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ORIGINAL ARTICLE

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Minimally invasive total disc replacement: surgical technique and preliminary clinical results

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Abstract Total disc replacement has become an option for the treatment of degenerative disc disease of the lumbar spine. A new generation of implants has been developed that can be implanted through minimally invasive anterior approaches to the lumbar levels L2/3, L3/4, L4/5 and L5/S1. However mid- and long-term data are still lacking. This paper describes the minimally invasive surgical approach – techniques as well as the preliminary results of our first 34 consecutive patients. The intervertebral spaces L5/S1, L4/5, L3/4 and L2/3 were each approached through slightly different, but standardized, mini-laparotomies either through a retroperitoneal or a transperitoneal route. The clinical results with a follow-up of up to 1 year show satisfactory outcomes in about 80% of the patients. Oswestry score as well as VAS values show significant changes during the postoperative course. There have been three complications (8.8%), two of which were specific to the implantation process, but were resolved with a good clinical outcome in both patients. The preliminary results suggest that total disc replacement may become a reasonable alternative to spinal fusion under the selection criteria used in this study.

Keywords Artificial disc · Degenerative disc disease · Lumbar spine · Total disc replacement · Low-back pain

Introduction

Degenerative disc disease remains a therapeutic challenge. The therapeutic gap that existed between conventional non-surgical treatment and spinal fusion surgery has been closed by a variety of so-called 'semi-invasive' techniques. Epidural catheter treatments, intradiscal electrothermal therapy (IDET), and partial (nucleus pulposus) or total disc replacement techniques have been developed and are being used more and more frequently in clinical studies, although safety and efficacy are not yet evidence based [1, 2, 3, 4, 5, 10, 11, 12]. This is also true for total disc replacement in the therapeutic regime of chronic discogenic low back pain. The clinical and radiological results thus have to be monitored closely. A new generation of implants for total disc replacement has been developed, designed especially for application through a minimally invasive anterior approach (Prodisc, Spine Solutions, Tuttlingen). It has been in clinical use since 1999. We report on the results of our own series of patients, which formed part of an international prospective clinical multicenter trial.

Implant and minimally invasive surgical technique

The clinical study was performed with a new generation implant (ProDisc). The modular implant technology allows a stepwise implantation, which fulfils all necessary criteria for a minimally invasive surgical access (Fig. 1). Preparation as well as application instruments play a key role in minimally invasive approaches for total disc replacement. Thus, all instruments for preparation of the implantation (probe implant, distractor, chisels) as well as

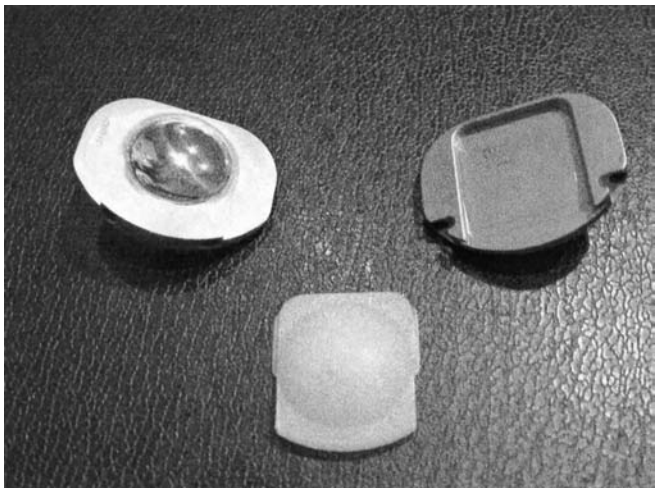

Fig. 1 ProDisc implant: modular design for minimally invasive step-by-step implantation

instruments for performing the implantation (applicator, distractor, inlay insertion, etc.) have been designed following microsurgical criteria (Table 1).

Surgical approaches

General remarks

Total disc replacement requires an anterior midline approach. Due to the designs of the implant, insertion into the intervertebral space must be performed strictly in the midline. This requires meticulous preoperative planning as well as a modification of the surgical technique, especially at L4/5 and higher levels.

