

Clinical Study

Five-year follow-up of clinical and radiological outcomes of LP-ESP elastomeric lumbar total disc replacement in active patients

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Received 13 March 2018; revised 14 May 2018; accepted 17 May 2018

Abstract

BACKGROUND CONTEXT: The surgical treatment of degenerative disc disease at the lumbar spine may involve fusion. Total disc replacement (TDR) is an alternative treatment to avoid fusion-related adverse events, specifically adjacent segment disease. New generation of elastomeric non-articulating devices has been developed to more effectively replicate the shock absorption and flexural stiffness of native disc.

PURPOSE: To report 5 years clinical and radiographic outcomes, range of motion (ROM), and position of the center of rotation after a viscoelastic lumbar TDR.

STUDY DESIGN: Prospective observational cohort study

PATIENT SAMPLE: Sixty-one patients

OUTCOME MEASURES: The clinical evaluation was based on visual analog scale (VAS) for pain, Oswestry disability index (ODI) score, short form-36 (SF-36) including the physical component summary (PCS) and the mental component summary (MCS), and general health questionnaire-28 (GHQ28). The radiological outcomes were ROM and position of the center of rotation at the index and the adjacent levels and the adjacent disc height changes.

METHODS: Our study group included 61 consecutive patients with monosegmental disc replacement. We selected patients who could provide a global lumbar spine mobility analysis (intermediate functional activity according to the Baecke score). Hybrid constructs had been excluded. Only the cases with complete clinical and radiological follow-up at 3, 6, 12, 24, and 60 months were included.

RESULTS: There was a significant improvement in VAS (3.3 ± 2.5 vs. 6.6 ± 1.7 , $p < .001$), in ODI (20 ± 17.9 vs. 51.2 ± 14.6 , $p < .001$), GHQ28 (52.6 ± 15.5 vs. 64.2 ± 15.6 , $p < .001$), SF-36 PCS (58.8 ± 4.8 vs. 32.4 ± 3.4 , $p < .001$), and SF-36 MCS (60.7 ± 6 vs. 42.3 ± 3.4 , $p < .001$). The mean location centers of the index level and adjacent discs were comparable to those previously published in asymptomatic patients. According to the definition of Zigler and Delamarter, all of our cases remained grade 0 for adjacent level disc height (within 25% of normal).

CONCLUSIONS: This series reports significant improvement in midterm follow-up after TDR, which is consistent with previously published studies but with a lower rate of revision surgery and no adjacent level disease pathologies. The radiographic assessment of the patients demonstrated the quality of functional reconstruction of the lumbar spine after LP-ESP viscoelastic disc replacement. © 2018 Published by Elsevier Inc.

Keywords:

Five years' follow-up; Back pain; Lumbar spine; Mean center of rotation; Total disc replacement; Viscoelastic disc replacement

FDA device/drug status: Not applicable.

Author disclosures: **J-YL:** Nothing to disclose. **J-PR:** Nothing to disclose. **M-AR:** Nothing to disclose.

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Introduction

Total disc replacement (TDR) is intended to restore normal spinal movement while also preventing adjacent level disc degeneration and facet joint deterioration, which may be associated with the kinematic and biomechanical changes produced by fusion. There are significant evidence-based scientific data to support the safety and efficacy of single-level lumbar TDR for patients meeting well-established selection criteria [1–5].

Although all artificial discs are intended to achieve the same ends, there is considerable heterogeneity in design. Uni- and biarticulated designs rely on bearing surfaces but do not replicate the elasticity and the rotation and translation control of the native disc. New generation of elastomeric non-articulating devices has been developed to more effectively mimic the shock absorption and flexural stiffness of a native disc [6]. The LP-ESP (GROUP FH ORTHO, Heimsbrunn, France) is a one-piece deformable but cohesive interbody spacer (Fig. 1). The first LP-ESP was implanted in 2004 for a clinical investigation and became available for all surgeons in 2006. The properties of this viscoelastic implant include providing six degrees of freedom, no fixed center of rotation, and a silent block function, which have been previously published [7,8]. One important characteristic of LP-ESP is the bumping effect and the elastic return of translation and rotation. To date, more than 3,000 implantations have been performed worldwide.

The aim of this study was to report clinical and radiological results at 5 years follow-up. The analysis, in accordance with the ethical standards of our institutions, is focused not only on clinical results but also on the range of motion (ROM) and mean center of rotation (MCR) of the implanted level as well as adjacent segments.

