CONTEMPORARY NEUROSURGERY

A BIWEEKLY PUBLICATION FOR CLINICAL NEUROSURGICAL CONTINUING MEDICAL EDUCATION

VOLUME 27 • NUMBER 18
September 15, 2005

Spinal Artificial Disc Replacement: Lumbar Arthroplasty

Part I

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Learning Objectives: *After reading this article, the participant should be able to:*

1. *Describe the various lumbar artificial disc replacement devices currently available for clinical application or undergoing experimental clinical trials in the United States.*
2. *Explain the advantages, shortcomings, and controversies related to various artificial disc designs.*
3. *Describe the results of the main completed clinical trials of artificial lumbar discs.*

This article is the first of two parts.

Artificial disc technology is designed to replace degenerated or injured discs with a prosthesis that allows for normal physiologic movement of the spine. According to Enterprise Knowledge, Inc., 391,050 spinal fusions were performed in the United States in 2002, and this number is expected to increase by about 25% in 2005. Artificial discs offer an alternative to arthrodesis, and arthroplasty is expected to replace up to 25% of fusion surgeries in the future.

The field of spinal arthroplasty has been developing over the past several decades. Despite the introduction of several different varieties of artificial discs, however, only a few have reached the level of clinical implementation. Initial attempts at artificial disc surgery date back to the 1950s, when Fernström implanted stainless steel balls into the disc spaces. More-recent innovations include efforts by Schellnac and Büttner-Janz in the 1980s with the introduction of the Charité SB disc (DePuy Spine). After decades of research and clinical trials, artificial disc replacement (ADR) is only now becoming a relatively common procedure in many European countries.

The first artificial disc prosthesis was approved by the FDA in October 2004. Several other versions are undergoing prospective randomized controlled clinical trials to prove their efficacy and safety in an attempt to obtain FDA clearance. This evolving technology is presenting neurosurgeons with an increasing number of new and different options. Parts I and II of this article provide an overview of artificial disc prostheses, including the indications for ADR and operative nuances.

The goals of ADR surgery are to restore disc space height, preserve motion segment flexibility and stability, re-establish the normal lordotic angle, and reduce or eliminate pain from motion or nerve compression. By preserving normal motion at the level of the surgery, additional stress and load-sharing at the adjacent levels is avoided, thus reducing accelerated degeneration to the adjacent levels associated with arthrodesis. Although these anticipated results sound very appealing, the use of ADR remains controversial because the theoretical advantages of ADR are not yet proven, and

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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 the recipient of grant/research funding from Medtronic Sofamor Danek (as principal investigator in the Bryan Artificial Disc Replacement Trial). Dr. Burneikiene has disclosed that she has no significant relationships with or financial interests in any commercial organizations pertaining to this educational activity.

The authors have disclosed that the use of all the artificial discs described in this article, with the exception of the Charité SB III, for the treatment of lumbar discogenic pain has not been approved by the U.S. Food and Drug Administration.

Wolters Kluwer Health has identified and resolved all faculty conflicts of interest regarding this educational activity.

Category: Category: Spine

Key Words: Artificial disc replacement, Lumbar arthroplasty, Spine surgery

long-term outcomes from prospective clinical studies are not yet known. It is possible that an anteriorly located center of rotation could increase facet loads up to 2.5 times, thereby adding increased stress and wear to the facet joints. All artificial disc designs, with the exception of the Maverick disc (Medtronic Sofamor Danek), are created with a center of rotation that is anterior to the normal physiologic center of rotation in the spine, which is in the posterior two-thirds at the disc space. This requires a more-posterior device placement than the physiological center of the disc space. This factor could result in additional placement errors. Only the ProDisc (Synthes Spine Solutions, Inc.) and Maverick have semiconstrained core designs, versus the unconstrained Charité prosthesis. The unconstrained core design could additionally increase facet loads, cause potential dislocations, or lead to instability. On the other hand, the Flexi-Core device (Stryker Spine) is a totally constrained design, which could limit motion and reduce translation.

Other controversies regarding ADR include biomechanical characteristics, including shock absorption, which has been tested for multiple devices. In one study, a metal-on-metal device was tested and compared with another device that had a polyethylene center core. Surprisingly, neither of these devices had effective shock absorption. Again, the theoretical and experimentally tested advantages or insufficiencies of these devices must be shown to hold up with long-term clinical outcomes.

