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Clinical Results with ProDisc: European Experience and U.S. Investigation Device Exemption Study

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Study Design. This study is based on a review of the literature related to the use of the ProDisc device and a report of the preliminary results of a prospective randomized study.

Objectives. To review European results related to the use of the ProDisc device and compare the results of this device to lumbar fusion in a prospective, randomized study being performed as part of a Food and Drug Administration-approved investigational study.

Summary of Background Data. There are two devices that have been used on a large-scale basis for total disc replacement. These are the SB Charitè and the ProDisc. Both devices were created in Europe and have been used there for more than 10 years. Reported results for these devices have been favorable, but there have been no prospective studies evaluating the outcome.

Methods. The literature related to the ProDisc was reviewed. The preliminary study data were based on one center's experience participating in the Food and Drug Administration Investigation Device Exemption study. There were 39 patients with a minimum 6-month follow-up. Patients were randomly assigned to receive either the ProDisc or undergo a combined anterior–posterior lumbar fusion in a ratio of 2:1 (ProDisc to fusion). Patients completed standardized questionnaires before surgery and at 6 weeks, 3 months, and 6 months after surgery. Data collection is continuing for the 12- and 24-month follow-up.

Results. Operative time, blood loss, and length of hospitalization were significantly less in the disc replacement group ($P < 0.05$). At the 3-month follow-up, the disc replacement group had a significantly greater improvement in Oswestry scores than did the fusion group. There were no differences in pain scores as measured by visual analog scales. Disc replacement patients had greater motion and there was a trend for this group to have greater satisfaction at the 6-month follow-up.

Conclusions. The preliminary results of this prospective randomized study found that peri-operative factors were more favorable in the disc replacement group than in the fusion group. There was a trend to greater patient satisfaction in this group. These early results suggest that total disc replacement may be a viable alternative to lumbar spinal fusion in patients with symptomatic disc disruption unresponsive to nonoperative care. Long-term follow-up is needed and is currently being collected for this study group. [Key words: spinal arthroplasty, lumbar spine, artificial disc] **Spine 2003;28:S163–S166**

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The device(s)/drug(s) that is/are the subject of this manuscript is/are being evaluated as part of an ongoing FDA-approved investigational protocol (IDE) or corresponding national protocol to compare the efficacy of lumbar ADR vs. 360° fusion.
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There are several different models of artificial lumbar discs being implanted in Europe. Only two of these, the SB Charitè III and the ProDisc are also undergoing Food and Drug Administration (FDA)-approved clinical trials in the United States. ProDisc has a small cohort of 64 patients who were implanted in the early 1990s in France and then followed up at 7 to 11 years after surgery. Additionally, ProDisc was made commercially available in Europe in 1999, and there are two published European studies of short to intermediate follow-up. Over 4000 ProDiscs have been implanted outside the United States since December 1999.

Materials and Methods

This article will describe the history of the device, its engineering considerations, and insertional technique. The European experience published by three surgeons will be described. Additionally, the randomized FDA Investigation Device Exemption (IDE) study started in the United States in October 2001 will be described, along with 6-month follow-up data from the participating institution with the largest patient base.

The ProDisc was designed in the late 1980s by Thierry Marnay, a French Orthopedic spine surgeon. Between March of 1990 and February of 1993, Marnay implanted this artificial disc into 64 patients. He elected to stop implantation at that point and observe his patients for several years. In 1999, great efforts were expended to find these patients and evaluate their clinical status 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 located and extensively studied. At their 7- to 11-year follow-up, all implants were intact and functioning. There had been no implant removals, revisions, or failures. Perioperative as well as long-term follow-up radiographs were inspected by both the operating surgeon and an independent American Orthopedic Surgeon. There was no evidence of subsidence on follow-up radiographs compared to the perioperative films. A significant ($P < 0.001$) reduction in patient-reported back and leg pain was identified, and 92.7% of these patients were "satisfied" or "extremely satisfied" with the procedure. There was no outcome difference between the one- and two-level ProDisc implantations (two-thirds of these patients had single level implants, whereas one-third had two level ProDiscs). Most importantly, at this long-term follow-up, there were no device-related safety issues, no untoward effects, no complications, and no adverse events.

