Spinal Artificial Disc Replacement: Cervical Arthroplasty

Part II: Indications, Surgical Technique, and Complications

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Learning Objectives: After reading this article, the participant should be able to:
1. Recall the selection and exclusion criteria used to evaluate patients for cervical arthroplasty.
2. Explain the surgical technique used to perform artificial disc replacement in the cervical spine.

This article is the second of two parts.
Cervical arthroplasty is a rapidly advancing surgical treatment option for cervical spine degenerative disc disease. Although early clinical studies have shown promise, long-term prospective clinical trials are needed to prove whether arthroplasty is capable of reducing adjacent level degeneration, preserving motion and normal biomechanics of the spine, or achieving effective clinical outcomes. This article reviews the design features, indications for cervical arthroplasty, surgical technique, available preliminary clinical outcomes, and complications are for cervical devices currently being evaluated in FDA-controlled Investigational Device Exemption prospective randomized clinical trials.

Indications
A large number of patients potentially could benefit from spinal arthroplasty; however, a number of less invasive procedures should be considered prior to total disc replacement. For example, posterior cervical foraminotomy has been demonstrated to eliminate unilateral radicular symptoms effectively in some patients. For patients with axial pain or stenosis in conjunction with spondylosis, the standard of care is anterior cervical discectomy and fusion. In Europe, where several different implants have been available for years, total disc arthroplasty accounts for only about 5% to 10% of cervical spinal procedures.

The indications for cervical spine arthroplasty are still evolving. Patient selection criteria should be based on the inclusion and exclusion criteria of currently completed or ongoing FDA clinical trials (Table 1). Ideal candidates include patients with symptomatic mild degenerative disc disease—including disc herniation with radiculopathy caused by foraminal osteophytes, soft disc herniation, or myelopathy—who have not responded to at least 6 weeks of conservative treatment. Axial neck pain as a solitary symptom has not been fully evaluated at this time in terms of suitability for cervical spine arthroplasty, and, therefore, is considered an exclusion criterion in the ongoing FDA clinical trials. Spinal arthroplasty never should be offered...
Table 1. Inclusion and Exclusion Criteria

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Bryan</th>
<th>Prestige ST (LP)</th>
<th>ProDisc-C</th>
<th>Kinflex/C</th>
<th>Mobi-C</th>
<th>CerviCore</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>≥21</td>
<td>≥18</td>
<td>18–60</td>
<td>18–60</td>
<td>18–69</td>
<td>18–65</td>
</tr>
<tr>
<td>Level</td>
<td>C3/C7, single</td>
<td>C3/C7, single</td>
<td>C3/C7, single</td>
<td>C3/C7, single</td>
<td>C3/C7, two levels</td>
<td>C3/C7, single</td>
</tr>
<tr>
<td>NDI</td>
<td>≥30</td>
<td>≥30</td>
<td>≥30</td>
<td>Moderate</td>
<td>≥30</td>
<td>≥30</td>
</tr>
<tr>
<td>Disk height</td>
<td>&lt;50%</td>
<td>—</td>
<td>&lt;50%</td>
<td>&gt;1 mm</td>
<td>≥25%</td>
<td>Significant</td>
</tr>
<tr>
<td>Failed conservative treatment</td>
<td>6 weeks*</td>
<td>6 weeks</td>
<td>&gt;6 weeks*</td>
<td>≥6 months</td>
<td>6 weeks</td>
<td>Yes</td>
</tr>
<tr>
<td>Radiulopathy/Myelopathy</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes*</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Exclusion criteria</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Axial pain (single symptom)</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Previous fusion</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Previous trauma</td>
<td>—</td>
<td>—</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>—</td>
</tr>
<tr>
<td>Spondylolisthesis</td>
<td>&gt;3.5 mm</td>
<td>Yes</td>
<td>&gt;3 mm and/or Significant</td>
<td>&gt;11 degrees</td>
<td>Significant</td>
<td>—</td>
</tr>
<tr>
<td>Absence of motion at the level to be treated</td>
<td>—</td>
<td>—</td>
<td>&lt;2 degrees</td>
<td>&lt;2 degrees</td>
<td>Yes</td>
<td>—</td>
</tr>
<tr>
<td>Osteopenia</td>
<td>Bridging</td>
<td>—</td>
<td>Bridging</td>
<td>Bridging</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Osteoporosis T score</td>
<td>≥–2.5</td>
<td>T score &lt; –2.5</td>
<td>Yes</td>
<td>T score &lt; –1.0</td>
<td>T score &lt; –2.5</td>
<td></td>
</tr>
<tr>
<td>Metal allergy</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>—</td>
</tr>
<tr>
<td>Obesity</td>
<td>Extreme</td>
<td>Morbid</td>
<td>No</td>
<td>BMI &gt;40</td>
<td>BMI &gt;35</td>
<td>—</td>
</tr>
<tr>
<td>Autoimmune disease</td>
<td>—</td>
<td>—</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Corticosteroid use</td>
<td>Yes</td>
<td>—</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

BMI, body mass index; NDI, neck disability index.