Given the implant's proximity to the spinal canal and nerve roots, the issue of "wear debris" also causes concern. Despite numerous experimental studies, the potential significance of this phenomenon on the endplates and the adjacent neurological elements remains unclear. In a long-term laboratory test of cyclical motion simulating more than 11 years of use, no wear debris particles were identified with the Charité disc. There was minimal deformation of the core, with less than 8% height loss expected in 10 years of use. Despite these experimental data, however, significant polyethylene wear was reported in one patient 12 years after implantation of the Charité disc. Another patient had polymer disintegration and associated osteolysis 2 years after surgery. The optimal patient age at the time of ADR surgery has been reported to be 45 to 50 years of age or younger. Early cases indicate a high likelihood that patients who undergo ADR at a young age will require additional surgery during their lifetime.

Although artificial discs are designed to restore motion, spontaneous solid fusion has been reported in 37 (59%) of 63 treated segments at 17 years of follow-up. The cause of this phenomenon is unclear, but fortunately (and ironically), clinical results are predominantly good to excellent in patients who experience spontaneous fusion.

Van Ooij and colleges reported a series of 26 patients at a mean of 53 months (range, 11 months–10.6 years) of follow-up after Charité ADR surgery that required artificial disc removal or reoperation. Reasons for reoperation included degeneration of other lumbar discs, facet joint arthrosis at the same or other levels, and subsidence of the prosthesis. It is unclear whether these problems were related to poor patient selection or poor operative technique, faulty implant design, or the natural history of adjacent level degeneration in patients with degenerative disc disease with or without arthrodesis. These 26 patients represented 5.2% (26 of 500) of a retrospectively reviewed cohort. Longer-term, prospective follow-up is needed to evaluate the efficacy of ADR fully.

Because very few artificial discs have been removed to date, there is limited information regarding salvage options. David and colleagues reported that the polyethylene core of a disc in one patient had fragmented after 9.5 years and was successfully replaced with a new Charité disc. Revision strategy for artificial disc prostheses must be defined further.

Artificial Discs Currently Available or Undergoing Trial

Charité

The Charité disc is the first and currently the only lumbar artificial disc to be approved by the FDA and is currently in a third-generation version (Charité SB III). The device has two concave cobalt chromium alloy endplates with anchoring teeth

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 adyson@lww.com.** Visit our website at LWW.com.

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

Subscription rates: *Personal:* $487 US, $527 Foreign. *Institutional:* $397 US, $401 Foreign. In-training: $107 US, $111 Foreign. GST Registration Number: 895524239. Send bulk pricing requests to Publisher. Single copies: $19.

