183 Cervical Total Disc Arthroplasty

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SUMMARY OF KEY POINTS

- Cervical disc arthroplasty is a safe and effective alternative to anterior cervical discectomy and fusion in selected patients with symptomatic cervical radiculopathy or myelopathy related to cervical degenerative disc disease.
- The advantages of cervical arthroplasty include maintenance of segmental mobility, a possible reduction of adjacent-segment degeneration, and avoidance of the limitations of fusion.
- The indications for cervical arthroplasty are not synonymous with those for cervical fusion, and this technique should not be assumed to be appropriate for all patients who may benefit from an anterior cervical discectomy and fusion.
- At present, seven artificial disc devices have been approved by the Food and Drug Administration for clinical use the United States.
- Although data suggest a favorable effect on decreasing adjacent segment disease following both one- and two-level implantation, this particular clinical benefit needs to be verified in subsequent studies.

Cervical disc replacement (CDR) preserves motion and has evolved as a potential alternative to spinal fusion for the treatment of cervical radiculopathy and myelopathy.[1] Although anterior cervical discectomy with fusion (ACDF) has been traditionally considered the definitive surgical treatment for symptomatic, single-level, cervical degenerative disc disease (DDD) in patients who have failed a trial of conservative management and provides excellent clinical results, concern for the development of symptomatic adjacent-level degeneration and loss of motion after fusion prompted interest in the development of implants designed to preserve motion, maintain anatomic disc space height and normal segmental lordosis.[2-6] With its potential to achieve these goals, CDR has emerged as an alternative to ACDF and posterior foraminotomy/discectomy for single- and two-level degenerative cervical disc disease.

Cervical arthroplasty has undergone a dramatic evolution since the development of the original Bristol/Cummins device.[7] Metal-on-metal implants have evolved in parallel with the development of novel design concepts incorporating metal alloys, polyethylene, and ceramics, and seven arthroplasty devices are currently approved for clinical application in the United States.[8-14] Although data do indicate the favorable effect of this procedure on adjacent segment disease following both one- and two-level implantation, this clinical benefit needs to be proved further in subsequent studies.[11,15] This chapter reviews the indications, technique and complication avoidance, and clinical outcome following CDR in light of the literature. Only the indications and devices currently approved by the U.S. Food and Drug Administration (FDA) are discussed in this chapter.

RATIONALE OF CERVICAL ARTHROPLASTY

The excellent clinical success rate and long-term experience with ACDF for the treatment of cervical degenerative disc disease raises the question as to the need for the development of alternate procedures.[16] Although fusion is beneficial to the symptomatic level, it may be detrimental to the remaining motion segments as it induces increased motion and abnormal intradiscal pressure recordings in adjacent disc segments, which translate into increased stress on the adjacent nonoperated discs.[3,17,18] Several studies have reported the radiographic development of adjacent segment degeneration (ASD) after ACDF procedures. Baba and associates[19] assessed more than 100 patients who underwent anterior cervical fusion for cervical myelopathy and observed new spinal canal stenosis above the previously fused segments in 25% of patients at an average follow-up of 8.5 years. Similarly, Gore and Sepic reported a 25% risk of developing new radiographic adjacent segment spondylosis 5 years following ACDF.[20] In a comparative radiographic study, Herkowitz and colleagues[21] evaluated 44 patients with 4.5 years of follow-up randomized to either ACDF or posterior foraminotomy without fusion for the treatment of cervical radiculopathy and found that the chances of developing ASD were similar between the two groups (41% for ACDF versus 50% for foraminotomy group) with no correlation between the development of ASD and the onset of new clinical symptoms referable to those radiographic changes. In a series of more than 800 patients who underwent posterior foraminotomy without fusion by Henderson and coworkers,[22] 9% of patients developed adjacent segment disease requiring additional surgery over an average follow-up of 2.8 years, demonstrating that the development of ASD may not be unique to anterior cervical fusion and could just reflect the natural history of the disease or failure to treat all of the symptomatic segments during the primary procedure.

Irrespective of the lack of clear correlation between radiographic changes following the anterior cervical fusion and clinical symptoms, a subgroup of patients with ACDF does develop symptomatic adjacent segment disease requiring treatment.[16,20] There has been an attempt to distinguish clinical versus radiographic adjacent segment problems after cervical fusion.[3] The term *adjacent segment degeneration* has been used to describe radiographic changes adjacent to a previous spinal fusion procedure that do not necessarily correlate with any clinical findings as compared to *adjacent segment disease,* which refers to the development of new clinical symptoms that correspond to segmental radiographic changes next to the level of a previous spinal fusion. Bohlman and colleagues, Gore and colleagues, and Williams and colleagues reported 9%, 14%, and 17% risks, respectively, of developing symptomatic adjacent segment disease following anterior fusion that required surgical treatment.[16,20,23] Hilibrand and coworkers[3] retrospectively reported the long-term follow-up of 409 anterior cervical decompression and stabilization procedures performed for radiculopathy or myelopathy. They found symptomatic ASD occurred at a relatively constant incidence of 2.9% per year during the 10 years after surgery. The results of this study have been interpreted by some as providing robust evidence for the development of ASD following ACDF.

