

# CONTEMPORARY NEUROSURGERY

VOLUME 29 • NUMBER 13

June 30, 2007

A BIWEEKLY PUBLICATION FOR CLINICAL NEUROSURGICAL  
CONTINUING MEDICAL EDUCATION

## Spinal Artificial Disc Replacement: Cervical Arthroplasty

### Part II: Indications, Surgical Technique, and Complications

Alan T. Villavicencio, MD, Sigita Burneikiene, MD, Robert Pashman, MD, and  
J. Patrick Johnson, MD

*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.
3. Describe potential future challenges associated with cervical arthroplasty.

*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

Dr. Villavicencio is Director of Research and Development, and Dr. Burneikiene is a Clinical Research Physician, Boulder Neurosurgical Associates, 1155 Alpine Avenue, Suite 320, Boulder, CO 80304; E-mail: atv@bnasurg.com ; Dr. Johnson is Director, Institute for Spinal Disorders, and Dr. Pashman is Director of Scoliosis and Spinal Deformity, Cedars Sinai Medical Center, Los Angeles, CA.

Dr. Villavicencio has disclosed that he is/was the recipient of grant/research funding from Medtronic Sofamor Danek (as principal investigator in the Maverick Artificial Disc Replacement Trial). Dr. Johnson has disclosed that he is/was a consultant/advisor to SpineWave, Alphatec, Flexuspine, and Johnson & Johnson and is/was a stock shareholder of SpineWave, Alphatec, Flexuspine, and Pioneer. Dr. Burneikiene and Dr. Pashman have disclosed that they have no significant relationships with or financial interests in any commercial organizations pertaining to this educational activity.

The authors have disclosed that the use of the artificial discs as described in this article for the treatment of cervical disorders has not been approved by the U.S. Food and Drug Administration.

Lippincott CME Institute, Inc., has identified and resolved all faculty conflicts of interest regarding this educational activity.

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

**Category:** Spine

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

**Table 1. Inclusion and Exclusion Criteria**

	Bryan	Prestige ST (LP)	ProDisc-C	KineflexIC	Mobi-C	CerviCore
<b>Inclusion criteria</b>						
Age	≥21	≥18	18–60	18–60	18–69	18–65
Level	C3/C7, single	C3/C7, single	C3/C7, single	C3/C7, single	C3/C7, two levels	C3/C7, single
NDI	≥30	≥30	≥30	Moderate	≥30	—
Disc height	<50%	—	<50%	≥1 mm	≥25%	Significant
Failed conservative treatment	6 weeks*	6 weeks	>6 weeks*	≥6 months	6 weeks	Yes
Radiculopathy/Myelopathy	Yes	Yes	Yes	Yes†	Yes	Yes
<b>Exclusion criteria</b>						
Axial pain (single symptom)	Yes	Yes	No	Yes	Yes	Yes
Previous fusion	Yes	Yes	Yes	Yes	Yes	Yes
Previous trauma	—	—	Yes	Yes	Yes	—
Spondylolisthesis	>3.5 mm	Yes >11 degrees	>3 mm and/or	Significant >11 degrees	>3.5 mm and/or	—
Facet joint arthrosis	—	—	Severe	Severe	Severe	—
Absence of motion at the level to be treated	—	—	<2 degrees	<2 degrees	Yes	—
Osteophytes	Bridging	—	Bridging	Bridging	No	No
Osteoporosis	T score ≥ -2.5	Yes	T score < -2.5	Yes	T score < -1.0	T score < -2.5
Metal allergy	Yes	Yes	Yes	Yes	Yes	—
Obesity	Extreme	Morbid	No	BMI >40	BMI >35	—
Autoimmune disease	—	—	Yes	Yes	Yes	Yes
Corticosteroid use	Yes	—	Yes	Yes	Yes	Yes

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.

to patients with incompetent posterior elements, instability, or severe facet arthrosis. Currently, insufficient cervical motion at the index level, bridging osteophytes, collapse of intervertebral disc space of greater than 50% of normal height, and severe osteoporosis also are contraindications.

## Complications

In addition to the standard potential complications associated with surgery and general anesthesia, several unique complications are associated with artificial disc replace-

ment, 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.

**EDITOR:** Ali F. Krisht, M.D.\*  
University of Arkansas for Medical Sciences

**ASSISTANT EDITOR:** Cargill Alleyne, Jr., M.D.\*  
Medical College of Georgia

**PRODUCTION ASSISTANT:** RONALDA WILLIAMS

**EDITORIAL BOARD:**  
Badih Adada, M.D.  
Ossama Al-Mefty, M.D.  
Rick Boop, M.D.  
Evandro de Oliveira, M.D.  
Allan Friedman, M.D.  
Gerardo Guinto, M.D.  
Douglas Kondziolka, M.D.  
Jacques Morcos, M.D.  
Tom O'rigitano, M.D.  
Nelson Oyesiku, M.D.  
Kalmon Post, M.D.  
Richard Rowe, M.D.  
Martin Weiss, M.D.  
M. Gazi Yaşargil, M.D.

