CHAPTER 39

ProDisc-L Total Disc Replacement

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KEY POINTS

- The ProDisc-L is a three-piece semi-constrained artificial lumbar disc consisting of two metallic end plates and a polyethylene inlay that is locked into the bottom end plate.
- The semi-constrained mechanics of the device allow it to share shear (translational) forces with the posterior facet joints.
- The small keels and titanium plasma-sprayed finish on the end plates allow for immediate fixation as well as longer term bony ingrowth.
- The ProDisc-L is the second artificial disc to receive U.S. Food and Drug Adminstration (FDA) approval for implantation after successfully completing Investigational Device Exemption (IDE) clinical trials: Several aspects of the clinical outcomes showed ProDisc-L actually to be superior to fusion, not simply equivalent.
- Multilevel disc replacements are possible with the ProDisc-L device, and they have been performed at two and three levels: Two-level disc replacement was part of the IDE clinical trials and will be reviewed for FDA approval.

INTRODUCTION

Thierry Marnay created the first ProDisc-L (or ProDisc-I) prosthetic disc in 1989 at Montpellier, France. The first human implantation was in 1990. To his credit, after inserting 93 implants in 64 patients with his colleague, Dr. Louis Villette, Marnay stopped to evaluate the long-term outcomes of his implant. Finally, in 2001, he published his results after an 8- to 10-year follow-up.[1,2] All implants remained intact without any migration or subsidence. Range of motion (ROM) of the spinal segments was maintained. There was significant reduction in back and leg pain, and almost 93% of the patients were satisfied and would have the surgery again. The promising results from his experience paved the way for the pivotal clinical trials recently completed here in the United States. Since 1999, up to the time of this writing, more than 16,000 ProDisc-L devices have been implanted worldwide.

The ProDisc-L (Synthes, West Chester, PA) lumbar artificial disc received full U.S. Food and Drug Administration (FDA) approval for implantation in August of 2006. Class I data from the U.S. Investigational Device Exemption (IDE) clinical trials, a multicenter prospective randomized and controlled study, revealed that the ProDisc-L device was not only equivalent to fusion in terms of clinical results but often superior in various measures of outcome, including patient satisfaction, earlier recovery, and work status. The two largest enrolling centers, The Spine Institute, Santa Monica, and Texas Back Institute, have published their interim results ahead of the complete multicenter data.[3–6]

INDICATIONS/CONTRAINDICATIONS

The inclusion and exclusion criteria for this device appears in Table 39–1, as listed for the pivotal FDA clinical trials. There were single-level and two-level surgical arms in the clinical trials, with one-level disc replacement having been approved and two-level disc replacement FDA approval likely to follow. The FDA has allowed some deviation from the strict requirements of the study on a carefully considered case-by-case basis, under the stipulation of "compassionate usage," such as for three-level disc replacements for disease spanning more than two levels, disc replacement next to prior fusions to avoid fusion extension, and so on.