Patients with preexisting degenerative changes and who were more than 60 years old had a more rapid onset of symptomatic adjacent-segment disease. It is intriguing that patients who had multilevel arthrodeses were significantly less likely to have symptomatic adjacent-segment disease than were those who had had a single-level fusion ($p < 0.001$).[19] Though still conjectural, with progression of natural history being an important factor in the development of ASD, the study by Goffin and colleagues[24] showed that the rate of radiographic ASD following arthrodesis for traumatic cervical injuries was 60% over 5 years, indicating that the development of adjacent segment disease is at least partly related to the arthrodesis itself and may not be blamed totally on the natural history of the disease.

There is biomechanical evidence demonstrating that CDR may allow for a more normal restoration of load transfer and kinematics at adjacent levels when compared with fusion.[25] Wigfield and associates[26] recorded and compared intradiscal pressures in adjacent levels of normal/untreated cadaveric cervical spines, spines treated with a simulated fusion, and spines treated with a CDR and found that the motion and pressures of adjacent segments in specimens treated with a CDR did not significantly differ from those in the normal/untreated spines. Similarly, Puttlitz and colleagues[27] demonstrated that spines treated with CDR approximated the intact motion in all three rotational planes at the affected level compared with normal cadaveric spines. In a clinical prospective study, Robertson and coworkers[28] compared the incidence of radiologic documented changes and symptomatic adjacent-level cervical disc disease after single-level discectomy and cervical fusion or arthroplasty using the Bryan disc and showed the appearance of new radiographic changes in 34.6% of the fusion-treated patients as compared to 17.5% of the arthroplasty-treated patients at 24 months ($p = 0.009$). New symptomatic adjacent degenerative disc disease occurred in 7% of the fusion group and in none of the arthroplasty group ($p = 0.018$). This study strengthens the argument that maintaining motion with arthroplasty after single-level disc disease may delay or prevent to a significant degree the associated radiologic disc degeneration. Although the initial and midterm data failed to demonstrate any benefit of CDR on ASD as purported, long-term results from the Prestige ST trial as well as data from a two-level arthroplasty study using the Mobi-C implant have shown encouraging results with a decreased incidence of adjacent segment disease following CDR as compared to that with ACDF.[11,15]

Another rationale for the use of CDR, as opposed to ACDF relates to the complications with pseudarthrosis and bone graft procurement for arthrodesis. It is generally believed that less soft tissue dissection, decreased esophageal retraction pressure, and the minimal profile of the current generation cervical disc replacements may result in a lower incidence of postoperative dysphagia following cervical arthroplasty as compared to instrumented ACDF.[29]

NOMENCLATURE, BIOMATERIALS, AND BIOMECHANICS

Fundamental to the principle of arthroplasty are the corollary concepts of repetitive stress and the generation of wear-related debris. Various factors are involved in the design of a cervical artificial disc such as (1) implant kinematics, (2) implant materials, (3) device subsidence, and (4) fixation to bone. The choice of material used in creating the device must be governed by three principles: articular surface wear, generation of wear debris, and host inflammatory response.[30] Many designs incorporate two different materials articulating with each other. In a metal-on-polymer pairing, the polymer wears preferentially, whereas in a metal-on-ceramic pair, the metal wears to a greater extent.[30,31] Metal wear debris generates a lesser inflammatory response compared to polymer debris.

An ideal artificial disc should resist corrosion and wear, reproduce the movements of a normal cervical disc without overloading adjacent biomechanical structures, be easy to insert, and be x-ray and magnetic resonance imaging (MRI) compatible.[30,31] Implant design characteristics are important for the function and longevity of CDR.[31-33] The articulating surfaces must be able to tolerate anticipated load without fatigue or failure, while minimizing friction, and they should have superior wear characteristics with minimal debris generation and exceed patient life expectancy. The presence of wear debris and the associated inflammatory response can be detrimental to the stability of the device and varies depending on the design of the disc (metal on metal versus metal on polymer). In addition, the implants must remain permanently affixed to the adjacent vertebral bodies.

