

## Current Status of Clinical Evidence and Indications for Cervical Arthroplasty

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*Learning Objectives:* After participating in this activity, the neurosurgeon should be better able to:

1. Illustrate indications for cervical artificial disc replacement surgery.
2. Evaluate clinical trial results for the currently FDA-approved cervical artificial discs.
3. Interpret complications associated with cervical artificial disc replacement surgery.

It has been predicted that cervical arthroplasty will replace fusion and become the new “gold standard” in the near future. Although short-term clinical results associated

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with cervical artificial disc replacement are promising, long-term benefits of reduced stress on the adjacent levels or effectiveness of cervical arthroplasty compared with anterior cervical discectomy and fusion (ACDF) remain unknown. The advantage of preserved segmental mobility should be weighed against potential negative effects on the facet joints and the possibility of late implant failure or loosening. Strict patient selection based on clear indications and absence of exclusion criteria should heavily outweigh the marketing enthusiasm.

### Background

We published a review on cervical arthroplasty in this newsletter in 2007 (vol. 29, nos. 12 and 13) that focused primarily on history, design features for various artificial discs, and surgical technique. At the time, few data were available on clinical outcomes. This article provides an update on indications and the current status of clinical evidence based on the results of prospective clinical trials that have become available. This article focuses on total disc replacement procedures and does not discuss disc

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**Category:** Spine

**Key Words:** Arthroplasty, Cervical artificial disc, Spine surgery

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regeneration and nucleus replacement techniques. This article provides a concise review of the currently available data that support the use of cervical arthroplasty as a reliable alternative to the gold standard ACDF. We hope to gain the attention of spine surgeons and insurance companies alike to help advocate for the use and approval of this procedure in the select patient group that can benefit from arthroplasty. After completing this activity, the reader should understand the strict indications for cervical arthroplasty, current outcomes data, and potential complications of this promising procedure.

Spine surgeons, young surgical candidates, and an aging elderly, but increasingly active, patient population are showing significant interest in this rapidly advancing technology. In a questionnaire distributed to surgeons attending an annual conference in 2007, 81% of the respondents reported that they were more likely to perform a cervical arthroplasty compared with the preceding year. However, more than 50% of respondents cited two main reasons why they still do not routinely choose cervical arthroplasty over ACDF: lack of long-term outcome data (56%) and lack of insurance coverage (53%). A total of 51% of all respondents predicted that cervical arthroplasty would replace fusion and become the new gold standard in the near future (Whang et al., 2009).

Artificial discs are widely used in more than 30 countries outside the United States and have been successfully used in Europe for two decades. The National Institute for Clinical Excellence (United Kingdom) published *Guidance on Prosthetic Intervertebral Disc Replacement* based on clinical data available before January 2004 and found that "current evidence on the safety and efficacy of prosthetic intervertebral disc replacement appears adequate to support the use of this procedure."

Cervical artificial discs fall into two categories in the United States: (1) FDA-approved for clinical use; and (2) investigational. Two cervical devices are FDA-approved: Prestige ST (Figures 1 and 2) and ProDisc-C. In May 2009, the FDA approved another device, the Bryan cervical disc, after initial conditional approval in 2007. However, the manufacturer still must provide a postmarket approval application amendment with the updated product labeling before the device may be distributed commercially. Several arti-

cial discs have completed or undergoing investigational device exemption (IDE) prospective randomized clinical trials (e.g., PCM, Secure-C, Mobi-C, and Advent).

Regardless of the status of FDA approval, most insurance companies continue to deny coverage for arthroplasty procedures in the United States, usually based on statements that long-term effectiveness and complication rates are unknown or that no difference in the incidence of adjacent level degeneration compared with ACDF has been proven. Other concerns expressed by insurance companies include unknown long-term durability, lack of initial stabilization measures (such as the anterior plate used to stabilize the spinal segment during a fusion), and placement of the devices in the intervertebral space rather than bone.



**Figure 1.** Prestige ST cervical artificial disc. (Image provided by Medtronic Sofamor Danek.)

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**Figure 2.** Plain x-rays. Anteroposterior (A) and lateral (B) views demonstrating the Prestige artificial disc.

plans cover cervical artificial disc (Prestige) replacement surgery at a single level between C3 and C7. Several workers' compensation programs (e.g., Colorado, Montana, Wyoming) cover this procedure on a case-by-case basis.

