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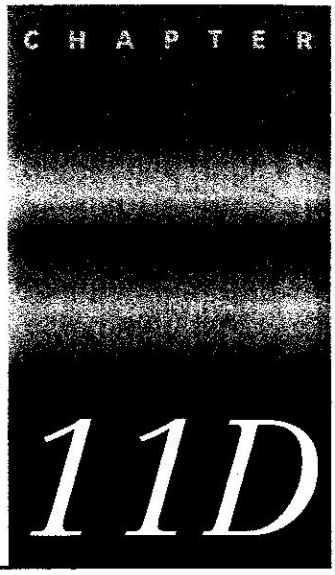

Cervical Arthroplasty: ProDisc-C®

Introduction

As the surgical standard of care to date for intractable neck and arm pain due to cervical degenerative disk disease or disk herniation, anterior cervical discectomy and fusion (ACDF) has been very effective. Delamarter et al. at our own center have shown that in the appropriately selected patient, symptoms are relieved reliably and early after surgery.[1-3] However, the long-term effects of motion-eliminating surgery in the spine, especially at multiple levels, have come under scrutiny recently. Several studies have documented the degeneration of adjacent segments after cervical fusion surgery. Hilibrand et al. reported a 2.9% per year rate of symptomatic degeneration of cervical segments adjacent to a fusion, with a reoperation rate of 66%.[4] Goffin et al. reported a 36% rate of clinical deterioration at 8 years, with a reoperation rate of 6%.[5] Katsuura et al. reported a 50% rate of adjacent segment degeneration at 10 years.[6] The apparently accelerated incidence of degenerative changes in disks adjacent to fused levels has led to the hypothesis that elimination of segmental motion leads to abnormal loading and motion of the remaining segment(s).

Anterior cervical discectomy, along with the removal of osteophytes, is necessary in order to remove the discogenic source of pain as well as anterior neural compression. It is well accepted that the anterior spinal column must be reconstructed after discectomy. Discectomy alone can lead to loss of intervertebral and foraminal height, kyphotic deformity, and increased pain. Traditionally, segmental reconstruction has been done with structural allograft or autologous bone. Anterior plating may be added to immobilize the reconstructed segment even further and encourage fusion. Various interbody fusion devices have been developed recently, all designed to impart disk space distraction and stability while fusion takes effect.

However, just as in the case of other major joints in the body, spinal reconstruction does not necessarily have to be immobile. With the increased attention being focused on adjacent segment disease, mobile anterior spinal reconstruction techniques have been developed, beginning with lumbar artificial disk replacement.[7-9] On the heels of encouraging results observed after the U.S. Food and Drug Administration (FDA) Investigational Device Exemption (IDE) clinical trials for the lumbar artificial disks, which have culminated in FDA approval for the Charité™ III prosthesis (DePuy Spine, Raynham, Massachusetts), clinical trials for cervical artificial disks have also recently been completed. This chapter represents

the clinical experience with the ProDisc-C® artificial cervical disk (Synthes, West Chester, Pennsylvania).

The ProDisc-C® Device

Design Rationale The ideal spinal segmental reconstruction technique will preserve as many of the physiologic properties of the intervertebral disk as possible. These include maintaining intervertebral viscoelasticity with as near-normal range of motion as possible. Intervertebral height needs to be maintained, as this will affect foraminal height as well. Furthermore, segmental lordosis is important to maintain spinal alignment. Ideally, the prosthesis design and placement technique should be simple to reduce operative time and morbidity, and to allow early recovery and return to function. Finally, it must be shown in a well-designed clinical trial that the prosthesis is at least as effective as the current standard of care, with the added potential benefit of reducing adjacent segment deterioration.

Device Characteristics The ProDisc-C® prosthesis (Fig. 11D-1) shares many of the physical characteristics of the ProDisc-L lumbar prosthesis. The device is essentially a ball-and-socket joint: the endplates are constructed of a cobalt-chrome alloy, and the articulating convex insert is made of ultrahigh-molecular-weight polyethylene (UHMWPE). Both of these are proven materials with an extensive track record in hip and knee arthroplasty. Both upper and lower endplates have slotted keels and titanium plasma spray coating. These design characteristics allow for immediate fixation onto the vertebral endplates, as well as long-term fixation via bony in-growth.

