Spinal Artificial Disc Replacement: Cervical Arthroplasty

Part I: History, Design, and Types of Artificial Discs

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Learning Objectives: After reading this article, the participant should be able to:
1. Describe the various cervical artificial disc replacement devices currently undergoing experimental clinical trials in the United States.
2. Explain the advantages, shortcomings, and controversies related to various cervical artificial disc designs.
3. Describe the results of the primary completed clinical trials of cervical artificial discs.

This article is the first of two parts.

Cervical arthroplasty is a rapidly developing surgical treatment option for degenerative disc disease of the cervical spine. This article reviews design features, indications for cervical arthroplasty, surgical technique, available preliminary clinical outcomes, and complications of the cervical devices currently being evaluated in FDA-controlled Investigational Device Exemption (IDE) prospective randomized clinical trials. Neural decompression and arthrodesis have been the mainstays of treatment for many cervical spinal conditions for more than 50 years. Artificial disc replacement surgery allows for effective decompression without sacrificing segmental motion, theoretically preserving the patient’s functional capacity. The importance of preservation of the spinal motion segment and restoration of normal physiologic biomechanics of the cervical spine is becoming increasingly recognized. Arthrodesis alters the biomechanics of the spine, possibly leading to further degeneration at adjacent levels. Early clinical studies have shown promise, but whether arthroplasty is capable of reducing adjacent level degeneration has not yet been proved in long-term prospective clinical trials.

History of Cervical Arthroplasty

The first cervical artificial disc prototype was created and implanted by Fernstrom in 1966. Eight patients had 13 corrosion-resistant, stainless steel ball-shaped prostheses with diameters of 6 to 10 mm implanted. More extensive experience with the same type of implants was reported by Reitz et al., who performed 75 arthroplasties on 32 patients with intractable headache and cervicobrachialgia. Both studies lacked long-term follow-up, and these artificial discs later were abandoned due to problems such as subsidence of the device and segmental hypermobility.

Proximity to the spinal cord, size constraints, and the functional complexity of the intervertebral disc have slowed the development of cervical arthroplasty and its implementation into clinical practice. Interest in cervical arthroplasty underwent a resurgence in the 1990s. The first generation of Cummins-Bristol ball-and-socket, metal-on-metal type implants

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was introduced in 1991, and during a 5-year period, devices were implanted at Frenchay Hospital in Bristol, United Kingdom. Among the problems identified with use of this device were the excessive disc space distraction required during insertion, with subsequent facet joint separation; the fact that only a single size was available; limited motion with the device; and screw complications. Nevertheless, it showed enough promise to warrant design improvements and eventually evolved into the Bristol-Cummins/Frenchay/Prestige discs.

Along with the advancement and development of the Bristol-Cummins artificial disc, an American inventor, Bryan, developed a new type of metal-on-plastic artificial disc. The first Bryan cervical disc was implanted in January 2000; since then, more than 6000 patients have been treated with this device.

Several cervical arthroplasty devices currently are being evaluated in FDA-controlled IDE prospective randomized clinical trials, and a number of new cervical devices are just now entering the IDE stage of investigation, providing the possibility that neurosurgeons will have multiple alternatives to cervical fusion in the near future.

**Artificial Disc Design**

The key features of cervical artificial disc design are the center of rotation, short- and long-term stability, and material interfaces. Artificial disc designs are classified as metal-on-metal, metal-on-polymer composite, ceramic-on-polymer composite, exclusively polymer composite, or ceramic-on-ceramic. Both modular and nonmodular devices come in three types: nonarticulating, uniarticulating, and biarticulating artificial discs. In terms of motion, discs may be categorized as constrained, semiconstrained, unconstrained, or biomimetic (i.e., mimicking physiologic movement). This variety of designs and materials represents an evolution of device patents and incorporation of information from experimental and clinical studies as they become available.

Unconstrained devices permit translation, which in the theory mimics normal physiologic motion, but they also may require more precise placement.

Constrained devices, while minimizing facet loads and conferring improved stability, typically have a fixed axis of rotation that requires more precise placement. Confirmation of the theoretical advantages of arthroplasty, such as prevention of adjacent level degeneration and mobility preservation, will require long-term follow-up studies. In addition, the effect of disc height restoration on the facet joints also is not known. Liu et al. performed an in vitro study to evaluate changes in the cervical spine facet articulation after arthroplasty. When the effect of an incremental increase in disc space height was measured as a change in the facet joint space increase and articulation overlap, a significant decrease in the facet joint articulation overlap and joint space increase was found. This study found that any increase in disc height from the previous position could alter biomechanics of the facet joint, which could result in subluxation and failure of the artificial disc.

Therefore, the importance of disc height restoration or the lack thereof must be judged cautiously until time-proven clinical results become available.

