ELSEVIER
SAUNDERS

Neurosurg Clin N Am 16 (2005) 651–656

NEUROSURGERY
CLINICS
OF NORTH AMERICA

The ProDisc Artificial Disc: Insertion Technique

Henry E. Aryan, MD, Frank L. Acosta Jr, MD,
Christopher P. Ames, MD*

Department of Neurosurgery, University of California–San Francisco, 505 Parnassus Avenue, M-779, San Francisco, CA 94143, USA

The ProDisc artificial lumbar disk is composed of three modular components:

- the inferior cobalt chromium molybdenum plate with a large central keel
- the ultra-high molecular weight polyethylene insert; and
- a superior cobalt chromium molybdenum plate with a central keel, for anchorage to the vertebral bodies.

The ultra-high molecular weight polyethylene (UHMWPE) insert snap-locks into the inferior plate and provides an inferior convex-bearing surface. The plate attached to the superior vertebral body maintains a highly polished surface that articulates with the convex polyethylene surface to allow motion of 13 degrees of flexion, 7 degrees of extension, 10 degrees of lateral bending, and 3 degrees of axial rotation [1]. The bony contact surfaces of the two cobalt chromium molybdenum (CoCrMo) plates are coated with a titanium plasma spray for better bony ongrowth. Additional stability is obtained by a large central keel that interdigitates with the vertebral body above and below [1].

The ProDisc was designed in the late 1980s by Thierry Marnay, a French orthopedic spine surgeon. From March 1990 to February 1993, Marnay implanted this artificial disc into 64 patients [2]. In 1999, these patients were studied to determine the long-term results of implantation. Three of these patients had died from unrelated causes, but 58 of the surviving 61 patients (95%) were found and studied extensively at 7- to 11-year follow-up. All implants were intact and functioning. There had been no implant removals, revisions, or failures. There was no evidence of subsidence (sinking or settling in bone) on follow-up radiographs compared with the perioperative films as reported by the operating surgeon as well as an independent orthopedic spine surgeon.

A significant ($P<.001$) reduction in patient-reported back pain and leg pain was identified; 92.7% of patients were "satisfied" or "extremely satisfied" with the procedure. Two thirds of these patients had single-level implants, and one third had two-level implants. There was no outcome difference between the single- and two-level implantations. Most importantly, at this long-term follow-up, there were no device-related safety issues, no untoward effects, no complications, and no adverse events [2].

The ProDisc is based on spherical articulations. It has metal endplates made of a CoCrMo alloy (Figs. 1 and 2). The convex bearing surface, snap-fit into the inferior end plate, is made of UHMWPE. The artificial disc is attached through a large central keel and two spikes on each endplate. Physiologically, the ProDisc matches the range of motion in flexion, extension, axial rotation, and lateral bending as a normal spine.

The device is modular, so the surgeon can customize the device to each patient's unique anatomic and physiologic requirements. There are two endplate sizes (medium and large), three heights of the polyethylene component (10, 12, and 14 mm), and two lordosis angles (6 and 11 degrees).

* Corresponding author.
E-mail address: amesc@neurosurg.ucsf.edu (C.P. Ames).

1042-3680/05/$ - see front matter
doi:10.1016/j.nec.2005.09.001

Fig. 1. Three components of the ProDisc.

The implantation instrumentation is straightforward and user-friendly. Minimal access approaches to the lumbar spine, (typically through a mini-retroperitoneal approach) are possible given the streamlined design of the instrumentation.

The endplates are inserted in a collapsed form so that overdistraction (or ''jacking open'') of the disc space is not required. Only after the metal endplates are seated in the vertebral bodies is the disc space distracted. The surgeon can appreciate the soft tissue tension and insert an appropriately sized UHMWPE implant within the disc space, snap-fitting it into the lower metal endplate to complete the assembly process within the body (Figs. 3 and 4).