The ProDisc is based on spherical articulations, with a convex polyethylene inferior component articulating with a concave superior metal component. The metal endplates are made of a cobalt chromium molybdenum alloy (CoCrMo) (Figure 3).

The convex bearing surface (ultra high molecular weight polyethylen [UHMWPE]) is modular and is snap-fit into the inferior endplate. Anchorage is through two spikes on each endplate as well as a large central keel, which controls rotation.

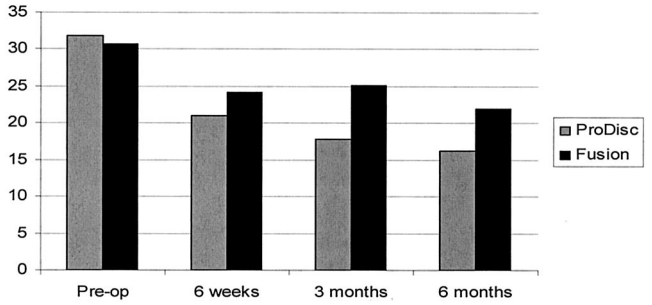

Figure 1. Comparison of the mean Oswestry scores.

The ProDisc matches normal ranges of motion in flexion, extension, axial rotation, and lateral bending both *in vitro* and *in vivo*.

Because it is modular, the surgeon can customize the device to each patient's unique anatomic and physiologic requirements at the time of implantation. 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°). The appropriate components are selected immediately before implantation and are assembled at that time (Figure 4).

The insertion instrumentation is streamlined, simple, and user-friendly, affording excellent surgeon visibility. The insertion instrument grasps the metal endplates within their footprint, so the exposure and annulotomy need only accommodate the width of the implant without requiring extra room for the insertion instruments. Minimal incision approaches to the lumbar spine, typically through a mini-retroperitoneal approach, are possible given the streamlined design of the instrumentation (Figure 5).

The endplates are inserted in a collapsed form, so that overdistraction of the disc space is not required. Once the metal endplates are placed into the evacuated disc space, with rotation controlled by the impaction of the central keel into a sagittal chisel cut in the vertebrae, the disc space is distracted. The surgeon can appreciate the soft tissue tension and insert an appropriately sized UHMWPE implant, snap-fitting it into the lower metal endplate to complete the assembly process within the body (Figure 6).

A multicenter FDA IDE study began in the United States on October 10, 2001, when the first ProDisc was implanted at the Texas Back Institute. Eighteen study centers are now participating in a prospective randomized study, comparing the ProDisc to the "gold standard" of a 360° (front and back) fusion. Patients are randomized 2:1 to ProDisc or fusion (Figure 7).

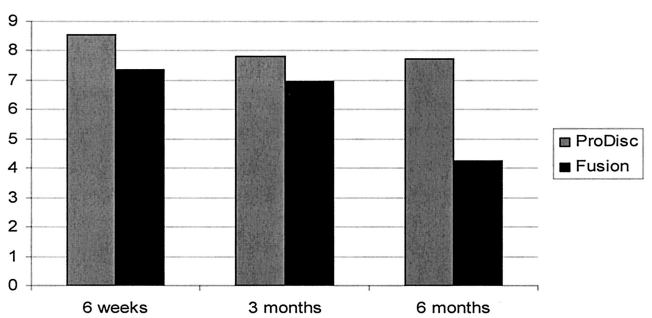

Figure 2. Comparison of satisfaction rates for ProDisc and fusion groups.

