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Radiological Results Five Years Following Lumbar Total Disc Replacement with a Controlled Mobile Core Prosthesis

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Abstract

Purpose: Total disc replacement must allow pain relief due to the resection of the painful disc, with preserving segmental mobility and function of the intervertebral joint. The aim of this study is to assess the efficacy and safety of a mobile-core lumbar prosthesis. This study reports both clinical (Part 1) and radiological (Part 2) assessments.

Method: Four hundred and eleven patients were included in a prospective and multicentric study with a 5-year follow-up. Radiological performance included mobility and lordosis of implanted segments. The occurrence of heterotopic ossification and the impact of the surgery on adjacent discs (motion and radiological signs of degeneration) were also explored.

Results: Restoration of segmental mobility (mean ROM=7.8 at 5 years), improvement and stabilization of lordosis as well as a reduced rate of heterotopic ossification were observed. Improvement of ROM in superior and inferior discs was observed but without hyper-mobility. Slight degeneration of superior and inferior discs was noted compared to preoperative status. The rate of reoperation on adjacent discs was low (3.2%).

Conclusion: This study showed satisfactory radiological results by restoring motion and preserving adjacent segments at 5 years' follow-up and confirmed the safety and efficacy of this lumbar total disc prosthesis with specific controlled-mobility core.

Keywords: Lumbar spine; Degenerative disc disease; Mobile prosthesis; Total disc replacement; Radiological efficacy

Introduction

While arthrodesis remains the standard treatment for degenerative disc disease (DDD), total disc replacement (TDR) is becoming a major competitor. The main limitations of lumbar arthrodesis are the failure to restore motion at the operated disc and, consequently, the impact on adjacent segment pathology. Indeed, the fusion of one or more segments will naturally encourage a shift in loads and strain onto adjacent segments, and there by modify, more or less, the mechanics of the entire spine in long-term [1]. TDR may, alternatively to the fusion technique, restore segmental motion and preserve the biomechanics of the spine [2,3]. The first generation of lumbar TDR has been used for over 30 years [4] and showed satisfactory results despite significant concerns regarding clinical outcomes such as facet overloading and adjacent segment disease. In order to respond to these concerns, a second generation of TDR devices is being developed with the intention of mimicking more closely the physiological conditions of a natural disc [5,6]. Many devices have been designed with the aim of motion preservation as a treatment of this debilitating disease [7]. Prostheses are now recognized for their clinical and radiological effectiveness [8-10]. The aim of our study is to assess both the efficacy and safety of lumbar disc prosthesis with controlled mobility in a prospective, multicentric trial at five years' follow-up. This study exhibits both a clinical (Part 1) and a radiological (Part 2) assessment.

Materials and Methods

Study

An observational prospective multicenter study of the efficacy and safety of the total disc replacement with Mobidisc® (LDR Médical, Troyes, France) in the treatment of lumbar degenerative disc disease was conducted at 8 French centers with 5 years' follow-up and an extension to 10 years (ongoing study). Prosthesis description, inclusion and exclusion criteria, statistical analysis, demographic, follow-up rate, clinical outcomes and complications are reported in Part 1 of this article.

Radiological outcomes

Radiological performance evaluations included mobility and lordosis of implanted segments, the occurrence of heterotopic ossification, and the impact on adjacent discs (motion, radiological signs of degeneration).

The mobility of index and adjacent discs (range of motion or ROM) was measured preoperatively and at each follow-up visit (6 weeks, 3, 6, 12, 24, 36 and 60 months) from lateral radiographic images in maximum Flexion/Extension. The percentage of implanted segments with improvement or deterioration of mobility at the last visit was determined. The curvature (lordosis) of the implanted segments was measured on radiographic images in standing neutral lateral positions preoperatively and at each follow up visit. Measurements for ROM and lordotic angles have been performed using Spine View software (SurgiView, version 2.4.2.5).

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Heterotopic ossifications (HO) of the implanted segments and on superior and inferior disc was analyzed by the same operator for all the patients and classified according to McAfee [11] classification based on radiographic images in neutral lateral position preoperatively and at 2, 3 and 5 years' follow-up. The classification has a 5-point grading system: grade 0=no HO; grade I=islands of bone in soft tissue, bone not present between planes formed by the endplates; grade II=bone present between the planes of the endplates, but not blocking motion; grade III=motion blocked by HO and/or postoperative osteophytes; grade IV=inadvertent bony ankyloses.

