Lumbar Total Disc Replacement by the Lateral Approach—Up to 10 Years Follow-Up

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■ OBJECTIVE: **This study aimed to analyze radiologic and clinical results with a minimum 5 years follow-up (FUP) of lateral lumbar total disc replacement for the treatment of symptomatic lumbar degenerative disc disease.**

■ METHODS: **We performed a prospective, single-center, clinical, and radiologic study. Patients were treated with lumbar total disc replacement (extreme lateral total disc replacement) by a lateral transpsoas approach. From 2005 to 2012, 60 patients were enrolled (31 male, 29 female; total, 66 levels; average age, 42.8 years [standard deviation (SD), 9.7 years, range, 22—64 years]; mean body mass index, 26.0 [SD, 3.4]). Clinical end points included visual analog scale and Oswestry Disability Index questionnaires, complications, and reoperation. Radiographic end points included heterotopic ossification (McAfee classification), adjacent level disease, and prosthesis migration or subluxation.**

■ RESULTS: **The mean surgical duration was 122 minutes (SD, 45 minutes) with mean 58 mL (SD, 21 mL) of estimated blood loss. No intraoperative complication occurred. The exceptions were 1 patient with postanesthesia apnea and 2 patients with quadriceps motor deficit (resolved within 4 months with physiotherapy). Of 60 patients, 9 were missed to FUP and 51 (85%) were enrolled in the study, with mean FUP of 92 months (range, 60—122 months). In total, 5 levels (9%; 5 of 55) required to be fused. Both removal of the prostheses and interbody fusion were performed by the lateral transpsoas approach. One patient experienced CrCo allergy (at 2 months); 4 experienced persistent pain from different causes (at 7, 9, 24, and 88 months). Five patients (10%) presented with progression at adjacent levels and 2 (4%) required surgery. One patient required sacroiliac fusion at 63 months. There were no complications during the retrieval surgeries. One partial disc migration occurred but the patient refused retrieval. There was no bone bridging in 9% of the discs (grade 0 heterotopic ossification): grade I, 22%; grade II, 31%; grade III, 20%; grade IV (fusion), 18%. Most heterotopic ossification cases (93%) occurred in the lateral aspect of the disc space, and mostly at the contralateral side of the surgical approach. Patient-reported outcomes significantly improved ($P < 0.01$) at the last FUP. Visual analog scale back pain score was preoperatively 8.5, early postoperatively 2.5, and at last FUP 3.1. Oswestry Disability Index was preoperatively 55%, early postoperatively 31%, and at last FUP 21%.**

■ CONCLUSIONS: **This study presents mid-term to long-term results of extreme lateral total disc replacement artificial disc for the treatment of lumbar degenerative disease, with fast mobilization, sustained pain relief, and improved physical function. Despite the low rate of ALDis, some discs evolved to ankyloses and others were retrieved. Lumbar artificial disc replacement by the lateral approach seems to be a safe and effective treatment.**

Key words
- DDD
- Heterotopic ossification
- Lumbar disc arthroplasty
- XL-TDR

Abbreviations and Acronyms
ALDeg: Adjacent level degeneration
ALDis: Adjacent level disease
DDD: Degenerative disc disease
FUP: Follow-up
HO: Heterotopic ossification
IDE: Investigational Device Exemption
ODI: Oswestry Disability Index
ROM: Range of motion
SD: Standard deviation
TDR: Total disc replacement
VAS: Visual analog scale
XL: Extreme lateral

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Citation: World Neurosurg. (2019) 122:e325-e333.
https://doi.org/10.1016/j.wneu.2018.10.033

*Journal homepage: **www.journals.elsevier.com/world-neurosurgery***

*Available online: **www.sciencedirect.com***

INTRODUCTION

With increasing life expectancy, aging of the population, and a more demanding and stressful work environment, spine disorders are becoming a common burden for individuals, and studies point out that low back pain is the most prevalent occupational disorder worldwide.[1]

Degeneration of the intervertebral discs is the most common cause of low back pain.[2] In the intervertebral disc degeneration pathway, the loss of disc hydration and turgor is one of the initiating steps.[3] Biomechanical changes across the functional spinal unit eccentrically load the vertebral end plate and facilitate inflammatory-mediated progression of degenerative disc disease (DDD).[4] Degenerative changes in the intervertebral disc can culminate in progressive facet arthrosis.[5] The patient may experience mechanical pain and symptoms coming from compression of neural structures. The gold-standard surgical option has been spinal fusion, but total disc replacement (TDR) can be considered if the functional spine unit has not reached mild to severe facet degeneration.[6]

The main advantages of placing the lateral TDR prosthesis by the lateral access are avoidance of mobilization of the great vessels and the preservation of the anterior longitudinal ligament, which leads to a more stable and physiologic construct.[7]

Given that our objective was to analyze radiologic and clinical results of patients with a minimum 5-year follow-up (FUP) of extreme lateral (XL) lumbar TDR.

METHODS

Study Design and Patient Selection

This was a prospective nonrandomized single-center study. Consecutive patients from 2005 to 2012 were enrolled in a clinical study. Inclusion-exclusion criteria are presented in **Table 1** and are summarized as follows: 18–70 years of age (skeletally mature) at the time of surgery; diagnosis of image-confirmed symptomatic DDD at 1 or 2 of the following levels of the lumbar spine: L1/L2, L2/L3, L3/L4, or L4/L5; preoperative Oswestry Disability Index (ODI) ≥30 points (on the 100-point scale); and unresponsive to conservative treatment for ≥6 months.

