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Original article

Comparison between total disc replacement and hybrid construct at two lumbar levels with minimum follow-up of two years

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ABSTRACT

Introduction: Lower back pain due to degenerative disc disease is a therapeutic challenge in young patients. Although arthrodesis is currently the gold standard for surgical treatment, improvement in total disc replacement techniques makes it possible to preserve segmental mobility with good results in one-level surgery. Nevertheless, the French National Health Authority does not recommend total disc replacement for multilevel surgery. Thus, hybrid constructs that combine one-level disc replacement with arthrodesis have been developed for multilevel indications.
Hypothesis: The outcome of two-level lumbar disc arthroplasty does not differ from hybrid constructs.
Methods: The clinical and radiographic outcomes of disc arthroplasty were compared to hybrid constructs for two-level degenerative disc disease in 72 patients after a continuous follow-up of at least 2 years. The patients were divided into two groups that were similar for the indication and type of implants.
Results: There was no statistical difference in pain relief (−3.9 points versus −3.5 points for lumbar VAS) or reduction in ODI (−29.5% versus −27.0%) between TDR and hybrid constructs, respectively. There was no statistical difference in range of motion at the level of arthroplasty (8.4° versus 7.6°) and no kinematic dysfunction was identified. The re-operation rate at two years for persistent lumbar pain was respectively 6.7% for two-level disc arthroplasty and 4.3% for hybrid constructs. The complication rate was 4.8% and 8.7% respectively.
Discussion: No difference was found in this comparison of two homogeneous series between two-level disc arthroplasty and hybrid constructs for the treatment of degenerative disc disease after two years of follow-up. Two-level disc arthroplasty may be an alternative for young patients depending on an evaluation of long-term results.
Level of evidence: Cohort observational study level III.

1. Introduction

Chronic lower back pain is the most frequent cause of reduced activity and absence from work in young subjects [1]. In this active population this may be due to degeneration of a single disc or sometimes of several discs making the surgical indication difficult to determine.

Arthrodesis is still the main surgical treatment option for lumbar disc pain [2]. Although results are satisfactory, they may be limited by nonunion, adjacent segment disease or facet joint degeneration, which may be even worse in young patients if multilevel arthrodesis is performed.

To limit these complications, lumbar total disc replacement (TDR) was developed in the 1980s [3] and has been used since to preserve lumbar spine segmental mobility and reduce adjacent segment disease [4].

Evaluation of single-level lumbar TDR in a non-inferiority study has been shown to be not unacceptably less effective than arthrodesis in the intermediate term [5–7]. The results of multilevel TDR are more controversial. Numerous authors did not find any significant difference between single-level TDR [8–10] and arthrodesis [11], although there was often a greater rate of complications in the former [12–15].

While the French National Health Authority (Haute Autorité de santé [HAS]) guidelines have validated single-level TDR they did

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not include two-level TDR. To follow these guidelines, hybrid constructs associating TDR and arthrodesis by anterior approach have been developed with good results [16,17].

To our knowledge there are no studies in the literature comparing lumbar hybrid constructs and two-level TDR. We evaluated a multicenter cohort of patients who were prospectively followed-up including all one- or two-level TDR with or without associated arthrodesis in patients operated for two-level degenerative disc disease.

The goal of this study was to compare hybrid constructs and two-level TDR in a homogenous population who were managed by the same team, with the same implants and for identical indications.

2. Materials and methods

This was a continuous, prospective observational multicenter study of 72 patients who were operated with MOBIDISC® (LDR Medical, Troyes, France) for two-level TDR (2TDR, $n = 48$) or by a hybrid system (H, $n = 24$) associating MOBIDISC® TDR and anterior arthrodesis using the ROI-A® (LDR Medical, Troyes, France) cage from 2003 to 2012 in four centers. All patients were managed with the same peri- and postoperative protocols.

