CHAPTER 25

ProDisc-C Total Cervical Disc Replacement

Rick B. Delamarter and **Ben B. Pradhan**

KEY POINTS

- The ProDisc-C is a two-piece semiconstrained artificial cervical disc consisting of two metallic end plates and a polyethylene liner fixed to the bottom end plate.
- The semiconstrained mechanics of the device allow it to share shear (translational) forces with the posterior facet joints.
- The plasma sprayed finish and small keels on the end plates allow for immediate fixation as well as longer term bony ingrowth.
- The enrollment phase of a U.S. pivotal Food and Drug Adminstration (FDA) IDE study has been completed for this device, and the 2-year follow-up data for the entire multicenter cohort are being studied before likely full FDA approval for implantation.
- Multilevel disc replacements are possible with the ProDisc-C device and have been performed at two and three levels.

INTRODUCTION

There have been limited published reports on the clinical results of cervical artificial disc replacement. Goffin et al[1] reported a 90% rate of good to excellent results at 1 to 2 years after cervical disc arthroplasty with the Bryan prosthesis. Wigfield et al[2] reported a 46% improvement in pain and a 31% improvement in disability 2 years after implantation of the Prestige cervical artificial disc. Our own institute[3] reported the early outcomes after ProDisc-C implantation, with significant reductions in visual analog pain and Oswestry disability scores. Longer term follow-up from the prospective, randomized, and controlled U.S. IDE trial at our center is reported in this chapter.

INDICATIONS/CONTRAINDICATIONS

The inclusion and exclusion criteria for this device appear in Table 25–1, as listed for the pivotal U.S. Food and Drug Administration (FDA) clinical trials. 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 two- and three-level disc replacements for multilevel disease, disc replacement next to prior fusions to avoid fusion extension, and so on.

DESCRIPTION OF THE DEVICE

The ProDisc-C prosthesis (Synthes, West Chester, PA) (Fig. 25–1) shares many of the physical characteristics of the ProDisc-L (Synthes, West Chester, PA) lumbar prosthesis. The device is essentially a ball-and-socket joint: The end plates are constructed of a cobalt-chrome alloy, and the articulating convex insert is made of ultra-high-molecular-weight polyethylene (UHMWPE). Both of these are proven materials with an extensive track record in hip and knee arthroplasty. Both upper and lower end plates have slotted keels and titanium plasma spray coating. These design characteristics allow for immediate fixation onto the vertebral end plates, as well as long-term fixation via bony ingrowth.

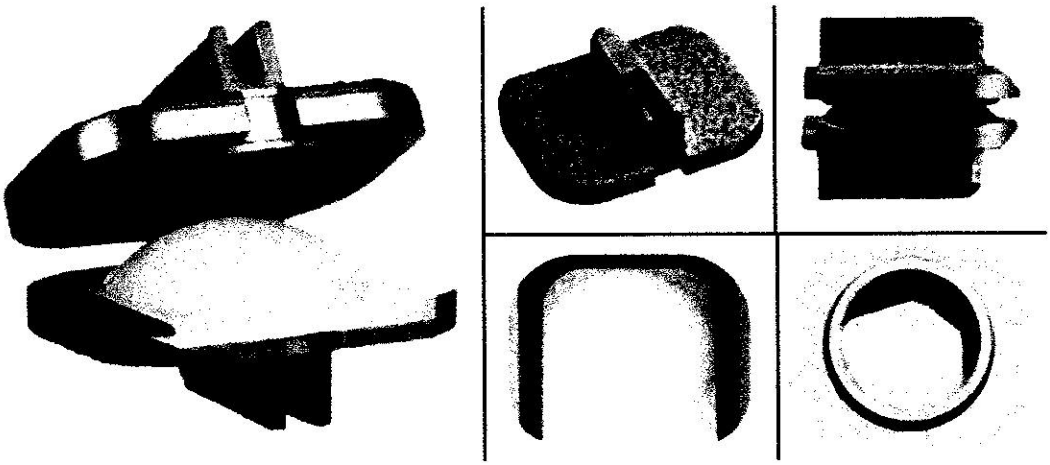
The UHMWPE insert is fixed onto the lower end plate. The kinematic philosophy of the ProDisc-C prosthesis again parallels that of the ProDisc-L. This is a semiconstrained device with a fixed axis of rotation. Rotation is allowed along all three axes. Translation is constrained. However, because the axis of rotation for the device actually lies inferior to the disc space, translation is not eliminated. Minute (~1 mm) anterior and posterior translational shift is allowed during flexion and extension (Fig. 25–2), as is seen physiologically. However, excessive translation is not allowed, protecting the facet joints from undue loading in the absence of the native disc. It is hoped that this method will prevent accelerated degeneration of the facet joints, which would otherwise bear the majority of the shear stabilization load in the presence of a nonconstrained artificial disc. However, the semiconstrained dynamics does shift shear load from the facets to the prosthesis-bone interface, highlighting the importance of the prosthesis fixation features mentioned earlier.