The UHMWPE insert is fixed onto the lower endplate. 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 since the axis of rotation for the device actually lies inferior to the disk space, translation is not eliminated. Minute (~1 mm) anterior and posterior translational shift is allowed during flexion and extension (Fig. 11D-2), as is seen physiologically. Excessive translation however is not allowed, protecting the facet joints

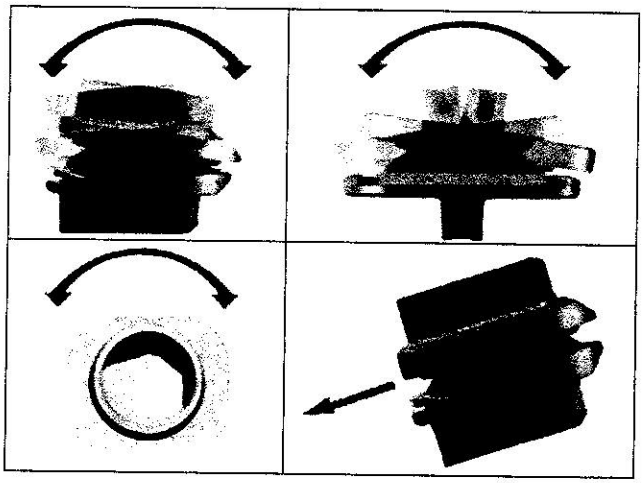

Figure 11D-2. The ProDisc-C® kinematics (Synthes, West Chester, Pennsylvania).

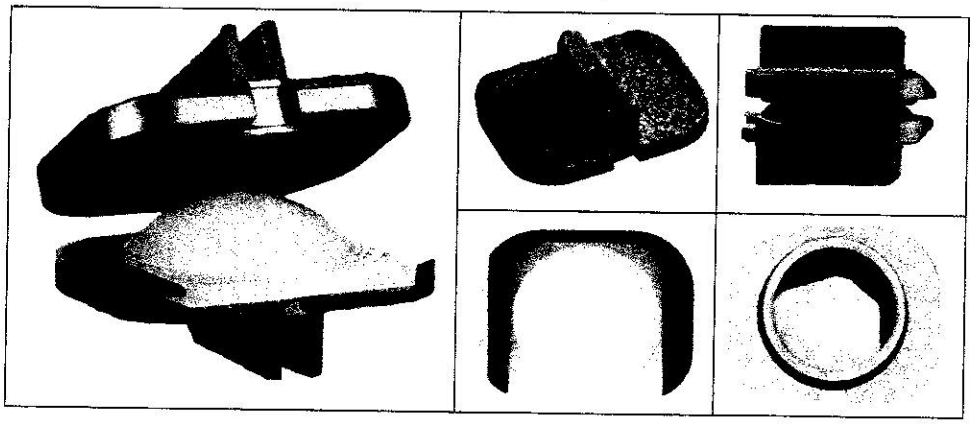

Figure 11D-1. The ProDisc-C® artificial cervical disc. (Reprinted with permission of Synthes, West Chester, Pennsylvania).

from undue loading in the absence of the native disk. This is hoped to 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 disk. The semiconstrained kinematics does, however, shift shear load from the facets to the prosthesis–bone interface, highlighting the importance of the prosthesis fixation features mentioned above.

Based on human anatomic studies,[10,11] four different prosthetic disk heights are available, ranging from 5 to 8 mm. Disk 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 allows a maximum of 20° of flexion-extension, 20° of side-to-side bending, and 12° of axial rotation.[12]

Implantation Technique A standard anterior approach to the cervical spine is performed. 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 disk space. Before performing the discectomy, another localizing radiograph is performed.

Once the operative level is confirmed, self-retaining retractors are placed mediolaterally and superoinferiorly (Fig. 11D-3). 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 disk, 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 (ala an external fixator) rather than simply a distractor (Figs. 11D-3, 11D-4). Not only does this provide distraction for easier removal of disk tissue, but also 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 also ensures precise and symmetric placement of the device keels within both vertebrae (avoiding any listhesis) (Fig. 11D-4).

Disk resection is performed entirely manually, with minimal need for endplate preparation (e.g.,

Figure 11D-3. Anterior exposure and discectomy.

Figure 11D-4. Trialing and chiseling under fluoroscopy.

Figure 11D-5. Insertion of prosthesis under fluoroscopy.

burring, milling, etc). The two keels and the porous-coated surfaces of the ProDisc-C® provide enough initial fixation to obviate any endplate milling or preparation, which remove endplate bone and can risk loss of segmental lordosis and implant subsidence. Occasionally, osteophyte resection or endplate 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 disk or osteophyte.

Once the disk space is adequately cleared, then trial sizing with the help of fluoroscopy is performed (Fig. 11D-4). The implant size that maximizes endplate coverage is chosen. Appropriate disk height is selected based on 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, then 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 (Fig. 11D-4). 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 under fluoroscopic guidance (Fig. 11D-5). The fixator, pins, and retractors are then removed, and closure is performed.

Clinical Experience

History There have been limited published reports on the clinical results of cervical artificial disk replacement. Goffin et al. reported a 90% rate of good to excellent results at 1 to 2 years after cervical disk arthroplasty with the Bryan® prosthesis (Medtronic Sofamor Danek, Memphis, Tennessee).[13] Wigfield et al. reported a 46% improvement in pain and a 31% improvement in disability 2 years after implantation of the Prestige cervical artificial disk.[14] We reported the early outcomes after ProDisc-C® implantation, with significant reductions in visual analog pain and Oswestry disability scores.[15] Longer term follow-up from the prospective, randomized, and controlled FDA IDE trial at our center is reported in this chapter.