Ceramic materials recently have been introduced for use in artificial discs. These can provide excellent wear resistance, but they rely heavily on critical manufacturing processes that can result in fractures if defective. Metal alloys and polymers are the materials most commonly used in spine arthroplasty. Polymers have a higher wear rate but lower stiffness, and they may offer some degree of shock absorption. Metals wear, corrode, and fracture; therefore, metal alloys are used to balance the unwanted qualities of one metal with desirable features of another: for example, titanium alloys are valued for their imaging characteristics and cobalt-chromium has excellent wear properties. Sekhon et al. compared MRI characteristics for the Bryan (Medtronic Sofamor Danek), Prodisc-C (Synthes Spine), Prestige LP (Medtronic Sofamor Danek), and PCM (Cervitech) devices.

Sagittal and axial T2-weighted MRI views at the implanted and adjacent levels were assessed for quality. The spinal canal, cord and neuroforamina visualization at the operated levels, as well as image quality at the adjacent levels, was significantly impaired in discs that contained metals.
other than titanium (i.e., PCM, Prodisc-C), compared with the discs made of titanium (i.e., Bryan, Prestige LP).

To address concerns regarding material longevity and wear debris, two devices were tested under physiologic load and motion conditions: a metal-on-metal and a metal-on-polymer type. Although the wear debris rate for the metal-on-polymer type device was twice as high as that of a metal-on-metal type device, both rates were within acceptable limits. Devices tested both in vitro and in vivo (once the devices were explanted) showed less wear than predicted. A lesser inflammatory response in metal-on-metal compared to metal-on-polymer devices was reported. However, wear debris in metal-on-metal discs is composed mainly of heavy metals, and patients with these types of implants have been found to have increased serum and urine levels of heavy metals. Long-term clinical or biologic effects of such deposition are unknown at this time.

Various types of keels, teeth, and osteoconductive coatings are used to facilitate short- and long-term fixation of the devices. The Bryan cervical disc prosthesis has a porous coating of titanium to promote bone ingrowth and permanent fixation. In vivo tests confirmed that the prostheses demonstrated bony ingrowth despite the lack of postoperative immobilization. Osteoconductive finishes such as calcium phosphate hydroxyapatite also may result in debonding, extra wear debris, and, possibly, osteolysis.

Another critical feature is the localization of the axis of rotation in artificial discs and whether it matches the physiologic center of rotation of an implanted segment. The physiologic center of rotation in the cervical spine has shown level-to-level differences, but it usually is located in the posterior half of the upper portion of the inferior vertebral body.

Some discs, especially those with a ball-and-socket design, have a fixed axis of rotation in the center of the disc and must be placed slightly posterior to match physiologic kinematics and avoid facet overloading. Other manufacturers claim that the normal center of rotation can be reproduced with an unconstrained type of disc design.

**Types of Cervical Artificial Discs Under Investigation**

Currently, no cervical artificial discs have been FDA approved and, consequently, none is available for implantation in the United States. All of the cervical devices currently are being evaluated in FDA-controlled IDE prospective randomized clinical trials.

**Bryan Disc**

The Bryan cervical artificial disc consists of a low friction elastic polymer nucleus and two anatomically shaped titanium alloy shells equipped with anterior rigid wings to prevent posterior migration. A flexible membrane forms a sealed space that contains saline to diminish friction and wear. This is a rotationally unconstrained type of design with a mobile axis of rotation, which allows 11 degrees in flexion/extension or lateral bending and 2 mm in translation. Five sizes are available, from 14 to 18 mm in diameter. The disc articulates via symmetric spherical bearing surfaces and has a porous

![Figure 1](image-url)  
*Figure 1.* Plain lateral x-rays demonstrating straight sagittal alignment (lordosis 0 degrees) before surgery (A) and kyphosis (−5 degrees) after implantation of the Bryan artificial disc (B).
Prestige Discs
Two modifications of the Prestige disc design currently are available—Prestige ST and Prestige LP. New design features in the latest generation of Prestige LT disc look promising. The prostheses are made from new titanium ceramic composite material that has improved wear characteristics and is image-friendly on CT and MRI scans. Long-term stability is achieved through a porous titanium spray coating in addition to dual rails on each component, which facilitate the initial implant’s stability. These elements replace the screws that previously were used to affix the device components to the bone. The disc comes in various sizes to accommodate variations in patient size and consists of two articulating components, a ball on the top and a trough on the bottom.

At the time this article was written, enrollment was completed for the Prestige LP clinical study, and preliminary clinical outcome results for the Prestige ST disc had been presented at the Annual Meeting of the American Association of Neurological Surgeons. A total of 120 patients had participated in this prospective clinical trial and were randomized (50/50) to the standard treatment of cervical discectomy and fusion or cervical discectomy followed by implantation of the Prestige ST artificial cervical disc. Preliminary results demonstrated equal clinical outcomes in both groups, which confirmed previously reported results for the Prestige II artificial disc.