Based on human anatomic studies, four different prosthetic disc heights are available, ranging from 5 to 8 mm.[4,5] Disc height restoration is key in maintaining cervical lordosis and foraminal height. Similarly, six different footprint sizes are available. The largest allowable footprint size is necessary to optimize load distribution and to decrease risk of subsidence. Angular motion in the sagittal, coronal, and axial planes is also matched to physiologic intervertebral motion, which is important if abnormal loading or motion is to be avoided in the remaining unaffected segments. Again, based on human anatomic studies, the ProDisc-C device

TABLE 25–1. Inclusion and Exclusion Criteria for the U.S. IDE Clinical Trials for ProDisc-C

Inclusion Criteria	Exclusion Criteria
1. Symptomatic cervical disc disease in only one vertebral level between C3 and C7 defined as neck or arm (radicular) pain; and/or functional/neurologic deficit with at least one of the following conditions confirmed by imaging (CT, MRI, or x-ray studies): a. Herniated nucleus pulposus; b. Spondylosis (presence of osteophytes); and/or c. Loss of disc height. 2. Age between 18 and 60 years. 3. Unresponsive to nonoperative treatment for 6 weeks or presence of progressive symptoms or signs of nerve root/spinal cord compression. 4. Neck Disability Index score greater than or equal to 15/50 (30%). 5. Psychosocially, mentally, and physically able to comply with the postoperative protocol. 6. Signed informed consent.	1. More than one vertebral level requiring treatment. 2. Marked cervical instability on resting lateral or flexion-extension radiographs: a. translation greater than 3 mm and/or b. greater than 11 degrees of angular motion. 3. Has a fused level adjacent to the level to be treated. 4. Radiographic confirmation of severe facet joint disease or degeneration. 5. Known allergy to cobalt, chromium, molybdenum, titanium, or polyethylene. 6. Clinically compromised vertebral bodies at the affected level(s) due to current or past trauma, e.g., by the radiographic appearance of fracture callus, malunion, or nonunion. 7. Prior surgery at the level to be treated. 8. Severe spondylosis at the level to be treated as characterized by any of the following: a. bridging osteophytes; b. loss of disc height greater than 50%; or c. absence of motion (<2 deg). 9. Neck or arm pain of unknown etiology. 10. Osteoporosis: If DEXA is required, exclusion defined as T score less than or equal to −2.5. 11. Paget's disease, osteomalacia, or any other metabolic bone disease. 12. Severe diabetes mellitus requiring insulin. 13. Pregnant or possible pregnancy in next 3 years. 14. Active infection—systemic or local. 15. Concurrent drugs that affect healing (e.g., steroids). 16. Rheumatoid arthritis or other autoimmune disease. 17. Systemic disease, including AIDS, HIV, hepatitis, and so on. 18. Active malignancy.