Degenerative changes of adjacent discs were also explored by the same operator according to the Lane classification [12] from radiographic images in neutral lateral position preoperatively and at 2, 3, and 5 years of follow-up. The classification has a 3-point grading system: grade 0=Normal joint space narrowing, no osteophytes anterior and posterior and no sclerosis; grade 1=mild joint space narrowing or small osteophytes anterior and posterior; grade 2=Moderate-severe joint space narrowing and/or moderate-severe osteophytes anterior and posterior. The evolution, for each adjacent disc compared to its preoperative baseline, is represented by the change (Δ) according to Lane classification as follows: Δ=0, grade unchanged; Δ=+1 or +2, grade increased by one or two points.

Lawrence terminology was followed [13] when talking of Adjacent Segment Pathology (ASP), with the separating of the Radiographical ASP (RASP) from the Clinical ASP (CASP) leading to surgery.

Results

A total of 411 consecutive patients were included in this study. Figure 1 illustrates a neutral and dynamic post-operative X-rays of L5-S1 prosthesis. Index level mobility (ROM) significantly increased after 3 months' post-operation and up to 5 years' follow-up (Figure 2). There

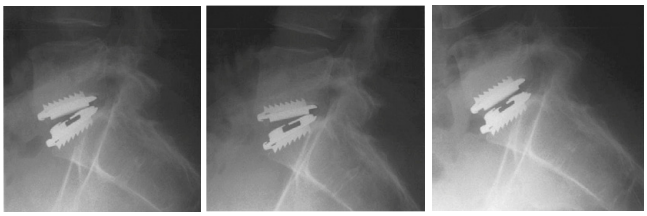

Figure 1: Illustrative example of a patient implanted at L5-S1 level. Neutral/extension/flexion lateral X-rays after 5 years FU.

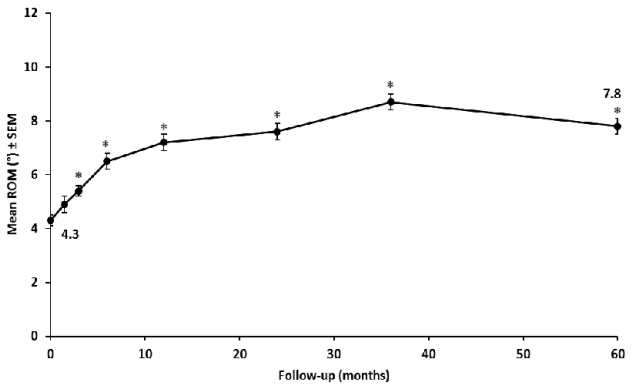

Figure 2: Motion at the index level, Range of Motion (ROM) ± SEM through follow-up: pre-operative, 6 weeks, 3, 6, 12, 24, 36 and 60 months. *Difference statistically significant compared to preoperative baseline, using Wilcoxon matched pairs Signed rank test.

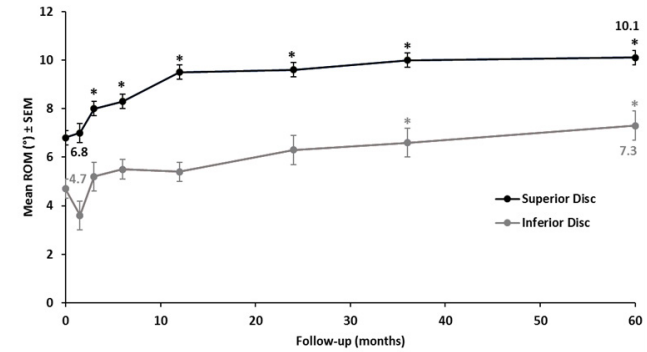

Figure 3: Range of Motion (ROM) at superior and inferior levels ± SEM through follow-up: pre-operative, 6 weeks, 3, 6, 12, 24, 36 and 60 months. *Difference statistically significant compared to preoperative baseline, using Wilcoxon matched pairs Signed rank test.

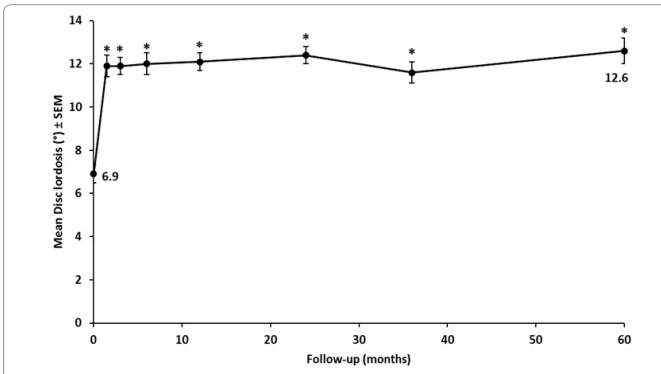

Figure 4: Disc lordosis at the index level ± SEM through follow-up: pre-operative, 6 weeks, 3, 6, 12, 24, 36 and 60 months. *Difference statistically significant compared to preoperative baseline, using Wilcoxon matched pairs Signed rank test.

