Cervical Arthroplasty

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Anterior cervical decompression and fusion (ACDF) is a common surgical technique for treating patients with symptomatic degenerative cervical disc disease, which is refractory to nonoperative therapy.[4,5,15] This exposure allows for safe neural decompression, and the arthrodesis effectively halts the degenerative process at the treated segment. Although the results of ACDF are generally in the good to excellent range, single-level procedures do alter spinal kinematics and multilevel procedures compromise global spinal motion. There is currently a tremendous interest in the preservation of the cervical spinal functional motion segment after anterior decompression. This may be accomplished with a total disc arthroplasty. The purpose of this communication is to present some of the data supporting the concept of cervical spinal arthroplasty and review the devices currently in United States Food and Drug Administration (FDA)-approved trials.

RATIONALE FOR CERVICAL ARTHOPLASTY

Single-level fusion does not seem to significantly alter the global mobility of the cervical spine, but motion is adversely affected when multilevel treatments are necessary. Although arthrodesis is beneficial to the diseased level, it may be detrimental to the remaining motion segments. It has been demonstrated that cervical arthrodesis increases motion at non-operated adjacent levels, and biomechanical studies have documented increased intradiscal pressure recordings in adjacent disc segments after fusion.[7,10,14,17] Increased motion and elevated intradiscal pressures cumulatively translate into increased stress on the adjacent non-operated discs, which can accelerate the rate of disc degeneration (1–3, 8, 12–14).

Hilibrand et al.[13] studied 374 patients and found that symptomatic adjacent segment disease occurred at a relatively constant rate of 2.9% during the decade after surgical fusion. Goffin et al.[12] showed that the rate of radiographic adjacent segment disease after arthrodesis for traumatic cervical injuries was not statistically different than that seen in patients undergoing fusion for symptomatic spondylosis. This key work suggests that the development of adjacent segment disease is likely to be accelerated by the arthrodesis itself. Cervical arthroplasty has the potential to provide the benefit of anterior neural decompression without compromising segmental mobility.

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INDICATIONS

Candidates for cervical arthroplasty include patients with normal cervical spinal alignment and mobility along with one of the following pathological entities: 1) radiculopathy caused by disc herniation (soft or hard), 2) radiculopathy caused by foraminal osteophytes, 3) myelopathy due to a soft disc herniation, or 4) any combination of the above entities. The clinical outcomes of myelopathic patients with congenital stenosis and hard cervical discs or osteophytes after anterior decompression and total disc replacement are uncertain at this time. Surgical candidates should have experienced a failure in medical management, including immobilization or traction, physical therapy, and anti-inflammatory medications.

Patients with marked degenerative changes and no segmental motion cannot be expected to regain mobility by implanting a total prosthetic disc replacement. Those with radiographic instability should be treated with an arthrodesis. Arthroplasty is contraindicated in the setting of significant segmental or global deformity. The outcomes of patients with isolated axial cervical pain who are treated with an arthroplasty have not been fully delineated. A recent history of infection or osteomyelitis would preclude the use of a prosthetic disc device. Other relative contraindications include rheumatoid arthritis, renal failure, significant osteoporosis, cancer, and chronic corticosteroid use.[9]

There are currently are seven artificial discs in United States FDA trials: Prestige ST, Prestige LP, Bryan, Pro-Disc-C, PCM, Kineflex, and CerviCore. A number of other devices are in position to begin trials in the near future. All of these devices are available in a variety of sizes to match patient anatomy, and each has specialized instruments to assist with implantation. The basic implant design and some trial details will be presented for each device.

PRESTIGE ST CERVICAL DISC REPLACEMENT

The Prestige device has it origins with Mr. Brian Cummins, who attempted to address the shortcomings of cervical arthrodesis 17 years ago when he began to develop

an artificial cervical disc in collaboration with the Department of Medical Engineering at Frenchay Hospital, Bristol, United Kingdom, in 1989.[6] His pioneering efforts in the development of a metal-on-metal artificial cervical disc laid the foundation upon which the current generation Prestige was built.