AIDS, acquired immunodeficiency syndrome; CT, computed tomography; HIV, human immunodeficiency virus; IDE, Investigational Device Exemption; MRI, magnetic resonance imaging.

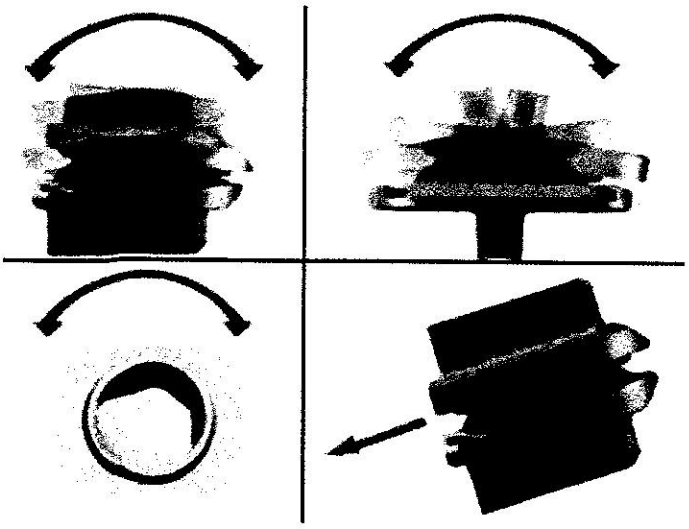


■ **FIGURE 25–1.** The ProDisc-C artificial cervical disc. *(Courtesy of Synthes, Paoli, PA).*

allows a maximum of 20 degrees of flexion-extension, 20 degrees of side-to-side bending, and 12 degrees of axial rotation.[6]

BACKGROUND OF SCIENTIFIC TESTING/CLINICAL OUTCOMES

The first ProDisc-C implantation was performed in December of 2002. Since then, more than 6,000 prostheses have been implanted worldwide at the time of writing of this chapter. Multilevel disc replacements have also been performed. In the original European studies, there have been no device-related failures reported. The first implantation in the United States was performed at our center in August of 2003. Since then, more than 200 implantations have been performed in 15 centers across the country as part of the U.S. IDE study and many more as part of a "continued access" or "compassionate use" allowance by the FDA. The study enrollment phase is complete, with the FDA now analyzing the data for 2 years of follow-up.



■ **FIGURE 25–2.** The ProDisc-C kinematics.

The U.S. IDE Trial

Table 25–1 lists the eligibility criteria for the U.S. IDE study on spinal arthroplasty with the ProDisc-C device versus anterior cervical discectomy and fusion. In general, patients were selected for degenerative disc disease at one level between C3 to C7 causing intractable neck and or arm pain. Table 25–2 lists the demographic characteristics of the patients enrolled at our site for one-level disc replacements. Results for our first 48 patients were recently reported at the North American Spine Society annual meeting.[7] This included 14 disc replacement patients in the randomized trial, 19 disc replacement patients in the continued access one-level disc replacement group, and 15 patients who underwent fusion from the randomized trial. Randomization was performed at a 1:1 ratio to anterior cervical disc replacement (ACDR) versus anterior cervical discectomy and fusion (ACDF). Pain, disability, and range of motion were evaluated at preoperative, 6 weeks, 3-, 6-, 12-, and 24- to 36-month follow-up visits. Because not all patients had reached 36-month follow-up, they were included in with the 24-month follow-up group.

Clinical outcome scores revealed significant improvements in Visual Analog Scale (VAS) scores for both neck pain (Fig. 25–3) and arm pain (Fig. 25–4) and ODI scores (Fig. 25–5) for both ACDR and ACDF patients. By 3 months, VAS (neck) scores were down by more than half in both disc replacement and in fusion patients. VAS (arm) scores improved even more significantly in both groups by 3 months. Both of these improvements stayed significant at 24 months and later. ODI scores similarly decreased at more than 24 months in disc replacement and fusion patients respectively, reaching values one half or less of preoperative values at final follow-up. Although all of the outcome measures decreased significantly from preoperative status ($P < 0.05$), they were not seen to be significantly different between treatment modalities (disc replacement versus fusion, $P > 0.05$).