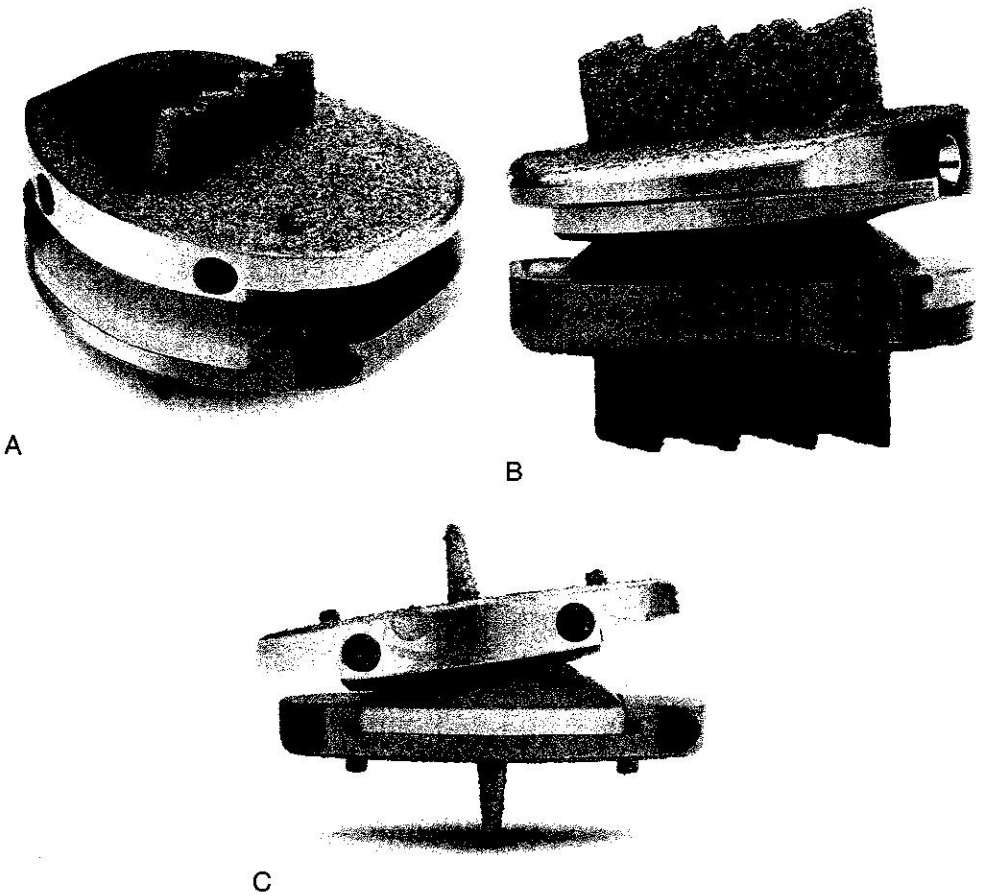
DESCRIPTION OF THE DEVICE

The first-generation ProDisc-L (ProDisc-I) had titanium end plates and a double keel. In 1999, it was upgraded to cobalt chrome end plates with a single keel (Fig. 39–1). The single serrated keel over each end plate, two small lateral pegs, along with the plasma-sprayed ingrowth surface give the implant immediate stability. The inlay is made of ultra-high-molecular-weight polyethylene (UHMWPE), which snap-locks to the inferior end plate, and thus has only one articulating convex side. The device is semi-constrained, allowing it to share the load with collateral structures such as the facet joints, ligaments, tendons, and muscles, especially in shear. This places more load at the device-bone interface but protects the facet joints. Axial rotation is unconstrained, and the axis of rotation of the superior end plate is angled posteriorly in the neutral position owing to the intradiscal lordosis of the prosthesis, consistent with the physiologic axis of rotation.[7]

TABLE 39–1. Criteria for Patient Enrollment in the FDA ProDisc-L Clinical Trials

Inclusion criteria	Exclusion criteria
Degenerative disc disease in one or two adjacent levels between L3 and S1	More than two levels of degenerative disc disease
Back and/or leg pain	End plate dimensions less than 34.5 mm ML or 27 mm AP
Failure of at least 6 months of conservative therapy	Known metal and/or polyethylene allergies
Oswestry score >20/50 (>40%)	Prior lumbar fusion surgery
Ability to comply with protocol and follow-up	Clinically compromised vertebral bodies due to prior trauma
Ability to give informed consent	Clinically significant degenerative facet disease
Radiographic evidence of disc degeneration includes:	Lytic spondylolisthesis and/or clinically significant stenosis
1. Decrease in disc height by at least 2 mm	Degenerative spondylolisthesis >grade I
2. Instability indicated by >3mm translation or >5 degrees of angulation, but less than Grade I slip	Back or leg pain of unknown etiology
3. Annular thickening and disc dessication on MRI	Objective diagnosis of osteoporosis (DEXA scan)
4. Herniated nucleus pulposus	Presence of metabolic bone disease (e.g., Paget's, osteomalacia)
5. Vacuum phenomenon	Morbid obesity (Body Mass Index >40)
	Pregnancy or expected pregnancy within 3 years
	Active infection
	Medications that retard healing (e.g., steroids)
	Autoimmune diseases (e.g., rheumatoid arthritis)
	Systemic diseases (e.g., AIDS, HIV, hepatitis) active malignancy

AP, anteroposterior; DEXA, dual-energy x-ray absorptiometry; FDA, U.S. Food and Drug Admmistration. ML, mediolateral, MRI, magnetic resonance imaging.