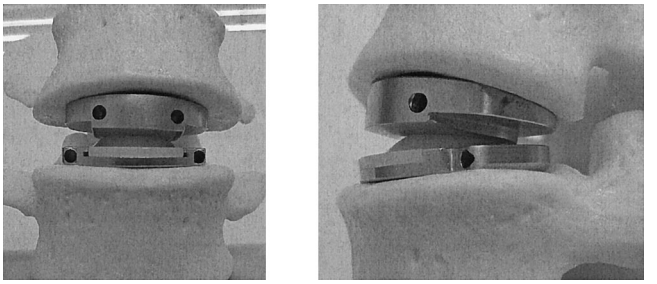

Figure 3. The Pro Disc assembled in the intervetedre space.

European Experience. In 2002, Marnay reported his 7- to 11-year results in the initial implantation group.[1] Ninety-three prostheses were implanted in 64 patients by the anterior approach between 1990 and 1993. Thirty-nine cases were single-level, 21 cases required two levels, and 4 cases were three-level implants. All patients enrolled had a history of chronic low back pain and had failed conservative therapy. Parameters measured by Marnay included clinical evaluations, Visual Analogue Scale (VAS), neurologic status, return to work, medication requirements, SF-36, Oswestry scales, and Beaujon scores. He also noted radiographic parameters including the height of the implant, motion, and any evidence of subsidence or resorption.

In this patient cohort with 95% follow-up of the survivors, at average follow-up of 8.6 years postsurgery, no ProDiscs had been explanted. Five patients with ongoing pain had been fused by a posterior approach. All implants were stable radiographically and showed no migration or subsidence. Subjective back pain as measured on VAS averaged 8.5 before surgery and 3.0 after surgery, and leg pain was reduced from 7.1 to 1.9. At final follow-up, 65% of the patients reported that they were "entirely satisfied," 28% "satisfied," and only 7% "not satisfied."

These patient-reported outcomes were supported by Oswestry, SF-36, and Beaujon scores.

In 2002, Mayer *et al* reported preliminary results in 34 consecutive patients within their practice in Munich, Germany.[2] Their follow-up averaged 5.8 months on patients implanted between June 2000 and March 2002. These patients demonstrated a 3.9-point decrease in VAS from their preoperative measurements. Oswestry scores, which averaged 19.1 points before surgery, were reduced after surgery by an average of 11.5 points. Before surgery, all patients reported back pain, but

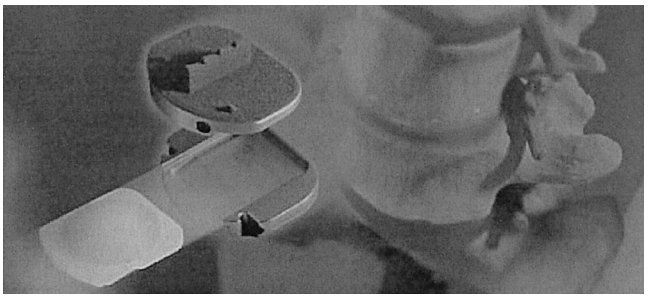

Figure 4. Modular design allows customization of the implant at the time of surgery. Two footprint sizes, two lordosis angles, and three choices of disc height are available.

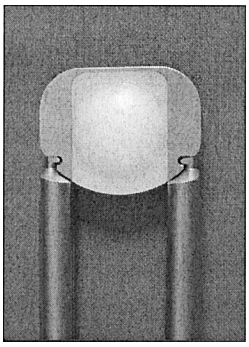

Figure 5. Insertion instruments group the metal endplates within their footprint, minimizing soft tissue dissection and vascular retraction.

only 24% reported pain at the postoperative evaluation. Subjectively, 82.6% of the patients were either "completely satisfied" or "satisfied."

In a prospectively designed study, Bertagnoli and Kumar reported the longer-term results of 134 ProDiscs implanted in 108 patients.[3] Follow-up ranged from 3 months to 2 years. Their patient population included 58 male and 50 female patients with an average age of 41.5 years. Preoperative diagnoses included disc degeneration with vertical instability in 67, failed disc surgery syndrome in 35, and transition zone syndrome in 6 patients. All patients had been treated conservatively for at least 6 months, and all had positive discography at the operated levels.

