

A 5-year Follow-up of a Controlled Mobile Core Lumbar Disc Prosthesis: Clinical Results

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Abstract

Purpose: Total disc replacement is an alternative to arthrodesis in degenerative disc disease in young patients suffering from persistent chronic back pain refractory to conservative treatments. 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.

Methods: Four hundred and eleven patients were included in a prospective and multicenter study with 5-year follow-up. The clinical assessment investigated ODI, VAS (lumbar and radicular) score, quality of life (SF-36), medication consumption, professional status, and complication occurrence after surgery.

Results: ODI significantly decreased at 5 years after surgery with an average improvement of 27.3%. Low back pain and radicular pain significantly decreased. SF-36 significantly increased for both the mental and physical components. Medication consumption also significantly decreased at 5 years. Professional status was improved with an increase in the proportion of working patients and a decrease in sick leave up to 5 years after surgery. All complications were reported with an overall reoperation rate of 14.6% (regardless the cause and the level of the lumbar spine).

Conclusion: This study showed satisfactory clinical results and patient satisfaction 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; Clinical efficacy

Introduction

Degenerative disc disease (DDD) is a common disease in the active population with a significant social and economic impact [1]. Once conservative therapies for lumbar DDD's are exhausted, surgical treatment is often elected. However, lumbar surgical procedures still present a challenge. Arthrodesis, the standard surgical method, has major drawbacks; it fails to preserve mobility and function of the treated segment and potentiates adjacent segment degeneration [2]. Total Disc Replacement (TDR) was invented as a therapeutic option for DDD and designed to help prevent the development of adjacent segment disease. This technique began to evolve approximately 30 years ago, [3] and has been increasingly employed as a viable surgical option over the past three decades. Many devices have been developed [4,5]. In addition, major technical improvements have been reported through time. Thus, surgeons involved in this technique have gained considerable experience. Previous published studies have established that TDR outcomes are at least equivalent to those of fusion, in both the short and long term [6,7]. Some authors have even reported it as being superior to fusion at one year [8] or at 2 years' follow-up (FU) [9]. TDR has also performed favorably compared to fusion with respect to adjacent level preservation and reoperation rates [10,11]. However, TDR may also have some disadvantages, such as complication related to anterior lumbar approach and device [12]. Mid and long term results are slowly accumulating while systematic reviews and meta-analysis continue to provide visibility on the different issues of lumbar DDD surgical treatment [13,14]. The aim of our study is to assess both the efficacy and safety of a second-generation lumbar disc prosthesis with controlled mobility in a prospective, multicentric trial at five years FU. This study exhibits both a clinical (Part 1) and a radiological (Part 2) assessment.

Materials and Methods

Study design

Between November 2003 and December 2008, 411 consecutive patients receiving Mobidisc® disc prosthesis were included in our prospective multicenter (8 French centers) study. Both clinical and radiological outcomes were assessed, at 6 weeks, 3, 6, 12, 24, 36 and 60 months after surgery, however, only the clinical assessment is presented in this part. The study is ongoing up to 10 years FU.

Inclusion criteria

Degenerative lumbar disc disease, chronic and disabling low back pain, resistant to medical treatment including rehabilitation failure for at least 6 months, after confirmation by radiological examination, MRI and CT-scans, patients aged from 18 to 60 years old.

Exclusion criteria

Posterior facet joint arthrosis, osteoporosis, instability of lumbar spine, scoliosis, spondylolisthesis. Learning curves, patients with previous lumbar surgery and patients in work-related injury are not excluded.

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Prosthesis

Mobidisc® (LDR Médical, Troyes, France) is a controlled mobile core lumbar disc prosthesis that allows restoration of the treated intervertebral segment mobility and approximates physiological mechanics [4,15]. The mobile core combines rotation with translation to preserve the physiological mobility of the treated segment and to preserve the action of the articular facets (Figure 1). Four peripheral stops control the mobility of the core within physiological limits and secure the implant. In order to better adapt to different anatomies, the prosthesis has evolved during the study to provide more primary anchoring by keels and more coverage of vertebral endplates by offering a wide range of dimensions suitable for all patients. Additionally, the plates are chamfered to avoid bone fracture following insertion.

