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Original article

Two-level lumbar total disc replacement: Functional outcomes and segmental motion after 4 years

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ABSTRACT

Introduction: Lumbar total disc replacement is an effective treatment for single-level discogenic lower back pain. But the replacement of two disc levels is controversial.
Hypothesis: Two-level total disc replacement will improve function while preserving spinal motion.
Material and methods: A continuous series of 108 patients (51 women, 57 men) surgically treated over two levels with the ProDisc-L implant (Synthes Spine) was evaluated retrospectively with an average follow-up of 4 years. Ninety-three of these patients were operated for L4/L5 and L5/S1 degenerative disc disease, while 15 were operated for L3/L4 and L4/L5 disease. The procedure was carried out through the left retroperitoneal approach in 65 patients, the right retroperitoneal approach in 42 patients and both approaches in 1 patient. The Oswestry score, lumbar VAS and radicular VAS were used to evaluate function. The motion of the prosthetic disc segments was evaluated using Cobb's method. Data were collected prospectively in the context of regular patient monitoring. A retrospective analysis was carried out by an independent examiner.
Results: The procedure led to a statistically significant improvement in the functional scores. The motion of the upper disc segment was 9° (0°–19°) in flexion/extension and 5.5° (2°–12°) in lateral bending. It was 6.2° (0°–14°) and 1.9° (0°–7°) at the lower disc segment. The range of motion was similar in L3/L4 and L4/L5, but was less in L5/S1. Lack of mobility was not correlated with alterations in the functional outcome. The complication rate was 18%.
Discussion: Two-level lumbar disc replacement improves spinal function while preserving its mobility. But this procedure is fraught with risks and must be carried out by a highly-experienced team. A longer follow-up is needed to evaluate the sustainability of the results and to detect any adjacent segment disease. The French National Authority for Health (HAS) has recommended against two-level lumbar disc replacement, so it no longer can be performed in France.

1. Introduction

Single-level lumbar total disc replacement (TDR) has been shown to be non-inferior to spinal fusion. Its use is generally accepted in very specific indications [1,2]. But disc replacement at two levels is controversial because of conflicting results [3–8]. Currently, a two-level procedure cannot be performed in France because the HAS (French National Authority for Health) has recommended against it. However, TDR has been shown to be non-inferior to spinal fusion for the treatment of two-level degenerative disc disease (DDD), while improving mobility and functional recovery in the short term [9]. The alternative is to use a hybrid construct [10,11] that combines fusion and arthroplasty, with preservation of segmental motion being the theoretical advantage of the latter.

The goal of this study was to evaluate the perioperative complications and functional outcomes in patients who had undergone two-level lumbar TDR after a minimum follow-up of 2 years. The spinal segment motion was evaluated at the last follow-up using radiographs.

2. Material and methods

This was a continuous retrospective study of 150 patients operated for two-level lumbar TDR who were evaluated at least 2 years after the procedure. Of these 150 patients, only those operated at L3/L4 and L4/L5 or L4/L5 and L5/S1 were included. Patients were

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excluded from the analysis if they did not have complete and usable preoperative and postoperative clinical and radiological records. In the end, the analysis was carried out on 108 patients (57 men, 51 women) having an average age of 46 ± 10 years (range 19–73). The average follow-up was 49 months (range 25–63).

The surgical indication was established in patients with multi-level symptomatic DDD that was resistant to medical treatment or well-conducted rehabilitation and presented Modic 0, 1 or 2 signs on MRI [12,13], or failing that, a positive lumbar discogram.

The procedure was carried out at L4/L5 and L5/S1 in 93 cases and at L3/L4 and L4/L5 in 15 cases. It was performed through the left retroperitoneal (anterolateral) approach in 65 patients, the right retroperitoneal approach [14] in 42 patients and both approaches in 1 patient. The ProDisc-L Total Disc Replacement system (Synthes Spine, West Chester, PA, USA) was used in all patients. This is a semi-constrained implant consisting of two cobalt-chrome alloy endplates with keels that are coated with porous plasma-sprayed titanium and an UHMWPE core that is clipped to the inferior endplate and articulates with the superior endplate through a convex dome. The average duration of the procedure was 111 ± 31 min (70–230) with an average blood loss of 316 ± 453 mL (50–3500). The surgical scar was 10 ± 2 cm (5–18) long on average.

Data was collected prospectively in the context of regular patient follow-up. The Oswestry Disability Index (ODI) and several EVA tests (lumbar pain, radicular pain and satisfaction) were performed preoperatively and then postoperatively to assess function at 3 months, 6 months, 1 year, 2 years and then every 2 years. Radiographic assessment consisted of standard A/P and lateral weight-bearing views, dynamics images (Fig. 1) and standing views of the entire spinal column. The segmental motion was evaluated using Cobb's method [15].

The data were analysed retrospectively by an observer who was not affiliated with the surgeons, implant designers and implant manufacturer. Statistical analysis was performed with Statview® software to compare preoperative and postoperative data with Student's *t*-test. Differences were considered significant if $P < 0.05$.