The Prestige ST (Medtronic Sofamor Danek, Memphis, TN) became available in 2002. It is constructed of stainless steel and consists of two articulating components attached to the cervical vertebrae with screws (*Fig. 21.1*). The ball-and-trough design of the Prestige ST provides relatively unconstrained motion comparable to that of a normal cervical spinal segment. The angulation between the base of the components and the anterior portion matches the normal anatomy of the cervical vertebrae. The surfaces of the device contacting the endplates are grit-blasted to promote bone osteointegration.

The Prestige ST FDA IDE study is a prospective, randomized trial comparing the Prestige ST with an arthrodesis with allograft and anterior plate. Enrollment criteria include primary symptomatic single-level disease that has not responded to conservative management. The randomization is 1:1, and a number of clinical, radiographic, and patient-derived outcome measures will be followed for a minimum of 2 years.

PRESTIGE LP

The Prestige LP is manufactured from a unique titanium ceramic composite material that is highly durable and image-friendly on computed tomographic and magnetic resonance imaging scans (*Fig. 21.2*). The ball-and-trough articulation is identical to that of the Prestige ST. Initial fixation is achieved via four rails, two on each component, which engage the vertebral bodies. A porous titanium plasma-spray coating on the endplate surface facilitates bone ingrowth and long-term fixation.

FIGURE 21.1 Prestige ST

FIGURE 21.2 Prestige LP

The FDA IDE study design has the same inclusion and exclusion criteria as the Prestige ST study. Patients are not randomized, and all enrolled receive an experimental device. The clinical, radiographic, and patient outcomes will be statistically compared with the data collected in the Prestige ST study.

BRYAN CERVICAL DISC

In the early 1990s, neurosurgeon Vincent Bryan conceived and developed the Bryan Cervical Disc. After extensive research and testing, the first Bryan Cervical Disc was implanted by Dr. Jan Goffin in Leuven, Belgium in January 2000.

The Bryan Cervical Disc prosthesis (Medtronic Sofamor Danek, Memphis, TN) is a cervical disc replacement designed to allow for motion similar to the normal cervical spine functional unit (*Fig. 21.3*).[11] This device consists of two titanium alloy shells with a polyurethane nucleus. The bone implant interface of each shell has an applied porous coating to facilitate ingrowth of bone and promote long-term stability. The nucleus is surrounded with a polyurethane sheath to establish a closed articulation environment. Sterile saline is injected into this sheath and functions as an initial lubricant. Titanium alloy seal plugs allow for retention of the saline lubricant.[16] Small anterior flanges on the shells serve to grasp the device for insertion.

A prospective, randomized FDA IDE trial has completed enrollment. The study population had primary single-level cervical disc disease. The randomization was 1:1, with the control arm receiving an allograft and plate. Numerous outcome parameters are being tracked and assessed.

FIGURE 21.3 Bryan Cervical Disc

PRODISC-C CERVICAL DISC

The ProDisc-C was developed using many of the same design principles as the ProDisc lumbar disc prosthesis. The implant materials, ball-and-socket design, and fixation features are similar to that of the lumbar device. The first implantations of the ProDisc-C were performed by the two clinician developers, Dr. Thierry Marnay (Montpellier, France) and Dr. Rudolf Bertagnoli (Straubing, Germany), in December 2002.

The ProDisc-C cervical disc (Synthes Spine, Paoli, PA) is a metal-on-polyethylene articulating device (*Fig. 21.4*). This modular implant consists of two cobalt-chromium-molybdenum endplates and an ultra-high molecular weight polyethylene (UHMWPE) inlay. The endplates of the prosthesis are initially secured to the vertebral bodies with central keels, and they have a plasma-sprayed titanium coating for long-term fixation stability. The UHMWPE inlay is pre-assembled into the inferior endplate.

A prospective, randomized clinical trial comparing the ProDisc-C with ACDF is currently underway in the United States. Patient randomization is performed using a 1:1 ratio of ProDisc-C recipients to ACDF control recipients in the treatment of symptomatic cervical disc disease at only one level between C3 and C7. A number of patient-derived outcome measures will be assessed. Additionally, the patients' pre- and postoperative clinical status, as determined by examination, will be evaluated, as will the radiographic outcome.