Average flexion-extension motion went from 9 degrees preoperatively to about 1 degree (essentially no motion) at more than 24 months postoperatively in the fusion group but was well preserved at about 12 degrees in the disc replacement group. Side bending went from 6 degrees to less than 2 degrees (essentially no motion) in the fusion group versus about 5 degrees in disc replacement patients. There were no major complications, technique or device-related, in any of the cases. Figure 25–6 represents the sagittal angular motion measured radiographically at the operated segment. As expected, motion is effectively eliminated at fusion levels, whereas angular motion is well preserved with the prosthetic discs.

So the conclusion of the U.S. IDE trial was essentially that ACDR preserves range of motion without compromising the results as compared with the current surgical standard of ACDF. It is hoped that in the long run, the preserved motion will decrease adjacent segment degeneration.

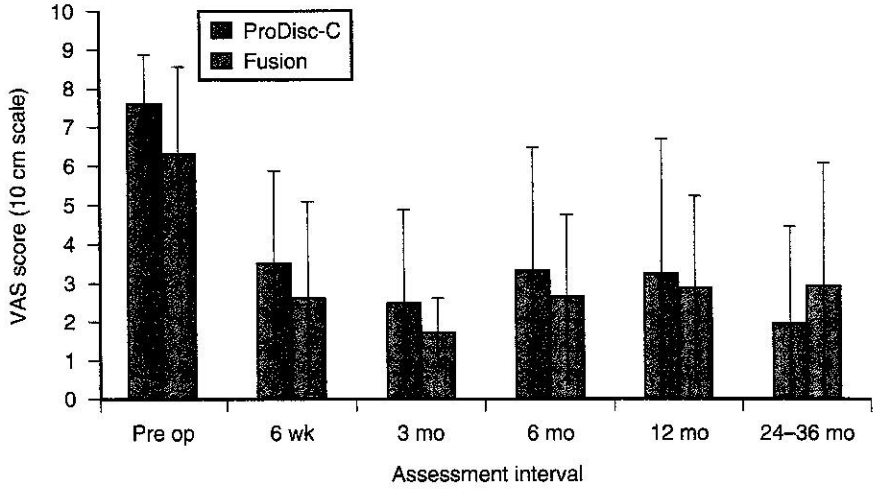
OPERATIVE TECHNIQUE

A standard anterior approach to the cervical spine is performed. Any operating table that allows supine positioning and fluoroscopy of the neck can be used. No external traction of the spine is necessary. A transverse skin incision is made over the level being operated, after localizing either by anatomic landmarks or with a lateral radiographic image (a fluoroscopy machine is used for the duration of instrumentation with the ProDisc-C). After incising through the skin, subcutaneous fascia, platysma muscle, and superficial layer of the deep cervical fascia, blunt dissection is performed first between the strap muscles medially and the sternocleidomastoid laterally then the tracheoesophageal bundle medially and the carotid sheath laterally. The prevertebral fascia is then split to expose the disc space. Before the discectomy, another localizing radiograph is performed.