was no significant change in ROM between 3 and 5 years. The amount of implanted segments with ROM >3°, which is commonly considered as mobile, increased from 50.4% (172/341) preoperatively to 76.2% (221/290) at 5 years post-operation. Furthermore, at 5-year follow-up, 73.5% (169/230) of the implanted segments had increased ROM and 26.5% (61/230) remained unchanged or had decreased ROM compared to the preoperative value.

Regarding adjacent levels, ROM also significantly increased in superior discs between 6 months and 5 years (Figure 3). Regarding inferior discs, ROM significantly increased at 3 and 5 years of follow-up. It is, however, noteworthy to mention that the number of inferior discs measured was limited as most surgeries concerned L5-S1 discs with no inferior disc.

As far as lordosis of the implanted discs is concerned, the angle significantly increased after implantation of the prosthesis from 6 weeks and up to 5 years (Figure 4). No loss of lordosis was noted over time.

HO in the operated segments increased gradually after prosthesis implantation (Table 1). This was limited, in extent, since HO at grade IV (equivalent to a fusion) only affected one operated segment after 5 years. In addition, occurrence of HO at 5 years of follow-up did not impact the mobility of the implanted segments as no loss of motion was observed in the long-term. Adjacent discs at the superior and inferior levels showed mostly light ossification (Table 1).

The degenerative status of adjacent levels was moderate after 5-year

	Preoperative			5 years		
Disc	**Implanted**	**Superior**	**Inferior**	**Implanted**	**Superior**	**Inferior**
Grade 0	205 (56.8%)	307 (87.5%)	89 (93.7%)	211 (70.6%)	187 (69.8%)	49 (92.5%)
Grade I	153 (42.4%)	44 (12.5%)	5 (5.3%)	21 (7.0%)	81 (30.2%)	3 (7.7%)
Grade II	3 (0.8%)	0	0	55 (18.4%)	0	1 (1.9%)
Grade III	0	0	0	11 (3.7%)	0	0
Grade IV	0	0	1 (1.1%)*	1 (0.3%)	0	0
* Not evaluated at 5 years due to instrumented fusion during the FU.						

Table 1: Heterotopic ossification (HO) at the index and adjacent levels (superior and inferior) according to McAfee classification. Numbers and percentages of analyzed discs were expressed preoperatively and at 5 years.

	Preoperative		5 years	
Disc	**Superior**	**Inferior**	**Superior**	**Inferior**
Grade 0	266 (74.5%)	50 (52.6%)	159 (59.3%)	32 (53.3%)
Grade 1	73 (20.4%)	18 (18.9%)	79 (29.5%)	12 (20.0%)
Grade 2	18 (5.0%)	27 (28.4%)	30 (11.2%)	16 (26.7%)

Table 2: Status of the adjacent levels (superior and inferior) according to Lane classification preoperatively and at 5 years.

	2 years		3 years		5 years	
Disc	**Superior**	**Inferior**	**Superior**	**Inferior**	**Superior**	**Inferior**
Δ=0	287 (97.0%)	56 (91.8%)	251 (90.6%)	53 (93.0%)	204 (77.6%)	52 (86.7%)
Δ=+1	9 (3.0%)	5 (8.2%)	25 (9.0%)	7 (7.0%)	54 (20.5%)	6 (10.0%)
Δ=+2	0	0	1 (0.4%)	0	5 (1.9%)	2 (3.3%)
Δ≥1	9 (3.0%)	5 (8.2%)	26 (9.4%)	7 (7.0%)	59 (22.4%)	8 (13.3%)

Table 3: Evolution of degenerative changes in the adjacent levels (superior and inferior) at 2, 3 and 5 years compared to their preoperative state assessed by Lane classification.

follow-up (Table 2). Degenerative status was more marked for superior discs with 22.4% (Δ+1 and Δ+2) versus 13.3% for inferior discs (Table 3).

Discussion

It is noteworthy that our study with 411 patients is the largest French series of TDR ever reported with a 5 years' follow-up [14]. Our study will be extended to up to ten years. It is a level IV evidence therapeutic study but the inclusion criteria were much less restrictive than usual randomized controlled trials (RCT), and designed as a « more real life » study. Neither the learning curve cases, nor the worker's compensation cases were excluded. In addition, this 8-center study involved 60% orthopedic surgeons and 40% neurosurgeons, which contributes to greater variability but also reflects a more representative outcome.