This study used a unique artificial disc for the TDR procedures. The XL-TDR (**Figure 1** [NuVasive Inc., San Diego, California, USA]) is a 2-piece device consisting of a metal-on-metal bearing surface with both components made of cobalt chrome molybdenum (CoCrMo) alloy and a surface coating of titanium and hydroxyapatite. The surgeons used the a retroperitoneal lateral transpsoas approach[8] for the insertion of the XL-TDR device.

Clinical End Points

Clinical evaluations included patient-reported assessments and clinical examination. FUP windows were preoperative, immediately after surgery, 6 weeks and 3, 6, and 12 months postoperatively, and annually thereafter. A visual analog scale (VAS; 0–100) documented pain and the ODI (0–100) quantified physical disability. Descriptive and comparative analyses were performed.

Adverse events and reoperations (retrieval and additional surgery at either index or adjacent level) were analyzed and reported. Adjacent level disease (ALDis) was defined by the need of reintervention because of symptomatic adjacent level degeneration (ALDeg).

Radiographic End Pointsl

Radiographic evaluations including TDR failures were screened based on a previous guideline (McAfee et al.[9]): 1) heterotopic ossification and spontaneous fusion (assessed using the McAfee classification[10]; grade 0–IV); 2) iatrogenic scoliosis (preoperative Cobb angle increased by ≥10°); 3) iatrogenic kyphosis (≥10° at the index disc level measured in the adjacent end plates); 4) device dislocation/migration; 5) device subsidence into the end plates; 6) vertebral fracture; 7) ALDeg defined as the radiologic progress of degeneration by the onset of ≥10° segmental kyphosis, and/or ≥50% loss of disc height, and/or ≥3 mm anteroposterior translation.[11] Two evaluators evaluated radiographic end points and the discrepancies were solved with consensus.

Statist

Statistical analyses were performed with a Student t test, Fisher exact test, and repeated measures analysis of variance with an α of 0.05. The statistical analyses were performed with Graphpad Prism 8 (GraphPad Software, California, USA).

Table 1. Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Age: 18–60 years	Previous lumbar fusion surgery at the operative level
Symptomatic lumbar degenerative disease: magnetic resonance imaging–confirmed disc degeneration, loss of disc height, bridging osteophytes	Previous lumbar laminectomy at the operative level
Symptomatic level L1-2, L2-3, L3-4, or L4-5	Previous complete lumbar facetectomy at the operative level
Preoperative Oswestry Disability Index ≥30	Previous bilateral retroperitoneal surgery
Unresponsive to conservative treatment for >6 months, or progressive neurologic symptoms	Radiographic signs of significant instability at operative level (>3 mm, >11° angulation different from adjacent level)
Willing and able to comply with the requirements defined in the protocol for the duration of the study	Bridging osteophytes or absence of motion <2°
Signed and dated informed consent	Radiographic confirmation of significant facet joint disease or degeneration
≥5 years of follow-up	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
	Body mass index >40 kg/m^2
	Active local or systemic infection