Overall, clinical outcomes were excellent in 90.8%, good in 7.4%, and fair in 1.8% (2 patients). There were no poor results. Nine patients of the 108 (8.3%) had residual leg or facetogenic back pain after surgery. Of the 54 patients in this group with greater than 1-year follow-up, 52 had returned to work. Thirty-five had resumed their usual occupations, whereas 17 required lighter duty. Only two patients were unable to return to work. All patients had increased range of motion at the operated levels.

By correlating their surgical results with the preoperative findings (number of levels, amount of degenerative disc and facet disease, adjacent level disc height, and presence of instability), Bertagnoli and Kumar were able to organize these indication complexes into predictive categories (Table 1). The best ("Prime") indication is a single level disc >4 mm in height with

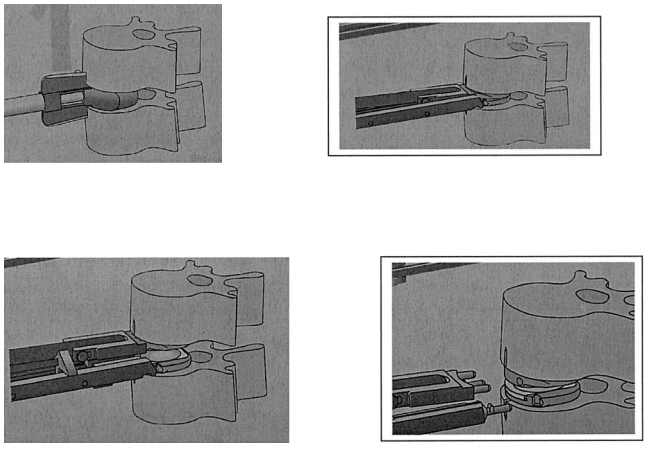

Figure 6. Distraction is performed in situ as the UHMPE insert is snapped into the lower endplate.

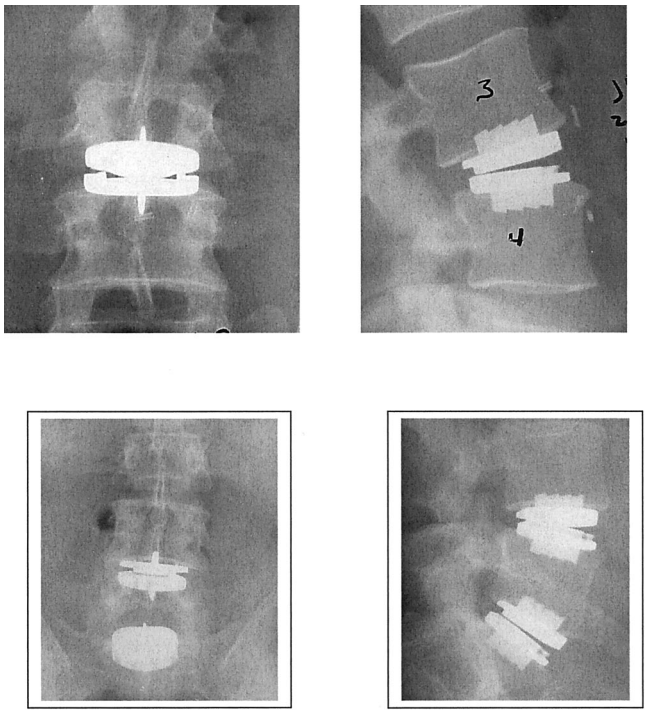

Figure 7. Single-level ProDisc at L3–4; two level ProDisc at L4–5 and L5–S1.

no OA changes in the facets, no adjacent level degeneration, and intact posterior elements without instability. A "Good" indication has a disc >4 mm tall, no significant facet degeneration, minimum degeneration of the adjacent discs, and minimal posterior instability (for example, is S/P microdiscectomy). A "Borderline" indication is a narrowed disc space with facet disease or is adjacent to a fused level. Bertagnoli and Kumar's "Poor" results occurred in grossly degenerated spines with secondary degenerative disease in the facets, with posterior element instability.