Preoperative planning includes magnetic resonance imaging (MRI) investigation of the lumbar spine, as well as three-dimensional computed tomography (3D CT) angiography, to evaluate the size, shape and topography of the retroperitoneal blood vessels (Fig. 2). This technique makes it possible to clearly visualize the venous and arterial bifurcation and also shows the topographical relation between the arterial and venous branches. With these preoperative data, surgical planning can be performed in detail. The knowledge of the individual vascular situation of the patient influences the surgical technique and, in rare cases, might lead to a contraindication for disc replacement (e.g. venous bifurcation covering completely the anterior circumference of the target disc space). All other preoperative planning criteria correspond to the ones that have been described for minimally invasive anterior interbody fusion (MiniALIF) [6, 7, 8, 9].

All implantations can be performed through a midline mini-laparotomy. The patients are placed in a neutral mini-ALIF position (*cave*: hyperextension of the lumbar spine increases segmental lordosis) (Fig. 3). The target level is localized under antero-posterior and lateral fluoroscopic control and marked on the skin. All implantations are performed through small 4- to 5-cm transverse skin incisions (Fig. 4). Because of anatomical and topographical details, each level has very specific technical demands.

Technique for the L5/S1 level

This is the easiest segment to approach. After exposure of the rectus fascial sheet, the linea alba is split in the midline, and the peritoneum is exposed. There are three options for exposing the L5/S1 disc space from anterior: retroperitoneal from the right side, retroperitoneal from the left side or transperitoneal. The 'approach decision' should follow the following guidelines.

Retroperitoneal approach from the right side

This approach should be the first choice. The peritoneum is bluntly detached from the inner abdominal wall on the right side. The transverse fascia has to be incised to mobilize the abdominal contents adequately. The psoas muscle as well as the common iliac artery with the urether are identified. Preparation is continued towards the midline between the urether (displaced medially) and the artery. Medial to the common iliac artery, the lateral circumference of L5/S1 can be exposed. In this area, the superior hypogastric plexus is very thin with rare and small branches, which decreases the risk of damaging this plexus. Blunt dissection of the prevertebral fat tissue including the plexus exposes the medial sacral artery and vein, which can then be clipped or coagulated and dissected. Thus L5/S1 can be exposed easily. The left common iliac vein

Table 1 Instrument and implant properties for minimally invasive implantation

Instrument	Properties
Distractor	Slim instrument design for small approach corridors
Probe implant	Same size as implant, fits through small corridor easy, coupling mechanism guides chisel
Chisel	Guided by probe implant, no additional space required
Implant applicator/distractor	Same width as implant, no additional space required, easy coupling/uncoupling, easy distraction and inlay insertion

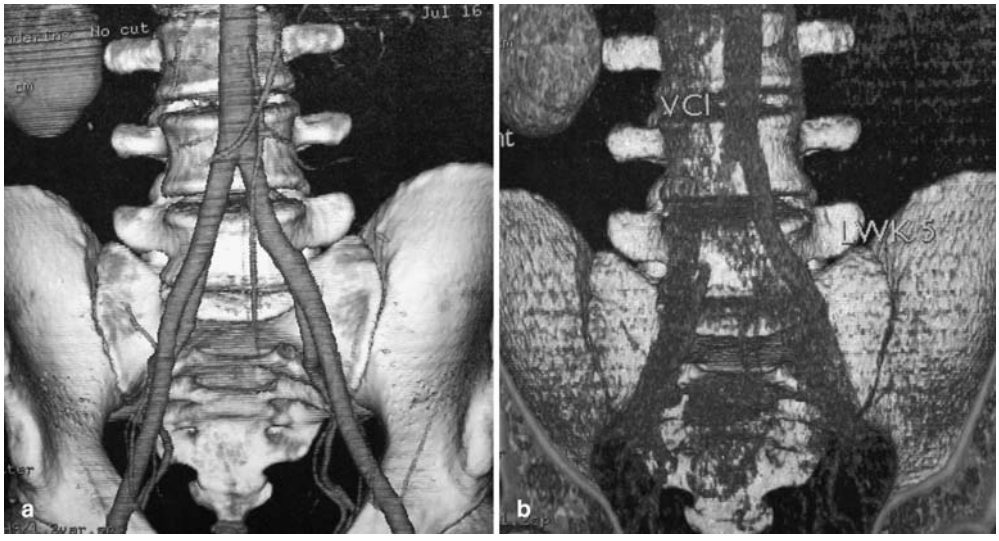

Fig. 2a, b Three-dimensional computed tomography (3D CT) angiography of the retroperitoneal blood vessels of the lumbar spine: **a** arterial branch, **b** venous branch