Nonetheless, limitations of this study must be pointed out: an uncontrollable risk of selection bias could not be avoided due to the multicenter design of the study and the habits in terms of patient recruitment by the investigators. The 80% follow-up rate at 5 years is in accordance with previous studies [14]. It can be explained first by the ongoing observational study, with young and active patients who do not come back unless they require additional medical attention. In addition, neither the patients, nor the surgeons received any fee to participate in the study.

The primary intention of TDR is to preserve and restore the implanted segment's motion and hopefully to maintain this benefit / improvement through time. In our study, at 5 years' follow-up, the mean ROM significantly increased compared to baseline, the mean improvement between baseline and last follow-up was maintained through time even if one can note a slight deterioration between 3 and 5 years, which was tested and found to be not significant. ROM is generally preserved at the implanted segment through time-course in literature. David [15] reported a mean ROM of 10.1° with a mean follow-up of 13.2 years and 90.6% of treated discs were mobile; Van de Kelft [16] with Maverick reported, at 4 years of follow-up, 13° for L4-L5 and 11° at L5-S1. Guyer [17] mentioned 6.4° at L4-L5 and 5.9° at L5-S1, Zigler [18] reported a mean ROM of 7.2° at five years and assessed that this was "within the normal range", but did not report the baseline value. ROM of the adjacent segments also significantly increased compared to baseline for both the superior and inferior disc, which has been an eagerly awaited result of TDR. This improvement of motion at adjacent level is the consequence of restoring natural mobility, rather than the hyper-mobility caused by fusion, since we find harmonious movement between the index and adjacent levels [10,19]. It is understood that fusion reduces ROM of the adjacent segments; however, an 11-year follow-up study of an artificial intervertebral disc on 35 patients [20] also showed decreased ROM. Thus, our study reported improvement of ROM of the adjacent segments compared to fusion and other [19] prosthesis. With regard to lordosis, at 5-year follow-up, there is no deterioration over time. Furthermore, at five years, only one case of fusion (grade IV according to MacAfee classification) was reported for all index and adjacent levels.

One of the rationale for using TDR as an alternative to fusion is to preserve the adjacent levels from iatrogenic degeneration which can lead to radiographical and/or clinical ASP (RASP, CASP). The fusion procedure has been accused by many authors of having deleterious effects, mainly due to the new biomechanical segmental conditions [2], but still to date the question remains controversial. Lee [21] in a systematic review concluded that RASP may occur at a higher rate after fusion than in «*De novo* spinal degeneration». Videbaeck [22] in a randomized study comparing PLF to PLF+ALIF with 8 to 13 years of follow-up, expressed the opinion that one should reconsider the indication of TDR to prevent ASP, given that there was no significant difference in terms of ASP rate after surgery in these two groups compared to the literature results in a symptomatic non-operated population. Xia [23] in a systematic review and meta-analysis of 94 papers and 34716 patients (TDR and fusion pooled), established that one fifth to one third of RASP will turn into CASP. The RASP rates after surgery is highly diverse according to a systematic review made by Harrop [24]. The TDR studies showed considerably lower results from 6.7% to 13% [24,25].

Finally, considering the CASP leading to surgery, the reported rates in fusion range from 4% to 27.6% [17]. TDR studies reported better rates ranging 1- 2.8% [12,15,17]. In our study, 3.2% patients had CASP leading to surgery (Part 1 of the paper) but all these patients had degenerative discs at the time of index surgery. More so, at 5 years of follow-up, 22.4% of the superior discs and 13.3% of the inferior discs had a worsening of Lane grade compared to their preoperative status, indicating radiographic degenerative changes in these discs.

Last but not least, with a mean ROM of 7.8° and a mean lordosis of 12.6° at 5 years we can state that prosthesis restore motion at the index level, and, with regards to progressive improvement of ROM at superior and inferior levels we can assert that it is related to significantly reduced pain (evaluated by ODI and VAS).

Conclusion

At five years of FU, our results confirm the previous results of literature about the TDR technique in terms of effectiveness and stability through time. Remarkably, the safety of TDR in terms of preservation of adjacent segments along the course of time, and particularly the low reoperation rates, which are the main drawbacks of the fusion technique, seem to be confirmed in the different reports as in our results, even if level 1 evidence, long-term results are still missing. Nonetheless, these different and more numerous mid- to long-term data are encouraging for the validation of the disc replacement technique in general as a legitimate part of the available surgical armamentarium against lumbar DDD.

Conflict of Interest

The author(s), except AP, has/have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this manuscript.

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