Inclusion criteria were patients with chronic and incapacitating lumbar pain due to two- degenerative disc disease that had not responded to medical treatment after at least 6 months, including unsuccessful physical rehabilitation. Patients had to be less than 60 years old and have severe degeneration of 2 lumbar discs with loss of disc height and/or modification of MODIC-type MRI signal. Exclusion criteria were lower back pain that was not considered to be degenerative disc disease, predominantly radicular pain, a spine deformity, or degenerative facet joint disorders. The indication for a hybrid construct was always chosen according to HAS guidelines in the rare cases of posterior single-level osteoarthritis.

All patients gave informed consent when prospective data was being obtained. This study followed the ethical standards determined by an ethics committee based on the principles of the Declaration of Helsinki.

The following data were obtained: morbidity, results of a self-administered questionnaire, preoperative full and lumbar spine dynamic lateral X-rays at 3 and 6 months, then at 1, 2, 3 and 5 years (Fig. 1).

The main judgment criterion was lower back pain according to the Visual Analogic Scale (VAS). Secondary criteria were the Functional Oswetry Disability Index (ODI), segmental mobility (range of motion [ROM]) and vertebral translation (VT) calculated with Spineview software (Surgiview, Paris, France) [18].

Statistical calculations were performed using Prism 5 for Windows® software (Version 5.01, 2007, GraphPad Software, Inc.). Comparison of means was performed using the Mann-Whitney test and $P \leq 0.05$ was considered to be significant.

3. Results

The distribution and preoperative patient characteristics are presented in Fig. 2 and Table 1. Four patients who were eligible and who underwent 2-level surgery were lost to follow-up, one in the H group and three in the 2TDR group.

Both groups were similar for the surgical indication (two-level degenerative disc disease), for the implants used, as well as for the surgical approach. The patients in each group were comparable except for age: they were significantly older in the H group.

The clinical and radiological results are presented in Table 2.

The rate of 2-year postoperative clinical follow-up was 94% in the 2TDR group and 96% in the H group and of radiological

Table 1
Comparison of groups at inclusion.

Characteristics at inclusion	Treatment		*P*
	Hybrid construct ($n = 23$)	Total disc replacement × 2 ($n = 45$)	
Age (years)			
Mean	44.9 ± 1.3	40.6 ± 0.86	0.0087
Min/Max	35.3/56.5	30.0/52.0	
BMI	25.1 ± 0.74	24.7 ± 0.53	> 0.05
VAS	5.5 ± 0.38	6.3 ± 0.33 ($n = 40$)	> 0.05
ODI	49.0 ± 2.8	51.7 ± 2.2 ($n = 40$)	> 0.05
Sex		> 0.05	
Men	9	16	
Women	14	29	
		($n = 90$)	
Level			–
L2-L3	0	1 (1.1%)	
L3-L4	0	11 (12.2%)	
L4-L5	19 (82.6%)	44 (48.9%)	
L5-S1	4 (17.4%)	34 (37.7%)	

BMI: body mass index (kg·m^2); VAS: Visual Analogic Scale; ODI: Oswestry Disability Index.

Table 2
Patient outcome after 2 years of follow-up.