Clinical outcomes

The primary endpoint was the assessment of functional disability measured by the improvement in the Oswestry Disability Index (ODI 0-100%). Back and radicular pain were investigated by the patient using a visual analog scale (VAS 0-10cm). Quality of life was measured by the SF-36 scale including both a physical (PCS) and mental (MCS) component. All clinical outcomes were determined by a self-administered questionnaire. Patients were also asked “If you have to



Figure 1: Components of Mobidisc® and assembled prosthesis.

	n (%) or Mean ± SD	Range	N
Age (years)	Mean = 41.8±7.0	19-59	411
Sex	Men: n = 31.9% (131/411) Women: n = 68.1% (280/411)	-	411
Preoperative sick leave (months)	Mean = 12.6±11.0	0.1-72.5	182
Previous lumbar surgery	No history n=259 (63.0%) At least one history: n=152 (37.0%) History on the target disc(s): n=132 (32.2%) History of lumbar arthrodesis: n=16 (3.9%)	-	411
Length of symptoms	< 1 year: n=81 (20.6%) 1-3 years: n=140 (35.5%) >3 years: n=173 (43.9%)	-	394
Procedure	1-implanted level: 368 cases (89.5%) 2-implanted levels: 42 cases (10.2%) 3-implanted levels: 1 case (0.2%) Hybrid surgery (prosthesis + arthrodesis): 6 cases (1.5%)	-	411
Implanted level	L2-L3: 1 case (0.2%) L3-L4: 17 cases (4.1%) L4-L5: 84 cases (20.4%) L5-S1: 266 cases (64.7%) L2-L3-L4: 1 case (0.2%) L3-L4-L5: 10 cases (2.4%) L4-L5-S1: 31 cases (7.5%) L3-L4-L5-S1: 1 case (0.2%)	-	411

Table 1: Demographic and preoperative clinical data of the study population.

	6 weeks	3 months	6 months	1 year	2 years	3 years	5 years
Patients expected	410	410	410	407	399	388	364
Patients reviewed	230	379	373	364	321	314	290
Missing visits	180	31	37	43	78	74	74
Early termination of study	1	0	0	3	8	11	24
Follow-up rate	56%	92%	91%	89%	81%	81%	80%

Table 2: Flow of participants through the various time-points of the study.

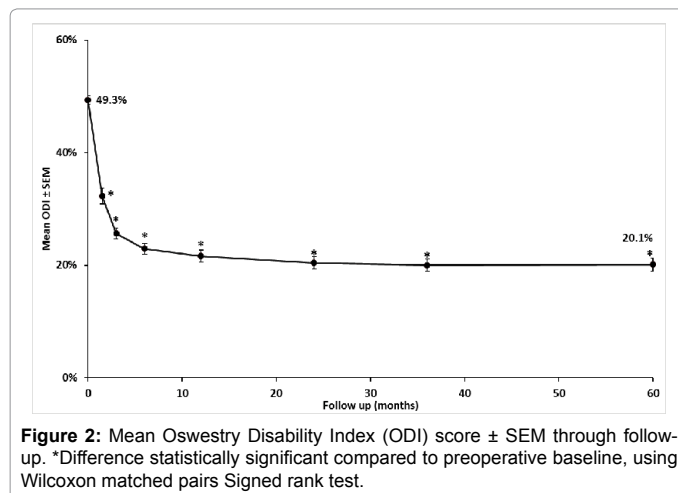


Figure 2: Mean Oswestry Disability Index (ODI) score ± SEM through follow-up. *Difference statistically significant compared to preoperative baseline, using Wilcoxon matched pairs Signed rank test.

do it again, would you do it again?” with three possible answers: Yes, No, Do not know.