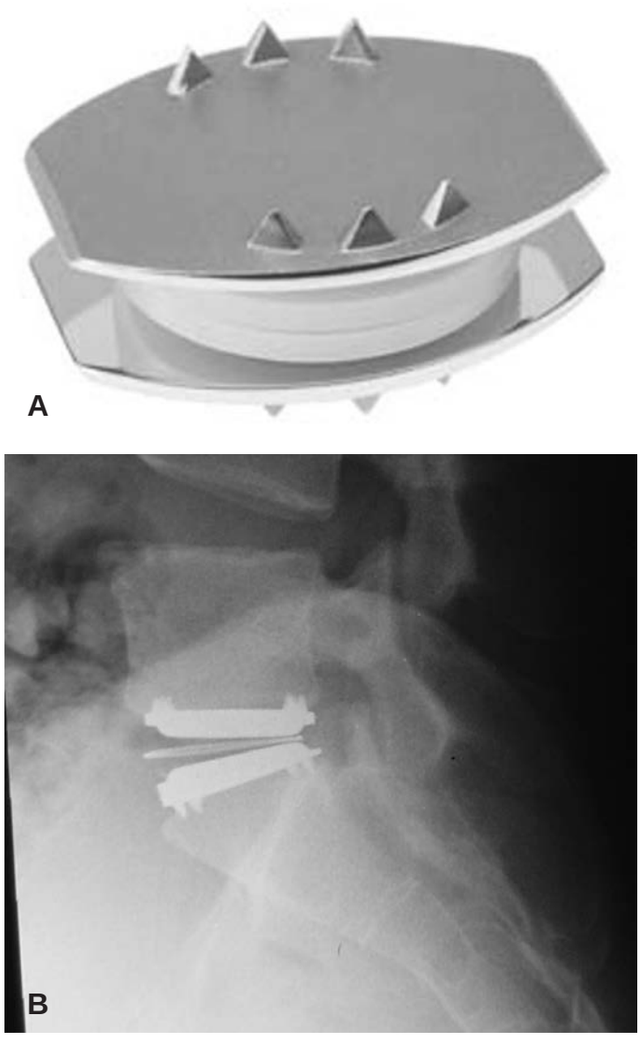

Figure 1. Charité artificial disc consisting of two concave cobalt chromium alloy endplates with anchoring teeth along with an ultra-high-molecular-weight floating polyethylene core (*A*) surrounded by a radiopaque ring between the endplates that is visualized on plain radiographs (*B*).

along with an ultra-high-molecular-weight floating polyethylene core surrounded by a radiopaque ring between the endplates (Fig. 1). The angulation of the chromium alloy endplates varies from 0 to 10 degrees, and five different heights and four endplate (footprint) sizes are available.

This design has been criticized as providing inadequate fixation to the vertebral endplate. This may be a potential advantage, however, if revision surgery is necessary, because the vertebral body-sparing fixation maintains the overall bony integrity of the vertebra. A primary concern of many surgeons is the fact that the Charité disc available in the United States does not have an endplate surface coating that allows for bony ingrowth and long-term fixation of the device. A supplemental filing to the FDA for a porous-coated version has been submitted. This is the version that is currently being used in Europe, which is a slight variation on the device approved in the United States. The multicenter FDA prospective randomized clinical trial in the United States compared the Charité SB III device to anterior lumbar interbody fusion (ALIF) with Bagby and Kuslich cage and autograft. Shorter hospital stays and higher satisfaction rates were reported in the investigational group (Table 1). However, 17% of patients in the ALIF group had graft harvesting pain, and the overall clinical outcomes were similar in both groups at 24 months of follow-up.

Several clinical studies have documented the European experience. LeMaire et al. reported outcomes at a mean follow-up of 51 months, with 79% of patients having excellent results and 87% of patients having returned to work. Most of the 10% complications were related to the anterior surgical

Table 1. Clinical Data and Patient Satisfaction

	Charité Artificial Disc Mean (SD)	Bagby and Kuslich Cage Mean (SD)
Total surgery time (min)	110.8 (47.7)	114.0 (67.8)
Estimated blood loss (mL)	205.0 (211.7)	208.9 (283.9)
Hospital stay (days)	3.7 (1.18)	4.2 (1.99)
Patient satisfaction	74%	53%

SD, standard deviation.

Figure 2. ProDisc artificial disc consisting of two cobalt chrome alloy endplates and a polyethylene core that is attached to the caudal endplate. The endplates have central anchoring keels that provide greater immediate fixation and are covered with a pure titanium plasmapore surface.

approach rather than to biomechanical failures of the prosthesis. Facet arthritis, osteoporosis, structural deformities, and secondary facet pain were some of the factors indicated in this study that can lead to failure.

Reoperation rates of up to 24% (9 of 46 and 12 of 50) have been reported in various studies. The results from one of these studies include two patients who underwent removal of the prosthesis. The authors concluded that poor surgical indications rather than failure of the prosthesis were the causes of the reoperations. Specific device-related complications were rare but included extrusion of the polymer core, subsidence of the device into the endplate, and loosening of the implant.

ProDisc

The ProDisc II artificial disc was designed by Marnay in the 1980s and consists of two cobalt chrome alloy endplates and a polyethylene core (Fig. 2). The design is a modular locking system, with a polyethylene core attached to the caudal endplate. The disc is inserted in a collapsed form, and the polyethylene core has a monoconvex shape that allows for slightly less distraction during insertion. Endplates have central anchoring keels that provide greater immediate fixation and are covered with a pure titanium plasmapore surface for bone in-growth. The endplates are available in two sizes (medium and large), three heights for the polyethylene component (10, 12, and 14 mm), and two lordosis angles (6 and 11 degrees), so the device can be customized to each patient's unique anatomic and physiologic requirements.