■ **FIGURE 39–1.** **A** to **C,** The ProDisc-L artificial lumbar disc. *(Synthes, West Chester, PA.)*

BACKGROUND OF SCIENTIFIC TESTING/CLINICAL OUTCOMES

The first ProDisc-L implantation was performed in 1999. Since then, more than 16,000 prostheses have been implanted worldwide at the time of writing of this chapter. Multilevel disc replacements have also been performed (Fig. 39–2). In the original European studies, there have been no device-related failures reported. In the United States, FDA-supervised multicenter clinical trials and 2-year follow-up have been completed, culminating in full FDA approval for human implantation in the United States in August 2006.

The U.S. Investigational Device Exemption Trial

Table 39–1 lists the eligibility criteria for the U.S. IDE study on spinal arthroplasty with the ProDisc-L device versus lumbar fusion. Table 39–2 lists some of the demographic characteristics of the patients enrolled in the U.S. multicenter IDE study. Results for the IDE multicenter study 2-year results were first reported at the American Academy of Orthopaedic Surgeons annual meeting.[8] This included 162 patients who underwent disc replacement and 80 patients who underwent fusion. Randomization was performed at a 2:1 ratio to disc replacement versus circumferential fusion. Pain, disability, and ROM were evaluated at preoperative, 6 weeks, and 3, 6, 12, 18, and 24 months follow-up visits.

Table 39–3 summarizes the results in terms defined by the FDA. Although pain on the Visual Analog Scale (VAS) decreased significantly in both disc replacement and fusion, there was no defined success criteria based on pain relief alone. Based on a 15% reduction in the Oswestry Disability Index (ODI), the success rate with disc replacement was 77% versus 65% with fusion. Although the study was designed to show at least equivalency in the two techniques, this showed that patients with ProDisc-L did significantly better. Based on a 15-point reduction in ODI, the success rate with ProDisc-L was 68% versus 55% with fusion. These showed an even greater margin of success of ProDisc-L over fusion. The failure rate, defined by reoperations, revisions, and removal or addition of devices, was low and no different between the ProDisc-L and fusion cases. Success as defined by an improvement in SF-36 showed a 79% success rate with ProDisc-L versus 70% with fusion, another benchmark that approached statistical significance. Finally, by radiographic definition (no migration, no subsidence, no loss of disc height, and ROM), the success rate in ProDisc-L was 92% versus 86% for fusion.

With this class I data showing equivalency and, in some cases, superiority of ProDisc-L over fusion, it must be kept in mind that this technology was designed to preserve motion, with the theoretical long-term benefit of retardation of accelerated adjacent-segment degeneration. Table 39–4 lists the sagittal ROM (flexion-extension) at the different follow-up time points. At 24 months, 94% of patients had motion with the physiologic range. The conclusion of the FDA IDE trial was essentially that ProDisc-L preserves ROM without compromising the results as compared with the current surgical standard of fusion, with the potential upside of decelerating adjacent-segment degeneration.