The first ProDisc-C® implantation was performed in December 2002. Since then, over 1,000 prostheses have been implanted worldwide. Multilevel disk replacements have also been performed. In the original European studies, there have been no device failures or need for revision surgeries. The first implantation in the United States was performed at our center in August 2003. Since then, over 200 implantations have been performed in 15 centers across the country as part of the FDA IDE study. The study enrollment phase is complete, with the FDA now analyzing the data for 2 years follow-up.

The FDA IDE Trial Table 11D-1 lists the eligibility criteria for the FDA IDE study on spinal arthroplasty with the ProDisc-C® device versus anterior cervical discectomy and fusion. In general patients were selected for degenerative disk disease at one level between C3 to C7 causing intractable neck and/or arm pain. Table 11D-2 lists the demographic characteristics of the patients enrolled at our site. Forty total patients were enrolled. Randomization was performed at a 1:1 ratio to anterior cervical disk replacement (ACDR) versus anterior cervical discectomy and fusion (ACDF). The ProDisc-C® was implanted in 24 patients, and ACDF was performed in 16 patients. Pain, disability, and range of motion were evaluated at preoperative, and 6 weeks, 3, 6, 12, and 18-month follow-up visits.

Clinical outcome scores revealed significant improvements in Visual Analog Scale (VAS) scores for both neck pain (Fig. 11D-6) and arm pain (Fig. 11D-7), and Oswestry Disability Index (ODI) scores as well (Fig. 11D-8) for both ACDR and ACDF patients. By 3 months, VAS (neck) was down from 6.6 to 3.0 in disk replacement patients, and 6.2 to 1.6 in fusion patients. VAS (arm) improved even more significantly, from 5.7 to 1.1 and 6.5 to 1.5 in disk replacement and fusion patients respectively by 3 months. Both of these improvements stayed significant at 18 months and later. ODI scores similarly decreased from 25 to 9 and 24 to 13 at over 18 to 24 months in disk replacement and fusion patients respectively. While all of the outcome measures decreased significantly from preoperative status ($P < 0.05$), they were not seen to be significantly different between treatment modalities (disk replacement versus fusion, $P > 0.05$).

Average flexion-extension motion went from 9.0° preoperatively to about 1° (essentially no motion) at over 18 months postoperatively in the fusion group, but was well preserved from 11.0° to 12.5° in the disk replacement group. Side bending went from 6° to less than 2° (essentially no motion) in the fusion group, versus 5.9° to 5.0° in disk replacement patients. There were no major complications, technique or device related, in any of the cases. Figure 11D-9 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 disks. Side-to-side bending averaged about 5°, whereas flexion extension averaged about 12°.

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

Complications No major technique- or device-related complications were observed. Table 11D-3 lists the complications for both the ACDR and ACDF patients. No revision surgeries or any other

Table 11D-1. FDA IDE Clinical Trials for ProDisc-C®: Inclusion and Exclusion Criteria

Inclusion	Exclusion
1. Symptomatic cervical disk disease in only one vertebral level between C3-C7 defined as: neck or arm (radicular) pain; and/or functional/neurological deficit with at least one of the following conditions confirmed by imaging (CT, MRI, or x-ray) a. Herniated nucleus pulposus b. Spondylosis (presence of osteophytes) and/or c. Loss of disk 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[13] score ≥15/50 (30%) 5. Psychosocially, mentally, and physically able to comply with 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 >3 mm and/or b. Angular motion >11° 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 disk height >50% or c. Absence of motion (<2°) 9. Neck or arm pain of unknown etiology 10. Osteoporosis: If DEXA is required, exclusion defined as T score ≤ −2.5[14] 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, etc. 18. Active malignancy

FDA, U.S. Food and Drug Administration; IDE, Investigational Device Exemption.
ProDisc® (Synthes, West Chester, Pennsylvania).

Table 11D-2. FDA IDE Clinical Trials for ProDisc-C®: Demographics

Average age (yr)	42.5	40.2
Gender (%m:%f)	38:62	29:71
Body mass index (BMI)	24.9	23.7
Workman's compensation status	25%	27%
Preoperative duration of neck pain (mo)	10.5	10.5

ACDF, anterior cervical discectomy and fusion; ACDR, anterior cervical disk replacement; FDA, U.S. Food and Drug Administration; IDE, Investigational Device Exemption.
ProDisc® (Synthes, Paoli, Pennsylvania).