Frequency of medication consumption (continuous, occasional, never) was explored as well as type of drugs (class 1 and 2 analgesics, opioids, NSAIDs, all mixed classes). Professional status was also tracked during pre- and post-operative visits with the following categories: inactive (retired, student, disabled or unemployed); active in employment, active on sick leave, on sick leave for an unrelated pathology.

Complications regarding surgical procedure including sexual ones, prosthesis failure, leading or not to reoperation were reported. Re-intervention as well as secondary surgeries were described.

Statistical analysis

All available data have been considered. The Wilcoxon matched-pairs Signed rank test was used for comparisons between pre-op and post-op continuous data such as ODI and VAS. The McNemar’s test was used for comparison of categorical data. The significance level was $p < 0.05$. Statistical analyses were conducted using GraphPad Prism V5.04 software.

Results

During the study period 411 consecutive patients were implanted with 455 prosthesis. The mean age of the patients was 41.8 ± 7.0 years (range 19-59), with the following gender distribution: men: 131 (31.9%) and women: 280 (68.1%). There were 132 patients (32.2%) with history on the target disc(s) and 16 (3.9%) with a history of lumbar arthrodesis. A single-level surgery was performed in 368 patients (89.5%), 2-levels in 42 (10.2%) and 3-levels in 1 patient. The L5-S1 intervertebral disc was the most replaced with 266 cases (64.7%). Table 1 summarizes demographic, preoperative clinical and surgery data. As presented in Table 2, the follow-up rate at 5 years was 80%.

Mean change compared to baseline	2 years	3 years	5 years
Δ ODI (n)	28.1% (264)	27.9% (259)	27.3% (251)
Δ VAS back pain (n)	4.0 cm (257)	4.0 cm (251)	3.8 cm (235)
Δ VAS radicular pain (n)	3.0 cm (247)	2.9 cm (245)	2.6 cm (222)

Table 3: Change in Oswestry disability index and VAS through time compared to preoperative status.

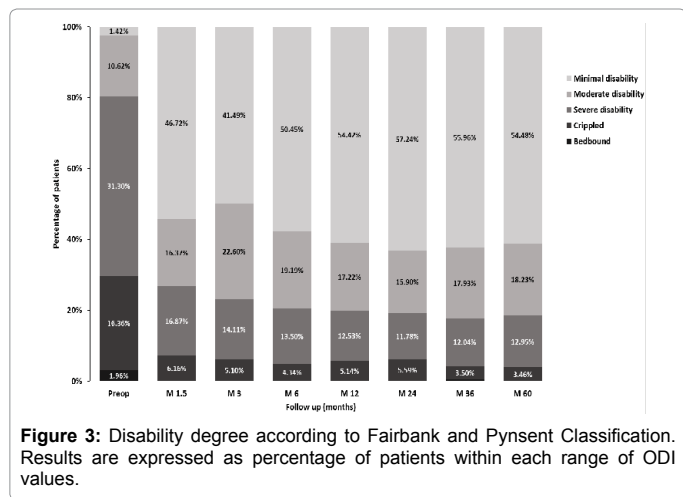


Figure 3: Disability degree according to Fairbank and Pynsent Classification. Results are expressed as percentage of patients within each range of ODI values.

Surgery related complications	Incidence n/N	Reoperation	Evolution
Hernia	7/411	5	5 resolved and 2 unspecified
Parietal hematoma	11/411	2	7 resolved and 4 unspecified
Superficial infection	2/411	1	2 resolved
Bladder obstruction	2/411	1	2 resolved (whose 1 resolved with catheterization)
Error in the implanted level	2/411	1	1 re-operated and 1 treated during the same operative time
Malposition of implant	6/411	3	3 without consequence and 3 resolved after reoperation
Material forgotten in situ	2/411	2	2 removed without consequence
Fracture of vertebral body	2/411	1	2 arthrodesis (1 conversion and 1 reoperation)
Sympathectomy disorders	12/411	0	7 resolved, 2 persistent and 3 unspecified
Retrograde ejaculation (male based N)	9/131	0	6 resolved and 3 persistent
Device related complications	Incidence n/N	Reoperation	
Device migration	7/411	3	4 without clinical consequence, 2 with revised assembly and 1 with conversion into arthrodesis
Secondary subsidence in the vertebral body	22/411	1	4 without clinical consequence and 1 with conversion into vertebroplasty
Keel fracture	2/411	0	2 without clinical consequence
Peri-prosthetic osteolysis	1/411	0	Subsidence associated with temporary radiculalgia
Clinical failure and adjacent disc diseases	Incidence n/N	Reoperation	
Recurrence of low back pain	-	28	28 arthrodesis without prosthesis removal
Adjacent disc diseases	-	13	5 arthrodesis, 5 TDR and 3 disc herniation removal