OPERATIVE TECHNIQUE

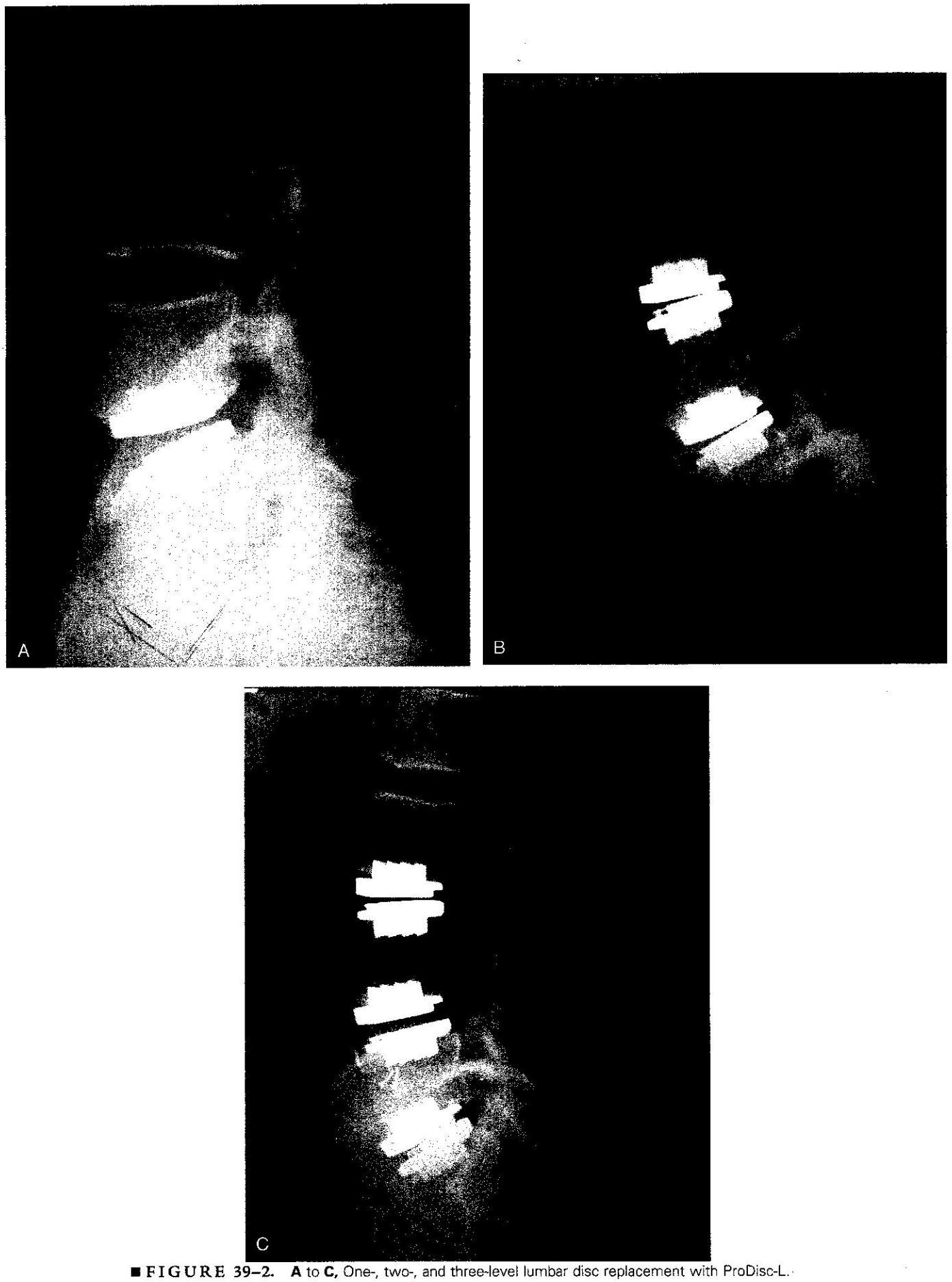
A standard anterior left-sided retroperitoneal approach to the lumbar spine is performed. Any operating table that allows supine positioning and fluoroscopy of the lumbar spine can be used. A small bump or inflatable support may be placed under the small of the patient's back for adjustment of lordosis during surgery to open up the disc space anteriorly. In our institute, we use a mini-incision less than 6 cm for one-level cases and about 8 cm for two levels. Intraoperative fluoroscopy is used throughout the operation to verify the placement of the prosthesis. Once exposure is obtained, an anteroposterior (AP) view confirms the level and identifies the midline, which is then marked with the cautery or osteotome (Fig. 39–3A). A complete discectomy is then performed (see Fig. 39–3B, C). Cartilage is removed from the vertebral end plates. If herniated disc material is identified on the preoperative magnetic resonance imaging scan, this may be removed through the anterior approach. In some cases, the posterior longitudinal ligament may have contracted, preventing 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 (Fig. 39–3D). A sagittal groove is then cut in the vertebral end plates in the exact midline using a chisel placed over the trial (Fig. 39–3E). This groove will accept the central keel of the implant. The trial is removed, and the final implant is then gently impacted into place with an insertion tool (Fig. 39–3F). The insertion tool allows distraction of the disc space for placement of the UHMWPE inlay, which snap-fits into position in the inferior end plate (Fig. 39–3G). After the insertion instrument is removed, gross inspection is made to ensure the UHMWPE inlay is properly flush against the inferior end plate (Fig. 39–3H), and final fluoroscopic views are taken to confirm correct position of the prosthesis.