### Indications

About 50% of patients requiring cervical fusion are estimated to be candidates for an arthroplasty procedure (Prudential Equity Report, December, 2005). Cervical disc replacement surgery is indicated for symptomatic cervical disc disease, myelopathy, and radiculopathy symptoms. This is a distinct difference compared with lumbar arthroplasty that should not go unrecognized. Unlike lumbar arthroplasty surgery, which primarily addresses axial back pain, cervical arthroplasty procedures are indicated for the treatment of symptoms associated with neurologic compromise. This difference is related to the fact that it is very difficult—and often impossible—to perform either a central canal or neuroforaminal decompression in the lumbar spine via an anterior approach. Thus, stenosis of the central canal or neuroforamen is a contraindication for lumbar artificial disc replacement. In contrast, anterior cervical approaches often are ideal for such decompressions, which may explain why better clinical outcomes have been achieved with cervical arthroplasty procedures than with lumbar artificial disc replacement.

It has been suggested in the literature that the primary reasons for early disappointing reviews with cervical artificial discs were poor patient selection and inaccurate surgical technique. Indications for currently approved artificial discs include intractable neck pain, radiculopathy, and myelopathy at a single level between C3 and C7. Patients should have failed a minimum of 6 weeks of conservative treatment and have at least one the following conditions: loss of disc height, spondylosis, or herniated nucleus pulposus. Some factors that disqualify patients from being good artificial disc candidates include:

- Osteoporosis, defined as a dual-energy x-ray absorptiometry bone mineral density T-score of 2.5 or less;
- Spinal segment instability > 2 mm; or
- Complete absence of movement at the index level, which usually is associated with severe spondylosis, bridging osteophytes, and collapse of the intervertebral disc space.

The indications for cervical arthroplasty are not nearly as broad as are those for cervical fusion. Any patient with too little or too much motion should be automatically excluded; these patients, however, are still good candidates for cervical fusion.

Not all prospective randomized clinical trials (ProDisc-C) have included patients with myelopathy or specifically evaluated the efficacy of cervical arthroplasty for this indication. Riew et al. analyzed clinical outcomes results in patients with myelopathy in a cross-sectional study based on multicenter clinical trials and concluded that the results of arthroplasty are equivalent to those of ACDF at 2 years of follow-up. However, only patients with focal disc herniation without retrovertebral compression and without multilevel stenosis or significant facet pathology were included in this analysis.

Several off-label uses for cervical arthroplasty have been described in the literature, which may influence the overall safety, efficacy, and long-term clinical outcomes in the future. For example, hybrid techniques have been reported that combine devices of various designs or fusion and motion preservation technology. The safety and efficacy of multilevel procedures, previous fusion at the adjacent level, and previous surgery at the treated level have not been established in the United States (or anywhere else to our knowledge).

### Clinical Outcomes

Although the Bristol-Cummins artificial joint (Prestige disc prototype) has been used in Europe since the late 1980s, well-documented clinical outcomes are lacking, and clinical data based on prospective randomized clinical trials have only reached 2 years of follow-up at this point. Results from multicenter, prospective, randomized controlled trials are available at [www.fda.gov](http://www.fda.gov) for the Prestige ST, Bryan, and ProDisc-C that compare cervical arthroplasty to cervical spinal fusion, with overall success defined based on the following criteria: an improvement of more than 15 points in neck disability index (NDI) score; maintenance or improvement in neurologic status; and no adverse events. Any subsequent surgery or intervention was classified as a “failure.” Based on these criteria, overall success was achieved in 79% vs. 70% (Prestige ST study), 81% vs. 71% (Bryan disc study), and 72% vs. 68% (ProDisc-C study) in the investigational and control groups, respectively.

The multicenter study that evaluated the Prestige ST Cervical System has reported 2-year follow-up clinical outcome results in 276 and 265 patients in the investigational and control groups, respectively. Statistical noninferiority of the investigational device was demonstrated on all clinical outcome measures. One of the primary outcome measures—improvement in neurologic status—demonstrated superiority for the Prestige ST artificial disc. Similar results were reported for the patients implanted with the ProDisc-C at the 6-month and 1-year follow-up examinations, but they became equivalent at 2 years. Patients in the Bryan group returned to work an average of 13 days earlier than the patients in the fusion group. Although there were no statistically significant differences achieved in alleviation of neck and arm pain, a higher NDI score was reported often for patients who received artificial discs compared with those who underwent fusion surgery (Heller et al., 2009).