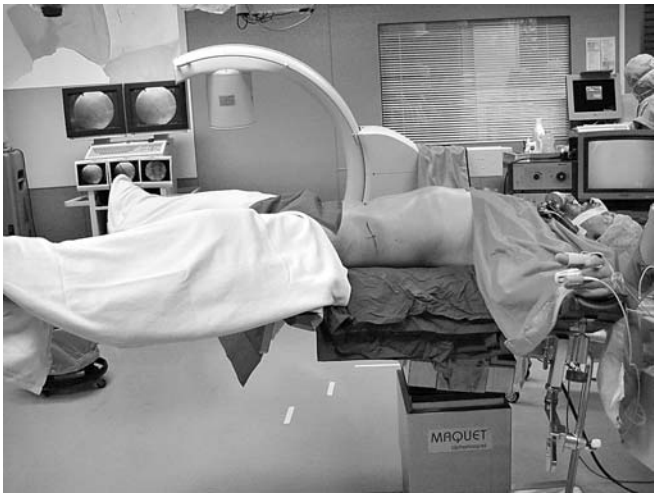

Fig. 3 Positioning of the patient (*nb* hyperextension must be avoided!)

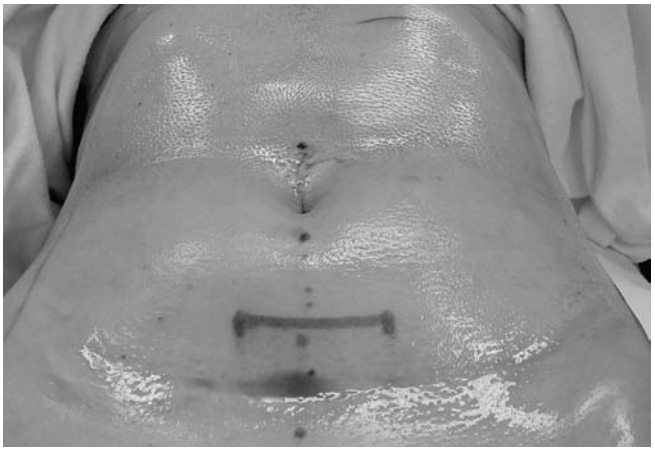

Fig. 4 Skin incision for mini-laparatomy

can be retracted carefully to the left (Fig. 5). This is the safest and easiest approach to L5/S1.

Retroperitoneal approach from the left side

This approach is chosen in cases with previous abdominal surgery in the lower right quadrant (e.g. appendectomy, gynecological operations, operation for abdominal hernia). The dissection process is the same as on the right side. Dissection is performed across the common iliac vein to the disc space L5/S1, which is sometimes difficult, especially if the vein has a large diameter. The plexus hypogastricus superior has to be pushed medially with care, avoiding any coagulation. These two factors make this approach the 'second-choice approach'; however, exposure of L5/S1 can be achieved as completely as from the right side.

Transperitoneal approach

In very obese patients, in patients who have had conventional abdominal surgery and in revision cases, the transperitoneal minimally invasive approach is the appropriate technique. It is the most direct way to L5/S1, and can be performed easily even in obese and previously operated patients [7].

Technique for the L4/5 level

Vascular anatomy determines the approach to L4/5 (see Fig. 2B). Due to the venous anatomy, the retroperitoneal approach from the left side is preferred in conventional surgery. Dissection can be performed across the aorta or the common iliac artery first. The arcuate line has to be incised in order to get adequate mobilization.