The main research questions were as follows:

- * Does LP-ESP provide consistent improvement of pain and function in patients with chronic low back pain?

- * Does LP-ESP maintain or restore motion to the index level of surgery quantitatively and qualitatively?
- * Does LP-ESP maintain or restore motion to the adjacent segments of the lumbar spine?

Materials and methods

We obtained approval from our institutional review board. All patients who were in this study provided written informed consent after having received verbal and written information.

Population

We analyzed a group of 142 patients who underwent TDR with 5 years follow-up. We excluded hybrid constructs and two level surgeries and we selected only those monosegmental disc replacement cases. Sixty-one patients were eligible with strict exclusion criteria (no missed follow-up visits, no missing films, and no poor exposure quality films so that radiological measurements are optimal and reliable). In all these cases, we had a perfect dataset with dynamic lateral radiographs to assess the mobility and rotation centers at the disc replacement and adjacent levels.

The indication for TDR was the conjunction of persistent back pain and monosegmental disc disease on the magnetic resonance imaging (showing “black disc,” annulus rupture, or Modic changes). As for our current practice, exclusion criteria for surgery included age older than 60 years, neurological deficit, stenosis, spondylolisthesis, and facet arthropathy. All patients had an intermediate functional activity according to the Baecke score [9]. According to the standard of care in our institutions and the applicable regulations of our health authorities, the surgical indication for disc replacement was based on a pluridisciplinary analysis of each case.

The surgeries were performed between July 2007 and December 2010. The data were analyzed by an independent observer who was not involved in patient selection, surgical



Fig. 1. LP-ESP viscoelastic prosthesis.

procedures, or follow-up process. The time points were 3, 6, 12, 24, and 60 months.

Clinical analysis

We used visual analog scale (VAS) (scored from 0 to 100) [10], the Oswestry disability index (ODI), and short form-36 questionnaire (SF-36, both physical and mental scores) [11] and general health questionnaire-28 (GHQ28). Additionally, the patients were asked if they considered the results satisfactory or not. We considered the surgery successful if there was no revision or reoperation surgery.

Radiological analysis

Radiographs of the lumbar spine were prospectively collected for the study before surgery and at each time point. The radiographs were analyzed with SpineView software (Surgiview Corporation, Paris, France) for assessing the ROM in flexion extension and the location of the MCR. The MCR is localized using its coordinates as described by Tournier et al. [12]: X is expressed as a percentage of the length of the vertebral end plate and Y as a percentage of the height of the posterior wall. The reference location of the MCR is in a circle, whose center is placed between 30% and 50% of the superior vertebral end plate, and whose diameter is 70% of the vertebral end plate size. The lordosis in the disc and the L1S1 lumbar lordosis were measured on the lateral view at every time point.

We studied the adjacent levels according to the classification for disc height alteration by Zigler and Delamarter: grade 0 (within 25% of normal height); grade 1 (mild,

25%–50% of normal height); grade 2 (moderate, 50%–75% of normal height); and grade 3 (severe, more than 75% of normal height). We looked at the occurrence of local ossifications or spondylolisthesis.

Statistical analysis

Data were analyzed using SPSS 16.0 (SPSS Inc, Chicago, IL, USA) with p value set at .05. The comparative tests were carried out using the matched Student *t* test for quantitative clinical parameters and the Mann-Whitney non-parametric test for qualitative data (ODI, VAS, SF-36, and GHQ28).

Results

Clinical results

There were 24 male and 37 female patients. The mean age at the time of surgery was 42.8 ± 7.7 years old (range: 27–60). The mean body mass index at the time of surgery was 24.2 ± 3.4 kg/m² (range: 18–33). The surgical level was L5S1 in 39 cases and L4L5 in 22 cases.

The results of the questionnaires (VAS, ODI, GHQ28, SF-36) are reported in Table 1. For the entire cohort, there was a statistically significant improvement in all outcome scores. The mean VAS decrease was 3.3 points (average improvement of 50% at 60 months follow-up). For the ODI, 82% of the patients had an improvement of more than 15% and 75% of patients had more than 25% improvement. The average decrease of the GHQ28 score was 11.6 points. The SF-36 improvement was 26.4% for the physical score and 18.4% for the mental score.