POSTOPERATIVE CARE

A soft back brace can be used for the first week or two to allow for wound protection. Otherwise, there is no extensive postoperative protocol. Patients can return to work as soon as they are comfortable, but they should allow 6 weeks before returning to recreational sports or full duty (if the job is physically demanding).

COMPLICATIONS AND AVOIDANCE

No major technique- or device-related complications were observed. Table 39–5 lists the complications for both the ProDisc-L and fusion patients. There were four cases of device migration, subsidence, or loose polyethylene requiring revision surgery



■ **FIGURE 39–2.** **A** to **C,** One-, two-, and three-level lumbar disc replacement with ProDisc-L.

TABLE 39–2. Patient Demographics

Patient Characteristic	Fusion ($n = 80$)	ProDisc-L ($n = 162$)	P-value (NS is $P > 0.05$)
Average age in years (std dev)	40.2 (7.6)	39.6 (8.0)	NS
Sex (% male:% female)	46:54	51:49	NS
Body mass index (std dev)	27.4 (4.3)	26.7 (4.2)	NS
Preoperative Oswestry Disability Index (std dev)	62.9 (13.4)	63.4 (12.6)	NS
Target level at screening	10.5	10.3	NS
L3-L4	3 (3.8%)	3 (1.9%)	NS
L4-L5	27 (33.8%)	54 (33.3%)	NS
L5-S1	50 (62.5%)	105 (64.8%)	NS

n, number; NS, not significant; std dev, standard deviation.

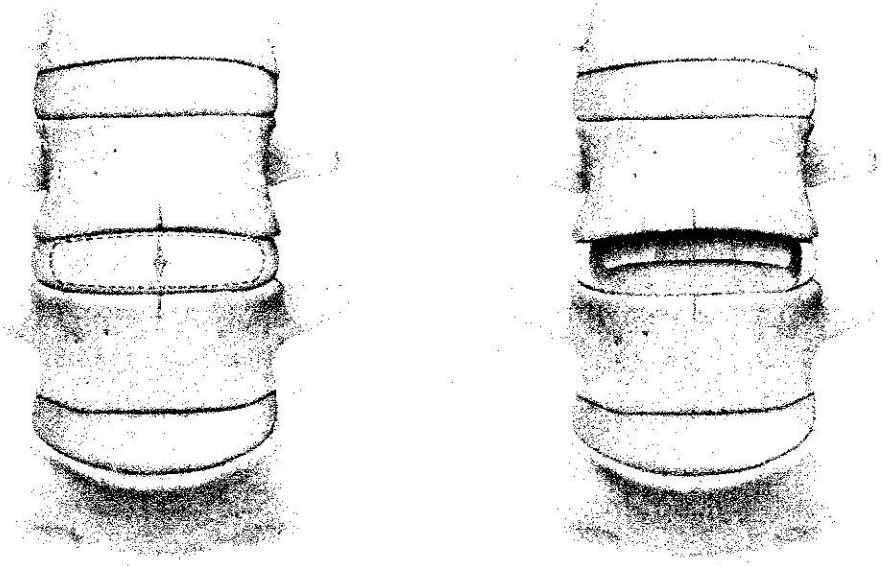
TABLE 39–3. Components of Overall FDA-Defined Success at 24 Months

	Fusion	ProDisc-L
ODI success	46/71	115/149
By 15% improvement criteria	(64.8%)	(77.2%)
ODI success	39/71	101/149
By 15-point improvement criteria	(54.9%)	(67.8%)
Reoperations/revisions/removal/supplemental fixation	2/75	6/161
	(2.7%)	(3.7%)
Maintenance or improvement of neurologic status	57/70	135/148
	(81.4%)	(91.2%)
SF-36 success (improvement over baseline)	49/70	118/149
	(70.0%)	(79.2%)
Radiographic success (fusion or >5 deg ROM at L3-L4, L4-L5, and >4 deg at L5-S1)	59/69	131/143
	(85.5%)	(91.6%)

deg, degree; ODI, Oswestry Disability Index; ROM, range of motion FDA, U.S. Food and Drug Admmistration.