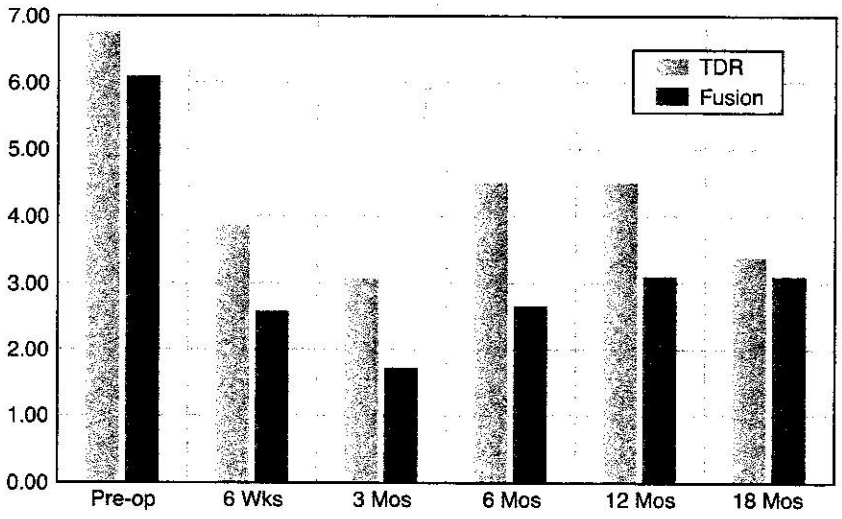

Figure 11D-6. Visual Analog Scale neck pain scores.

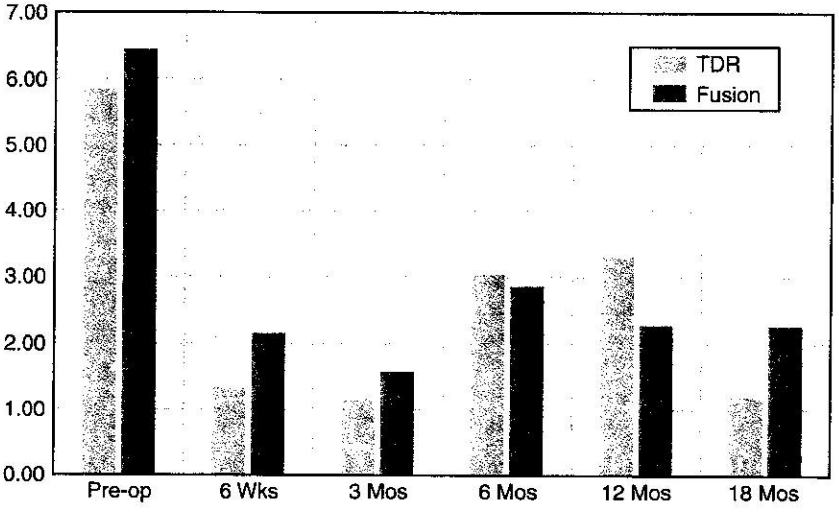

Figure 11D-7. Visual Analog Scale arm pain scores.

kind of reoperation has been necessary. No device migration or subsidence has been seen to date. No pseudarthroses were seen in the ACDF patients. The incidence of prolonged dysphagia, defined loosely as patient-subjective swallowing difficulty lasting more than 6 weeks, was minimal in either group. Patients claiming dysphagia were still eating a regular diet with solid foods. No swallow studies or any other postoperative 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.

Multilevel ACDR with ProDisc-C® Degenerative disk disease is unfortunately commonly a multilevel problem. The same factors that predispose a certain segment to herniate or degenerate can affect other levels as well. With rigid enrollment

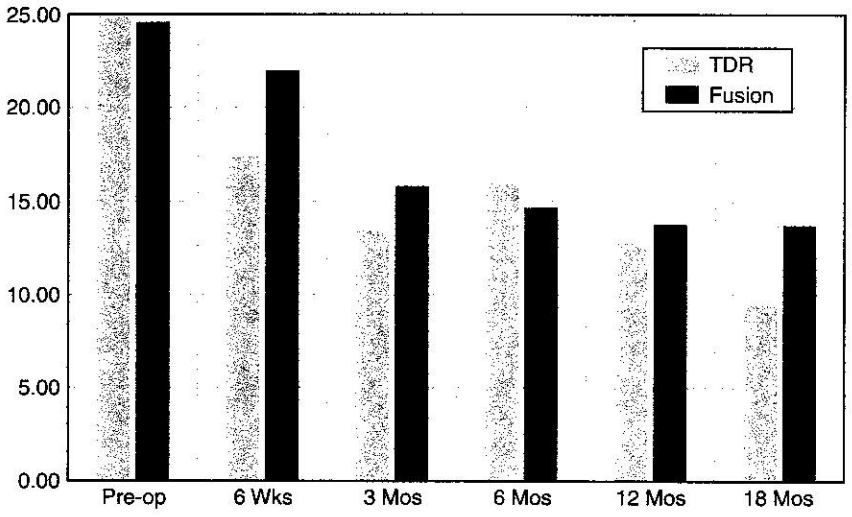

Figure 11D-8. Oswestry Disability Index scores.