ProDisc-C
The design of the ProDisc-C is similar to that of the lumbar ProDisc prosthesis and consists of two forged cobalt-chromium-molybdenum alloy endplates and a polyethylene inlay component fixed to the inferior endplate. The two metal endplates are covered with a plasma-sprayed pure titanium coating to help ensure long-term stability, in addition to the central keels that initially provide stability of the implant. This modular device is inserted as a one-piece construct. It comes in five anatomic footprint sizes and four heights.

Multiple centers in the United States are involved in a prospective, randomized clinical trial evaluating the safety and efficacy of the ProDisc-C comparing with anterior cervical discectomy and fusion (ACDF). Preliminary results demonstrated no statistically significant differences between ACDF and arthroplasty patient groups with regard to neurologic function, including scores on the Visual Analogue Scale, Neurologic Disability Index, or Short Form-36 General Health Survey. An increase of overall motion was achieved in flexion (3.2 degrees) and extension (7.0 degrees), with lateral bending decreased by 5.5 degrees.

PCM Disc
The PCM ("porous-coated motion") disc was developed in collaboration with cervical spine surgeons from the United States, Europe, and Brazil and was approved for clinical trials in the United States in December 2004.

Two modifications of the PCM disc were developed to address the destabilizing effect of resection of the posterior longitudinal ligament (PLL)—a low-profile PCM disc for patients in whom the PLL is preserved, and a fixed PCM disc with screws for use when the PLL is removed. This artificial disc design consists of two cobalt-chrome alloy endplates with an intervening low friction, ultra-high-molecular-weight polyethylene spacer. The spacer allows the upper endplate to slide and rotate forward and backward relative to the lower endplate. A rectangular shape is used to maximize support in the lateral areas. The endplates have serrated surfaces with a titanium-calcium phosphate bone ingrowth coating to enhance postoperative stability. Two layers of pure titanium plasma are sprayed onto the back of the endplates, followed by an electrochemically applied calcium phosphate hydroxyapatite layer. Biomechanical studies have demonstrated axial rotation slightly higher than physiologic and limited (85% to 95%) flexion/extension range of motion for this semiconstrained device.

Kineflex/C Disc
The Kineflex/C disc (SpinalMotion) has a mobile bearing design, which allows translational movements within limits defined by the retention rings. This metal-on-metal disc comes in two sizes and has a locating fin for initial stability (Figure 2). It was used previously in South Africa, but no clinical data reporting clinical experience are available at the time of this writing.

Mobi-C Cervical Disc
The Mobi-C (LDR Medical) is the only implant that has been approved for clinical investigation at both one and two levels in the cervical spine. The Mobi-C uses a self-centering mobile bearing and semiconstrained design that allows 6 degrees of freedom along with a supposedly more-natural range of freedom.
on the inferior plate along with spine compression control system limit the insert’s mobility and theoretically could prevent migration of the device. Initial stability is achieved with the help of lateral self-retaining teeth, which have an inclined shape to facilitate easier insertion of the device and provide anchorage thereafter. The self-centering feature insures self-positioning of the superior plate vs. the inferior plate, which also can simplify device implantation.

**Secure-C Disc**
Currently undergoing clinical trials, the Secure-C (Globus Medical) disc consists of three parts: two metal, cobalt-chrome alloy endplates with porous coated bone-contacting surfaces and a semiconstrained ultra-high-molecular-weight polyethylene core. The clinical study is expected to involve almost 400 participants, including 100 nonrandomized training cases.

**CerviCore Disc**
The CerviCore disc (Stryker Spine) has a saddle-shaped, metal-on-metal design (Figure 4) with dual centers of rotation. The plates are coated with a titanium spray and have three spikes that provide initial fixation of the device to the bone. This disc recently has entered a phase of clinical evaluation in U.S. clinical trials.

**Cerpass Disc**
The Cerpass (NuVasive), an original ceramic-on-ceramic disc, is awaiting FDA approval for investigation. The manufacturers of this device believe that it will provide better durability and eliminate potential problems of wear debris. This design incorporates self-centering features that should ensure correct placement during implantation.

**Readings**
1. The first cervical artificial disc was implanted by Reitz.

True or False?

2. The main goals of the arthroplasty procedure are preservation of the motion segment and flexibility.

True or False?

3. Three key aspects of cervical artificial disc design are the center of rotation, short- and long-term stability, and material interfaces.

True or False?

4. Unconstrained artificial discs have a fixed axis of rotation.

True or False?

5. Metal alloys and polymers are the materials most commonly used in spine arthroplasty.

True or False?

6. Metal-on-polymer discs have a higher inflammatory response than metal-on-metal devices.

True or False?

7. A fixed axis of rotation in the center of the disc perfectly matches physiologic kinematics of an implanted segment.

True or False?

8. The Bryan cervical artificial disc is a rotationally unconstrained type of artificial disc with a mobile axis of rotation.

True or False?


True or False?

10. Cervical artificial discs that have been evaluated so far in FDA-controlled Investigational Device Exemption prospective randomized clinical trials have demonstrated superior clinical outcomes compared with cervical fusion.

True or False?