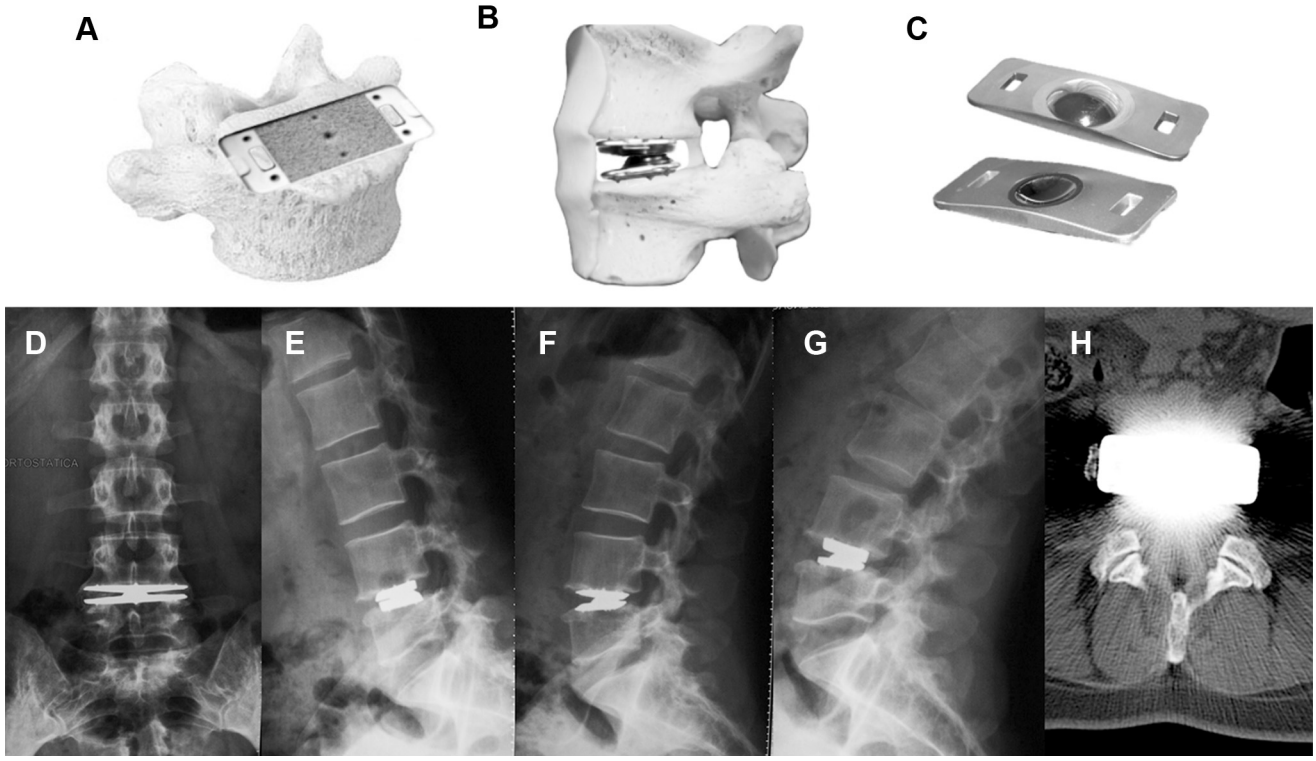

Figure 1. Case example of 1-level lumbar arthroplasty with dynamic radiographic study and good facet status at 7 years follow-up. (**A**) Axial view of the XL-TDR; (**B**) Lateral view of the XL-TDR; (**C**) View of the 2 piece that compose the XL-TDR; (**D**) Antero-posterior radiography of the XL-TDR; (**E**) Lateral (flexion) radiography of the XL-TDR; (**F**) Lateral (neutral) radiography of the XL-TDR; (**G**) Lateral (extension) radiography of the XL-TDR, (**H**) Axial radiography of the XL-TDR.

RESULTS

Demographic and Surgical Data

Sixty patients (66 levels; 31 male, 29 female) were treated with lateral TDR between 2005 and 2012. The mean age 42.8 years (standard deviation [SD], ±9.7; range, 22–64). Mean surgical duration was 122 minutes (SD, ±45) with mean 58 mL (SD, ±21) of estimated blood loss. No major intraoperative complication occurred. After surgery, fast mobilization occurred, with 95% of patients able to walk on the same day.

Table 2. Patients' Enrollment and Dropout During the Study

	Patients	Levels
Total initially enrolled	60	66
Lost to follow-up	9	11
Revised	5	5
Included in 5-year to 10-year analysis	46	50
Included in the study	51	55

Table 2 details the number of patients enrolled in this study. Of 60 patients, a minimum of 5 years of data were unavailable for 9 patients (15% of missed FUP). Fifty-one patients and 55 levels were included in the long-term analysis (mean FUP, 93 months; range, 60–122). In most patients, the L4-L5 level was involved (42 of 55 levels analyzed), followed by L3-L4 (10 levels) and L2-L3 (3). Seventeen patients (31%) were treated with hybrid constructs (fusion at L5-LS1 and TDR above).

Clinical Results

Clinical parameters improved in both VAS and ODI scores (Figure 2) were compared with preoperative scores immediately after surgery and maintained at low levels in long-term FUP. Mean pain levels (VAS) improved from 85/100 to 25/100 ($P < 0.001$) at 1 week FUP and to 33/100 ($P < 0.001$) at minimum 5 years FUP, representing improvements of 71% and 61%, respectively. The mean preoperative ODI was 55.4, which decreased to 31.1 ($P = 0.001$) at 1 week FUP, and to 22.1 at 5 years ($P < 0.001$), representing improvements of 44% and 66%, respectively.

From the total implanted TDRs, 5 discs (7.5% from total levels and 9% from total patients) required retrieval and reversion to interbody fusion. The reason for revision was mechanical back pain caused by motion in 4 of 5 patients and CrCo allergy in 1

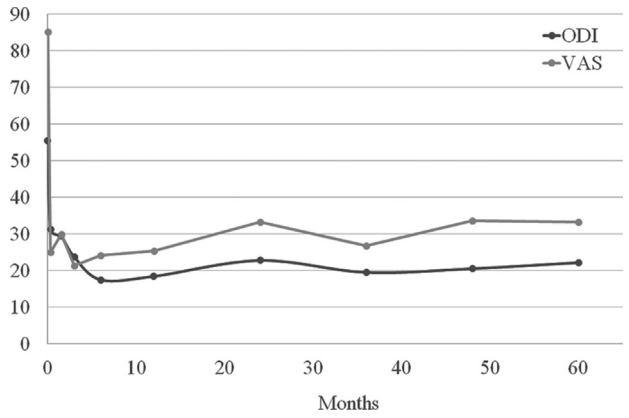

Figure 2. Clinical outcomes up to a minimum 60 months follow-up. All postoperative scores were statistically significantly better ($P < 0.05$). ODI, Oswestry Disability Index; VAS, visual analog scale.