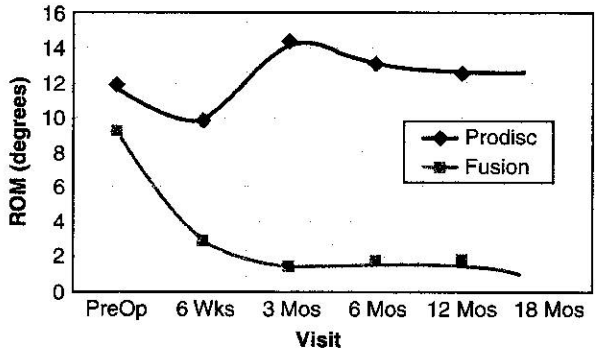

Figure 11D-9. Sagittal angular motion in degrees.

criteria such as in the FDA IDE clinical trials for ProDisc-C®, a large portion of the population suffering from cervical disk degeneration may be excluded from being treated with spinal arthroplasty. Patient selection is certain to evolve as surgeons become more experienced with the procedure.

At our center, based on the preliminary results of disk arthroplasty in previously enrolled patients, and based on the design of the ProDisc-C® device, the FDA has allowed the "compassionate" use of two- and three-level arthroplasty in qualified patients with special circumstances—patients in whom

Table 11D-3. Complications from the FDA IDE study of ProDisc-C® vs. ACDF

Implant migration/subsidence	0/24 (0%)	0/16 (0%)
Nonunion	NA	0/16 (0%)
Prolonged dysphagia	2/24 (8%)	1/16 (6%)
Postop swallow study, laryngoscopy, or other throat work-up	0/24 (0%)	0/16 (0%)
Superficial infection	1/24 (4%)	1/16 (6%)
Deep infection	0/24 (0%)	0/16(0%)
New transient symptoms[a]	2/24 (8%)	2/16(12%)

[a]Subsided by 6 weeks to 3 months postop.
ACDF, anterior cervical discectomy and fusion; FDA, U.S. Food and Drug Administration; IDE, Investigational Device Exemption.
ProDisc (Synthes, West Chester, Pennsylvania).

multilevel fusion would impart unusual hardship or impairment in their lives or careers. To date there have been six three-level and four two-level ACDRs at our center, with more pending. The results so far reveal that pain relief from neck pain and arm pain is just as significant (Figs. 11D-10, 11D-11) as with one-level ACDRs, with no difference in effectiveness based on number of disks replaced (from one to three levels). Disability improvement was marked with two- or three-level disk replacements as well (Fig. 11D-12). Motion preservation with multilevel disk replacement was also seen to be quite effective and physiologic at each replaced level. This is discussed in more detail in the next section.

Motion Analysis The objective of total disk arthroplasty is not only to restore or maintain motion, but also to achieve physiologic motion. Either hypermobility or hypomobility may lead to abnormal stresses and accelerated degeneration, defeating the purpose of arthroplasty. Therefore, the motion at and adjacent to cervical segments with disk replacement(s) was critically analyzed at our center (Table 11D-4).

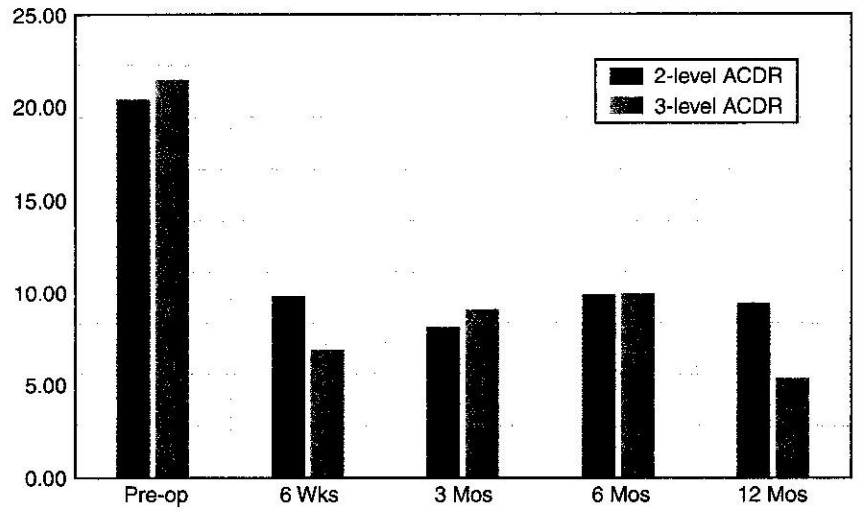

Figure 11D-10. Visual Analog Scale neck pain scores, multilevel anterior cervical disk replacement.