With the development of numerous artificial discs since the early 2000s, the Cervical Spine Study Group developed a nomenclature system for cervical arthroplasty.[34] Artificial discs are categorized by material, articulation, fixation, design, and kinematics. They can be classified as nonarticulating, uni-articulating, or bi-articulating. Various designs include metal on metal (Prestige ST and LP; Medtronic Sofamor Danek, Memphis, TN), metal on polymer (Bryan, Medtronic Sofamor Danek; ProDisc-C, Synthes Spine, West Chester, PA; Mobi-C, LDR Medical, Troyes, France), ceramic on polymer, or ceramic on ceramic. Discs are either modular with replaceable parts or nonmodular. Some have points for vertebral body fixation and some have surfaces that promote bone ingrowth at the disc–end plate interface. With regard to motion, they may be constrained, semiconstrained, or unconstrained. Constrained devices restrict motion to less than that seen physiologically, semiconstrained devices allow physiologic motion, and unconstrained devices rely on soft tissue and the inherent compression across the disc space to limit motion. Each of these devices is available in a range of heights and depths to accommodate individual variances in anatomy. The currently approved cervical artificial discs are listed in Box 183-1.

INDICATIONS AND CONTRAINDICATIONS

The indications for cervical arthroplasty are not nearly as robust as those for cervical fusion, and this technique should not be assumed to be appropriate for all patients who may benefit from an ACDF. Ideally, patients receiving an artificial disc should have normal cervical spinal alignment and mobility along with one of the following pathologic entities: radiculopathy caused by disc herniation or foraminal osteophytes or myelopathy caused by disc herniation producing spinal cord compression from C3 to C7 with or without axial neck pain.

It has been shown that CDR is as effective as ACDF for the management of cervical myelopathy due to single-level disc abnormality when used for a soft central disc herniation.[35] Currently in the United States, CDR is FDA approved for intractable neck pain with radiculopathy or myelopathy at a single or two levels between C3 and C7 in a patient who has failed a

BOX 183-1 Currently Approved Cervical Artificial Discs

- Bryan
- Mobi-C
- PCM
- Prestige LP
- Prestige ST
- ProDisc C
- Secure C

minimum of 6 weeks of conservative treatment.[11,13,36] At present there are six devices that are FDA approved for single-level implantation and one device approved for both single- and two-level implantation in the United States.[8,11-15,37]

The importance of careful patient selection cannot be overemphasized for the success of CDR.[9-11,13,36,38] Factors to consider when selecting suitable candidates for arthroplasty include the disc height at the level of degeneration, inherent range of motion, and cervical alignment. Cervical arthroplasty is contraindicated in the setting of significant segmental or global deformity. Similarly, patients without preexisting motion or spinal instability should not be treated by a CDR. Arthroplasty requires the dorsal elements to be intact and functional, so patients with suspected ligamentous or facet disease are not suitable candidates. Those with cervical kyphosis, cervical spondylolisthesis, previous laminectomy, osteoporosis, metabolic bone disease, or cervical trauma are not ideal either.[9-11,13,36,38] A history of infection or osteomyelitis would preclude the use of a prosthetic disc device. Other relative contraindications include rheumatoid arthritis, renal failure, osteoporosis, cancer, preoperative corticosteroid medication, ankylosing spondylitis, ossification of the posterior longitudinal ligament, and diffuse idiopathic skeletal hyperostosis.

CERVICAL ARTHROPLASTY: THE CLINICAL EVIDENCE

A number of randomized controlled trials have provided high-quality evidence demonstrating that the safety and efficacy of CDR are equivalent to that for ACDF. None of the studies showed that CDA resulted in inferior clinical outcomes relative to ACDF, and depending on the study there were superior outcomes in some parameters. The reader is referred to the specific papers to review the data in detail.[8,12-15,37]

The 2- and 4-year results from the first prospective, randomized U.S. FDA investigational device exemption trial for two-level total disc replacement with the Mobi-C cervical artificial disc versus anterior discectomy and fusion were published demonstrating the safety and efficacy of cervical artificial discs even for two level implantation.[10,11]

EFFECT OF CERVICAL DISC REPLACEMENT ON ADJACENT SEGMENT DISEASE

Although prevention of ASD has been a compelling rationale for CDR, there is no conclusive supporting clinical evidence for this hypothesis at this point. Most of the studies to date have only shown that CDR patients fared as well as or slightly better than ACDF patients in terms of achieving clinical success and certainly in maintenance of motion at the index level. Surprisingly, assessment of adjacent segment disease was not a primary objective in any of the FDA studies. The study by Mummaneni and associates[13] looking at number of second surgeries at adjacent levels reported a significantly higher rate of adjacent level surgeries in ACDF group as compared to arthroplasty group. However, it is important to recognize that surgery at the adjacent level is not the same as adjacent segment disease. The FDA IDE study reported by Coric and associates[9] described significantly higher rates of adjacent level degeneration (ALD) in the ACDF group as compared to the arthroplasty group. The number of adjacent level surgeries was higher in the arthroplasty group as opposed to ACDF group, but the difference was not statistically significant. The Bryan and Prodisc C IDE authors did not comment on the adjacent segment disease in either of the reports. The results of various systematic reviews and meta-analyses have been conflicting depending on the studies included in the analysis and the methods used.[5,6,36,39-43] As mentioned earlier, as the long-term results of US FDA trials on various cervical arthroplasty become available, the beneficial effect of CDR on ASD may become apparent, as was seen in the 7-year follow-up results from the Prestige study.[15]