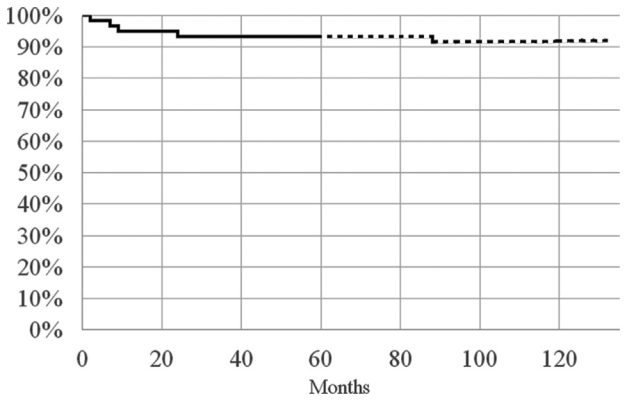

Figure 3. Total disc replacement retrieval survival curve. Five discs were removed, 4 of them in the first 2 years. *Solid line* represents minimum completed follow-up for the entire cohort. The *dotted line* represents ongoing follow-up period.

patient. In 2 of the 4 patients who developed mechanical back pain, the prostheses were not well sized to the disc space. A survival curve plots the surgical revisions time frame (Figure 3). Four of 5 revision patients (80%) were operated on in the first 2 years of FUP, and 1 patient 88 months after disc implantation. The surgical team used the ordinary lateral transpsoas route for interbody fusion in all patients as the revision strategy. Surgeons could easily detach the disc from the end plates by reaching the interface with a Cobb elevator. Surgical intervention produced solid interbody fusion in all patients.

Figure 4 provides a case example of a failed disc. A 43-year-old man presented with low back pain for 1.5 years refractory to conservative care. In imaging examinations, DDD was found at L3-L4 with disc dehydration and reduced height. Adjacent levels were healthy. The patient underwent a left-sided lateral approach for insertion of an XL-TDR at L3-L4. The surgical procedure took 90 minutes and there was 50 mL of estimated blood loss, without complications. The patient stood up and walked on the same day. Radiologic control showed good positioning of the disc in the coronal and sagittal planes but did not cover the vertebral end plates from the lateral to lateral edges. For 4 years, the patient had normal physical activities without pain, including practice of sports and riding motorcycles. The patient had an accident with no damage to the lumbar spine structures. A little pain appeared with decubitus change and when changing from a sitting to a standing position. At 5-year FUP (Figure 4B), a grade III heterotopic ossification (HO) was observed at the contralateral side to the primary approach. After unsuccessful conservative measures, the surgeons retrieved the XL-TDR by a lateral approach (88 months FUP) and the reversion to fusion resolved the patient's symptoms.

The study documented 4 adverse events unrelated to the XL-TDR spine level. At 12 months of FUP, 1 patient developed persistent stenosis at the interbody fusion level (below the XL-TDR) and needed direct posterior decompression. One patient developed untreatable pain in the sacroiliac joint and was treated with minimally invasive sacroiliac joint fusion at 63 months FUP. Two patients (4%) presented with ALDis and received spine fusion at 24 and 96 months FUP. Figure 5 presents data on 1 patient. The level above the double-level TDR was healthy before surgery (Figure 5A). At 8 years FUP, it had clearly degenerated (Figure 5C and D) and become symptomatic. The patient underwent lateral interbody fusion, resulting in relief of the symptoms and successful bone fusion (Figure 5E and F).

Radiologic Results

Figure 6 shows the results of HO at the last FUP. Forty-five patients underwent radiography and/or computed tomography to evaluate bone bridging at the operated level. The most prevalent HO presentation was grade II (31%; 14 patients), in which HO was present between the planes formed by the vertebral end plates but yet allowed spinal motion. Also, there was a total absence of osteophytes in 9% (grade 0; 4 patients); small osteophytes that do not appear in the disk space in 22% (grade I; 10 patients); osteophytes in the disk space that limited motion in 20% (grade III; 9 patients); and inadvertent arthrodesis caused by ankyloses around the artificial disc in 18% (grade IV; 8 patients). Radiographic evaluations showed that 82% of the implanted prostheses maintained motion (HO grades 0–III) at the last FUP. Different HO grades had no direct influence on clinical outcomes reported by the patients (VAS and ODI, $P > 0.05$).

In all patients (100%) presenting with HO, the ossification appeared in the lateral part of the disc. In addition to the lateral osteophytes, 7% presented with anterior ossification, and in 5%, a posterior ossification was also seen. Only 3% of the discs presented with bone growth in the ipsilateral side of surgical approach, whereas 33% showed bilateral HO and 64% had HO only in the contralateral side. Therefore, HO at the contralateral side appeared in 97% of the patients with HO. Bridging bone grew up mostly from the end plate portions not covered by the TDR, as shown in Figure 7.

During FUP, in 4 patients (10%), the lumbar coronal curve had increased (iatrogenic scoliosis). No disc created a kyphotic segment. Six TDRs (13%) had developed minor subsidence into adjacent vertebral end plates, and no vertebral fracture occurred. Up to the final FUP, 5 patients (10%) had progressed with