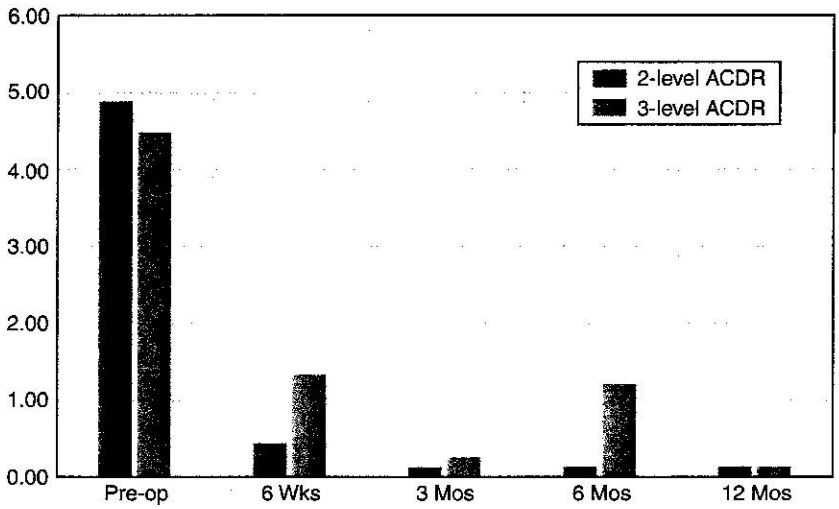

Figure 11D-11. Visual Analog Scale arm pain scores, multilevel anterior cervical disk replacement.

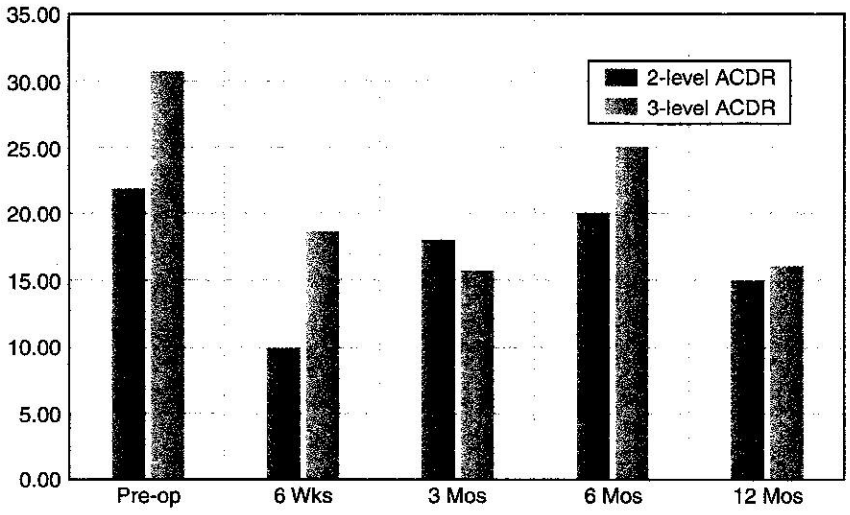

Figure 11D-12. Oswestry Disability Index scores, multilevel anterior cervical disk replacement.

Table 11D-4. Treated and Adjacent Untreated Segmental Range of Motion Measurements

Preop segmental ROM at treated level		7.5	7.8	10.0
6-wk postop	at treated level	12.0	No flex-ext x-ray	10.0
segmental ROM	at 2nd ACDR if present, below	12.5	No flex-ext x-ray	10.7
	at 3rd ACDR if present, below	6.5	No flex-ext x-ray	7.1
Change in segmental ROM at treated level, 6 wk		+4.5	No flex-ext x-ray	
Last follow-up	at treated level	13.6	~0	10.0
segmental ROM	at 2nd ACDR if present, below	9.5	only 1-level ACDF	10.7
	at 3rd ACDR if present, below	8.5	only 1-level ACDF	7.1
Change in segmental ROM at treated level, last follow-up		+6.1	−7.8	
ROM, untreated adjacent level above, preop		13.0	8.9	
ROM, untreated adjacent level above, 6 wk		8.0	No flex-ext x-ray	
ROM, untreated adjacent level above, last follow-up		10.7	15.8	
Change in ROM, untreated adjacent level above, 6 wk		−5.0	No flex-ext x-ray	
Change in ROM, untreated adjacent level above, last follow-up		−2.3	+6.9	
ROM, untreated adjacent level below, preop		7.1	4.3	
ROM, untreated adjacent level below, 6 wk		5.5	No flex-ext x-ray	
ROM, untreated adjacent level below, last follow-up		4.5	8.0	
Change in ROM, untreated adjacent level below, 6 wk		−1.6	No flex-ext x-ray	
Change in ROM, untreated adjacent level below, last follow-up		−2.6	+3.7	

[b]Average of range of motion of the same segments in unaffected patients.
ACDF, anterior cervical discectomy and fusion; ACDR, anterior cervical disk replacement; ROM, range of motion.
ProDisc® (Synthes,West Chester, Pennsylvania).

