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ORIGINAL STUDY

Intervertebral prosthesis versus anterior lumbar interbody fusion : one-year results of a prospective non-randomised study

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The authors conducted a prospective non-randomised study on the ProDisc™ intervertebral prosthesis versus anterior lumbar interbody fusion (ALIF). The first group included 14 patients, the second group 10 patients. In the ProDisc group the Oswestry Disability Index improved from ± 38.42 preoperatively (60 being the worst possible condition) to ± 15.21 after 6 months and to ± 12.5 after 12 months. This was definitely better than the ALIF group, where the corresponding figures were ± 38, ± 25 and ± 21.4.

The ProDisc patients also scored better with respect to duration of hospitalisation, blood loss and operation time. The complications were comparable in both groups.

Keywords : spine ; disc prosthesis ; fusion.

INTRODUCTION

The artificial lumbar disc is an alternative to arthrodesis. Its purpose is to restore the basic motion of the intervertebral segment and to protect the adjacent levels against unphysiologic loading. Experience with peripheral joint replacement has demonstrated, in general, that motion preservation yields better functional results than does arthrodesis. Despite this, spinal fusion has remained the most common treatment of disabling mechanical low back pain, with satisfactory outcomes in 65 to 93 percent of the patients (*4, 5*). Success rates vary, depending on the diagnosis, number of previous operations, prior fusion attempts and number of levels fused (*7-10*).

The concept of total disc arthroplasty was first described by Fernström in 1966 (*2*). Over the last decade, there has been renewed interest in disc arthroplasty. Multiple European authors have reported early and intermediate-term results of total disc arthroplasty.

The ProDisc prosthesis versus ALIF has been used in this study. To show advantages of ProDisc different parameters were analysed, such as gender and age of patients, Oswestry index, hospitalisation time, and complications.

PATIENTS AND METHODS

The indications for artificial disc replacement (fig 1) or ALIF (fig 2) in this prospective non-randomised study were symptomatic degenerative disc disease or lumbar spondylosis, resistant to at least 6 months of conservative therapy, and objectively documented by computed tomography (CT) or magnetic resonance imaging (MRI), in patients between 18 and 60 years of age.

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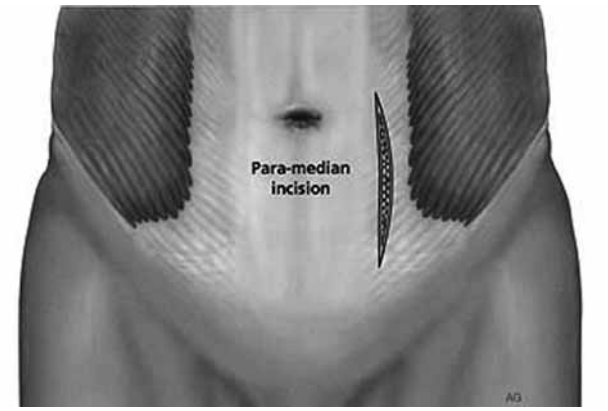

Fig. 1. — The surgical approach

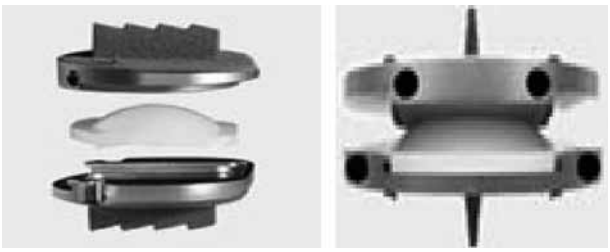

Fig. 2. — The ProDisc artificial disc

Twenty-four patients were enrolled : 14 men and 10 women. Their mean age was 44 years (range : 29 to 60). Fourteen patients underwent a single disc replacement (ProDisc®), either on level L3L4, L4L5, or L5S1 (table I) ; 10 patients underwent anterior lumbar intervertebral fusion by means of a cage filled with autologous iliac crest bone (table II). Both groups were comparable as to male/female ratio, age, spinal level, and preoperative Oswestry Disability Index (table I, II). The Oswestry Disability Index was expressed in absolute values, with 60 reflecting the worst possible condition. The Index was calculated before the operation, at 6 months, and at 12 months. Statistical analysis was not done, given the small size of the groups. The total follow-up period was one year. Complications, duration of the hospitalisation, blood loss and operation time were noted in both groups.

The implant used was the "Prodisc", manufactured by Synthes, Switzerland. The device is composed of three components. The two metal plates have a keel. The metal surface in contact with bone, including the keel, is covered with hydroxyapatite to enhance bony ongrowth.

The anterior fusion operations were performed either before the disk prostheses became available, or in patients who did not have the financial support for a Prodisc prosthesis, and in some cases in patients with marked spinal stenosis.

Surgical technique

In both groups the spine was approached through a "mini" left lower quadrant retroperitoneal approach. A longitudinal para-umbilical incision was made (fig 1). The rectus muscle was retracted laterally, and the preperitoneal space was entered at the level of the arcuate line or just below it. The peritoneum was retracted laterally. Hand-held medial-lateral retractors were used. Exposure of L5-S1 was done between the vascular bifurcation. Exposure of L3-L4 or L4-L5 required dissection and retraction of the aorta and vena cava to the right. The midline of the spinal column was marked with radiopaque markers in the vertebral body above the index disc. This was confirmed fluoroscopically, prior to the discectomy. Cobb elevators were used to separate the disc from the endplates. Subsequently, curettes and rongeurs were used to perform a thorough discectomy down to subchondral bone, along the endplates and as far as the posterior longitudinal ligament. Symmetrical distraction and restoration of the normal disc height was accomplished by means of a central spreader. Distractors and implant trials determined the appropriate implant size. Finally, an artificial disc (fig 2), or a fusion cage filled up with autogenous iliac crest grafts (fig 3), was implanted into the disc space under fluoroscopic control. In the fusion group no posterior fixation was added.