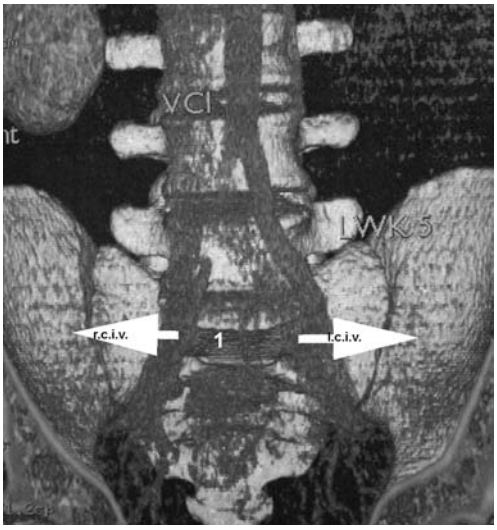

Fig. 5 Three-dimensional CT angiography: direction of vascular mobilization and retraction at L5/S1 (*r.c.i.v.* right common iliac vein, *l.c.i.v.* left common vein, *1* ligation of medial sacral artery and vein)

However, retroperitoneal exposure of L4/5 has its limitations in a minimally invasive approach. Mobilization of the abdominal contents is more difficult through a 4- to 5-cm skin incision. The same is true for preparation and retraction of the blood vessels. Due to the lordotic curve of the lumbar spine, the distance between the L4/5 disc space and the anterior abdominal wall is quite short. This makes a direct transperitoneal approach reasonable. Easy orientation and dissection of the superior hypogastric plexus and the perivascular tissues are further advantages. Exposure of the disc space follows the vascular situation (Fig. 6). Care has to be taken to ligate and dissect all segmental arterial and venous branches as well as the ascending lumbar vein on the left side to prevent indirect injury to these structures.

Technique for the L2/3/4 levels

The approach to L3/4 and L2/3 needs modifications on the skin-to-spine-route. The skin incision is usually at the level of, or above, the umbilicus. If it is at the umbilical level, a small, longitudinal paramedian incision on the left side is preferred. Retroperitoneal exposure is much more difficult at these levels, since the peritoneum is adherent to the posterior rectus sheet. Innervation of the rectus muscle must be preserved and the integrity of the fascial indentations at these levels must be respected. It is thus recommended to expose the retroperitoneal space in two steps: (1) longitudinal midline incision of the anterior rectus sheet 5 mm lateral to the linea alba and exposure of the left rectus muscle, and (2) dissection anterior to the muscle to its lateral border and opening of the retroperitoneal space. Thus, the peritoneum can be detached from the posterior rectus sheet from left lateral to the midline. The exposure is then continued by opening of the posterior rectus sheet close to the midline and retroperitoneal dissection from the left to the right. In obese patients, again, a transperitoneal route is recommended. The various options of vascular preparation are shown in Fig. 7.

After removal of the nucleus pulposus and after endplate preparation, the implant is positioned according to manufacturer's guidelines.

Materials and methods

Study design

This was a prospective, non-randomized clinical multicenter study. All patients had to give written informed consent. Study documen-

