–5.[2,19,32] The Charité US IDE data showed that although the primary TDR procedure resulted in a rate of vascular complication of 3.4%, vascular injury occurred in 16.7% of the revision cases.[19] Although experience to date is limited, case reports describing the successful use of the lateral approach, which does not require anterior mobilization of the major vessels, to revise anteriorly placed TDR devices have been presented with encouraging results.[22] Primary placement of a lumbar TDR device from a lateral approach leaves multiple safer surgical approach options should removal and revision be necessary (as demonstrated by uneventful revision of 2 cases in the current study). Not only can the contralateral retroperitoneal approach be performed easily, but because the primary procedure does not create scar formation in or around the anterior vasculature, an anterior approach (either trans- or retroperitoneal) can more safely be performed.

Moreover, the lateral approach to TDR device placement also appears to be more forgiving, perhaps leading to fewer technical or device-related failures requiring revision. Anterior TDR surgery requires precise placement of the device, in the midline for coronal stability, and in a posterior location for appropriate range of motion of the device. The precise placement of devices from the anterior approach, however, can be difficult. The results of the Charité US IDE trial showed less-than-ideal placement of the devices in 17% of patients and that placement correlated with both improved ROM and clinical outcomes.[18] The 10-year experience of Lemaire and colleagues[15] showed that, in that series of Charité surgeries, 25% of the devices implanted were not centered in the frontal plane, and 40% were not in an ideal posterior location. Rundell et al.[30] concluded that posterior positioning of a device provided a more physiological load sharing between the vertebral bodies and facets. Results of an obliquely anterolateral approach found significant subsidence related to poor placement.[17] In contrast, lateral placement of a device allows for easy identification of the frontal midline via cross-table anteroposterior fluoroscopy and central placement of the device via alignment of the midline device markings with the spinous processes. Additionally, the device length is designed to span the entire disc space, with easily identifiable landmarks of the lateral borders of the vertebrae, thus easily ensuring coronal balance. The kinematic center of rotation is located posteriorly within the device, so insertion of the device in the midline laterally provides ideal placement and rotation.

The ALL not only provides an anterior restraint to extension, but also to axial rotation. It has been shown that resection of the ALL leads to hypermobility of the segment and potential facet arthrosis at the same and adjacent levels.[5,30] White and Panjabi[34] have reported that removal of both the anterior and posterior longitudinal ligaments increases horizontal translation by 33%, creating instability and increasing facet stress. In a biomechanical study, implantation of an anterior TDR device resulted in an increase in extension motion by 35% in single-level and 83% in 2-level procedures, prompting the authors to raise a concern for significantly elevated facet strains.[7] In fact, facet arthrosis was reported in 30% of patients in a clinical study of the Maverick device.[14] A finite element analysis of anterior TDR placement found that modeling the resuturing of the ALL had a strong effect on loading, and the authors concluded that reconstruction of the ALL would help to restore the biomechanics to normal.[29] Another study reported that preserving the ALL and placing the implant's access of rotation posteriorly within the disc space may restore spinal stiffness in the sagittal plane and reduce facet loads to those of the intact condition.[6] Although anteriorly placed TDR devices require resection of the ALL and anterior annulus, the XLIF approach to TDR placement preserves these structures and therefore results in a construct that constrains the device from anterior expulsion, provides better ligamentotaxis and sagittal balance, and prevents excessive loading of the facet joints.

Studies of endplate strength have shown that the posterior part of the endplate is stronger than the anterior part and that the lateral margins are the strongest, whereas the center of the endplate, where most implants are currently placed, is the weakest area.[10] A laterally placed TDR device can take advantage of the strongest regions of the vertebral endplates for initial and long-term stability. The lateral TDR device in use via the XLIF approach spans the dense ring apophysis on either side of the endplate and provides a surface area coverage of > 50% of the endplate surface.