RESULTS

The ProDisc patients improved from a preoperative Oswestry-score of ± 38.42 to ± 15.21 after 6 months and to ± 12.5 after 12 months. The ALIF patients improved from a mean preoperative Oswestry score of 38 to 25 after 6 months and to 21.4 after 12 months, which was definitely less favourable. Hospitalisation was shorter in the ProDisc group : ± 3.85 days versus ± 6.3 days. Mean blood loss was only 100 ml in the ProDisc group, versus 330 ml in the ALIF group. Operation time was ± 1h33 versus 2 h 15.

Table I. — ProDisc

Gender	Age (years)	Level	Oswestry preop.	Oswestry at 6 mo.	Oswestry at 12 mo.	Complications	Hospitalisation	Blood loss	Operation time
male	51	L4L5	49	15	15	0	3 days	100 ml	1h30
male	44	L5S1	48	23	15	0	3 days	100 ml	1h20
male	50	L5S1	32	10	10	0	4 days	100 ml	1h40
male	38	L5S1	43	10	10	0	3 days	100 ml	1h30
female	57	L5S1	46	17	10	0	3 days	100 ml	1h30
female	46	L5S1	35	10	10	facet arthritis	10 days	100 ml	1h40
male	50	L4L5	29	12	11	sciatica	3 days	100 ml	1h30
female	45	L5S1	37	10	10	0	4 days	100 ml	1h40
male	53	L3L4	48	15	12	subsidence	3 days	100 ml	1h30
male	31	L5S1	36	17	12	sciatica	3 days	100 ml	1h35
female	31	L5S1	25	17	13	0	3 days	100 ml	1h40
female	38	L5S1	45	17	10	0	4 days	100 ml	1h30
male	39	L5S1	27	15	12	0	4 days	100 ml	1h40
female	36	L5S1	38	25	25	0	4 days	100 ml	1h30
m/f = 8/6	**43.5 (31-57)**	**L3L4 : 1 L4L5 : 2 L5S1 : 11**	**38.42 (25-49)**	**15.21 (10-25)**	**12.5 (10-25)**		**3.85 days (3-10)**	**100 ml**	**1h33 (1h20-1h40)**

Table II. — ALIF

Gender	Age (years)	Level	Oswestry preop.	Oswestry at 6 mo.	Oswestry at 12 mo.	Complications	Hospitalisation	Blood loss	Operation time
female	50	L5S1	39	15	15	0	8 days	300 ml	2h10
male	60	L4L5	45	30	30	0	9 days	300 ml	1h40
male	43	L4L5	40	25	15	0	6 days	300 ml	2h
male	29	L5S1	30	20	17	0	6 days	300 ml	2h10
male	33	L5S1	34	25	20	0	6 days	300 ml	2h20
female	48	L5S1	37	30	24	haemorrhage	6 days	300 ml	3h
female	50	L5S1	38	30	28	0	6 days	600 ml	2h30
male	40	L4L5	35	20	20	0	5 days	300 ml	2h10
female	39	L4L5	36	25	20	0	6 days	300 ml	2h
male	54	L5S1	46	30	25	0	5 days	300 ml	2h30
m/f = 6/4	**44.6 (29-60)**	**L3L4 :0 L4L5 :4 L5S1 :6**	**38 (30-46)**	**25 (15-30)**	**21.4 (15-30)**		**6.3 days (5-9)**	**330 ml**	**2h15 (1h40-3h)**

Complications in the ProDisc group included subsidence of the implant in one patient, facet arthritis noted after 6 months in another, and transient sciatica in two patients. In the ALIF group, intra-operative haemorrhage occurred in one case, due to specific technical difficulties.

Fig. 3. — The cage, filled with autogenous iliac crest grafts, used for anterior lumbar interbody fusion (ALIF).

DISCUSSION

The small size of the groups and the limited follow-up period do not allow firm conclusions. However, the ProDisc group scored definitely better from most viewpoints : Oswestry Disability Index, duration of hospitalisation, blood loss and operation time. Moreover, ProDisc patients were active sooner than fusion patients. Complications were comparable in both groups. As to the future, motion preservation is another advantage of the artificial disc and it may avoid degeneration of adjacent segments.

It is striking that a recent prospective, randomised, multicentre Food and Drug Administration study showed a similar superiority of the Charité artificial disc versus ALIF (*1*).

In a multicentre retrospective study, Griffith *et al* (*3*) also reported significant pain relief using the Link SB Charité prosthesis ; however, the authors identified a 6.5% incidence of implant failure including migration, device failure (plate breakage, plate fissuring, polyethylene wear) or dislocation, in 6 of 93 patients. Most of the complications occurred with the first and second generation of Link implants. All four teams using the Link prosthesis insisted that proper patient selection is essential to obtain a successful outcome.

Lemaire *et al* (*6*) discussed 105 cases, treated with a Charité disc, after a mean follow-up period of 51 months and found an excellent outcome in 79% with a return-to-work rate of 87%. The authors identified factors leading to clinical failure, such as posterior facet arthritis, osteoporosis, structural deformities, and secondary facet pain.

Lumbar total disc replacement may become an important competitor to arthrodesis in the future.

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