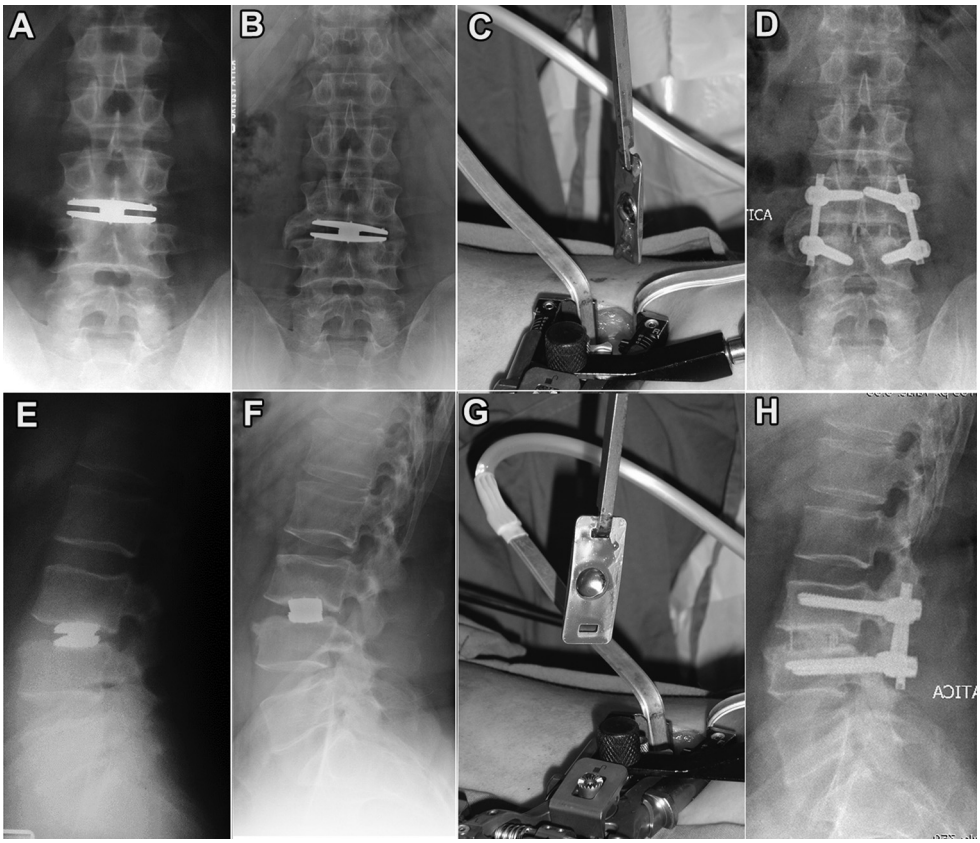

Figure 4. Retrieval example of an undersized artificial disc that developed mechanical back pain: (**A**, **E**) radiographs at 6 weeks follow-up; (**B**, **F**) radiographs at 5 years follow-up; (**C**, **G**) intraoperative disc removal; (**D**, **H**) postrevision images.

degeneration at the adjacent level (ALDeg) and 2 (4%) developed ALDis with further surgical intervention (at 24 and 96 months).

No disc completely migrated from the disc space, although 1 disc (2%) had partly migrated in the direction of the canal. Figure 8 shows the part-migration case: female, 60 years old, low back and irradiated pain to left limb, magnetic resonance imaging showed L4-L5 DDD with disc protrusion and facets with effusion. A surgical procedure was carried out without adverse events, and the patient experienced relief of all symptoms soon after surgery. Six weeks flexion/extension films showed increased motion at L4-L5 (Figure 8A). The patient remained asymptomatic throughout 2 years FUP; however, facet pain appeared along with disc

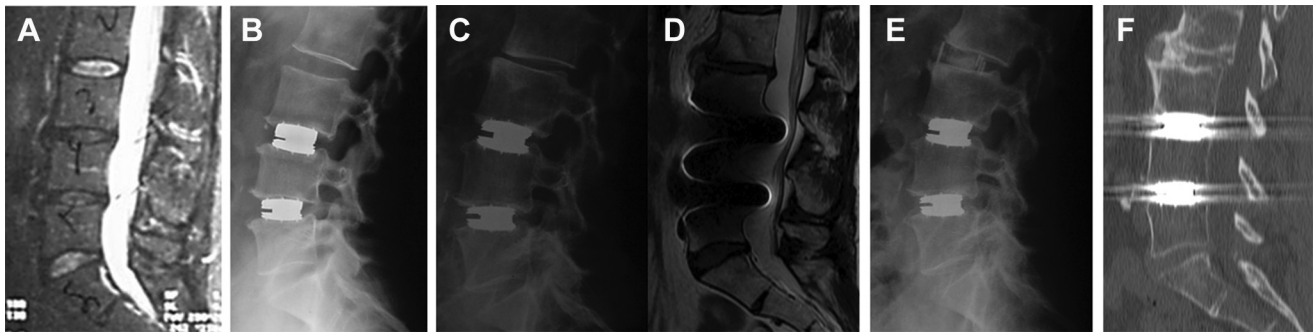

Figure 5. Illustrative case of adjacent level degeneration and adjacent level disease that required fusion above the total disc replacement construction. (**A**) Preoperative magnetic resonance imaging with healthy L2-L3 intervertebral disc. (**B**) 6-week radiograph with 2-level total disc replacement. (**C**, **D**) 8-year follow-up images showing evident adjacent level degeneration at L2-L3. (**E**, **F**) 3-year examinations after L2-L3 fusion.