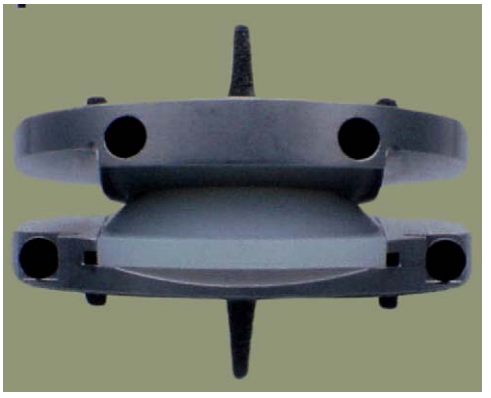

Fig. 2. Assembled ProDisc.

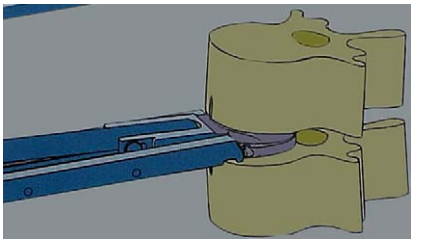

Fig. 3. Insertion of the ProDisc metal endplate.

General surgical technique

The ProDisc is implanted using an anterior approach to the lumbar spine [1]. Intraoperative fluoroscopy is used throughout the case to verify the placement of the prosthesis. Once exposure is obtained, an antero-posterior view confirms the level and identifies the exact midline, which is marked with the cautery. A complete discectomy is then performed. Cartilage is removed from the vertebral endplates. If herniated disc material is identified on the preoperative MRI, this may be removed through the anterior approach. In some cases, the posterior longitudinal ligament has contracted and prevents re-expansion of the disc space, so this must be released from the posterior vertebral body with a forward-angled curette. Once the normal anatomic height has been restored with distraction under fluoroscopy, a trial is placed to help select the proper disc size, angle, and height. A sagittal groove is then cut in the vertebral endplates in the exact midline using a chisel placed over the trial. This groove will accept the central keel of the implant. The trial is removed, and the final implant is then gently impacted into place on an insertion tool. The insertion tool allows distraction of the disc space for placement of the UHMWPE liner, which is snap-fit into position. After the insertion instrument is removed, gross inspection is made to ensure the

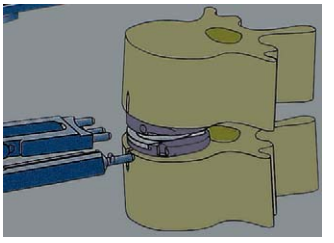

Fig. 4. Disc inserted and complete (with polyethylene core in place).

UHMWPE liner is properly flush against the inferior endplate, and final fluoroscopic views are taken to confirm correct position of the prosthesis (Figs. 5–8).

Anterior midline approach

Due to the designs of the implant, insertion into the intervertebral space must be performed strictly in the midline [3,7]. This requires meticulous preoperative planning as well as a modification of the surgical technique, especially at L4/5 and higher levels. Preoperative planning includes MRI investigation of the lumbar spine and often three-dimensional CT angiography to evaluate the size, shape, and topography of the retroperitoneal blood vessels. This technique makes it possible to clearly visualize the venous and arterial bifurcation and also shows the topographic 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 (eg, venous bifurcation covering completely the anterior circumference of the target disc space).

The implants are placed through a midline mini-laparotomy. The patients are placed in a neutral mini-ALIF position (hyperextension of the lumbar spine increases segmental lordosis). 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. Because of anatomic and topographic details, each level has very specific technical demands.

The L5/S1 level

After exposure of the rectus fascial sheet, the linea alba is split in the midline, and the peritoneum is exposed [3,7]. There are three options for exposing the L5/S1 disc space anteriorly: retroperitoneally from the right side, retroperitoneally from the left side, and transperitoneally.

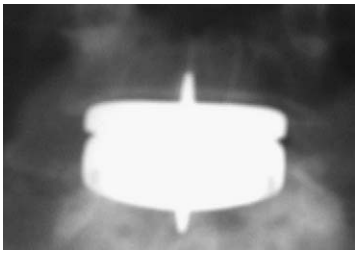

Fig. 5. Implanted ProDisc.