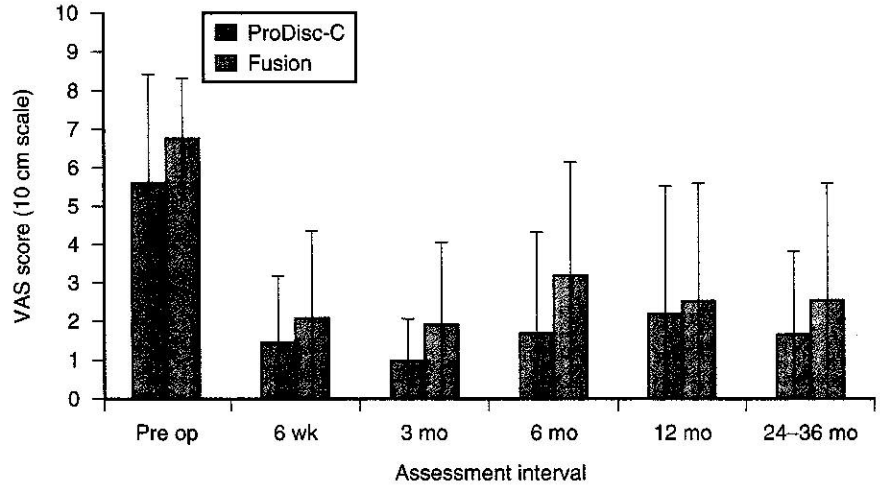
TABLE 25–2. Patient Demographics

Patient Characteristic	ACDF (allograft + plate) ($n = 15$)	ACDR (ProDisc-C) ($n = 33$)	*P*-Value (NS is > 0.05)
Average age (years)	42.5	40.1	NS
Gender (% male: % female)	33:67	20:80	NS
Body mass index (BMI)	24.9	23.7	NS
Workman's compensation status	27%	20%	NS
Preoperative duration of neck pain (months)	10.5	10.3	NS
Active smokers	1 (6.6%)	4 (16.7%)	NS

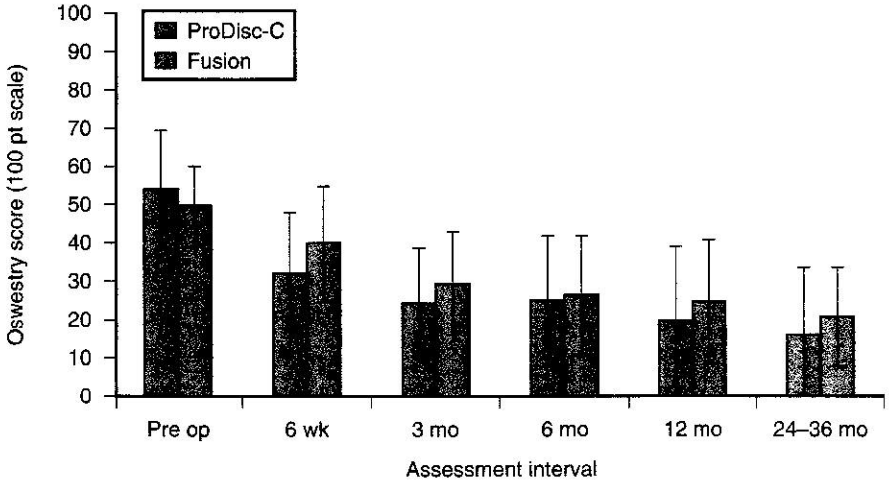
ACDF, anterior cervical discectomy and fusion; ACDR, anterior cervical discectomy replacement.



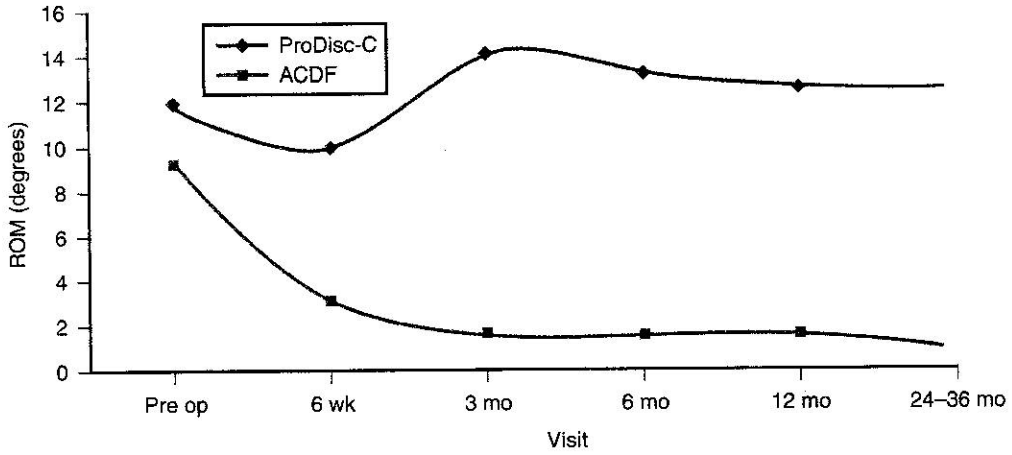
■ **FIGURE 25–3.** Visual Analog Scale (VAS) neck pain scores.