3. Results

Results of the segmental motion analysis are given in Table 1. Overall, the two levels remained mobile in flexion/extension and lateral bending; the range of motion was significantly greater in the upper segment. Specific analysis of the motion of each type of construct found no differences between the two levels in the L3/L4 and L4/L5 constructs, but significantly lower values in the lower segment of the L4/L5 and L5/S1 constructs. Motion in the L4/L5 segment was unaffected by the type of construct used.

Table 1
Intraprosthetic motion (degrees).

	Flexion/extension	Lateral bending
Level 1	9 ± 5.7 (0–19)	5.5 ± 3.2 (2–12)
Level 2	6.2 ± 4.5 (0–14)	1.9 ± 2.4 (0–7)
P	< 0.05	< 0.05
L3/L4	8± 5.7 (1–14)	6.9 ± 3.2 (3–10)
L4/L5	8 ± 7.0 (1–14)	2.2 ± 3.2 (0–7)
P	n/s	n/s
L4/L5	7.3 ± 8.2 (1–19)	4.3 ± 3.7 (0–8)
L5/S1	4.4 ± 5.2 (1–12)	0.75 ± 0.95 (0–2)
P	< 0.05	< 0.05
L4/L5 (upper level)	8 ± 7.0 (1–14)	2.2 ± 3.2 (0–7)
L4/L5 (lower level)	7.3 ± 8.2 (1–19)	4.3 ± 3.7 (0–8)
P	n/s	n/s

n/s: not significant.

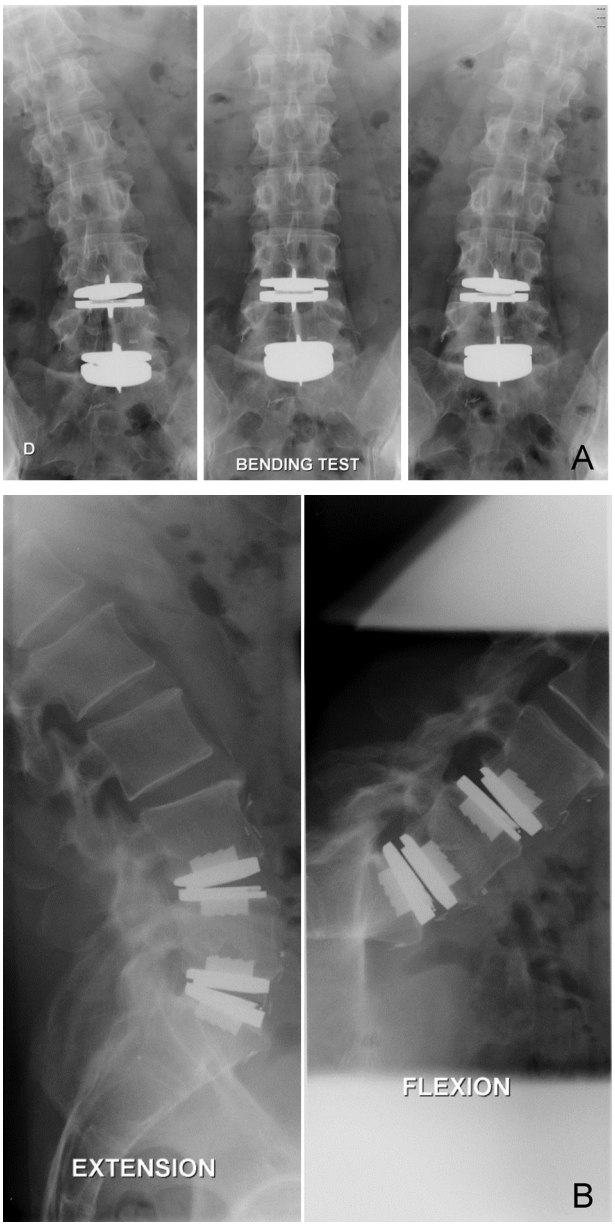

Fig. 1. A. Dynamic lateral bending X-rays for L4/L5; B. Dynamic flexion/extension X-rays.

Functionally, there was a significant improvement in the ODI, lumbar VAS and radicular VAS; the satisfaction VAS was 7.9 at the last follow-up (Table 2, Fig. 2).

If a "mobile segment" is defined as one with more than 2° motion, then three types of progression were observed: constructs where motion was preserved on both levels (74% of cases, including 87% of L4/L5–L5/S1), constructs where motion was preserved in the upper segment (21% of cases) and constructs without any motion (7% of cases). No significant differences were found between these

Table 2
Functional results.

	Preoperative	Last follow-up	Δ	*P*
ODI/50	25 ± 9	12 ± 10	−50%	< 0.05
Lumbar VAS	7.1 ± 2	2.8 ± 2.4	−60%	< 0.05
Radicular VAS	5.4 ± 3.1	2.6 ± 3	−52%	< 0.05
Satisfaction VAS	–	7.9	–	–