PCM

The Porous Coated Motion (PCM) prosthesis (Cervitech, Inc., Rockaway, NJ) uses a metal-on-polyethylene articular surface (*Fig. 21.5*). The cobalt-chromium-molybdenum alloy components are covered with a TiCaP porous coating for enhancement of bone ingrowth and long-term fixation. Immediate fixation is achieved by inserting the prosthesis in a "press-fit" fashion.

The PCM is currently the subject of an FDA-approved IDE study of its use in patients with single-level disc degeneration or herniation and radiculopathy or myelopathy. Patients will be followed for 2 years, and both clinical and radiographic outcome criteria will be reviewed and compared with a randomized control group of patients treated with fusion using allograft bone and a plate. Notably, the use of the implant adjacent to previous single-level fusions is possible in the PCM IDE study, an application many anticipate to be most promising in the future use of cervical arthroplasty implants.

FIGURE 21.4 ProDisc-C Cervical Disc

FIGURE 21.5 PCM

KINEFLEX C

The Kineflex C prosthetic disc (Spinal Motion, Inc., Mountain View, CA) was developed in South Africa and was first implanted in Johannesburg in 2002. The device uses a three-piece modular design consisting of two cobalt-chromium-molybdenum endplates and a mobile core. The opposing sides of the endplates have highly polished concave articulating surfaces. The core is indented at its equator to permit seating within a retention ring, which is an integral part of the inferior endplate (*Fig. 21.6*). This prevents subluxation of the core. Initial fixation is achieved via a central keel and a pyramidal surface. The endplate surface is plasma-sprayed with titanium to promote osseointegration for long-term stability.

A multicenter, prospective, randomized study of the Kineflex C is currently underway. The study compares reconstruction with the Kineflex C to an arthrodesis after anterior discectomy in patients with primary single-level symptomatic cervical disc disease that is refractory to conservative management. Clinical status, patient-derived outcomes, and radiographic assessments will be performed for 2 years after surgery.

CERVICORE

The CerviCore disc (Stryker Spine, Allendale, NJ) is a total cervical disc replacement constructed of cobalt-chromium alloy (*Fig. 21.7*). The articulation occurs across a pair of saddle-shaped bearing surfaces. Two fins, containing three fixation spikes apiece, provide immediate stability for each of the components. The bony contact surfaces have a titanium plasma-spray coating to encourage bone ingrowth.

FIGURE 21.6 Kinexflex C

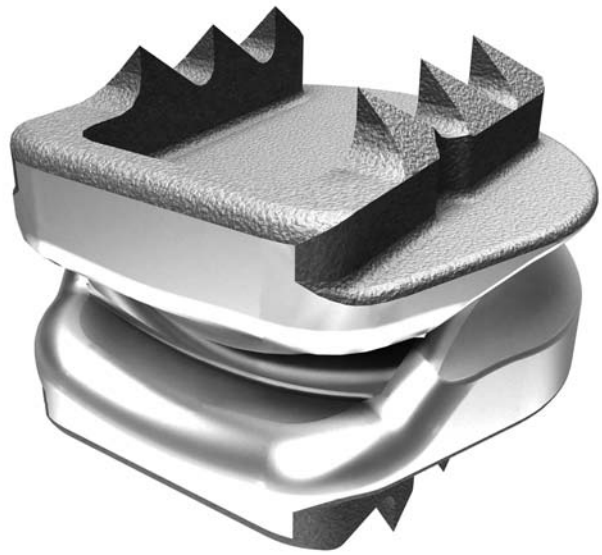

FIGURE 21.7 CerviCore

The CerviCore disc is currently being investigated in an FDA study. This multicenter, prospective trial compares the CerviCore device with anterior cervical fusion in a 1:1 randomization design. Subjects must have primary single-level symptomatic degenerative disc disease that is refractory to nonoperative management. The clinical and radiographic outcomes and patient-derived outcomes of the two groups will be assessed and compared.

CONCLUSION

There is great optimism that cervical arthroplasty will improve the already good to excellent results achieved with anterior cervical decompression and fusion for symptomatic cervical disc disease. A number of FDA-approved trials are underway assessing seven different total cervical disc replacements. These studies will provide useful information concerning the surgical treatment of cervical spondylosis.

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