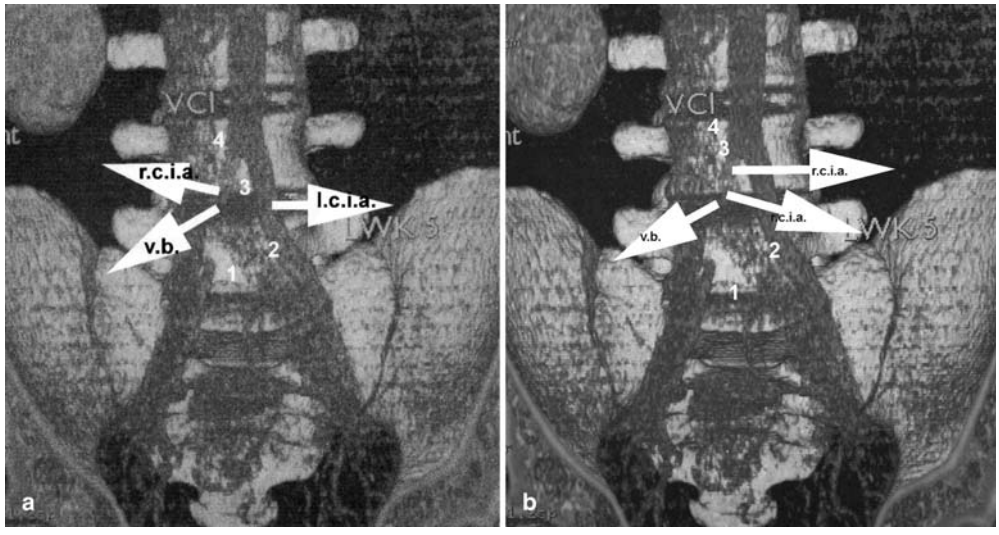

Fig. 6a, b Three-dimensional CT angiography: direction of vascular mobilization, retraction and branches to be ligated – most common variants at L4/5. **a** Approach between arterial bifurcation, lateral to venous bifurcation (*v.b.* venous bifurcation, *r.c.i.a.* right common iliac artery, *l.c.i.a.* left common iliac artery; ligations of *1* medial sacral vein, *2* ascending lumbar vein, *3* medial sacral artery, *4* segmental vein L5 left). **b** Approach between venous and arterial bifurcation (*v.b.* venous bifurcation, *r.c.i.a.* right common iliac artery; ligation of *1* medial sacral vein and artery, *2* ascending lumbar vein, *3* right segmental artery L4, *4* left segmental vein L4)

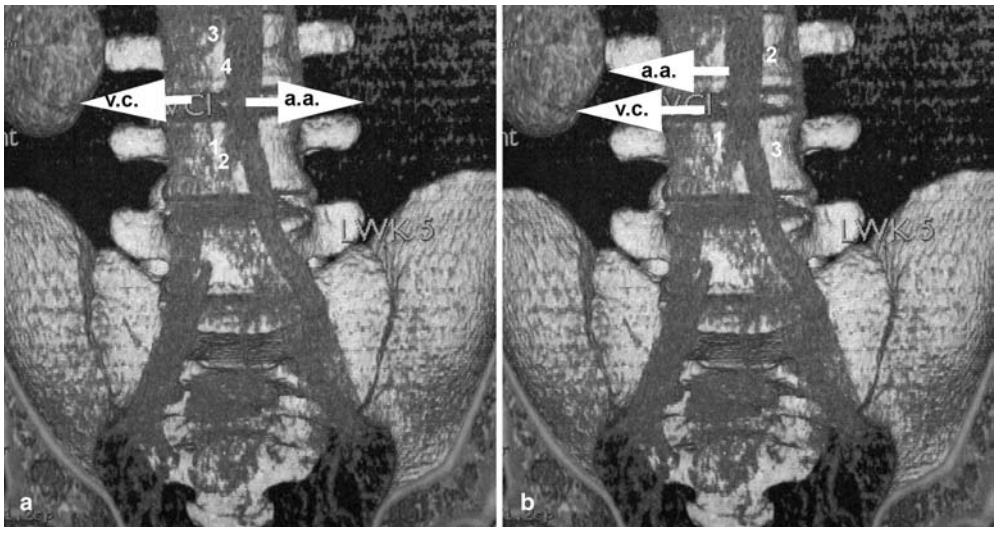

Fig. 7a, b Three-dimensional CT angiography: direction of vascular mobilization, retraction and branches to be ligated – most common variants at L2/3/4. **a** Approach between the vena cava and the abdominal aorta (*v.c.* vena cava, *a.a.* abdominal aorta; ligation of *1* segmental vein L4 left, *2* segmental artery L4 right, *3* segmental vein L3 left, *4* segmental artery L3 right). **b** Approach from the left side. (*v.c.* vena cava, *a.a.* abdominal aorta; ligation of *1* segmental vein L4 left, *2* segmental artery L3 left, *3* segmental artery L4 left)

tation was standardized, and included the visual analog scale (VAS), the Oswestry Disability Score, the SF36 Health Questionnaire and numerous clinical and radiological parameters. Data acquisition was performed preoperatively and at 3, 6, 12 and 24 months postoperatively. For each follow-up visit, radiographs of the lumbar spine in antero-posterior and lateral projection plus functional views in flexion and extension were acquired.

Patient selection

The indications were mono- or bisegmental lumbar disc degeneration and postoperative disc degeneration, as well as osteochondrosis and degeneration of levels adjacent to a former lumbar fusion. In all patients, symptoms had not responded to an extensive course of outpatient and inpatient physiotherapy including fluoroscopy-guided infiltrations as part of the preoperative workup. Conservative treatments were performed for more than 6 months in all patients. The symptoms of the patients had to be concordant with the results of preoperative imaging.

Contraindications were all kinds of translational instability (e.g. spondylolisthesis), spinal stenosis, significant osteoarthritis of the facet joints, deformities, infection or tumor, unwillingness to comply with study requirements regarding follow-up visits and radiological controls, previous fusion attempts in the affected levels, pregnancy and incomplete worker's compensation procedures.