In this motion analysis study, 43 patients were included, 26 DR and 15 ACDF patients. There were 18 one-level and 15 one-level ACDFs. Follow-up ranged from 1 to 2 years (mean, 18 months). There were also six three-level and four two-level ACDRs, as allowed by the FDA for compassionate use in qualified patients with special circumstances. The ProDisc-C® prosthesis was able to restore a more normal range of motion at the degenerated level(s), from an average of 7.5° preoperatively to 12° immediately postoperatively, and 13.6° at final follow-up (both P <0.05). In multilevel ACDR, at each individual treated segment, the range of motion (ROM) was maintained and approximated that of physiologic ROM (as measured from radiographs in patients where those segments were unaffected). In contrast, the adjacent segment motion above an ACDF was increased significantly (Fig. 11D-13) compared to ACDR (8.9° preop to 15.8° postop in fusion, versus 13.0° to 10.7° in ACDR; P <0.05). Adjacent segment motion below the treated level was also significantly different between fusion and disk replacement (4.3° preop to 8.0° in fusion, versus 7.1° to 4.5° in DR; P <0.05). There was a trend to actually decreasing motion at segments adjacent to a DR, although these numbers were not statistically significant. Hypermobility at adjacent segments in fusion patients was also manifested by translational listhesis and irregularity of the curvature formed by the posterior vertebral edges (Fig. 11D-13).

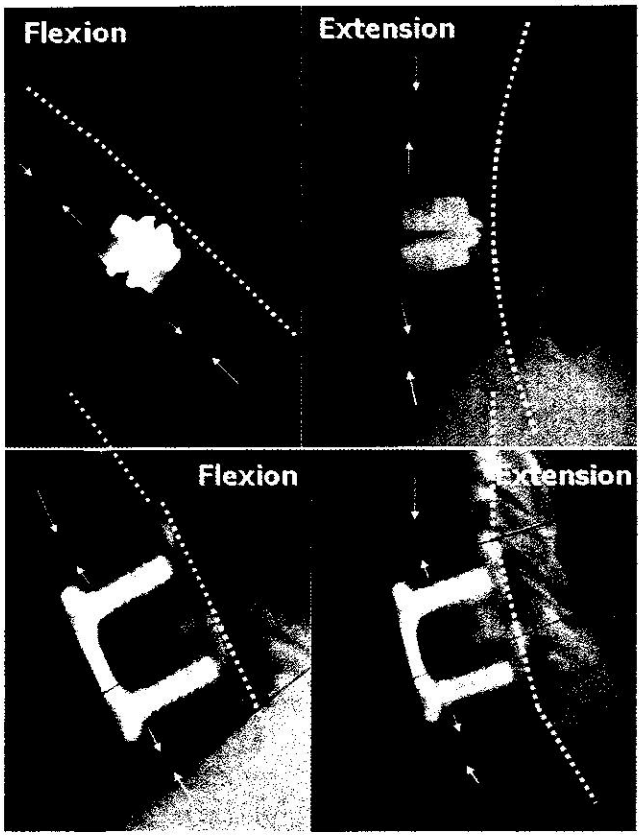

Figure 11D-13. *Top*: Flexion-extension radiographs after cervical disc arthroplasty reveals relatively normal range of motion of adjacent segments, with the posterior vertebral edges forming a smooth curve. *Below*: Flexion-extension radiographs after cervical fusion reveal hypermobility at the adjacent segments, with sharper angulation of posterior vertebral edges, and in this case, even some anterior translation.

In conclusion, ACDR with ProDisc-C® not only retained mobility, but was able to do so while imparting relatively normal physiologic range of motion, both at the treated and untreated segments, in contrast to anterior cervical discectomy and fusion, which imparts hypermobility to adjacent segments. Moreover, multilevel cervical disk replacement is able to maintain physiologic range of motion at each of the treated segments—indicating that in the properly selected patient, motion is not concentrated in any one of the multilevel prostheses.

Cervical Alignment Artificial disks represent a dynamic (mobile) reconstruction of the spinal column, and as such are unproven in cases of spinal deformity or preservation of spinal alignment when used for multiple levels. Long-term effects on cervical lordosis, especially after multilevel ACDR, have not been reported. A recent report demonstrated the early loss of local lordosis with one-level ACDR using the Bryan® prosthesis.[16] An analysis of segmental as well as overall sagittal and coronal cervical alignment with one to three-level disk replacements was also conducted at our center. This was compared with ACDF.