*6-week conservative treatment period may be waived in case the presence of progressive symptoms.

**Severe myelopathy excluded.

Complications

In addition to the standard potential complications associated with surgery and general anesthesia, several unique complications are associated with artificial disc replacement, including incomplete pain relief due to inadequate decompression, nerve root or spinal cord injury, hematomas, and infection. Seven of the 11 reported Bryan disc (Medtronic Sofamor Danek) failures have been secondary to incomplete neurologic decompression. Proper sizing of the implant is critical to a good outcome. Improper sizing can result in loosening and dislocation of the implant or its components, as well as breakage of the metal plate. Consequences of an implant migration tend to be less dangerous, because implantation is done via an anterior approach.
Subsidence into cancellous bone is less common than in the lumbar spine, because axial load stresses are substantially lower. Subsidence can be prevented by selecting a device of appropriate size, so that as much coverage of the bone plates as possible is provided. Particular attention should be paid to endplate preparation and maintenance of structural integrity of the remaining endplate and vertebral body. Patients with osteoporosis should not be offered arthroplasty. Even patients with sufficient bone structure at the time of surgery are at risk for late subsidence or device failure, given that these implants are made to last for a few decades. Finally, artificial disc implants may fail over time due to wear of the materials. Therefore, complete evaluation of the safety of cervical artificial discs will not be possible until the results from much longer-term studies that track the lifespan of the implants become available.

An unexpectedly high rate of heterotopic ossification (16 [17.8%] of 90 patients) has been observed at 12 months follow-up in the Bryan Disc Study performed by the European Consortium. Ten (62%) of these 16 patients had less than 2 degrees of motion at the operated level. Cummins et al. reported similar results: three of 14 discs (21%) were fused by 7 to 12.7 years follow-up after implantation of the

![Figure 1. The dual milling guide is being secured onto the retractor.](image)

![Figure 2. The Bryan cervical artificial disc is inserted into the prepared interbody space.](image)

![Figure 3. Implied Bryan cervical artificial disk.](image)

![Figure 4. Intraoperative fluoroscopy, lateral view, to verify correct position of the disc.](image)
Bristol-Cummins device. Fusion has been noted more frequently in older and male patients. Trauma to the longus colli muscle has been thought to be one of the factors facilitating the formation of paravertebral ossification. It is thought that perioperatively administered nonsteroidal anti-inflammatory drugs, abundant intraoperative irrigation, and limited retraction to the muscles may help prevent this complication. In current practice, patients with a diagnosis of ankylosis and those with loss of disc space height greater than 50% are not considered candidates for arthroplasty.

Limited information is available regarding salvage options and revision surgery. To date, only 11 Bryan, three Prestige (Medtronic Sofamor Danek), and three PCM (Cervitech) devices are known to have been explanted. However, revision surgery for cervical artificial discs is thought to be technically much less difficult and risky than lumbar artificial disc revision surgery.

**Surgical Technique**

This brief description of the primary components of the surgical technique for insertion of an artificial cervical disc is based on the procedure for the Bryan disc. Proper surgical training is required for insertion of each type of disc, of course. Each manufacturer has device-specific nuances and recommendations depending on their disc’s unique design.

Before the surgery, CT and MRI studies of the target disc space(s) are obtained, and the size of the prosthesis is selected with the help of a magnification template. The patient is positioned supine with the neck and head supported on the operating table and fluoroscopic images in anteroposterior and lateral planes are obtained. The anterior surgical approach to the cervical spine is straightforward and is very similar to the exposure obtained for anterior cervical decompression and fusion. A horizontal incision is made, and the index disc level is exposed after fluoroscopic localization of the level using a needle on the skin to ensure a perfect trajectory. After the disc space is exposed anteriorly, the correct level is confirmed fluoroscopically. The longus colli muscle is elevated broadly, and the retractor frame is positioned. Adequate exposure is confirmed by inserting the specialized dual track-milling guide into the incision and placing it on the anterior surfaces of the vertebral bodies. It is very important to avoid overretraction during this procedure. The special incision template is used to mark the annulus fibrosis according to the previously determined implant size, and the appropriate section of the annulus is excised.