In addition to the discussed advantages of a laterally placed disc replacement, the clinical results presented herein are in line with or compare favorably to reports of lumbar TDRs placed from an anterior approach. In the largest and most consistent series, the US IDE trials, clini-

TABLE 2: Published 2-year data for LDR devices*

Characteristic	Charité†	ProDisc-L‡	Maverick§	XL TDR
no. of patients enrolled	205	161	160	36
no. of patients at 2 yrs FU	176	147	50	29
mean op time (min)	111	121	102	130
mean estimated blood loss (ml)	205	204	243.4	60
mean LOS (days)	3.7	3.5	2.2	1.4
average VAS improvement	41 points/57% ↑	39 points/56% ↑	NA	64 points/70% ↑
mean ODI improvement	48%	46.1%	36%	61%
ODI success	64%¶	68%/69%¶	82%	83%/83%¶
SF-36 (% of patients w/ improvement)	72	79.2	64.6	92.6
neurological deficits at 2 yrs (% of patients)	17.6	8.8	NA	0
nonneurological approach-related complications	1% major; 9.8% other	0% major; 1.2% retrograde ejaculation; 1.2% DVT	NA	0%
revision rate (%)	5.4	3.7	NA	5.6
ROM	7.5°	7.7°	NA	8.6°

* DVT = deep vein thrombosis; LOS = length of hospital stay; NA = data not available; ↑ = increase.

† Data from Blumenthal et al.[3]

‡ Data from Zigler et al.[36]

§ Data from Gornet et al.[9]

¶ The Charité and ProDisc studies reported success as a 25% decrease in ODI scores, rather than the 15-point decrease used as the standard definition in subsequent studies. The values to the left of the virgule are based on the 15-point decrease definition; those to the right are based on the 25% change.

cal success per improvements in ODI has been on the order of 64% for the Charité device,[3] 68% for the ProDisc-L device,[36] and 82% for the Maverick device.[9] In the current study, the clinical success by ODI definition of improvement ≥ 15 points was 83%. These and additional outcomes are summarized alongside the results of the current study for comparison in Table 2. Noteworthy, and a testament to the aforementioned benefits of the lateral approach over the anterior approach, are the lower estimated blood loss, hospital stay, complication rates, and reoperation rates in the current study compared with those from the US IDE device trials.

Studies on TDR invariably report maintenance of motion alongside clinical outcomes. Indeed, the intent of the procedure, as an alternative to fusion, is to preserve motion. However, there are few data to support that maintenance of motion results in improved clinical outcome scores. In the current study, the average ROM was within normal limits and in line with values in prior reports:[1,3,12,14,15,18,33,36] an average of 8.6° at 24 months, compared with 7.5° in the Charité trial[18] and 7.7° in the ProDisc-L trial.[36] However, ROM was not predictive of clinical success. Longer-term follow-up is required to determine whether the preservation of motion provides a protective effect at the adjacent levels, as suggested by recent reports.[4,11,13,15]

Conclusions

The XLIF approach for TDR surgery offers some inherent advantages over the traditional anterior approach. The mid- to long-term clinical results fulfill the promise of a safer and less-invasive exposure and demonstrate maintenance of pain relief and functional improvement. The benefits of this technique—avoiding mobilization of the great vessels, preserving the ALL, minimal morbidity, and wider revision options—suggest a promising new direction for TDR procedures.

Disclosure

Financial and material support for this research were provided by NuVasive, Inc., in the form of coverage for nonreimbursable study-related imaging costs and provision of devices.

Author contributions to the study and manuscript preparation include the following. Acquisition of data: Oliveira, Pimenta, Schaffa, Coutinho. Analysis and interpretation of data: Oliveira, Marchi. Drafting the article: Marchi. Critically revising the article: Oliveira. Reviewed final version of the manuscript and approved it for submission: all authors. Statistical analysis: Oliveira. Study supervision: Pimenta.

References

1. Bertagnoli R, Yue JJ, Shah RV, Nanieva R, Pfeiffer F, Fenk-Mayer A, et al: The treatment of disabling single-level lumbar discogenic low back pain with total disc arthroplasty utilizing the Prodisc prosthesis: a prospective study with 2-year minimum follow-up. **Spine 30:**2230–2236, 2005
2. Bertagnoli R, Zigler J, Karg A, Voigt S: Complications and strategies for revision surgery in total disc replacement. **Orthop Clin North Am 36:**389–395, 2005
3. Blumenthal S, McAfee PC, Guyer RD, Hochschuler SH, Geisler FH, Holt RT, et al: A prospective, randomized, multicenter Food and Drug Administration investigational device exemptions study of lumbar total disc replacement with the CHARITE artificial disc versus lumbar fusion: part I: evaluation of clinical outcomes. **Spine 30:**1565- 1575, 2005
4. David T: Long-term results of one-level lumbar arthroplasty: minimum 10-year follow-up of the CHARITE artificial disc in 106 patients. **Spine 32:**661–666, 2007
5. Denozière G, Ku DN: Biomechanical comparison between fusion of two vertebrae and implantation of an artificial intervertebral disc. **J Biomech 39:**766–775, 2006