■ **FIGURE 25–4.** Visual Analog Scale (VAS) arm pain scores.



■ **FIGURE 25–5.** Oswestry Disability Index (ODI) scores.



■ **FIGURE 25–6.** Sagittal angular motion in degrees.

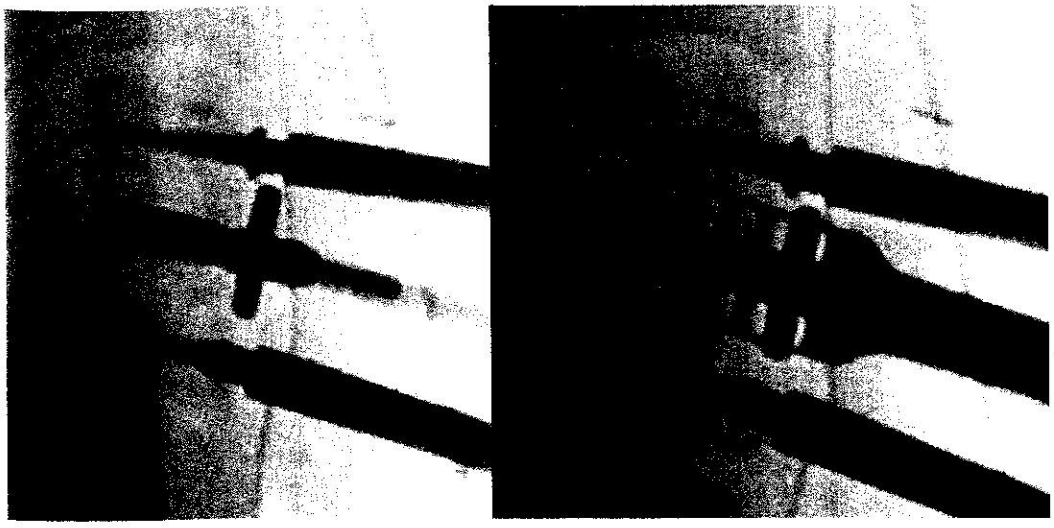
Once the operative level is confirmed, self-retaining retractors are placed mediolaterally and superoinferiorly (Fig. 25–7). The fluoroscopy machine is positioned to allow anteroposterior and lateral imaging during the procedure. Midline in the anteroposterior plane is marked on the vertebral bodies spanning the operative disc, using the fluoroscopy machine. Manual discectomy is then performed.

Specialized pin distractors are then placed in the spanning vertebral bodies. These pins are actually fastened onto the distractor using nuts, making this device a rigid fixator (similar to an external fixator) rather than simply a distractor (Fig 25–7 and 25–8). Not only does this provide distraction for easier removal of disc tissue but it also provides rigid stabilization during instrumentation so that the relative alignment of the vertebral bodies is maintained. This prevents excessive jolting movements of the vertebral bodies and neural elements during impacting of the implant, and it also ensures precise and symmetric placement of the device keels within both vertebrae (avoiding any listhesis, see Fig. 25–8).