VAS	Hybrid construct	Total disc replacement × 2	*P*
	$n = 23$	$n = 45$	
Mean	2.0 ± 0.41	2.6 ± 0.37	0.50
Median (Q1/Q3)	1.5 (0.40/2.8)	1.9 (0.20/4.7)	
Min/Max	0.0/6.5	0.0/8.5	
Δ VAS[a]	$n = 23$	$n = 40$	
Mean	−3.5 ± 0.47	−3.9 ± 0.41	0.47
Median (Q1/Q3)	−3.2 (−2.0/−5.4)	−4.4 (−2.3/−5.7)	
Min/Max	+0.70/−7.4	+1.6/−8.5	
Δ ODI (%)	$n = 23$	$n = 40$	
Mean	−27.0 ± 3.3	−29.5 ± 3.1	0.81
Median (Q1/Q3)	−30.0 (−17.5/−39.0)	−26.0 (−16.0/−48.0)	
Min/Max	+8.0/−54.0	+14.0/−70.0	
ROM (°)	$n = 23$	$n = 40$ (niv. sup.)	
Mean	7.6 ± 1.1	8.4 ± 0.87	0.65
Median (Q1/Q3)	6.7 (3.2/13.2)	9.0 (2.7/12.2)	
Min/Max	0.60/18.0	0.0/19.0	
		$n = 38$ (niv. inf.)	
Mean		6.5 ± 0.92	–
Median (Q1/Q3)		5.9 (1.9/11.0)	
Min/Max		0.0/21.0	
Anteroposterior translation[b]	$n = 15$	$n = 29$ (niv. sup.)	
Mean	1.2 ± 0.19	1.4 ± 0.16	0.79
Median (Q1/Q3)	1.2 (0.67/1.6)	1.2 (1.0/1.5)	
Min/Max	0.0–2.8	0.23–4.4	
		$n = 30$ (niv. inf.)	
Mean		1.0 ± 0.14	–
Median (Q1/Q3)		0.99 (0.34/1.5)	
Min/Max		0.0–3.3	

Mean ± standard deviation from the mean. VAS: Visual Analogic Scale; ODI: Oswestry Disability Index; ROM: range of motion.

[a] Δ VAS = preoperative VAS − postoperative VAS.

[b] For 10° of ROM.

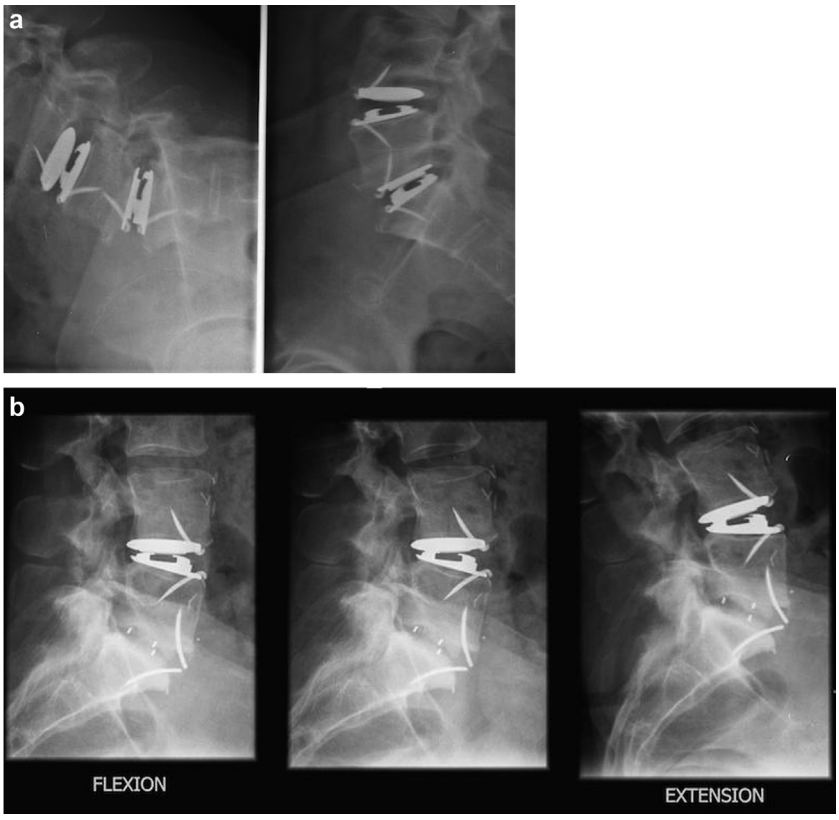

Fig. 1. X-ray control for range of motion study: a: two-level disc arthroplasty in maximum flexion and extension; b: hybrid construct, disc arthroplasty on top of an anterior arthrodesis.

follow-up was 83% and 96% respectively. There was no significant difference between the 2TDR and H groups for the VAS (−3.9 and −3.5 points) or the ODI (−29.5% and −27.0%).