Forty-three patients were included in this spinal alignment study, and consisted of 26 DR and 15 ACDF patients (Table 11D-5). There were 18 one-level and 15 one-level ACDFs. Follow-up ranged from 1 to 2 years (mean, 18 months). There were also six three-level and four two-level ACDRs, as allowed by the FDA for compassionate use in

Table 11D-5 Segmental and Overall Cervical Sagittal and Coronal Alignment for 1-3 level ACDR vs. ACDF

Preop segmental lordosis (across affected levels only)	1.4	0.2
6 week (1st follow-up) segmental lordosis (across treated levels only)	6.1	4
Last follow-up segmental lordosis (across treated levels only)	4.2	3.4
Change in segmental lordosis at 1st follow-up	+4.7	+3.8
Change in segmental lordosis at last follow-up	+2.8	+3.2
Preop overall cervical lordosis (C1-T1)	35.9	39.5
1st follow-up overall lordosis (C1-T1)	35.6	34.5
Last follow-up overall lordosis (C1-T1)	37.4	36.3
Change in overall lordosis at 1st follow-up	−0.3	−5.0
Change in overall lordosis at last follow-up	+1.5	−3.2
Preop overall coronal alignment	~Neutral	~Neutral
1st follow-up overall coronal alignment	~Neutral	~Neutral
Last follow-up overall coronal alignment	~Neutral	~Neutral
Change in overall coronal alignment 1st follow-up	~0	~0
Change in overall coronal align last follow-up	~0	~0

ACDF, anterior cervical discectomy and fusion; ACDR, anterior cervical disk replacement.
ProDisc® (Synthes, West Chester, Pennsylvania).

qualified patients with special circumstances. Segmental lordosis increased immediately postoperatively in both ACDR and ACDF patients (by 4.7° and 3.8°, respectively; $P > 0.05$), and this increase was maintained in both groups at final follow-up (by 2.8° and 3.2°, respectively; $P > 0.05$). Overall cervical lordosis was maintained by both ACDR and ACDF. Cervical lordosis after ACDR went from 35.9° preop to 35.6° immediate postop and 37.4° at final follow-up ($P > 0.05$), and after ACDF went from 39.5° preop to 34.5° immediate postop and 36.3° at final follow-up ($P > 0.05$). Coronal alignment was also maintained by both ACDR and ACDF, not changing from neutral preop to postop and at final follow-up ($P > 0.05$). These trends were true for one-, two- or three-level DR.

In conclusion, single- and multilevel cervical ACDR with the ProDisc-C® prosthesis was able to preserve coronal and sagittal cervical alignment, both segmental and overall, at up to 2 years after surgery. Our results show that the ability of these devices to maintain mobility does not compromise restoration or preservation of spinal alignment (Fig. 11D-14).

Discussion

Our experience with the ProDisc-C® artificial cervical disk suggests that cervical disk replacement is a viable surgical alternative to fusion for cervical disk degeneration and/or herniation, with preservation of motion and alignment at the treated vertebral levels, and without compromising clinical outcomes. While it is yet too early for the FDA 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.

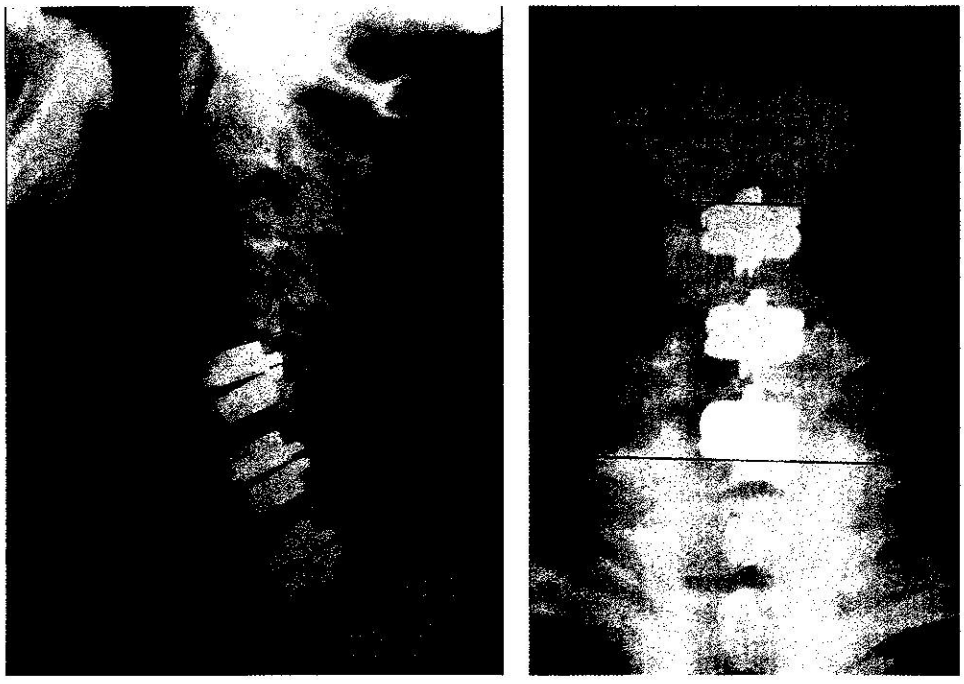

Figure 11D-14. Example of measurement of sagittal and coronal alignment in multilevel cervical artificial disc replacement.

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