Average patient satisfaction levels decreased through the

Table 1. Bertagnoli Criteria for Total Disc Replacement

Indications	Disc Levels	Accompanying Features
Prime	Single level	>4 mm remaining disc height No OA changes to facet joints No adjacent level degeneration Intact posterior elements
Good	Single level/ double level	>4 mm remaining disc height No primary OA changes to facet joints Minimum degeneration of adjacent discs Minimum posterior segment instability, *e.g.,* postmicrodiscectomy
Borderline	Single/double/ triple level	<4 mm remaining disc height Primary OA changes to facet joints Minimum adjacent level degeneration Minimum posterior segment instability Adjacent to fusions
Poor	Single/double/ triple level	Gross degeneration of the spine Secondary OA changes to the facet joints <4 mm disc height remaining at the adjacent levels Posterior segment instability

categories, with rates of 98% in the Prime category, 93% in the good category, and 83% in the borderline category. Bertagnoli and Kumar noted that the overall outcome of disc replacement surgeries might be compromised by the inclusion of patients with borderline and poor indications. He encouraged surgeons to place great emphasis on the appropriateness of their indications for arthroplasty.

Experience in the United States. The ProDisc FDA IDE study was designed to compare the efficacy of ProDisc to 360° lumbar fusion at one or two adjacent levels from L3–S1 and has been ongoing since October 2001. There are 18 centers participating in this study. By the end of April 2003, nearly 500 U.S. patients had been implanted as part of the study. Multicenter data will be collected and presented to the FDA at the completion of the study.

The first 39 patients who reached 6-month follow-up at the Texas Back Institute study site have had their data evaluated. The Class I data from this prospective randomized study allow comparison of the 6-month results of 28 patients receiving ProDisc (3 were nonrandomized "teaching" cases at the beginning of the study) and 11 who were fused. As per study design, data sets were collected before surgery, and at 6 weeks, 3 months, and 6 months after surgery.

The groups were similar in demographics including gender, age, weight, smoking history, preoperative medication usage, nonoperative treatment, and prior surgeries.

Intraoperative data showed a statistically significant decrease in operative time and blood loss in the ProDisc patients. Additionally, lengths of stay were shorter in the ProDisc patients than in the fusion patients (2.1 days *vs.* 3.5 days).

Postoperative rehabilitation was more rapid in the ProDisc patients, who demonstrated significant improvements in range of motion compared to their preoperative values and had better motion than the fusion patients. Fusion patients had a slower recovery rate to independent ambulation, and were slower to return to recreational activities. The average return to work was 8 weeks in the ProDisc group and 16 weeks in the fusion group.

In the ProDisc group, Oswestry scores steadily decreased after surgery. Possibly as a result of postoperative immobilization, increased Oswestry scores were noted in the fusion group at the 3-month evaluation. Visual analogue scale scores were decreased in both groups, more so in the ProDisc group, but differences were not statistically significant. Satisfaction scores declined sharply in the fusion group at 6 months, trending towards significance.

■ Key Points

- Total disc replacement was associated with less blood loss, reduced operative time, and reduced length of hospital stay compared to combined anterior–posterior lumbar fusion.
- There was a trend for more favorable outcome among patients who received the total disc replacement.
- Long-term follow-up and a greater number of patients are needed for stronger comparisons between the two treatment groups and are currently being collected.
- Total disc replacement may be a viable option to lumbar fusion in patients with symptomatic disc degeneration unresponsive to nonoperative care.

References

1. Marnay T. Lumbar disc replacement: 7 to 11-year results with Prodisc. *Spine J* 2002;2:94S.
2. Mayer HM, Wiechert K, Korge A, et al. Minimally invasive total disc replacement: surgical technique and preliminary clinical results. *Eur Spine J* 2002; 11(suppl 2):S124–S130.
3. 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(suppl 2):S131–S136.