Preservation of motion is thought to be one of the major advantages of arthroplasty as compared with cervical fusion. In addition to increased range of motion (ROM), arthroplasty in cadaveric specimens has been shown to cause decreased ROM at the adjacent levels as well as maintain the adjacent level intradiscal pressure compared with the intact spine. Fusion models exerted increased intradiscal pressure in both the anterior and posterior annulus on flexion and extension at adjacent levels and increased ROM. Maintaining the normal ROM and intradiscal pressures in adjacent levels theoretically may prevent the development of accelerated adjacent level degenerative disc disease. Conversely, increased motion

at the index level can create an additional stress on the facet joints and lead to poor clinical outcomes.

Prospective randomized control studies have shown that one-level arthroplasty maintains an average motion of 2.36 to 9.36 degrees in flexion and extension, compared with 0.5 to 0.95 degrees of motion in the fusion groups. However, it is unknown whether maintaining motion leads to better clinical outcomes in these studies.

Currently, no well-documented or prospective long-term clinical trials are available that indisputably prove that radiographic or clinical symptoms at the adjacent level after fusion or arthroplasty can be attributed to an accelerated degeneration process as opposed to the natural progression of the disease. Moreover, the connection between the motion and adjacent level degeneration is not clear. Theoretically, stress load alterations may lead to the accelerated development of adjacent level degenerative disc disease. A few other risk factors are described in the literature, such as single-level arthrodesis, the presence of adjacent level degeneration at the time of the index surgery, fusions ending adjacent to the most common levels of cervical degeneration (C5–C6 and C6–C7), and kyphotic deformity. Some of these factors cannot be eliminated by simply replacing fusion with arthroplasty.

Different disc designs also may alter the degeneration process at the adjacent levels. Two types of artificial discs currently are available: semiconstrained (i.e., motion is limited within the normal physiologic movement range) and unconstrained (i.e., provides no mechanical constraints). The latter may add additional stress on the facet joints. The center of rotation is another important characteristic of the disc design, which can be either fixed or mobile. The physiologic center of rotation in a normal disc of the cervical spine is not fixed, so discs with a mobile center of rotation theoretically are more likely to reproduce physiologic movements of the cervical spine. However, if this mobile center of rotation is not perfectly in line with normal physiologic conditions, it may result in added strain to the facet joints. Because of the complexity of all these parameters, only long-term and well-designed clinical studies can give an answer to the question of how all of these biomechanical factors will interact and affect the adjacent levels. Although it is unclear at this point whether motion will be the single factor determining the progression of adjacent level degenerative disc disease, the short-term clinical results are promising. In a recently published cohort study with a mean follow-up time of 20 months, 18% of patients undergoing arthroplasty developed radiologic evidence of adjacent level disease compared with 41% of ACDF patients who underwent single-level surgeries. When two-level surgeries were evaluated, 57% of patients who had ACDF demonstrated radiologic signs of adjacent level degeneration, compared with only 33% of patients with arthroplasty (Kim et al., 2009).

The lower rates of adjacent level degeneration disease were reported in a study that evaluated reoperations. Authors analyzed data from multiple (IDE) clinical trials and compared the rate of reoperations in arthroplasty versus fusion. There were 649 arthroplasty patients and 580 control arthrodesis patients. Four patients (0.6 %) with

arthroplasty underwent reoperation at the adjacent level within 28 months, versus 13 patients (2.2 %) of the ACDF group ( $p = 0.01$ ), suggesting that adjacent level disease requiring reoperation in the short-term period is significantly higher in the fusion group.

Biomechanical studies using cadaveric specimens have been performed to test adjacent level disc pressure and facet joint force. The arthroplasty group demonstrated similar adjacent-level disc pressures but also had slight increases in the facet joint force in extension. This potential increase in facet joint stress is a critical factor when choosing patients for arthroplasty. Patients with any facet pathology may not be able to tolerate an increased load in the posterior elements. When testing ROM, it was determined that the arthroplasty specimens had an increased or stable ROM in the treated segment, but the adjacent levels experienced slightly decreased ROM. The cadaveric findings of similar adjacent-level disc pressures and decreased ROM in these adjacent levels after arthroplasty may help explain the proposed reduction of adjacent level disease in cervical arthroplasty.