All patients were operated according to the surgical philosophy described above. Postoperatively, the patients were mobilized on the day after surgery. With physiotherapeutic advice, most patients were able to be discharged a few days postoperatively.

Results

Patient population

Between June 2000 and March 2002, 34 patients were operated. Gender distribution was 12 males and 22 females. Average age was 44.0 years, ranging from 25.2 to 65.4 years. The predominant diagnosis was degenerative disc disease in 61.8% (21 patients), while disc degeneration in combination with a median nucleus pulposus herniation was found in 11.8% (four patients). Five patients (14.7%) had a postoperative osteochondrosis following disc surgery, three patients (8.8%) had a disc degeneration adjacent to a spinal fusion, and one patient had a dislocated nucleus replacement device at the affected level (Table 2). The lumbosacral motion segment, L5/S1, was affected in most cases (24 patients; 70.6%). In three patients (8.8%) it was L5/6, in a further three patients L4/5 was symptomatic, and in three patients we found a bisegmental affection in L4/5 and L5/S1. One patient (2.9%) had an affection of L2/3.

Table 2 Diagnosis for total disc replacement (*FBS* failed back syndrome)

Degenerative disc disease	61.8% (21/34)
Degenerative disc disease + disc herniation	11.8% (4/34)
FBS/postop. osteochondrosis	14.7% (5/34)
Adjacent level degeneration	8.8% (3/34)
Degenerative following nucleus replacement	2.9% (1/34)

Intra-operative data

In 54.8% a transperitoneal approach was used and in 45.2% a retroperitoneal midline approach was used. Mean operating time was 130.9 min, ranging from 88 to 300 min, with a standard deviation of 45.9 min. Average blood loss was 117 ml per level (range 30–350 ml).

The Prodisc implant is available in two sizes. The "medium" size was used in 36 of 37 affected segments, and "large" was used at one level. The implant with 6° lordosis angle was used in 65.4%; the 11° angle was used in 34.6%. The polyethylene inlay of 10 mm height was used in 34 segments, the 12-mm inlay in two segments and the 14-mm inlay in one segment.

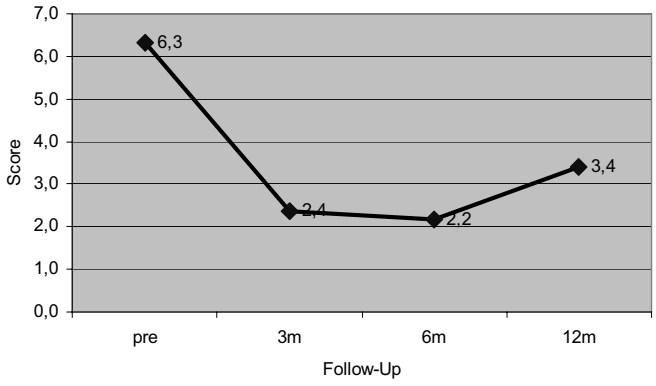

Fig. 8 Visual analog scale (VAS) pre-operatively and after total disc replacement

Clinical results

Twenty-six of 34 patients (76.5%) attended at least one follow-up visit for evaluation. The remaining patients had not yet finished the first 3-month interval postoperatively. Average follow-up was 5.8 months, with a standard deviation of 3.0 months.

The VAS scale averaged 6.3 points preoperatively. It was reduced by 3.9 points on average, ranging from 8.4 points reduction to 7.5 points increase (Fig. 8).

The Oswestry score ranged from 1 to 32 points before surgery, with an average of 19.1 points (standard deviation 7.4 points). It was reduced postoperatively by an average of 11.5 points. The change in the postoperative score ranged from 27 points reduction to an increase of 12 points (standard deviation 9.6 points) (Fig. 9).

While all patients had low-back pain before surgery, 76% had no low-back pain at the time of their latest follow-up.

Presently, we do not see any difference in clinical outcome between the subgroups of those patients previously operated or between the patients with a bisegmental versus those with a unisegmental implantation.