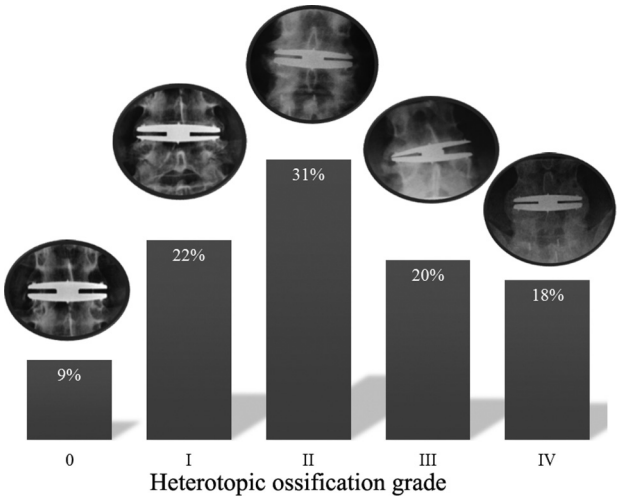

Figure 6. Incidence of heterotopic ossification per McAfee classification (grade 0–IV) and case examples of each grade.

hypermobility. The facet infiltrated at 2 and 2.5 years FUP. Conservative care with exercises was successful; however, imaging examinations showed progressive dislocation of the disc (**Figure 8C** and **D**). After consulting with one of the doctors from our service, the patient presented with pain on inclination and rotation test of the left side, but the neurologic function was preserved. The patient refused to receive revision surgery.

DISCUSSION

The biggest series using the XL-TDR device is found in a study reported in 2015 from a multicenter U.S. Investigational Device Exemption (IDE) clinical trial, with 64 patients and up to 3 years FUP.[12] The present study is the longest FUP with a laterally placed lumbar TDR, with 51 patients. Following previous early and mid-term reports,[13,14] in this long-term analysis, sustained clinical outcomes and a low rate of iatrogenic adverse events were found. From a radiologic perspective, the main finding was a high rate of natural HO formation with no clinical impact.

Historically, prostheses have been implanted by an anterior approach with the need for anterior longitudinal ligament removal. The insertion of a TDR by a lateral approach may bring the benefit of maintenance of the anterior longitudinal ligament, as suggested by other investigators.[15] Biomechanical tests with the lateral TDR show a controlled motion with decreased range of motion (ROM) in all directions, with the neutral zone closer to intact in all directions.[16] Clinical results[12-14] have shown that the prosthesis maintained a similar motion compared with the pre-operative ROM.

It is intuitive to infer that the ROM of either an intact disc or an artificial disc will decrease during life. Wuertinger et al.[17] observed that 62.7% of the implanted discs at L5-S1 presented with $<5^\circ$ of ROM at a minimum 5 years FUP. These investigators found that the results of early FUP were similar to those preoperatively but there was a further reduction in ROM at the mid-term and final visits. It is still debatable if the decrease of motion would produce the worst clinical outcomes. The study by Wuertinger et al.[17] showed that reduction in ROM does not negatively correlate with the patient's clinical signs and symptoms, but other investigators have found the opposite.[18]

One of the causes of reduced ROM in spinal arthroplasty seems to be the bone formation around the prosthesis, or so called, heterotopic bone (HO) formation. From short-term to long-term FUP, the incidence of bone formation around the disc increases. HO is multifactorial, with different factors that may affect the incidence and characteristics: time after surgery, surgical technique, end plate work, prosthesis model, patient factors, and others. Reports of SB Charité (DePuy Spine, Raynham, Massachusetts, USA) disk replacement show HO formation from 6% to 15% with short-term FUP (2 years)[10,19,20] and up to 71% with 11-year FUP.[21] After 11 years of TDR, Lu et al.[21] reported 8.6% of spontaneous fusion (patients graded as HO class IV in our work). Of patients, 20% presented with an ROM of $<2^\circ$, and the other 28 discs had a mean ROM of 5.4°. In the 11-year Charité study by Lu et al.,[21] decreased ROM was related to the more advanced HO formations. Another study[22] included both ProDisc and Charité with an average 104 months FUP and showed that HO decreased ROM but was not related to worst clinical outcomes. A controversial study by Putzier et al.[23] showed a 60% rate of spontaneous ankylosis after 17 years with the Charité TDR.

In contrast to previous studies that used anterior-placed TDR and reported the occurrence of anterior or posterior HO,[24] this study used a TDR placed by a transpsoas approach. The lateral technique postulates the end plate work from the ipsilateral to the contralateral side of the disc space. Using the lateral approach, most HO occurrences appear lateral to the artificial disc. It seems that discectomy and end plate cleaning are sufficient to allow some bone growth, and surgeons should control end plate bleeding to prevent future HO.[12]

A recent study by Malham and Parker[7] analyzed 12 patients treated with the same lateral TDR as that used in our study, and any patient with HO was reported up to 48 months of FUP (average; 27.5 months; minimum, 18 months). In the XL-TDR IDE trial, Marchi et al.[13] reported 3 patients (10%) with HO interfering with segmental motion (grade II or III) at 3 years FUP. In the 36-month FUP analysis of patients, contralateral bone formation had already been reported (13.9%). In our study, we report 96% of the HO occurrences in the contralateral side (36% bilateral and 61% in 1 side only). In the lateral approach, 1 potential facilitator of HO is related to the surgical technique itself. The first step of the discectomy is a rectangular cut in the ipsilateral annulus, followed by complete removal of the structure along with the nucleus pulposus. On the other hand, the contralateral annulus is removed, once it is detached from one of the adjacent vertebral body, with a portion remaining attached to the other vertebra. The contralateral annulus tissue may act as a scaffold for bone bridging. Other factors that may facilitate the occurrence of HO are undersizing the prosthesis and/or leaving lateral extremities of the plateaus not covered by the prosthesis.