Table 4: Description of the main complications and all reoperations. Incidence and reoperation cannot be added because the same patient can be affected by one or several complications and reoperations.

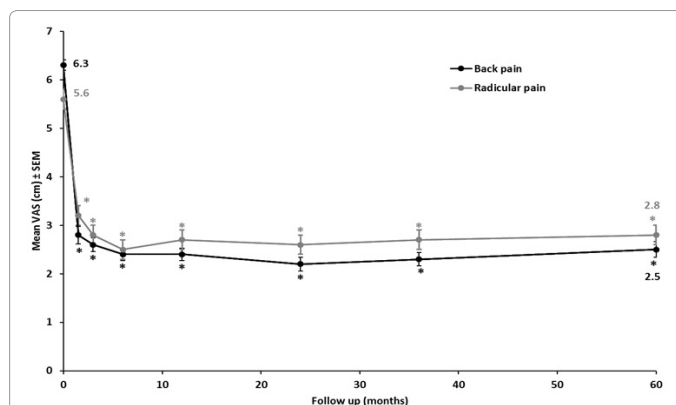


Figure 4: Mean VAS for back and radicular pain score ± SEM through follow-up. *Difference statistically significant compared to preoperative baseline, using Wilcoxon matched pairs Signed rank test.

The assessment of functional disability underlined a significant reduction in ODI score compared to preoperative baseline; this improvement was observed as soon as 6 weeks and up to 5 years (Figure 2) after prosthesis implantation. The improvement in ODI score compared to preoperative value averaged 28.1% at 2 years and remained stable up to 5 years after surgery (Table 3). This improvement was confirmed when using Fairbank and Pynsent classification (that suggested 5 levels of ODI: 0% to 20%, 21% to 40%, 41% to 60%, 61% to 80%, and 81% to 100%) [16], which underlined a continuous increase in the proportion of patients in the minimal disability group and a great decrease in the proportion of patients in the “Crippled” and “Severe disability” groups from 2 years to 5 years (Figure 3).

The overall reoperation rate for all combined causes at 5 years was 14.6% (60 patients re-operated following a surgery-, device-, clinical failure-related complication, or due to a secondary surgery for another segment of the lumbar spine). In these re-interventions 13 (3.2%) are related to adjacent disc diseases. An overview of main complications reoperations is provided in Table 4. After the prosthesis was improved to its current version, there were no more keel fracture documented, also there were a few secondary subsidence in the vertebral body (5/22) reported.

Mean VAS for back pain and radicular pain showed a significant decrease in pain from 6 weeks and up to 5 years (Figure 4). This improvement is given in Table 3. Global satisfaction of patients was sustained by the answers to the question “If you had to do it again, would you do it again?” where 90% of patients answered “yes” at both 2 years and 5 years. Patients quality of life (SF-36 score) significantly improved compared to the preoperative baseline (Figure 5); this improvement was demonstrated for both physical and mental components, from 6 weeks after surgery and up to 5 years.

Medication consumption before and after surgery was tracked and reported in Figure 6. A striking decrease of the percentage of patients with a continuous consumption was evidenced, going from 72% pre-op to 22% 5 years after surgery. Concurrently, an increase in the rate of patients who never consume medication was reported, ranging from 7% preoperatively to 60% after 5 years post-op. McNemar’s test was significant (p<0.0001).