Table 1
Clinical scores

Global results						
Mean±SD	PREOP	3 M	6 M	12 M	24 M	60 M
N	120	120	120	120	117	61
VAS score	6.6±1.7	3.7±1.9	3.4±2.1	3.5±2.3	3.4±2.4	3.3±2.5
ODI	51.2±14.6	30.3±17.6	24.5±17.6	21.8±16.3	20.6±17.3	20±17.9
GHQ28 score	64.2±15.6	52.5±14.7	52.7±15.8	52.2±15.4	50.6±15.4	52.6±15.5
SF-36 PCS score	32.4±3.4	48.4±3.9	51.9±3.9	55.6±3.9	59±3.9	58.8±4.8
SF-36 MCS score	42.3±3.4	50.8±3.4	52.8±3.5	53±3.6	58.7±3.5	60.7±6.6
Percentage of ODI improvement						
		3 M	6 M	12 M	24 M	60 M
ODI 15% improvement/preoperative		72	82	85	85	82
ODI 25% improvement/preoperative		59	75	82	83	75
Patients satisfaction						
(%)		3 M	6 M	12 M	24 M	60 M
No benefit		1	1	2	2	0
Non-satisfactory		4	5	7	5	5
Satisfactory		61	45	43	40	42
Excellent		34	49	48	53	53

M, months; SD, standard deviation; VAS, visual analog scale; ODI, Oswestry disability index; GHQ28, general health questionnaire-28; SF-36, short form-36; PCS, physical component summary; MCS, mental component summary.

Table 2
Follow-up 1, 2, and 5 years: ROM at the implanted and adjacent levels

	Follow up (y)	L5S1 TDR			L4L5 TDR		
		L5S1	L4L5	L3L4	L5S1	L4L5	L3L4
ROM ° mean (SD)	1	5.9 (4)	8.7 (5.8)	9.4 (4.9)	6.7 (4.3)	5.8 (3.9)	10.5 (4.7)
	2	6.4 (3.3)	6.2 (5.8)	8.6 (5.7)	7.4 (5.2)	7.8 (4.3)	8.3 (5.3)
	5	7.2 (3.3)	8.5 (4.8)	8.5 (4.6)	8.8 (5.1)	7.3 (4)	8.2 (4.5)

ROM, range of motion; SD, standard deviation; TDR, total disc replacement.

Additional surgeries were performed in five cases. In three cases, the additional procedures were initially planned in the surgical program: one case had adjacent L3L5 posterior pedicular dynamic stabilization system above an L5S1 TDR and two L5S1 TDR cases had additional laminectomies (L2L3 and L5S1). In two cases, the additional procedure was a secondary revision procedure for fusion (both L4L5 cases). One was decided because of a progressive subsidence of the implant in the L4 inferior end plate after 3 years. The other case was considered as a clinical non-success of the TDR: a secondary posterior fusion was decided but this procedure did not bring any significant improvement.

In the 56 remaining patients, none experienced facet joint pain. One patient with sacroiliac pain needed local injections.

Radiological results

Fifty-six cases (36 L5S1 and 20 L4L5 TDR) were radiologically studied (exclusion of the three cases with additional surgeries and the two posterior fusion cases).

The average ROM at the LP-ESP level was 5.9±4.0° at 1 year, 7.0±3.8° at 2 years, and 7.3±3.5° at 5 years. Detailed results are reported in Table 2. The global mobility of the lumbar spine and the segmental mobility (TDR and adjacent levels) at each time point are presented in Fig. 2 in the