The European experience with the ProDisc initially demonstrated 90.8% excellent results, although 9.3% of patients experienced progression of disc degeneration at adjacent levels. After 7 to 11 years of follow-up, Marnay's group reported that 74.5% of patients had excellent or good results and 25.5% had poor results. A multicenter, prospective, randomized clinical study in the United States, with both single- and double-level study arms at L3–S1 comparing the investigational device to the circumferential fusion, showed similar outcome results. ProDisc is the only artificial disc currently in FDA trials that is being investigated for multilevel placement. No implant removals have been reported to date, but dislodgement of the polyethylene spacer because of improper insertion has been reported.

Figure 3. Maverick artificial disc consisting of two cobalt-chromium-molybdenum alloy, metal-on-metal, ball-and-cup components with a grooved and beaded hydroxyapatite-covered endplate surface.

Figure 4. FlexiCore artificial disc. The design is similar to the Maverick metal-on-metal design, but the FlexiCore disc has a fixed center of rotation. Shaped endplates have small spikes and surface coating for bone ingrowth into the metal, which supplements fixation to the endplate.

Maverick

The Maverick artificial disc consists of two cobalt-chromium-molybdenum alloy, metal-on-metal, ball-and-cup components with a grooved and beaded hydroxyapatite-covered endplate surface designed to assist bone ingrowth (Fig. 3). Two large keels also help provide immediate stability after the implantation, but these preclude future arthroplasty with the same device at contiguous levels. The two metal-on-metal plates in the Maverick are interchangeable and are available in three sizes and heights, with two available angles. There is no polyethylene wear concern. The degree of metal wear has been tested with simulated loading, and it has been reported that the amount and character of wear debris is insignificant compared with that required to produce a physiological response.

A multicenter prospective randomized FDA trial compared patients in an investigational group (Maverick) to patients undergoing ALIF with the LT-Cage tapered fusion device and InFUSE Bone Graft (both Medtronic Sofamor Danek). Patients with degenerative disc disease were treated at a single level from L4–S1. The study finished enrollment in the United States several months ago, and the device is currently available only through continued access via regional principal investigators in a nonrandomized fashion.

FlexiCore

The FlexiCore device is similar to the Maverick metal-on-metal design but has a fixed center of rotation (Fig. 4). Shaped endplates have small spikes and surface coating for bone ingrowth into the metal, which supplements fixation to the endplate. This device is inserted as a single entity from a straight anterior or anterolateral position. The manufacturer claims that its mechanical performance is beyond

that required physiologically, but no clinical data have been published to support this claim.

A multicenter prospective randomized clinical study is currently enrolling patients with degenerative disc disease at a single level in the lumbosacral spine (L1–S1). Patients are randomized at a 2:1 ratio to receive the investigational treatment or to control (anterior-posterior fusion with anterior bone graft and posterolateral fusion using pedicle screws). Inclusion criteria are similar to those for the other clinical trials, but in this clinical study, patients are excluded if their leg pain is greater than their back pain.

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From the Editor:

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1. The first prototype of an artificial disc was inserted in the 1980s.

   True or False?

2. A main goal of the arthroplasty procedure is preservation of the motion segment and flexibility.

   True or False?

3. The anteriorly located center of rotation could decrease facet loads up to five times.

   True or False?

4. The unconstrained core design could result in decrease of facet loads.

   True or False?

5. Devices with a polyethylene center core design have demonstrated more effective shock absorption characteristics compared with metal-on-metal devices.

   True or False?

6. The multicenter FDA prospective randomized clinical trial in the United States demonstrated similar overall clinical outcomes in the Charité lumbar disc and the anterior lumbar interbody fusion patient group at 24 months of follow-up.

   True or False?

7. The multicenter prospective randomized clinical trial in the United States demonstrated similar overall clinical outcomes in the investigational ProDisc patient group compared with the circumferential fusion control patient group.

   True or False?

8. The Charité artificial lumbar disc approved for clinical use in the United States has a porous endplate surface coating that allows for bony ingrowth and long-term fixation.

   True or False?

9. Poor surgical indications rather than failure of the prosthesis represented the majority of causes of reoperation in the one of the studies evaluating the reasons for surgical revision involving the Charité artificial disc.

   True or False?

10. Reoperation rates of up to 24% have been reported after Charité artificial disc replacement.

    True or False?

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