A complete discectomy is performed using rongeurs and curettes, leaving the fibrotic portion of the annulus fibrosis. The cartilaginous endplates are removed, taking care to prevent excessive anterior bone removal. At this time the anterior osteophytes also should be removed, using the burr, with an attempt made to preserve the anterior cortex of the vertebral body. Disc space distractors are used to open the interspace up to 8.5 mm wide. If required, neural decompression is achieved in the standard fashion. Next, the midline is determined in these two dimensions using transverse and sagittal centering. The endplates are prepared and shaped using precision milling instruments after the center of the disc has been established. The dual milling guide is secured onto the retractor (Figure 1). The endplate surfaces are then milled for proper placement and fit of the prosthesis. During the milling process, a rim is created to provide initial stability for the device. Preservation of the cortical endplates decreases the risk of subsidence, heterotopic ossification, and implant loosening.

The trial spacers are placed into the interbody space, and the optimal implant size is confirmed radiographically with AP and lateral views. The disc is then guided and inserted into the prepared disc space with the help of an implant inserter (Figure 2). Gentle tapping can be applied to seat the disc fully. Once the disc is firmly in place, the distracting tension is taken off the vertebral bodies above and below, thus compressing the artificial disc and holding it in place (Figure 3). The correct position is verified using intraoperative fluoroscopy (Figure 4).

Total disc arthroplasty is expected to become more reproduducible and consistent as new devices are developed. Proper positioning is crucial. This depends especially on precise machining of the endplates to ensure a proper bone-prosthesis interface and an exact midline placement. Mobi-C (LDR Medical) and ProDisc-C (Synthes Spine) implant designs permit the use of a considerably simplified surgical technique. ProDisc-C insertion requires precise placement of keel cuts. The self-centering mobile bearing technology used in the Mobi-C disc is more forgiving, and exact positioning of the device is less important. Some of the newer artificial discs (e.g., Prestige or PCM) have sleeker profiles and require less retraction during insertion.

**Postoperative Period**

Physical therapy can be started on postoperative day number one and typically focuses on strength-building and flexibility. Patients are given a home exercise program at discharge. No major restrictions are imposed on regular activities after surgery, and the patient may return to work as soon as he or she feels up to it. Earlier return to work or normal daily activities has been reported after arthroplasty procedures than after standard cervical fusion.

**Postoperative Mobility of the Various Devices**

The cervical spine is highly mobile and, depending on the vertebral level involved, permits movement in all directions, with an average range of motion from 8 to 24.5 degrees in flexion/extension; 3.2 to 6.7 degrees in lateral bending, and 2.1 to 38.9 degrees in axial rotation. In vivo analysis of the Bryan cervical artificial disc has demonstrated that the prosthesis is capable of maintaining preoperative biomechanical properties of the cervical spine, but it cannot alter or restore “normal” function. “Almost physiological” segmental motion on radiographs, normal intradiscal pressure in adjacent levels, and shorter postoperative recovery without the need for postoperative immobilization are potentially advantageous. However, the most important questions have yet to be answered: Will cervical arthroplasty achieve a statistically significant clinical benefit over fusion? How will this technique affect long-term clinical outcomes? Will
maintenance of motion last over extended periods, taking into account that one of the main complications in the initial studies was paravertebral ossification? On the other hand, will the short-term benefit of motion preservation lead to significant long-term problems?

We hope that all of these questions will be answered when long-term results from the prospective randomized clinical trials become available. In the meantime, currently available short-term clinical outcomes data suggest that results following cervical fusion and arthroplasty are similar.

Readings


From the Editor:

I am very pleased to announce that retroactive to Volume 25, Issue 1, the American Association of Neurological Surgeons attests that this educational activity has been recognized for co-sponsored/endorsement for 1.5 Category 1 CME credits of the American Association of Neurological Surgeons’ Continuing Education Award in Neurosurgery.
Total disc arthroplasty accounts for approximately 50% of all cervical spine procedures performed in Europe.

True or False?

2. Patients with axial neck pain as their only symptom are ideal candidates for cervical arthroplasty procedure.

True or False?

3. Severe facet arthrosis is considered a contraindication to implantation of an artificial disc.

True or False?

4. Improper sizing can result in loosening and dislocation of an implant or its components and breakage of the metal plate.

True or False?

5. Arthroplasty should not be offered to patients with osteoporosis.

True or False?

6. Subsidence into cancellous bone is one of the most commonly encountered complications in cervical arthroplasty.

True or False?

7. Heterotopic ossification was observed in 17.8% of patients in the Bryan Disc Study performed by the European Consortium, and trauma to the longus colli muscle is thought to be one of the factors facilitating the formation of paravertebral ossification.

True or False?

8. Newer cervical artificial disc designs require considerably simplified surgical techniques and less retraction during insertion.

True or False?

9. Preservation of the cortical endplates decreases the risk of subsidence, heterotopic ossification, and implant loosening.

True or False?

10. It may be possible to determine clinical outcomes once long-term results from prospective randomized clinical trials become available.

True or False?