\* Dr. Krisht has disclosed that he has no significant relationships with or financial interests in any commercial organizations pertaining to this educational activity. Dr. Alleyne has disclosed that he is a consultant for Cordis.

The continuing education activity in *Contemporary Neurosurgery* is intended for neurosurgeons, neurologists, neuroradiologists, and neuropathologists.

### Contemporary Neurosurgery

(ISSN 0163-2108) is published bi-weekly by Lippincott Williams & Wilkins, Inc., 16522 Hunters Green Parkway, Hagerstown, MD 21740-2116. **Customer Service: Phone (800) 787-8981 or (410) 528-8572. 24-Hour Fax (410) 528-4105 or E-mail [audrey.dyson@wolterskluwer.com](mailto:audrey.dyson@wolterskluwer.com).** Visit our website at [LWW.com](http://LWW.com).

Copyright 2007 Lippincott Williams & Wilkins, Inc. All rights reserved. Priority Postage paid at Hagerstown, MD, and at additional mailing offices. POSTMASTER: Send address changes to Contemporary Neurosurgery, Subscription Dept., Lippincott Williams & Wilkins, 16522 Hunters Green Parkway, Hagerstown, MD 21740-2116.

Publisher: Daniel E. Schwartz • Customer Service Manager: Audrey Dyson

Subscription rates: *Personal:* \$508.98 US, \$553 Foreign. *Institutional:* \$428.98 US, \$438 Foreign. In-training: \$108.98 US, \$113 Foreign. GST Registration Number: 895524239. Send bulk pricing requests to Publisher. Single copies: \$17. **COPYING:** Contents of *Contemporary Neurosurgery* are protected by copyright. Reproduction, photocopying, and storage or transmission by magnetic or electronic means are strictly prohibited. Violation of copyright will result in legal action, including civil and/or criminal penalties. Permission to reproduce in any way must be secured in writing from: Permissions Dept., Lippincott Williams & Wilkins, 351 W. Camden Street, Baltimore, MD 21201; Fax: (410) 528-8550; E-mail: [arnetta.queen@wolterskluwer.com](mailto:arnetta.queen@wolterskluwer.com). For commercial reprints, E-mail [matt.westcoat@wolterskluwer.com](mailto:matt.westcoat@wolterskluwer.com).

PAID SUBSCRIBERS: Current issue and archives (from 1999) are available FREE online at [www.lwwnewsletters.com](http://www.lwwnewsletters.com).

*Contemporary Neurosurgery* is independent and not affiliated with any organization, vendor, or company. Opinions expressed do not necessarily reflect the views of the Publisher, Editor, or Editorial Board. A mention of products or services does not constitute endorsement. All comments are for general guidance only; professional counsel should be sought for specific situations. Indexed by Bio-Sciences Information Services. For information on CME accreditation, see back page.



**Figure 1.** The dual milling guide is being secured onto the retractor.



**Figure 2.** The Bryan cervical artificial disc is inserted into the prepared interbody space.

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 arthro-

plasty. 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 3.** Implanted Bryan cervical artificial disc.



**Figure 4.** Intraoperative fluoroscopy, lateral view, to verify correct position of the disc.

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 reproducible 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

Coric DF, Finger, Boltes P. Prospective randomized controlled study of the Bryan cervical disc: early clinical results from a single investigational site. *J Neurosurg Spine* 2006;4:31-35.

Cummins B H, Robertson JT, Gill SS. Surgical experience with an implanted artificial cervical joint. *J Neurosurg* 1998;88:943-948.

DiAngelo DJ, Foley KT, Morrow BR, et al. In vitro biomechanics of cervical disc arthroplasty with the ProDisc-C total disc implant. *Neurosurg Focus* 2004;17(3): E7.

Johnson JP, Laurusen C, Cambron HO, et al. Sagittal alignment and the Bryan cervical artificial disc. *Neurosurg Focus* 2004; 17(6): E14.

Leung C, Casey AT, Goffin J, et al. Clinical significance of heterotopic ossification in cervical disc replacement: a prospective multicenter clinical trial. *Neurosurgery* 2005;57:759-763.

Liu JN, Ebraheim A, Haman SP, et al. How the increase of the cervical disc space height affects the facet joint: an anatomy study. *Spine* 2006;31:E350-354.

Mummaneni PV, Haid RW. The future in the care of the cervical spine: interbody fusion and arthroplasty. Invited submission from the Joint Section Meeting on Disorders of the Spine and Peripheral Nerves, March 2004. *J Neurosurg Spine* 2004;1:155-159.

Oskouiian RJ, Whitehill R, Samii A, et al. The future of spinal arthroplasty: a biomaterial perspective. *Neurosurg Focus* 2004; 17(3):E2.

Pickett GE, Rouleau JP, Duggal N, et al. Kinematic analysis of the cervical spine following implantation of an artificial cervical disc. *Spine* 2005;30:1949-1954.