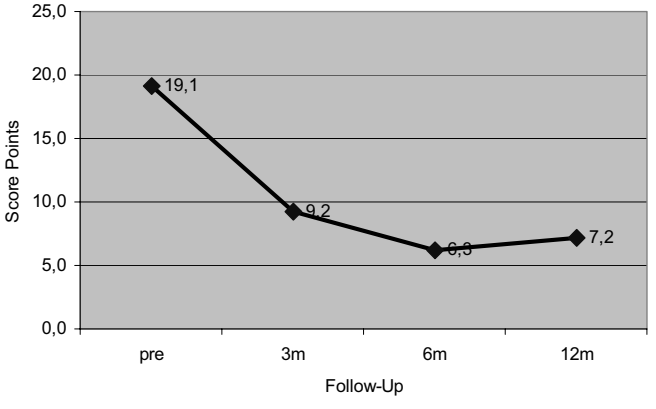

Fig. 9 Oswestry Low Back Disability Index pre-operatively and following total disc replacement

The duration of the postoperative hospital stay averaged 12.0 days (range 4–25 days).

At the time of the latest follow-up, 60.9% of all patients were "completely satisfied", while 21.7% were "satisfied", which gives an overall success rate according to the subjective rating of 82.6%. However, all of the 17.4% who were not satisfied with the clinical result stated that they would undergo the operation again if they were again faced with that choice.

Radiological results

Regarding all 37 devices implanted, we saw no loosening of the implant and no migration. Follow-up radiographs showed no change in the function of the implant over time. Endplates of the adjacent vertebrae did not show any subsidence.

Complications

In 91.2% of all patients, we did not see any complications. We have seen three complications related to the surgical procedure. There were no intra-operative complications, no general complications and no deaths. No patient in our series had to be fused in a re-operation of the affected segment. We did not see any superficial or deep infections.

One patient experienced a nerve root irritation of the L5 nerve root several days postoperatively. Computed tomography revealed an extra-foraminal protrusion of nucleus material compromising the L5 nerve root on the left side. Neurological examination was normal. A 3-week outpatient course of conservative treatment and perineural infiltrations led to complete and permanent pain reduction.

One other case showed substantial pain reduction in the immediate postoperative course. Five weeks later, an increase of pain was noted with no notable trauma. Radiographs showed an inlay dislocation anteriorly. The surgical revision revealed an intact polyethylene inlay. The endplates were solidly fixed and showed no signs of loosening. They were removed and the whole device was replaced by a new implant. We believe that this case was a technical failure at the time of the first implantation, when the polyethylene inlay obviously was not completely snapped into the inferior endplate. The ongoing clinical course was uneventful, pain reduction was achieved, and radiographic controls were normal. One patient complained of a retrograde ejaculation at 3 months follow-up.

Conclusions

These are preliminary results with a new implant for total disc replacement. As compared to a first-generation com-

peting implant system, which has been in clinical use since 1984, there are striking differences with respect to the design and implantation technique [1, 4]. The major advantage of this kind of implant is that removal of the disc, distraction of the intervertebral space and insertion of the device can be performed through standardized minimally invasive approaches, which have already been used successfully for anterior lumbar interbody fusion with slight modifications. Minimally invasive approaches are possible even in difficult anatomical regions such as L4/5 and higher lumbar levels. The perioperative results show that iatrogenic morbidity is very low. All patients could get out of bed the day after the operation. For study and academic reasons, we kept most of the patients in hospital for more than 1 week; however, our data suggest that the majority of the patients will be able to leave the hospital after a few days where there is an uneventful perioperative course. Intra-operative data are virtually the same as with anterior interbody fusion, except for the fact that there is no co-morbidity at the donor site for bone grafts [6]. Although this was not a randomised study, the early clinical results are promising. There were two "specific" complications, which were resolved and ended up with a favorable clinical result. The postoperative L5 root irritation in one patient was most probably the result of inadequate removal of the nucleus pulposus. Since the implant is space-occupying, there might be a certain risk that remaining disc tissue is pushed towards the spinal canal or the foramen while the implant is impacted into the disc space. The second complication (anterior dislocation of the polyethylene inlay) was definitely a technical error during the implantation. The snap-locking mechanism of the inlay prevents dislocation, but requires precision during the insertion. The anterior border of the inlay must be in line with the anterior border of the inferior endplate. Even slight "steps" of less than 1 mm should not be tolerated.

In summary, although preliminary, the results suggest, that total disc replacement for the indications mentioned above might be a reasonable alternative to lumbar fusion.

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