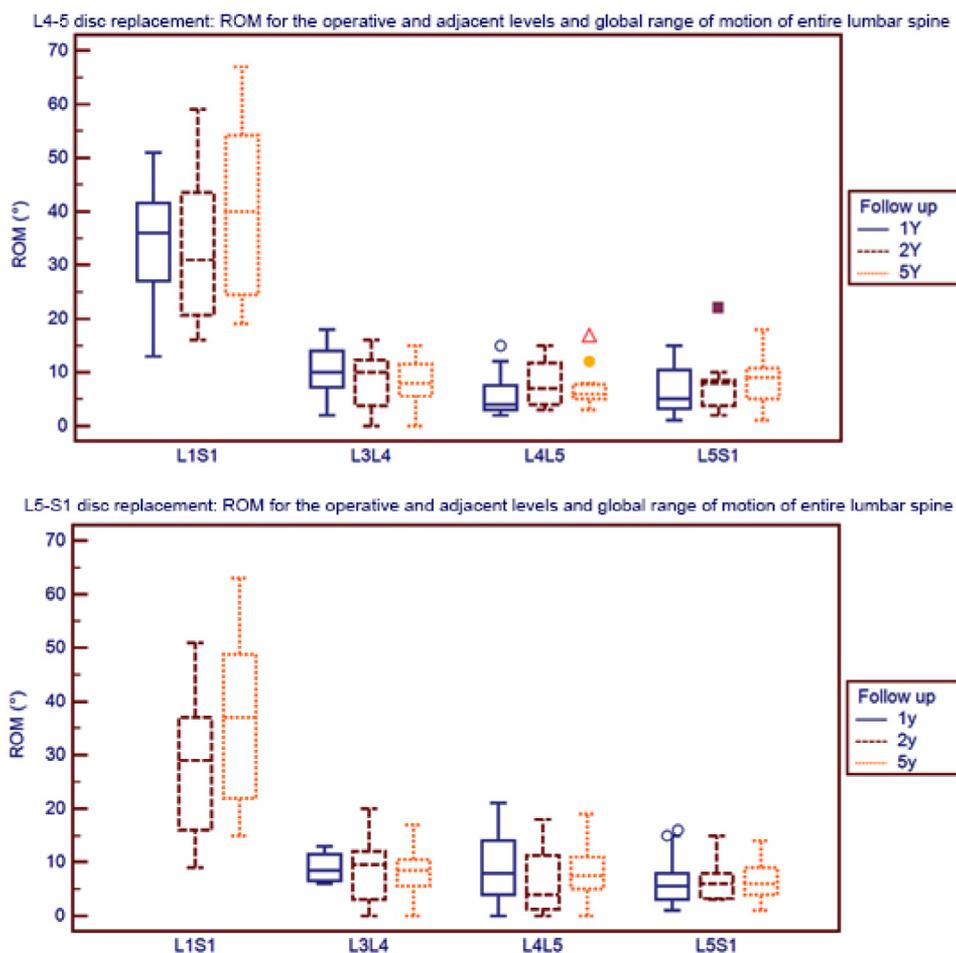


Fig. 2. Mobility of each level and the whole lumbar spine in cases with L4L5 and L5S1 LP-ESP implants.