Treatment failure was defined as persistent or recurrent incapacitating lower back pain resulting in revision arthrodesis. After a mean 49.6 months of follow-up, treatment had failed in eight patients (17.8%) in the 2TDR group, including three (6.7%) before two years. After a mean follow-up of 35 months, treatment had failed in one patient (4.3%) in the H group.

All complications were recorded: there were no thromboembolic events, no hematomas requiring revision surgery and no complications associated with the hardware. Two cases presented with a feeling of reduced volume ejaculate in the 2TDR group and four in the H group. Two patients (4.8%) presented with a complication associated with the surgical approach in the 2TDR group (a deficit at L5 and genito-femoral nerve dysesthesia) and two patients (8.7%) in the H group (a deficit in the left S1 and sympathetic dysfunction) with no surgical revision.

There was no significant difference in segmental range of motion between the two groups (2TDR: 8.4° versus H: 7.6°) for L4-L5. The mean range of motion for the adjacent level below surgery in the 2TDR group was 6.5°. The rates of immobile segments

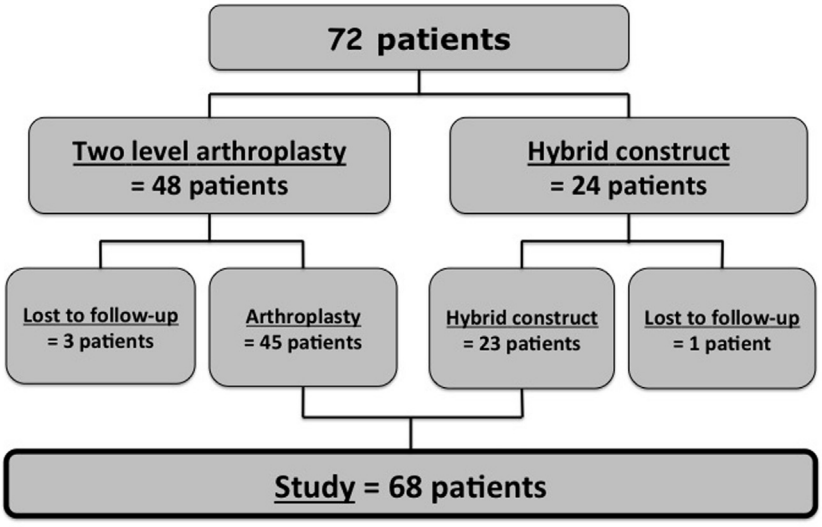

Fig. 2. Patient's flow chart.

or with limited range of motion (ROM below 4°) were not significantly different between the 2TDR (12 disc replacements or 15.4%) and H groups (5 replacements or 21.7%). The results of radiological non-mobility were not correlated to the clinical results. Vertebral translation for 10° of ROM of the adjacent level above surgery was 1.4 mm in the 2TDR group and 1.2 mm in the H group ($P = 0.79$) and 1.0 mm in the adjacent level below surgery.

4. Discussion

Our study did not show any significant difference in pain relief two years after surgery between the 2TDR and H groups. Results with hybrid constructs do not seem to be better than two-level TDR for the decrease in lower back pain and the ODI score. Segmental mobility was preserved at the level of the disc replacements with both techniques. These results must be considered in relation to the minimum follow-up of 2 years and the small size of the study groups.

The two groups were similar for surgical indication and the material used, but not for age. This can be explained by the more frequent facet joint osteoarthritis in older patients, for whom hybrid constructs were indicated.