6. Dooris AP, Goel VK, Grosland NM, Gilbertson LG, Wilder DG: Load-sharing between anterior and posterior elements in a lumbar motion segment implanted with an artificial disc. **Spine 26:**E122–E129, 2001
7. Erkan S, Rivera Y, Wu C, Mehbod AA, Transfeldt EE: Biomechanical comparison of a two-level Maverick disc replacement with a hybrid one-level disc replacement and one-level anterior lumbar interbody fusion. **Spine J 9:**830–835, 2009
8. Geisler FH, Blumenthal SL, Guyer RD, McAfee PC, Regan JJ, Johnson JP, et al: Neurological complications of lumbar artificial disc replacement and comparison of clinical results with those related to lumbar arthrodesis in the literature: results of a multicenter, prospective, randomized investigational device exemption study of Charité intervertebral disc. **J Neurosurg Spine 1:**143–154, 2004
9. Gornet MF, Mathews HH, Burkus JK, Johnson DR, Rahn KA, Peloza JH, et al: Maverick total disc replacement: initial report of 24-month clinical outcomes from six investigational centers. **Spine J 6 (Issue 5, Suppl 1):**66S, 2006
10. Grant JP, Oxland TR, Dvorak MF: Mapping the structural properties of the lumbosacral vertebral endplates. **Spine 26:** 889–896, 2001
11. Guyer RD, McAfee PC, Banco RJ, Bitan FD, Cappuccino A, Geisler FH, et al: Prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of lumbar total disc replacement with the CHARITE artificial disc versus lumbar fusion: five-year follow-up. **Spine J 9:**374–386, 2009
12. Huang RC, Girardi FP, Cammisa FP Jr, Tropiano PT, Marnay T: Long-term flexion-extension range of motion of the prodisc total disc replacement. **J Spinal Disord Tech 16:**435–440, 2003
13. Huang RC, Tropiano P, Marnay T, Girardi FP, Lim MR, Cammisa FP Jr: Range of motion and adjacent level degeneration after lumbar total disc replacement. **Spine J 6:**242–247, 2006
14. Le Huec JC, Mathews H, Basso Y, Aunoble S, Hoste D, Bley B, et al: Clinical results of Maverick lumbar total disc replacement: two-year prospective follow-up. **Orthop Clin North Am 36:**315–322, 2005
15. Lemaire JP, Carrier H, Sariali H, Skalli W, Lavaste F: Clinical and radiological outcomes with the Charité artificial disc: a 10-year minimum follow-up. **J Spinal Disord Tech 18:**353–359, 2005
16. Lim MR, Girardi FP, Zhang K, Huang RC, Peterson MG, Cammisa FP Jr: Measurement of total disc replacement radiographic range of motion: a comparison of two techniques. **J Spinal Disord Tech 18:**252–256, 2005
17. Marshman LAG, Friesem T, Rampersaud YR, Le Huec JC, Krishna M: Subsidence and malplacement with the Oblique Maverick Lumbar Disc Arthroplasty: technical note. **Spine J 8:**650–655, 2008
18. McAfee PC, Cunningham B, Holsapple G, Adams K, Blumenthal S, Guyer RD, et al: A prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of lumbar total disc replacement with the CHARITE artificial disc versus lumbar fusion: part II: evaluation of radiographic outcomes and correlation of surgical technique accuracy with clinical outcomes. **Spine 30:**1576–1583, 2005
19. McAfee PC, Geisler FH, Saiedy SS, Moore SV, Regan JJ, Guyer RD, et al: Revisability of the CHARITE artificial disc replacement: analysis of 688 patients enrolled in the U.S. IDE study of the CHARITE Artificial Disc. **Spine 31:**1217–1226, 2006
20. Ozgur BM, Aryan HE, Pimenta L, Taylor WR: Extreme Lateral Interbody Fusion (XLIF): a novel surgical technique for anterior lumbar interbody fusion. **Spine J 6:**435–443, 2006
21. Patel AA, Brodke DS, Pimenta L, Bono CM, Hilibrand AS, Harrop JS, et al: Revision strategies in lumbar total disc arthroplasty. **Spine 33:**1276–1283, 2008
22. Pimenta L, Díaz RC, Guerrero LG: Charité lumbar artificial disc retrieval: use of a lateral minimally invasive technique. Technical note. **J Neurosurg Spine 5:**556–561, 2006