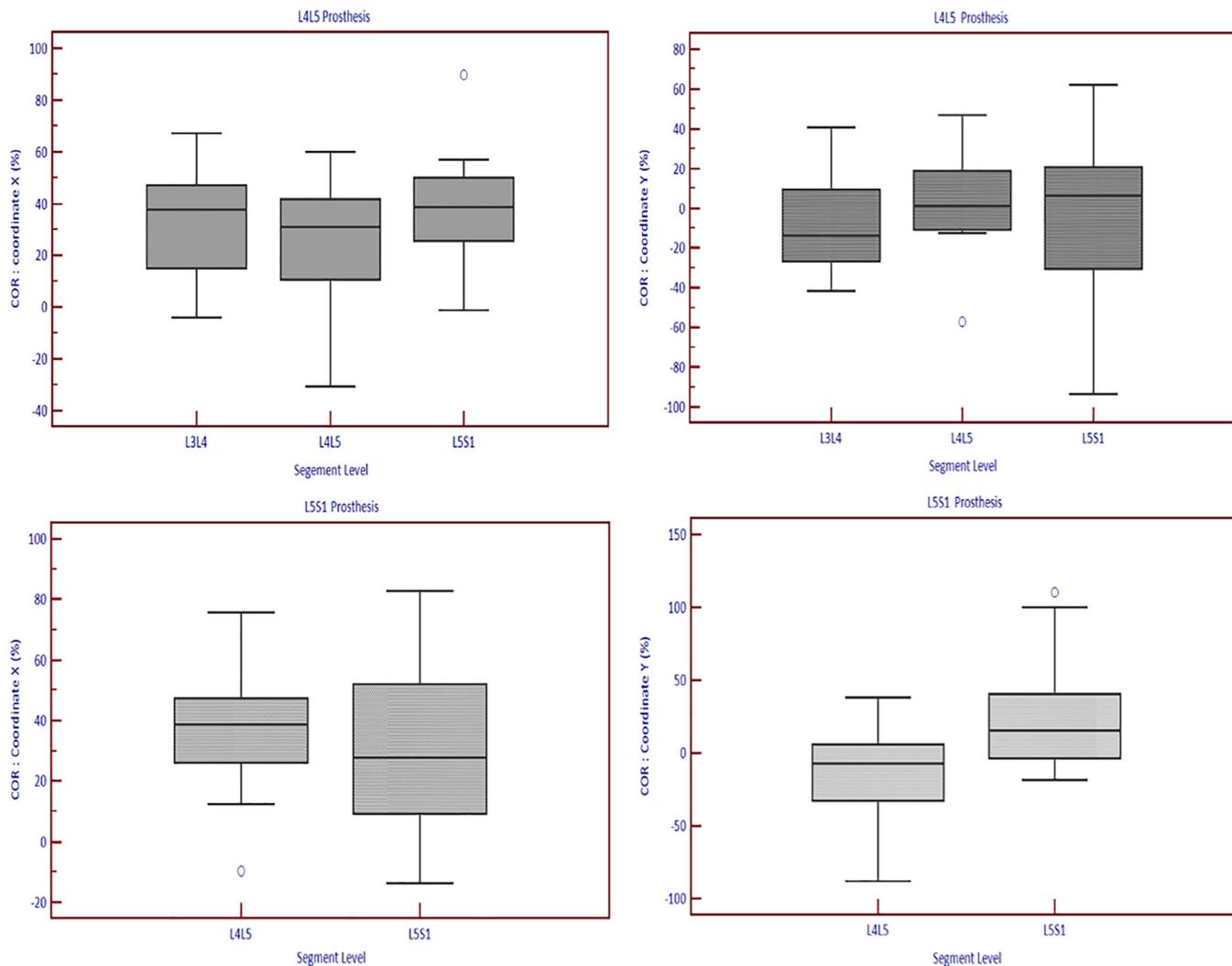


Fig. 3. X and Y coordinates of the mean center of rotation (MCR) at the implanted and the adjacent levels. (Origin=upper posterior angle of the lower vertebral body; Unit=length of the upper end plate of the lower vertebral body for X, height of the posterior wall of the lower vertebral body for Y).

case of L4L5 and L5S1 separately. The LP-ESP mobility for the 56 cases was significantly correlated with the global L1–S1 ROM ($p < .001$ Pearson coefficient 0.67). The same result was observed when considering only the L5S1 TDR group ($p < .001$ Pearson coefficient 0.71) or the L4L5 cases ($p < .001$ Pearson coefficient 0.65).

The location of the MCR at 5 years is reported in Fig. 3 for L4L5 and L5S1 cases. In all cases, the MCR was located in the zone described by Tournier et al.

The lordosis in the intervertebral space at the index level and the whole lumbar lordosis (L1S1) are reported on Table 3.

We did not observe local ossifications nor osteolysis on the standard x-rays. All patients remained grade 0 for disc height at adjacent levels according the classification of Zigler and Delamarter.

Discussion

This study aims at assessing the midterm clinical outcomes after TDR with LP-ESP focusing on mobility and MCR of disc replacement implant and adjacent levels as well as the mobility of whole lumbar spine. Clinical results are

Table 3
Follow-up 1, 2, and 5 years: lordosis in the disc (DL) and L1S1 lumbar lordosis (LL)

	Preoperative	Postoperative	3 M	6 M	12 M	24 M	60 M
LL	55.8±10	55.2±12.6	58.5±12.5	59.2±11.3	59.4±13.5	58.3±13.1	57.7±10
DL	7.3±4.8	2.6±2.9	3.5±2.6	3.8±2.8	5.0±4.5	3.9±3.8	3.5±2.4