In short-term FUP, the HO formation is not advanced and may not play a role in diminishing ROM, as shown previously.[10] However, the clinical impact of advanced HO has not been

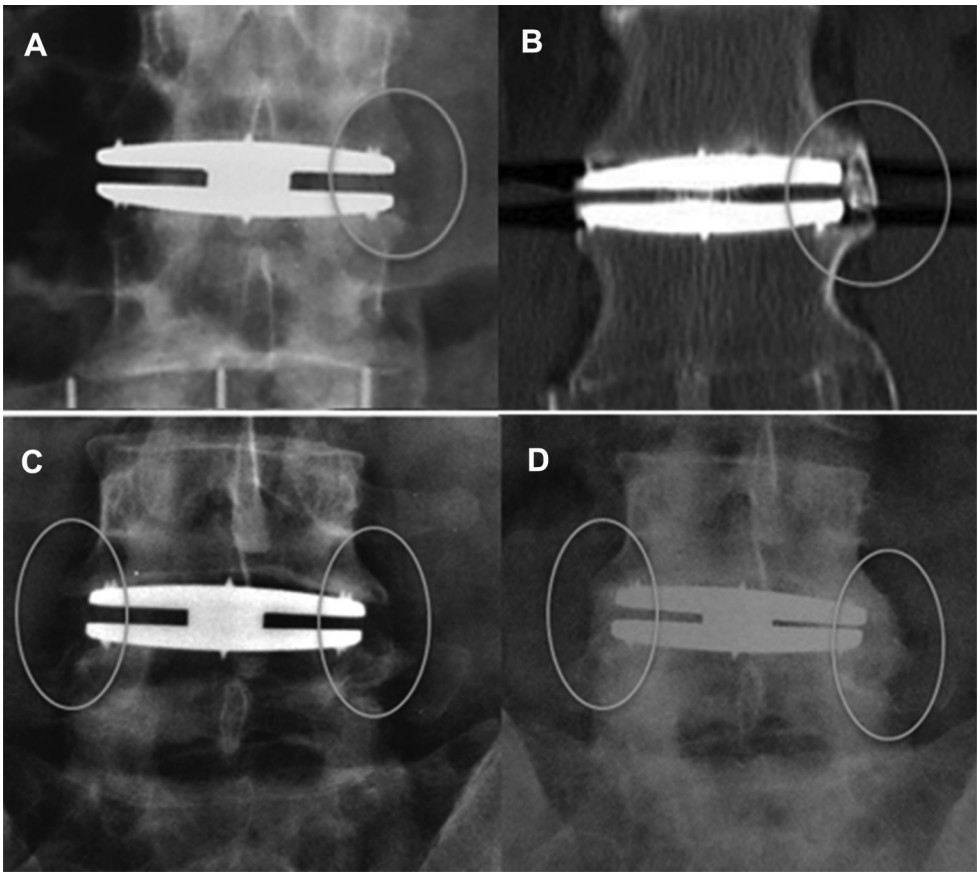

Figure 7. Bridging bone emerged from lateral portion of the end plate not covered by the artificial disc. Case example 1 (*top*): (**A**) 6 weeks and (**B**) 7 years follow-up. Case example 2 (*bottom*): (**C**) 6 weeks and (**D**) 2 years follow-up. Circles highlight free end plate regions and the resulting heterotopic ossification in follow-up images.

established. As in other lumbar TDR studies,[21,24,25] in our series, there was no significant difference in clinical outcomes between the patients regarding HO. As reported by other investigators,[10] a successfully functioning lumbar artificial disc replacement is shown in conjunction with periarticular ossification, which may be merely an incidental radiographic finding. In cervical spine as well, it has been reported that functional improvement is maintained despite the presence of HO after TDR.[26-28]

One of the theoretic objectives of TDR is to prevent or diminish the occurrence of ALDeg. Although many studies report only operative ALDeg (ALDis), we evaluated both purely radiologic progression of degeneration (ALDeg) and degeneration that required surgery (ALDis). Zigler et al.[29] analyzed ALDeg and ALDis in a 5-year FUP comparative study between TDR (ProDisc-L [DePuy Spine, Raynham, Massachusetts, USA]) and 360° fusion with 236 patients. Progression of DDD (ALDeg) at 5 years was observed in 9.2% of patients with TDR and 28.6% of patients with fusion. ALDis was required for 1.9% of patients with TDR and 4.0% of patients with fusion. ALDeg is multifactorial but it is increasingly accepted that damage to the posterior ligamentous complex and sagittal imbalances are important risk factors for ALDeg and ASDis.[30] Rates of ALDis from long-term reports show similar results: 2.2% in an analysis with 5—10 years FUP after ProDisc II (Synthes, Paoli, Pennsylvania, USA)[31] and 2.9% in an 11-year study with Charité. Fusion plus the presence of abnormal end-fusion alignment (usually kyphosis) seems to be a major factor in creating end-fusion stresses that result in ASDeg and ASDis.[30]

The primary aim of TDR was motion preservation, but it has been found that the artificial disc can adjust and gain lordosis at the index segment.[17,32] As has been suggested, the TDR may permit a postoperative shift of the segment into a point of equilibrium, around which some motion may suffice to adjust during activities of daily living. More importantly, the alignment of the segment may play a role in preventing ALDeg once this gain of lordosis accompanies a compensatory reduction of lordosis at the cranially adjacent segment.[17,33] In addition, other investigators[34] found that progression of degeneration correlated not with ROM values but with the onset of coronal tilt of the artificial cervical disc. One hypothesis deriving from those findings may be that reduced ALDis seen in TDR may come partly result from reduction of adjacent ROM and partly from natural spinal alignment.