Disc resection is performed entirely manually, with minimal need for end plate preparation (e.g., burring, milling, and so on). The two keels and the porous-coated surfaces of the ProDisc-C provide enough initial fixation to obviate any end plate milling or preparation, which removes end plate bone and can risk loss of segmental lordosis and implant subsidence. Occasionally, osteophyte resection or end plate flattening with a bur or Kerrison rongeur may be necessary. The posterior longitudinal ligament may or may not be removed depending on the location of herniated disc or osteophyte.

Once the disc space is adequately cleared, trial sizing with the help of fluoroscopy is performed (see Fig. 25–8). The implant size that maximizes end plate coverage is chosen. Appropriate disc height is selected based upon the tightness of fit and the relative heights of the unaffected adjacent segments. Overstuffing or undersizing of the implant can both compromise stability and range of motion. Once the size of the implant is selected, an osteotome is slid over the trial (which acts as a stop) and malleted through the previously marked midline on the vertebrae to create a channel for the keels (see Fig. 25–8). A sharp chisel is followed by a box osteotome to widen the slot for the keels. This prevents excessive stress on the vertebrae during implant placement and also prevents posterior displacement of bony fragments. After the chiseling, the actual implant is then carefully malleted into place

■ **FIGURE 25–7.** Anterior exposure and discectomy.



■ **FIGURE 25–8.** Trialing and chiseling under fluoroscopy.

■ **FIGURE 25–9.** Insertion of prosthesis under fluoroscopy.

under fluoroscopic guidance (Fig. 25–9). The fixator, pins, and retractors are then removed, and closure is performed.

POSTOPERATIVE CARE

A soft neck collar 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 comfortable but should allow 6 weeks before returning to recreational sports or full duty (if the job is physically demanding).

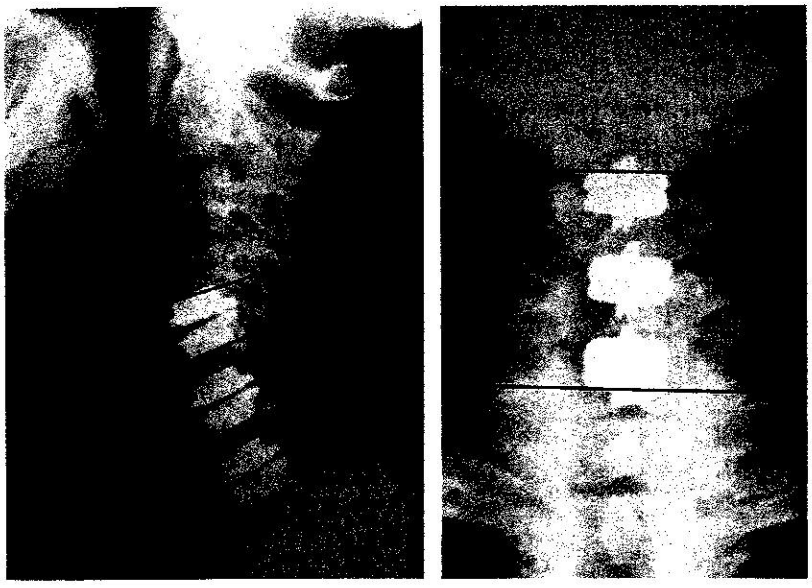
COMPLICATIONS AND AVOIDANCE

No major technique- or device-related complications were observed. Table 25–3 lists the complications for patients undergoing ACDR and ACDF. There was one revision surgery in each group. No device migration or subsidence requiring further treatment has been seen to date. This may be related to the screening out of osteoporotic patients, who would be high risk for such issues. The incidence of prolonged dysphagia, defined loosely as patient-subjective swallowing difficulty lasting more than 6 weeks, was

TABLE 25–3. Complications From the U.S. IDE Study of ProDisc-C Versus ACDF

Complication	ProDisc-C (%)	ACDF (allograft + plate) (%)
Implant migration/subsidence	0/33 (0)	0/15 (0)
Nonunion	NA	1/15 (6.7)
Revision surgery	1/33 (3)	1/15 (6.7)
Prolonged dysphagia	2/33 (6)	1/15 (6.7)
Postoperative swallow study, laryngoscopy, or other throat workup	0/33 (0)	0/15 (0)
Superficial infection	1/33 (3)	1/15 (6.7)
Deep infection	0/33 (0)	0/15 (0)
New transient symptoms	2/33 (6)	2/15 (13.4)

ACDF, anterior cervical discectomy and fusion; IDE, Investigational Device Exemption.
*Subsided by 6 weeks to 3 months after surgery.