23. Pimenta L, Schaffa TD: Surgical technique: eXtreme lateral interbody fusion, in Goodrich JA, Volcan IJ (eds): **eXtreme Lateral Interbody Fusion (XLIF).** St. Louis, MO: Quality Medical Publishing, 2008, pp 87–104
24. Rajaraman V, Vingan R, Roth P, Heary R, Conklin L, Jacobs G: Visceral and vascular complications resulting from anterior lumbar interbody fusion. **J Neurosurg 91 (1 Suppl):** 60–64, 1999
25. Rodgers WB, Cox CS, Gerber EJ: Early complications of extreme lateral interbody fusion in the obese. **J Spinal Disord Tech 23:**393–397, 2010
26. Rodgers WB, Cox CS, Gerber EJ: Experience and early results with a minimally invasive technique for anterior column support through eXtreme Lateral Interbody Fusion (XLIF). **Touch Briefings: US Musculoskeletal Review 1:**28–32, 2007 http://www.touchmusculoskeletal.com/files/article_pdfs/rodgers.pdf [Accessed September 24, 2010]
27. Rodgers WB, Cox CS, Gerber EJ: Intraoperative and early postoperative complications in extreme lateral interbody fusion (XLIF): An analysis of 600 cases. **Spine J** [in press], 2010
28. Rodgers WB, Cox CS, Gerber EJ: Minimally invasive treatment (XLIF) of adjacent segment disease after prior lumbar fusions. **Internet Journal of Minimally Invasive Spinal Technology.** http://www.ispub.com/journal/the_internet_journal_of_minimally_invasive_spinal_technology/volume_3_number_4_1/article/minimally-invasive-treatment-xlif-of-adjacent-segment-disease-after-prior-lumbar-fusions.html [Accessed September 24, 2010]
29. Rohlmann A, Zander T, Bergmann G: Effect of total disc replacement with ProDisc on intersegmental rotation of the lumbar spine. **Spine 30:**738–743, 2005
30. Rundell SA, Auerbach JD, Balderston RA, Kurtz SM: Total disc replacement positioning affects facet contact forces and vertebral body strains. **Spine 33:**2510–2517, 2008
31. Sasso RC, Foulk DM, Hahn M: Prospective, randomized trial of metal-on-metal artificial lumbar disc replacement: initial results for treatment of discogenic pain. **Spine 33:**123–131, 2008
32. Scott-Young M: Strategy for revision disc replacement surgery, in McAfee P, Geisler F, Scott-Young M (eds): **Roundtables in Spine Surgery. Vol 1, No 2.** St. Louis: Quality Medical Publishing, 2005
33. Tropiano P, Huang RC, Girardi FP, Cammisa FP Jr, Marnay T: Lumbar total disc replacement. Seven to eleven-year follow-up. **J Bone Joint Surg Am 87:**490–496, 2005
34. White A, Panjabi M: **Clinical Biomechanics of the Spine, ed 2.** Philadelphia: JB Lippincott, 2001
35. Zeegers WS, Bohnen LM, Laaper M, Verhaegen MJ: Artificial disc replacement with the modular type SB Charité III: 2-year results in 50 prospectively studied patients. **Eur Spine J 8:**210–217, 1999
36. Zigler J, Delamarter R, Spivak JM, Linovitz RJ, Danielson GO III, Haider TT, 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 32:**1155–1163, 2007

Manuscript submitted October 27, 2009.
Accepted September 20, 2010.
Portions of this work, including early and interim reports, were presented in abstract/poster/oral presentation form at the International Meeting of Advanced Spine Techniques (IMAST) in 2009, 2008, and 2007; the Spine Arthroplasty Society (SAS) Meetings in 2009, 2008, 2007, and 2006; the American Association of Neurological Surgeons (AANS) Meeting in 2007; the WorldSpine Meeting in 2007; the AANS/CNS Joint Section on Spinal Disorders and Peripheral Nerves in 2008; SpineWeek in 2008; and the Society for Minimally Invasive Spine Surgery (SMISS) Meeting in 2008.
Please include this information when citing this paper: published online December 17, 2010; DOI: 10.3171/2010.9.SPINE09865.
Address correspondence to: Luiz Pimenta, M.D., Ph.D., Instituto de Patologia da Coluna, Rua Vergueiro, 1421 - Sala 305, 04101-000 São Paulo, Brazil, email: LuizPimenta@luizpimenta.com.br.