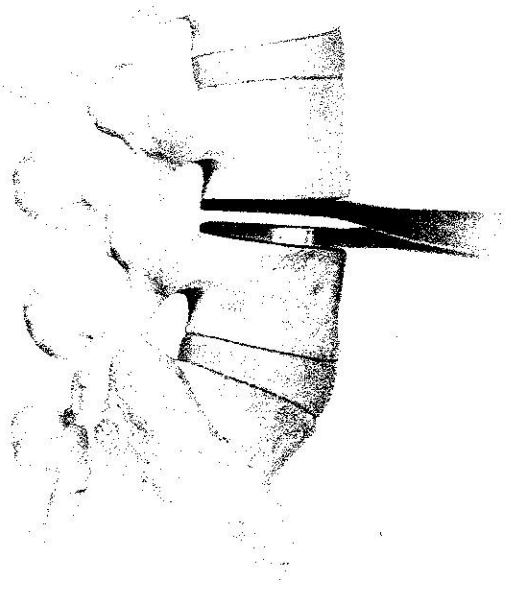
TABLE 39–4. Time Course of Mean Flexion-Extension Range of Motion (Degrees)

	Month 3	Month 6	Month 12	Month 18	Month 24
Fusion	1.0	0.9	0.9	0.8	0.7
ProDisc-L	6.3	6.1	7.0	7.1	7.7



A B

■ FIGURE 39–3. **A,** Marking of midline. **B,** Discectomy performed all the way back to the posterior longitudinal ligament.



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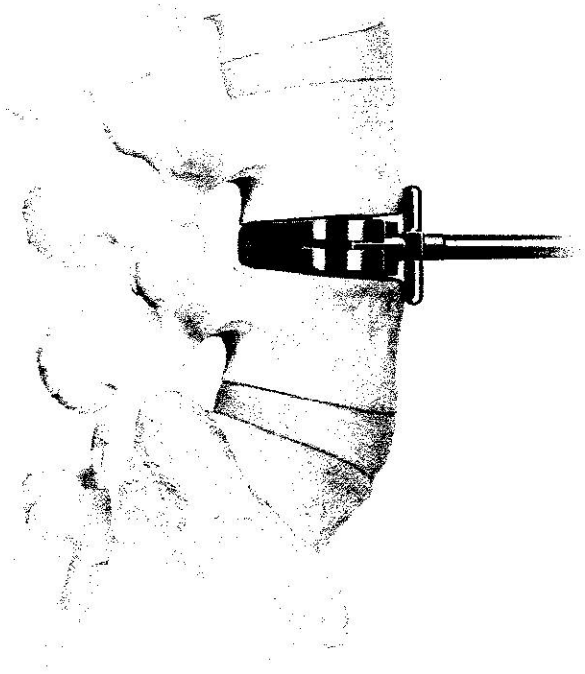

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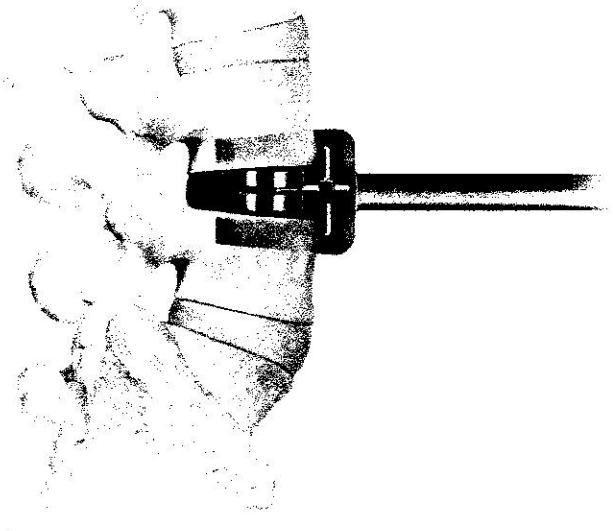