Porchet F, Metcalf NH. Clinical outcomes with the Prestige II cervical disc: preliminary results from a prospective randomized clinical trial. *Neurosurg Focus* 2004;17:E6.

**View past,\* current, and future issues of your paid subscription to *Contemporary Neurosurgery* online for free! Follow these instructions to log-on to your account.**

1. Locate your **12-digit account number** on the mailing label of your current issue.
2. Go to: **www.lwwnewsletters.com**.
3. From the choices on the top yellow toolbar, select **"Sign On."**
4. In the spaces provided, enter your **"Username"** and **"Password."** Your *username* will be the letters **LWW (case sensitive)** followed by the 12-digit account number on your address label. We have provided an easy-to-remember **"default" password** for you: Simply type the numbers **1234**. (This password **cannot** be changed.)
5. Click **"Sign On."**
6. Click **"Access My Account."**
7. Click **"View or Renew Subscriptions."** Click on **"Contemporary Neurosurgery,"** and select the current or archive issue you wish to view. All issues are posted in PDF format. You will need Adobe Acrobat Reader installed on your computer to view the issues. To download your free copy of Acrobat Reader, visit **www.Adobe.com**.

**If you have any questions or problems regarding your print or electronic account, please call 1-800-787-8981.**

\* Archive issues are available as far back as 1999.

## 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.

To earn CME credit, you must read the CME article and complete the quiz on the enclosed form, answering at least 70% of the quiz questions correctly. **Select the best answer and use a blue or black pen to completely fill in the corresponding box on the enclosed answer form.** Please indicate any name and address changes directly on the answer form. If your name and address do not appear on the answer form, please print that information in the blank space at the top left of the page. Make a photocopy of the completed answer form for your own files and mail the original answer form in the enclosed postage-paid business reply envelope. Your answer form must be received by Lippincott CME Institute, Inc., by **June 29, 2008**. At the end of each quarter, all CME participants will receive individual issue certificates for their CME participation in that quarter. These individual certificates will include your name, the publication title, the volume number, the issue number, your participation date, and the AMA credit awarded. For subscribers who elect to participate in the CNE program for AANS credit, each certificate will also include the official AANS credit statement. For more information, call (800) 787-8981.

**Online quiz instructions:** To take the quiz online, go to <http://cme.LWWnewsletters.com>, and enter your **username** and **password**. Your **username** will be the letters **LWW** (case sensitive) followed by the 12-digit account number on your mailing label. You may also find your account number on the paper answer form mailed with your issue. Your **password** will be **1234**; this password **may not** be changed. Follow the instructions on the site. You may print your official certificate **immediately**. Please note: Lippincott CME Institute, Inc., **will not** mail certificates to online participants.

Lippincott Continuing Medical Education Institute, Inc., is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

Lippincott Continuing Medical Education Institute, Inc., designates this educational activity for a maximum of 1.5 *AMA PRA Category 1 Credits*<sup>™</sup>. Physicians should only claim credit commensurate with the extent of their participation in the activity. 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 Surgeon's Continuing Education Award in Neurosurgery. Lippincott CME Institute, Inc., will continue to provide the American Association of Neurological Surgeons, in February of each year, with an annual listing of the participants and their CME credits earned.

- |   |   |
|---|---|
| <p>1. Total disc arthroplasty accounts for approximately 50% of all cervical spine procedures performed in Europe.</p> <p style="text-align: center;"><b>True or False?</b></p>             | <p>6. Subsidence into cancellous bone is one of the most commonly encountered complications in cervical arthroplasty.</p> <p style="text-align: center;"><b>True or False?</b></p>  |
| <p>2. Patients with axial neck pain as their only symptom are ideal candidates for cervical arthroplasty procedure.</p> <p style="text-align: center;"><b>True or False?</b></p>            | <p>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.</p> <p style="text-align: center;"><b>True or False?</b></p> |
| <p>3. Severe facet arthrosis is considered a contraindication to implantation of an artificial disc.</p> <p style="text-align: center;"><b>True or False?</b></p>                           | <p>8. Newer cervical artificial disc designs require considerably simplified surgical techniques and less retraction during insertion.</p> <p style="text-align: center;"><b>True or False?</b></p>   |
| <p>4. Improper sizing can result in loosening and dislocation of an implant or its components and breakage of the metal plate.</p> <p style="text-align: center;"><b>True or False?</b></p> | <p>9. Preservation of the cortical endplates decreases the risk of subsidence, heterotopic ossification, and implant loosening.</p> <p style="text-align: center;"><b>True or False?</b></p>  |
| <p>5. Arthroplasty should not be offered to patients with osteoporosis.</p> <p style="text-align: center;"><b>True or False?</b></p>  | <p>10. It may be possible to determine clinical outcomes once long-term results from prospective randomized clinical trials become available.</p> <p style="text-align: center;"><b>True or False?</b></p>  |