■ **FIGURE 25–10.** Example of multilevel cervical artificial disc replacement, 12 months after surgery.

minimal in either group. Patients claiming dysphagia were still eating a regular diet with solid foods. No swallow studies or any other post operative throat evaluations were needed for further persistent swallowing, breathing, or vocal difficulties in either study group. Transient new symptoms were observed in two patients each in the ACDF and ACDR groups. These were defined as spontaneous new-onset radiculopathy, numbness, or subjective weakness. All new symptoms subsided by 6 weeks to 3 months after surgery.

ADVANTAGES/DISADVANTAGES: ProDisc-C TOTAL CERVICAL DISC REPLACEMENT

Advantages	Disadvantages
Semiconstrained motion is facet protective	Greater device-bone interface loading
Good fixation features (keels, coating)	Questionable risk of vertebral fractures (especially during multilevel use)
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 U.S. FDA clinical data available	
Multilevel disc replacements possible and clinical data also available (2 and 3 levels)	
Good experience: more than 6,000 implanted worldwide at time of writing (Aug 2006)	
Easily revisable (both approach and device extraction with designated instruments)	

FDA, Food and Drug Administration.

CONCLUSIONS/DISCUSSION

Our experience with the ProDisc-C artificial cervical disc suggests that cervical disc replacement is a viable surgical alternative to fusion for cervical disc degeneration and herniation, with preservation of motion and alignment at the treated vertebral 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.

This particular device has been used extensively for multilevel use, with as good or better clinical outcomes as compared with single-level surgeries and with good preservation of motion at each replaced level, good preservation of spinal alignment at each replaced level, and great patient satisfaction scores (Fig. 25–10). The technique and instrumentation are facile and streamlined, but the instruments continue to be refined still. One of the salient improvements has been in the way the keel cuts are made in the vertebrae: A drill with a protective guide has been built to seamlessly drill the keel grooves on the bone, thus minimizing the risk of vertebral splitting fractures, especially when performing multilevel disc replacement. The drill also minimizes malleting on the spine.

REFERENCES

1. Goffin J, Van Calenbergh F, van Loon J, et al: Intermediate follow-up after treatment of degenerative disc disease with the Bryan Cervical Disc Prosthesis: single-level and bi-level. Spine 28:2673–2678, 2003.
2. Wigfield CC, Gill SS, Nelson RJ, et al: The new Frenchay artificial cervical joint: results from a two-year pilot study. Spine 27:2446–2452, 2002.
3. Delamarter RB, Pradhan BB: Indications for cervical spine prostheses, early experiences with ProDisc-C in the USA. Spine Art 1:7–9, 2004.
4. Panjabi M, Duranceau J, Goel V, et al: Cervical human vertebrae: quantitative three-dimensional anatomy of the middle and lower regions. Spine 16:861–869, 1991.
5. Yoganandan N, Lumaresan S, Printat F: Biomechanics of the cervical spine, Part 2: Cervical spine soft tissue responses and biomechanical modeling. Clin Biomech 16:1–27, 2001.
6. White A, Panjabi M: Clinical Biomechanics of the Spine. Philadelphia, J. B. Lippincott Co., 1990, pp 110–111.
7. Pradhan BB, Delamarter RB, Bae HW, et al: 2- to 3-Year Results with the ProDisc-C Cervical Disc Replacement from the US Clinical Trials. North American Spine Society annual meeting, Seattle, WA, September, 2006.