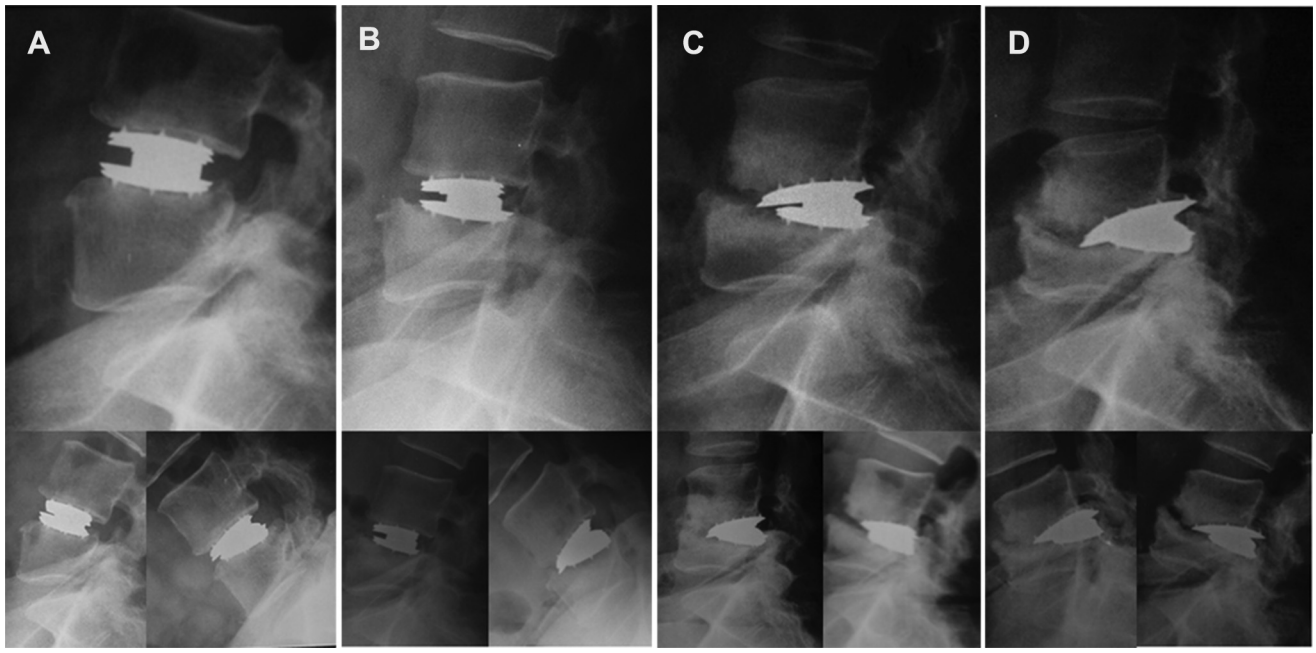

Figure 8. Radiographic images from the patient with disc displacement. (**A**) 6-week radiograph with proper disc positioning; (**B**) 2-year image that shows inferior end plate remodeling; (**C**) 5-year image with evident posterior displacement; (**D**) 10-year radiograph showing displacement.

Revision rates vary from 5% to 33% in long-term lumbar anterior-placed TDR studies.[21,31,35-37] Most failed revision cases in our study were not caused by a prosthesis mechanical error but mainly by clinical symptoms that did not improve after surgery, such as mechanical back pain. In addition, we noted 1 case (2%) of delayed partial device migration. In the IDE trial using the same disc model, no device migrations were noted among the 64 patients up to 3 years FUP. In Malham and Parker's study,[7] 2 in 12 patients (17%) had early prosthesis dislocation as a result of prosthesis undersizing. These patients were revisited from the same lateral incision for prosthesis removal and received interbody fusion. The lateral approach has been used as a salvage procedure for either lateral[14,38,39] or anterior-placed[39-41] implants.

Some limitations should be pointed out: 1) this case series was a (noncomparative) single-center study; 2) there was a limited number of patients, but with low missed FUP rate; 3) we could not access the progression of DDD at adjacent segments more properly (e.g., with the Pfirrmann classification) because magnetic resonance imaging is not the standard of care to follow up these patients; and 4) ROM was not accessed at the final FUP because radiographic examinations were not performed in a single imaging center, so we did not have an orthogonal view to access the angular difference between flexion and extension films.

CONCLUSIONS

The XL-TDR prosthesis allowed for fast mobilization, sustained pain relief, and improved physical function with a low rate of ALDis (4%) and 5 (9%) cases of retrieval of the prosthesis, showing that lateral TDR was effective and feasible for treating mild DDD.

Although 91% of the levels presented some grade of HO, it was not correlated with poorer clinical outcomes. More studies are needed to identify the reasons why HO occurred at the contralateral side of the surgical access in 97% of patients.

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Conflict of interest statement: The authors declare that the article content was composed in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Received 13 August 2018; accepted 4 October 2018

Citation: World Neurosurg. (2019) 122:e325-e333.
https://doi.org/10.1016/j.wneu.2018.10.033

Journal homepage: ***www.journals.elsevier.com/world-neurosurgery***

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1878-8750/$ - see front matter