### Complications

Potential problems with arthroplasty during the immediate perioperative period were extensively described in the prospective randomized clinical trials. These reported complications (e.g., device-related complications that required reoperation, revision, or removal of the device) were similar or diminished in comparison with those seen with traditional ACDF. Other potential complications specifically associated with the artificial discs or materials used include such problems as increased stress on the facet joints, adjacent level degeneration, segmental kyphosis, mechanical implant failure, heterotopic ossification (HO), or generation of wear debris.

One potential complication from cervical arthroplasty is HO, which can cause loss of motion at the level of the arthroplasty. The rate of this complication has been reported in the literature to be as high as 12% (with 2 years of follow-up). Several studies have demonstrated that a postoperative course of nonsteroidal anti-inflammatory drugs (NSAIDs) reduces the incidence of HO. In fact, the postoperative regimen for the Pro-Disc C device recommends a 2-week postoperative course of NSAIDs in effort to prevent HO.

The role of the facet joints has drawn increased attention recently from researchers but often is underappreciated by surgeons. Any significant arthropathy of the facet joints should not be ignored when determining whether a patient is a good candidate for arthroplasty. Increased motion at the spinal segment in such a patient can cause additional stress on the severely degenerated facet joints and lead to poor clinical outcomes.

Overly aggressive restoration of disc height by inserting a device with a profile higher than ideal can easily cause overdistraction in the degenerated spinal segment, resulting in severe neck pain and muscle spasms as well as long-term postoperative neuropraxia from a nerve stretch injury. Criteria for some of the FDA-controlled clinical trials excluded patients with an intervertebral disc space collapse of more

than 50% of normal height, not only to prevent overdistraction, but also to exclude patients with symptoms of severe circumferential degeneration of the cervical spine (facet pain as well as discogenic pain). In vitro studies demonstrated that the inappropriate increases in disc space during disc replacement surgery could cause subluxation of the facet joints and failure of the artificial disc. The potential for overdistraction cannot be ignored even if these exclusion criteria are no longer mandatory for the FDA-approved devices.

### Conclusions

Short-term clinical results associated with cervical artificial disc replacement are promising. Long-term benefits of reduced stress on the adjacent levels or effectiveness of cervical arthroplasty compared with ACDF remain unknown. The advantage of preserved segmental mobility should be weighed against the potential negative effects on the facet joints and the possibility of late implant failures or loosening. In the meantime, strict patient selection based on clear indications and lack of exclusion criteria should heavily outweigh the marketing enthusiasm. After completing this activity, readers should have an understanding of the current indications for cervical arthroplasty, outcomes data, and potential complications. Cervical arthroplasty is a highly debated topic in spine surgery, and practical application of the reviewed content should allow readers to have a better understanding of this ever-developing procedure.

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| <p>1. Cervical arthroplasty is widely performed in more than 30 countries outside the United States.<br/><b>True or False?</b></p> <p>2. Unconstrained-design cervical artificial discs are better options than others for patients with moderate facet arthropathy.<br/><b>True or False?</b></p> <p>3. The multicenter study that evaluated the Prestige ST Cervical System has reported 2-year follow-up clinical outcome results indicating an improvement in neurologic status that demonstrates superiority for the Prestige ST artificial disc over fusion surgery.<br/><b>True or False?</b></p> <p>4. Arthroplasty in cadaveric specimens has been shown to cause decreased range of motion at the adjacent levels and to maintain the adjacent level intradiscal pressure compared with the intact spine.<br/><b>True or False?</b></p> <p>5. A postoperative course of nonsteroidal anti-inflammatory drugs may reduce the incidence of heterotopic ossification after arthroplasty.<br/><b>True or False?</b></p> | <p>6. Overdistraction of the disc space could cause subluxation of the facet joints and failure of the implant.<br/><b>True or False?</b></p> <p>7. Patients with myelopathy and symptoms of radiculopathy are not good candidates for arthroplasty.<br/><b>True or False?</b></p> <p>8. Central canal or neuroforaminal decompression can be easily performed during cervical arthroplasty.<br/><b>True or False?</b></p> <p>9. Indications for currently approved artificial discs include intractable neck pain, severe arthropathy of the facet joints, and radiculopathy or myelopathy at a single level between C3 and C7.<br/><b>True or False?</b></p> <p>10. Prospective FDA-controlled trials demonstrated that device-related complications that required reoperation, revision, or removal of the device were similar or diminished compared with those seen with traditional anterior cervical discectomy and fusion.<br/><b>True or False?</b></p> |
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