As far as professional status was concerned, the mean duration of the preoperative sick leave was 12.6 months while the mean duration of sick leave was 8 months after surgery. The percentage of “working” patients was 36.8% at pre-op and increased after 12 months (67.3%) up to 71.6% at 5 years FU (Figure 7). The percentage of patients “on sick

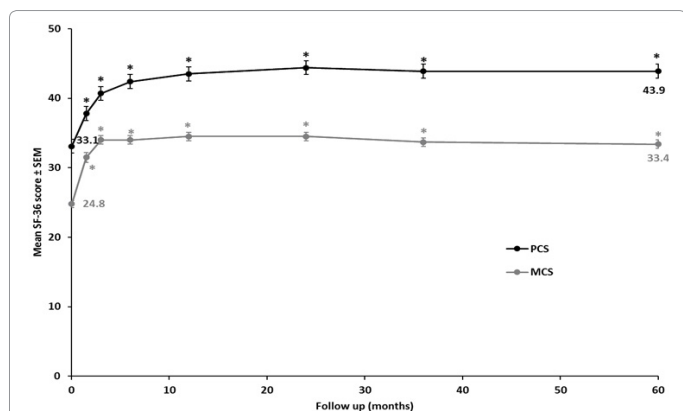


Figure 5: Mean SF-36 score ± SEM through follow-up, with PCS: Physical Component Scale, MCS: Mental Component Scale. *Difference statistically significant compared to preoperative baseline, using Wilcoxon matched pairs Signed rank test.

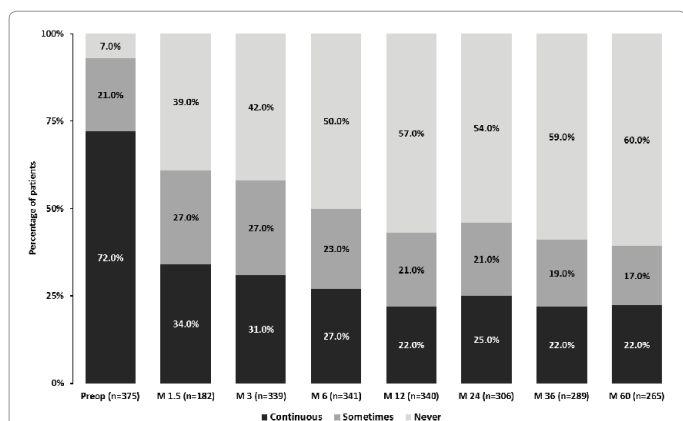


Figure 6: Medication consumption, analgesic use in the overall population (all types are considered: analgesics, opioids, NSAIDs). Results are expressed as percentage of patients at each follow-up.

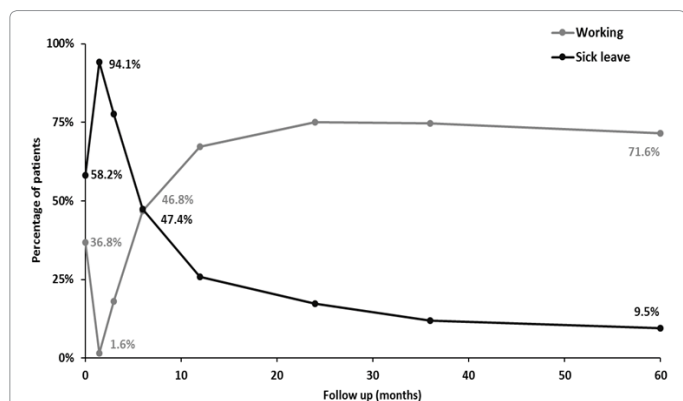


Figure 7: Professional status evolution through follow-up. Results are expressed as percentage of patients at each follow-up.

leave” decreased from 58.2% at post-op to 9.5% 5 years after surgery. McNemar’s test was significant ($p < 0.0001$) for working status.