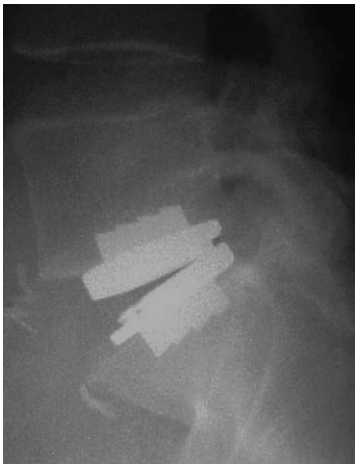

Fig. 6. ProDisc artificial disc (patient bending backward).

Retroperitoneally from right side

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 [3,7]. The psoas muscle as well as the common iliac artery with the ureter are identified. Preparation is continued toward the midline between the urether (displaced medially) and the artery. Medial to the common iliac artery, the lateral circumference

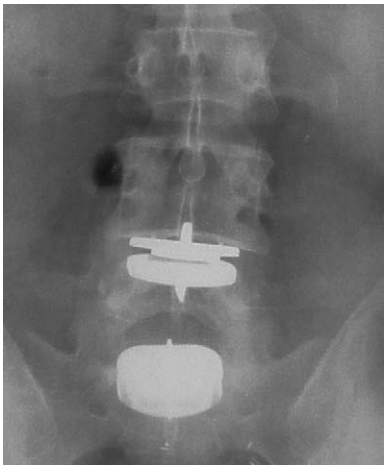

Fig. 7. Implanted ProDisc view from the front.

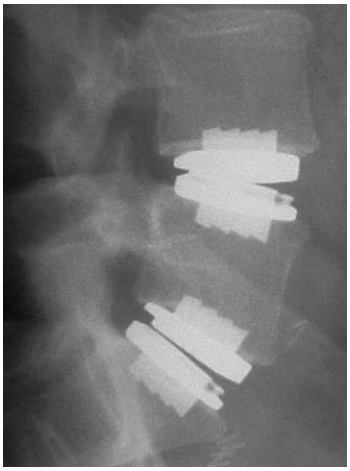

Fig. 8. Side view of ProDisc at L4/L5 and L5/S1.

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 can be retracted carefully to the left.

Retroperitoneally from left side

This approach is used in cases with previous abdominal surgery in the lower right quadrant (eg, 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 [3,7]. The plexus hypogastricus superior has to be pushed medially with care, avoiding any coagulation. The 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 [3,7].

The L4/L5 level

Vascular anatomy determines the approach to L4/5. 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 to obtain adequate mobilization [3,7]. 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. Because of 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. 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.

The L2/L3 and L3/L4 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 [3,7]. 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, because 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. After removal of the nucleus pulposus and after endplate

preparation, the implant is positioned according to manufacturer's guidelines.

Ongoing studies

The ProDisc has been implanted in over 5000 patients in Europe since December 1999 [5–7]. A multicenter US Food and Drug Administration (FDA) study was started in the United States in October 2001. The first ProDisc in the United States was implanted at the Texas Back Institute on October 3, 2001 [8,9]. Nineteen study centers participated in the prospective randomized study, comparing the ProDisc to the current standard treatment of a 360° (front and back) fusion using allograft in the intervertebral space and pedicle screws with autograft posteriorly [4].

The randomization protocol was 2:1, with two out of every three study participants receiving a ProDisc and one in three receiving fusion. The ProDisc could be implanted at L3/L4, L4/L5, or L5/S1. There was also a concurrently running two-level ProDisc replacement study. In the two-level study, patients could be randomized into a 2:1 format if they had two adjacent levels of symptomatic disc disease between L3 and S1. After surgery, patients are to be followed for 24 months and then annually until the last patient in the study is 24 months postoperative.

The single level study arm completed enrollment in April 2003. Since May 2003, ProDisc study centers have been allowed to implant a small number of nonrandomized patients with single-level ProDiscs as part of an FDA-allowed continued access trial. Patients must meet the same inclusion criteria as in the randomized study. Safety data is collected on these patients in the same way it was collected on the randomized patients, but they are assured a ProDisc.

