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.

No benefits or funds were received in support of this study.
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 L3-L4, L4-L5, or L5-S1 (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 2h15.
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.
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 lumbar fusion: Part I: Evaluation of clinical outcomes. Spine 2005; 30: 1565-1575.

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.

REFERENCES