Discussion

This multicentric study represents the largest French series of patients at 5-year follow-up evaluating a mobile-core TDR lumbar prosthesis. The clinical results summarized in this part are encouraging and confirm the results of other studies [4,15,17].

In this study, every clinical outcome (ODI, VAS, quality of life, medication, and professional status) was improved at all-time points after surgery and at final FU, with statistical significance, compared to baseline. Patient satisfaction remained steadily high through time. These results are in accordance with the current literature, where numerous studies have reported significant functional and clinical improvements with the TDR technique using different devices [18]. In a meta-analysis of 7 randomized clinical trials (RCT), and 1584 patients, Rao, and al. [7] reported that a significantly higher percentage of TDR patients showed satisfactory outcomes compared to fusion patients, and they emphasized the lack of long-term complications in published data.

The long-term results of lumbar TDR became available a decade ago [19,20]: their results were like ours in terms of clinical efficacy and stability through time. When the first long-term results of RCTs became available [6,21] they showed no statistical differences regarding clinical outcomes between fusion (BAK cages and 360° respectively) and the TDR groups. Siepe et al [22] reported 7.4 years’ results with highly significant and stable improvement of clinical outcomes compared to baseline, except for VAS (no dissociation of lumbar VAS from radicular) which was slightly but significantly deteriorated from 48 months onward, but for this author, below any threshold of admitted clinical relevance. This kind of deterioration was not observed in our study. Park [23] reported similar significant long-term deterioration in a level IV study with a minimum of 5 years of follow-up.

In literature, the overall complication rates in fusion ranges generally between 10 and 33 % approximately [24] and up to 89% [9] when accounting any adverse event, including the slightest ones occurring regardless of the causation. These complications are usually reported as more important for fusion than for TDR [18,24]. However, Zigler, [11] showed similar complication rates for fusion compared to TDR, but life-threatening and severe complications were more frequent in fusion patients.

The overall reoperation rate for all combined causes at 5 years was 14.6%; this rate is comparable to fusion reoperation rates at mid- and long-term FU in literature, which ranges from 8.7% to 18% [6]. This reoperation rate is also in accordance with other mid-and long-term TDR studies which ranged from 0% to 12.7% [6,19,22]. Many sexual disorders are resolved and we conjectured that they mostly occurred during the initial training period (learning curves). After the prosthesis evolved, there were less device related complications reported. The rate of reoperation for adjacent disc diseases was 3.2%, which corresponds to the natural history of lumbar degenerative disc disease [25], making it difficult to separate adjacent events from natural degeneration.

A major limitation of the study is missing data. Although the number of patients lost to follow-up or lost to early termination of study seems relatively low with a follow-up rate of 80% at 5 years.

The evaluation criteria presented here are relevant and robust criteria validated by the literature for these pathologies [16]. The primary endpoint is the change in the ODI score. The validity of this criterion is limited only by missing data, which was minimal. The secondary endpoints are validated and widely recognized clinical criteria (pain, quality of life, complications, drug consumption, and employment status).

This study offers the advantages of including a heterogeneous population with a significant number of patients long-term followed-up. The unrestricted inclusion/non-inclusion criteria allow the examination of arthroplasty with a controlled mobile core lumbar disc

prosthesis in real-world conditions. Therefore, the transposability of this study to real-world practice seems more authorized here than in most randomized clinical trials (IDE type) that include highly homogenous subject groups that provide limited representation of the general patient population. Thus, in condition of the subjects' compliance with the indications and contra-indications of the instruction manual of the prosthesis, the results of this study are generalizable to the general population of surgeons and patients.

Conclusion

Results at 5 years' follow-up on 411 patients confirmed the safety and efficacy of this mobile-core TDR device with respect to clinical outcomes and thereby patients' well-being. These results remain favourable in light of the surgeon training period and the prosthesis indications/contraindications. Radiological results in Part 2 confirm beneficial outcomes.

Conflict of Interest

The author(s) 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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