The two-level study arm completed enrollment in November 2003. Continued access in this arm began in January 2004, in which a limited number of patients may be treated at study sites with two-level ProDisc surgery as long as they meet the original study criteria and continue follow-up for collection of safety data.

ProDisc is the only one of the artificial discs undergoing FDA trials that is being investigated for multiple-level lumbar disc disease.

Inclusion criteria are degenerative disc disease in 1 or 2 adjacent L3/S1 segments causing back and/or leg pain with radiographic corroboration. Patients must be 18 to 60 years old, have failed at least 6 months of conservative therapy, have an Oswestry score of greater than 20/50, and be able to comply with the protocol and follow-up.

Exclusion criteria include more than two symptomatic diseased levels, known allergy to the implant components, prior lumbar fusion surgery, clinically compromised vertebral bodies from trauma, clinically significant degenerative facet disease, lytic spondylolisthesis or spinal stenosis, degenerative spondylolisthesis greater than grade I, pain that defies diagnosis, osteoporosis, metabolic bone disease (including Paget's disease and osteomalacia), or small vertebral bodies. Additional exclusion criteria are morbid obesity; pregnancy (or interest in becoming pregnant within the next 3 years); active infection; medication that interferes with healing (eg, steroids); rheumatoid arthritis or other autoimmune disease; systemic disease such as AIDS, HIV, or active hepatitis; and active malignancy (clinical signs within the past 5 years).

Patients are followed up at standard intervals. At each follow-up visit, patients complete short forms, are examined, and have radiographs taken. The postoperative follow-up intervals are at 2 weeks, 6 weeks, 3 months, 6 months, 12 months, and 2 years. Annual visits are required until the study closes.

Interim data analyses from the Texas Back Institute has demonstrated that ProDisc patients have lower blood loss, shorter operative times, and average 1 day less in hospital stay than the randomized fusion controls [8,9]. Return-to-work data suggest that disc replacement patients can return to work earlier, both for light duty as well as unrestricted work activity, than the fusion patients. Both arthroplasty and fusion groups show a statistically significant reduction in their visual analog scores and functional Oswestry scores compared with their preoperative levels.

A decision by the FDA regarding clinical release will likely be made in 2005.

References

[1] Delamarter RB, Fribourg DM, Kanim LE, Bae H. ProDisc artificial total lumbar disc replacement: introduction and early results from the United States clinical trial. Spine 2003;28:167–75.

[2] Tropiano P, Huang RC, Girardi FP, Marnay T. Lumbar disc replacement: preliminary results with ProDisc II after a minimum follow-up period of 1 year. J Spinal Disord Tech 2003;16:362–8.

[3] Mayer HM. A new, microsurgical technique for minimal invasive anterior lumbar interbody fusion (Mini-ALIF). Spine 1997;22:691–700.

[4] Hanley EN Jr, David SM. Lumbar arthrodesis for the treatment of back pain. J Bone Joint Surg 1999;81: 716–30.
[5] David TH. Lumbar disc prosthesis: a study of 85 patients reviewed after a minimum follow-up period of five years. Rachis Revue de Pathologie Vertebrale 1999;11:1–7.
[6] Bertagnoli R, Kumar S. Indications for full prosthetic disc arthroplasty: a correlation of clinical outcome against a variety of indications. Eur Spine J 2002;11: 131–6.
[7] Mayer HM, Wiechert K, Korge A, Qose I. Minimally invasive total disc replacement: surgical technique and preliminary clinical results. Eur Spine J 2002;11: 124–30.
[8] Zigler JE, Burd TA, Vialle EN, Sachs BL, Rashbaum RF, Ohnmeiss DD. Lumbar spine arthroplasty: early results using the ProDisc II: a prospective randomized trial of arthroplasty versus fusion. J Spinal Disord Tech 2003;16:352–61.
[9] Zigler JE. Lumbar spine arthroplasty using the ProDisc II. Spine J 2004;4:260–7.