Table 4
Revision surgery rates after TDR and reported history in the literature*

	Secondary surgeries at index level	Secondary surgery at another lumbar level	ROM at index level
Zigler and Delamarter [13]	Prodisc-L 8% (13 cases) including 6 posterior fixations for pain 2 additional postdecompression	0%	7.2±4.1°
Park et al. [14]	Prodisc-L0	NA	NA
Guyer et al. [15]	Kineflex-L 11.8% (24 cases) Device removal 2 (1.0%) (lymphocytic reaction) Device replacement 1 (0.5%) Device revision 1 (0.5%) Supplemental fixation 8 (3.9%) Posterior decompression 12 (5.9%) Charité 11.6% (22 cases) Device removal 6 (3.2%) Device 1 (0.5%) Supplemental fixation 10 (5.3%) Postdecompression 5 (2.6%)	NA	>4° in 70.6%
Guyer et al. [16]	Charité 7 cases (7.7%) 6 posterior fixations, 1 posterior decompression	0	Approximately 6° using the 5° cutoff point to determine motion: 17 (18.9%) cases showed lack of motion Using the 3° cutoff point to determine motion: 14 (15.5%) cases showed lack of motion
Skold et al. [17]	Charité, Prodisc, Maverick 9 (11.25%)	7 (8.75)	NA
The current series	2 posterior fusions (3.2%) (L4L5 levels)	0	6.8±3.7°

TDR, total disc replacement; ROM, range of motion; NA, not available.

* Clinical success (Food and Drug Administration definition) was considered to have been achieved when all four of the following criteria were met:

- 1: either 15 or more points improvement in ODI.
- 2: no device failure.
- 3: no major complication.
- 4: no neurological change.

consistent with other published series. The level of activity of the patients cannot compare with the data in the other series [13–17]. We observed a low level of adverse events and specifically no facet joints problems.

Several short-term and midterm studies on TDR have reported statistically significant improvement in clinical outcomes [8,18–20]. The facet joint pain was not well investigated previously in TDR studies. Van de Kelft and Verguts reported that 16% of patients developed facet joints pain requiring non-steroidal anti-inflammatory drugs or local injection and radiofrequency facet denervation with ball-and-socket prosthesis [21]. Zigler and Delamarter reported 119 patients with an average follow-up of 53.4 months. The incidence of adjacent level disease was 9.2%. Progression of facet joint pain was observed in 20.0% of the patients [13]. We did not find in the current study any adjacent level disease in any of our patients at 5 years follow-up. Based on our observation, our hypothesis is that the viscoelastic nature of LP-ESP without constraining the centers of rotation can provide more protection of the facet joints and adjacent levels. This hypothesis must be confirmed with longer term analysis.

The number of revision surgeries in our study is lower than previously reported series (see Table 4). We hypothesize that the monoblock design of the LP-ESP implant avoids segmental

instability and subsequent revision. In addition, the elasticity of the implant may prevent progressive soft tissue stretching and delayed local instability. Also the viscoelastic characteristics of the implants seem forgiving at the time of implantation regarding its positioning. In our study, we did not found any bone ingrowth failure at the end plates.

The radiological analysis demonstrated that the ROM was comparable to other published series at the index level. The global ROM of the lumbar spine data were also consistent with previously published data regarding the physiological spine adjusted to the age [22]. The MCR analysis and the study of segmental and global mobility of the lumbar spine demonstrated a rather encouraging postoperative evolution. The MCR is less precise than the analysis with continuous or instantaneous basis, or at multiple points in the motion cycle. Nevertheless, this qualitative analysis is clinically accessible and allows comparisons with previously published paper about normal lumbar spine functional mobility [23,24]. The results for MCR location are consistent with data reported by Aiyangar et al. [23] for the normal lumbar spine. The lumbar lordosis remained stable overtime as if self-adjusted in spite of the local change induced by the prosthesis.

The silent block design of LP-ESP provides an interesting specificity as its conception induces a limitation of axial

rotation, which may contribute on itself to the protection of the facets joints at the operated level and probably help preventing adjacent level disease. It could be the key factor that makes the difference regarding rotational instability problems reported with other implants experimentally [25] or clinically [26]. The control and limitation of segmental lordosis and its evolutive adaptation (see Table 3) could be an additional protective factor for the facets. Unfortunately, no other comparative TDR series are available yet in the literature to provide 5 years follow-up for MCR and global mobility of the lumbar spine after monosegmental disc replacement.

Conclusion

This LP-ESP viscoelastic disc replacement series reports significant improvement in midterm clinical outcomes, consistent with previously published studies. We also observed a surprisingly low rate of revision surgery and no adjacent level disease or facet joints problems. The radiological study of segmental and global mobility and measurement of MCRs at the index and adjacent levels demonstrate the quality of functional reconstruction of the lumbar spine after LP-ESP viscoelastic disc replacement. These favorable radiological findings, the protection of facets, and the control of local rotation are relevant arguments keep interest on this generation of silent block implants.

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