Although a review of the literature published in 2008 did not reach firm conclusions on the risk factors of failure of TDR, older patients, L5-S1 replacement or multilevel TDR and the presence of posterior facet joint degeneration more frequently influenced the results [19]. Park et al. found a significant increase in posterior facet joint degeneration after two-level TDR (50% vs 13% after one level) but did not report whether preoperative facet joint status was similar between the 2 groups and also showed that facet degeneration was significantly correlated to frontal plane malposition [20]. Ching et al. showed the importance of proper positioning of disc replacements on the coronal plane and that multilevel replacements may be less reproducibly functional than single-level TDR [15].

To our knowledge there are no comparative studies in the literature on this topic. The decrease in the VAS and the ODI following two-level arthroplasty varies between 2.8 and 4.8 points and 13 and 39.9% respectively [8,9,11,12]. The only published study in the literature on hybrid constructs shows a decrease of 4.5 points and 24.9 points in the VAS and ODI, respectively [17].

In our series the difference in the failure rates after the longest follow-up can be explained by the longer follow-up in the 2TDR group (47 months versus 33 months) and the learning curve (6/8 patients with failures in the 2TDR group were operated during the first three years of inclusion). Nevertheless, the rate of patients requiring revision surgery before two years was comparable between the two groups 6.7% and 4.3% in the 2TDR and H groups, respectively.

In our study none of the patients required surgical revision for a complication due to the implants or the surgical approach. The complication rates (4.8% and 8.7%, respectively) were comparable to those reported by the HAS in 2007 for one-level TDR (between 4.5 and 9.4%) but less than those reported for multilevel replacements (up to 20%).

In a series of 20 two-level lumbar TDR, Siepe et al. [13] reported a complication rate of 30% and revision in 20% (compared to 14% and 5% for one-level TDR). In the largest published French series of two-level TDR [12], the complication rate was 18% and the early revision rate was 2.8%. Complications were vascular in 8.3% (thrombosis of the iliac vein, hematoma, phlebitis), infectious (4.6%), associated with hardware in 2.8% (extrusion of polyethylene, subsidence) and neurological in 0.9%. Aunoble et al. reported a complication rate of 9.5% for hybrid constructs [17].

The experience acquired in this field, and the training of surgeons for this difficult technique have probably helped reduce the rate of complications over time.

Our results confirm that range of motion was preserved equally in both segments with two-level replacements (8.4° upper disc level and 6.5° lower disc level). The range of motion preserved in L5-S1 was comparable to that of the upper adjacent segment which enhances the protective effect against adjacent segment disease. We did not identify any radiographic kinematic dysfunction after a mean 47 months of follow-up in the 2TDR group: no hypermobility, excessive vertebral translation or paradoxical mobility.

A cadaveric study by Erkan et al. [16] did not show any significant difference in mobility in L4-L5 compared to a healthy spine whatever the type of replacement. Our study confirms these results in vivo and the mean ROM were similar at comparable levels in both groups. Huang et al. [21], reported that a ROM above 5° was significantly correlated with a lower risk of developing adjacent segment disease which is the main goal of TDR. We obtained good preservation of segmental mobility in our patients with two-level TDR and single-level hybrid replacements (84.6% of ROM > 4° after a mean 47 months of follow-up) and (78.3% at 33 months of mean follow-up) respectively with no development of hypermobility or paradoxical motion.

5. Conclusion

Our study did not find any difference in improvement in lower back pain after two years of follow-up between patients operated by two-level TDR or a hybrid construct. The failure rate following two-level TDR was higher than with the hybrid construct and the rate of early complications lower than that previously described for the two techniques. No kinematic complications were found with two-level TDR and there was good preservation of range of motion. This study suggests that additional studies evaluating 2-level TDR for 2-level degenerative disc diseases are needed in young patients with chronic lower back pain, an indication which is actually excluded by HAS guidelines.

Disclosure of interest

K.A. and P.-M.L. declare that they have no competing interest.

J.A., J.-P.S., J.B., J.D.: co-inventor of the implant used in the study who receives royalties. Management of traveling and housing fees for invitations to conferences as an auditor.

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