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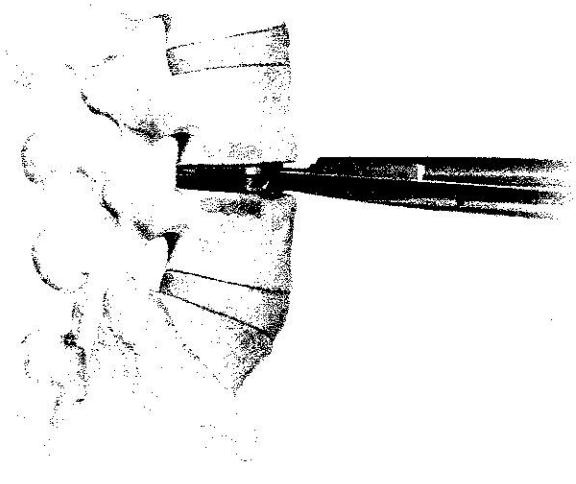
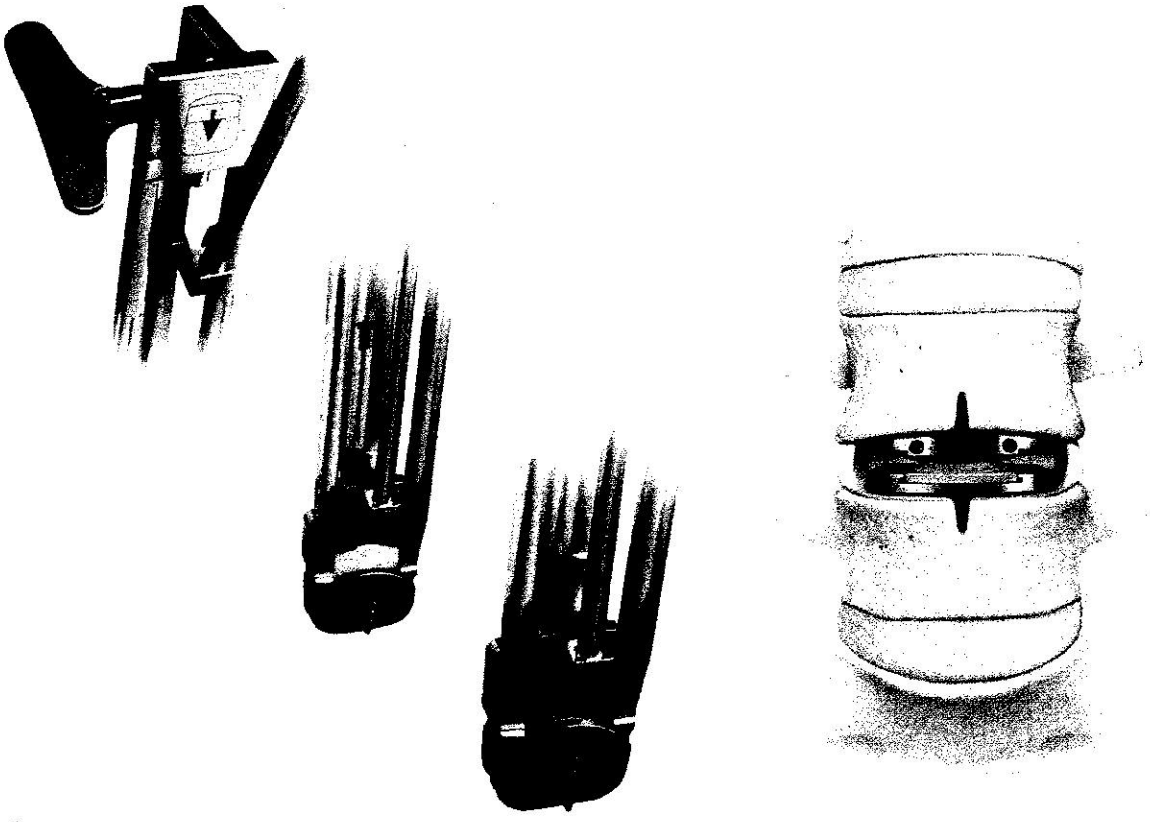