POTENTIAL COMPLICATIONS AND COMPLICATION AVOIDANCE

Complications following cervical arthroplasty can be attributed to patient selection, surgical technique, or the implant itself. Errors in patient selection can be avoided by selecting those patients who meet the previously discussed criteria.[36] Patients with facet arthropathy, preoperative instability, osteoporosis, metabolic bone disease, previous dorsal cervical surgery, or sagittal deformity are not ideal candidates for arthroplasty and CDR should preferably be avoided in this group of patients.[44]

Complications related to surgical technique include those related to surgical approach and implantation technique. Though the use of CDR can obviate complications like pseudarthrosis and graft donor site morbidity, it is not immune from common approach-related complications, which are the same as those for ACDF and include vascular damage, dysphagia, hoarseness of voice, hematoma, and chances of neurologic injury.[45,46]

In general, when implanting artificial discs, strict attention to patient positioning is crucial to achieving the desired alignment.[47,48] The neck should be in a neutral or lordotic position. Because cervical arthroplasty is not meant for sagittal deformity correction, the proper positioning of the patient is critical. Complete bilateral compression with uncinate resection should be performed, as persistent nerve root compression may not be well tolerated in the setting of preservation of motion. Selection of the correct size of the implant is also important. Small implants may migrate with repeated motion and large implants may limit range of motion because distraction of the facets and dorsal ligaments will hinder the motion preservation mechanism. Specific complications related to CDR are summarized in the following paragraphs.

Heterotopic ossification (HO) is defined as formation of the bone outside the skeletal system. Heterotopic ossification after cervical TDR was first reported by Parkinson and Sekhon in 2005.[49] There have since been multiple reports of HO following arthroplasty with variable incidence among different studies.[36] Leung and colleagues[50] reported an almost 20% incidence of HO at 1 year with 60% of the patients with HO having less than 2 degrees of motion at the affected level. Use of abundant intraoperative irrigation and limited muscle retraction has been advocated to potentially decrease or prevent the development of postoperative HO. Considering the potential of HO resulting in loss of motion at the operated level,[51] use of adequate irrigation intraoperatively and nonsteroidal anti-inflammatory drugs (NSAIDs) during the perioperative period have been recommended in the literature.[12,48]

Postcervical kyphosis is another complication following CDR. The development of kyphosis may result in an adverse outcome, and the subsequent loss of motion is not favorable.[52,53] The possible causes of postoperative kyphosis after CDR may be excessive drilling of the dorsal end plate, asymmetric end plate preparation, suboptimal angle of the implant insertion, structural absence of lordosis in the implant design, surgical removal of the posterior longitudinal ligament (PLL), and preexisting kyphosis.[52,53]

Implant migration or subsidence, though rare, remains a potential complication following CDR.[54-58] It can manifest as

an alteration in postoperative cervical spine alignment or can even result in neurologic symptoms.[55] This may lead to disc space collapse, causing nerve root compression and restricting the desired motion of the arthroplasty. Again, inadequate preparation of the implant space can be a contributing factor. The following actions may help to avoid or reduce the chances of implant subsidence: preserving the underlying structural integrity of the vertebral end plate; using the widest possible device footprint to engage the stronger peripheral bone; avoiding implants with a large height in the setting of a collapsed disc; and avoiding cervical arthroplasty procedures in patients with osteopenia, metabolic bone disease, or who are taking medications that may cause abnormal or decreased bone quality. Subsidence may also occur in osteoporotic patients whose end plates are not violated.

Vertebral fracture is also a potential complication after cervical disc arthroplasty, and though this can occur with any of the available devices, several cases have been reported in patients undergoing implantation with a keeled prosthesis.[27,59,60] Chiseling required for cutting the keel can result in fracture of the vertebral body, especially in patients with poor bone quality. Insertion of multiple level CDRs creates two centralized keel cuts within the same vertebral body, which can lead to fracture.[61] Osteolysis secondary to the inflammation response to the disc itself can also weaken the bone and lead to vertebral fracture.

CONCLUSION

The exciting CDR technology sustained the initial challenge of demonstrating clinical success that is equivalent to that for anterior cervical fusion, while at the same time preserving normal motion at an affected level. Long-term results from studies on CDR will further clarify its role in the prevention of ASD. As studies have begun to demonstrate, because of the feasibility and benefits of more than one level CDR and its value when used as a hybrid construct, the future of CDR remains promising and this technology may see wider applications in the future.

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