F

■ **FIGURE 39–3. Cont'd** **C,** Discectomy performed all the way back to the posterior longitudinal ligament. **D,** Trialing for size, height, and lordosis. **E,** Chisel cut for the keels. **F,** Placement of end plates in collapsed form.



G H

■ **FIGURE 39–3. Cont'd.** **G,** Distraction of end plates and locking of the polyethylene inlay. **H,** The construct is inspected to ensure that there is no step or gap between the polyethylene inlay and the inferior end plate.

TABLE 39–5. Complications From the U.S. IDE Trials of ProDisc-L Versus Fusion

Complication	Fusion	ProDisc-L
Clinically significant blood loss (>1,500 mL)	2 (2.5%)	0 (0.0%)
Dural tear	2 (2.5%)	0 (0.0%)
Edema	3 (3.8%)	8 (4.9%)
Gastrointestinal (e.g., ileus)	22 (27.5%)	32 (19.8%)
Genitourinary	4 (5.0%)	14 (8.6%)
Infection (all superficial)	2 (2.5%)	0 (0.0%)
Migration, not requiring surgery	1 (1.3%)	3 (1.9%)
Migration, requiring surgery	0 (0.0%)	4 (2.5%)
Motor deficit at index level	0 (0.0%)	4 (2.5%)
Numbness at index level	1 (1.3%)	0 (0.0%)
Reflex change	0 (0.0%)	1 (0.6%)
Retrograde ejaculation	1 (1.3%)	2 (1.2%)
Subsidence, not requiring surgery	1 (1.3%)	2 (1.2%)
Subsidence, requiring surgery	0 (0.0%)	0 (0.0%)
Venous thrombosis, deep	1 (1.3%)	2 (1.2%)
Vessel damage/bleeding	6 (7.5%)	5 (3.1%)

IDE, Investigational Device Exemption.

in the ProDisc-L group. There were four cases of motor deficits at the index level with ProDisc-L, and this may be related to the slightly more meticulous access and retraction necessary for the device compared with femoral ring allograft insertion. There was a very low rate of retrograde ejaculation in both surgery groups.

ADVANTAGES/DISADVANTAGES: PRODISC-L TOTAL DISC REPLACEMENT

Advantages	Disadvantages
Semi-constrained motion is facet protective	Greater device-bone interface loading
Good fixation features (keels, coating)—stays where you put it, so salvage would simply need posterior fusion.	Would be difficult to remove, both from a revision approach standpoint and because of fixation
Familiar cobalt-chrome and polyethylene materials	Long-term data (5 to 10 years) from class I data are still pending
No device protrusions beyond disc space	Questionable risk of polyethylene debris
Class I FDA clinical data available	Anecdotal reports of vertebral fractures (in small patients)
Multilevel disc replacements possible and clinical data also available (2 and 3 levels)	
Good experience: over 16,000 implanted worldwide at time of writing (Aug 2006)	

FDA, US Food and Drug Administration.

CONCLUSIONS/DISCUSSION

This particular device has been used extensively for multilevel use, with as good or better clinical outcomes as compared to single-level surgeries, and with good preservation of motion at each replaced level, with good preservation of spinal alignment at each replaced level, and with great patient satisfaction. The technique and instrumentation are facile and streamlined.

The experience with the ProDisc-L Artificial Disc and class I data now released by the FDA suggest that lumbar disc replacement is a viable surgical alternative to fusion for disc degeneration, with preservation of motion and alignment at the treated levels, and without compromising clinical outcomes. Although it is yet too early for the U.S. clinical trials to offer any definite proof of benefit against accelerated adjacent-segment degeneration, the fact that normal intervertebral motion is preserved at the treated segment is encouraging. Longer term safety and efficacy studies are in progress.

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