

CONTEMPORARY NEUROSURGERY

VOLUME 27 • NUMBER 19
September 30, 2005

A BIWEEKLY PUBLICATION FOR CLINICAL NEUROSURGICAL
CONTINUING MEDICAL EDUCATION

Spinal Artificial Disc Replacement: Lumbar Arthroplasty

Part II

Alan T. Villavicencio, M.D., Sigita Burneikiene, M.D., and J. Patrick Johnson, M.D.

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

1. Describe the criteria for patient selection for lumbar arthroplasty.
2. Explain the surgical technique for artificial disc replacement in the lumbar spine.
3. Describe postoperative management of patients undergoing artificial disc replacement in the lumbar spine.

This article is the second of two parts.

Surgical Indications for Lumbar Artificial Disc Replacement

Indications for artificial disc replacement (ADR) are still being developed for each of the different devices. Table 1 lists inclusion and exclusion criteria for the procedure. Currently, lumbar disc arthroplasty is indicated in skeletally mature patients for one-level degenerative disc disease at L4–S1 by use of the Maverick (Medtronic Sofamor Danek) and Charité (DePuy Spine) devices; at L1–S1 with the FlexiCore device (Stryker Spine); or for one- or two-level disease at L3–S1 with the ProDisc (Synthes Spine Solutions,

Inc.). The ideal candidate for artificial disc replacement surgery has low back pain of discogenic origin with no significant facet joint changes, no previous fusion surgeries or other operations involving the facet joints at the level in question, no canal stenosis, and no more than 3 mm of spondylolisthesis. The patient should have received at least 6 months of conservative treatment with unsuccessful results.

Because the nerves usually are not decompressed completely during the arthroplasty procedure, limited radiculopathy pain may or may not be relieved by disc and neuroforamen height restoration. Restoration of normal motion may worsen radicular pain if a posteriorly herniated disc or foraminal stenosis continues to impinge on the nerve root.

Bertagnoli et al. defined the ideal candidate for the Charité artificial disc as having single-level degenerative disc disease, disc height greater than 4 mm, no osteoarthritic changes of the facets, no adjacent level degeneration, and intact posterior elements. The Charité Center for Musculoskeletal Surgery (Berlin, Germany) has reported, in 17 years of long-term follow-up, that incorrect preoperative indications were responsible for 56% of poor clinical outcomes at that center. The authors concluded that arthroplasty is not indicated for advanced disc degeneration or spondylolisthesis.

Technique of Lumbar Artificial Disc Placement

All of the artificial discs have some device-specific nuances for insertion. This description is general and clearly

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; and Dr. Johnson is Director, Institute for Spinal Disorders, 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 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: Spine

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

Table 1. Inclusion and Exclusion Criteria for Artificial Disc Replacement

	Charité	ProDisc	Maverick	FlexiCore
Inclusion criteria				
Age (years)	18–60	18–60	18–70	18–60
Level	L4–S1, single	L3–S1, two levels	L4–S1, single	L1– S1, single
Oswestry disability index score	> 30/50	> 20/50	≥30/50	≥40/50
Visual analog score	> 40/100	—	≥20/100	≥40/100
Failed conservative treatment	≥6 months	≥ 6 months	≥6 months	≥6 months
Axial pain	Yes	Yes	Yes	Greater than leg pain
Radiculopathy	Yes*	Yes	Yes	Yes
Exclusion criteria				
Previous fusion	Yes	Yes	Yes	Yes
Spondylolisthesis	>3 mm	>3 mm or 5 degrees	Yes	>4 mm
Scoliosis	>11 degrees	—	—	>10 degrees
Facet joint arthrosis	Yes	Yes	Yes	Yes
Stenosis	—	< 8 mm	Yes	Moderate/severe
Osteoporosis	Yes	> 2.5	Yes	Yes
Metal allergy	Yes	Yes	Yes	Yes
Obesity	Yes	Yes	—	Yes
Autoimmune disease	Yes	Yes	Yes	Yes
Steroid use	Yes	Yes	Yes	Yes

* Without nerve root compression.

cannot replace proper surgical training for insertion of each type of disc.

Implantation of any artificial disc begins with preoperative planning. The correct component size usually is estimated prior to surgery by use of CT or MRI scans to select appropriate footprint sizes.

The patient is positioned on the operating table in the supine position with arms across the chest and the affected levels of the spine over the table break. The ability to adjust the table (to flex or extend the spine by “breaking” the bed) during the arthroplasty procedure sometimes makes it easier to implant the device. A left retroperitoneal approach (Fig. 1) is usually chosen. A 4- to 6-cm incision is made, and the dissection is carried down through the subcutaneous tissue. The rectus sheath is exposed and divided, and the peritoneum is dissected from the fascia transversalis for 2 to 3 cm in both directions. The retroperitoneal space is entered lateral to the psoas muscle. The posterior sheath is divided, and, using

blunt dissection, the ureter and abdominal contents are dissected away from the iliac vessels. After the iliac vessels are carefully exposed, the joint space of the vertebral bodies is accessed (L5–S1 at the bifurcation; Fig. 2A), L4–L5 between vessels is retracted to the right, and the sympathetic chain is retracted to the left (Fig. 2B). The central sacral vessels are ligated and divided for the L5–S1 exposure.

The Omni retractor (Omni-Tract Surgical) is used to provide complete side-to-side exposure of the intervertebral space. The anterior intervertebral disc tissue blunt dissection is performed. The operative level and vertebral body midline are confirmed using anteroposterior (AP) fluoroscopy. The anterior longitudinal ligament is then either excised completely or incised superiorly and laterally and reflected inferiorly for later reapproximation and suturing. Although, in theory, better spinal segment biomechanics could be restored by reconstruction of the anterior longitudinal ligament, most surgeons have found this technique

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 Origitano, 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 and Dr. Alleyne have disclosed that they have no significant relationships with or financial interests in any commercial organizations pertaining to this educational activity.

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

Copyright 2005 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:* \$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. **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: permissions@lww.com. For commercial reprints, contact Carol Bak: Phone (410) 528-4163 or E-mail cbak@lww.com.

PAID SUBSCRIBERS: Current issue and archives (from 1999) are available FREE online at 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.

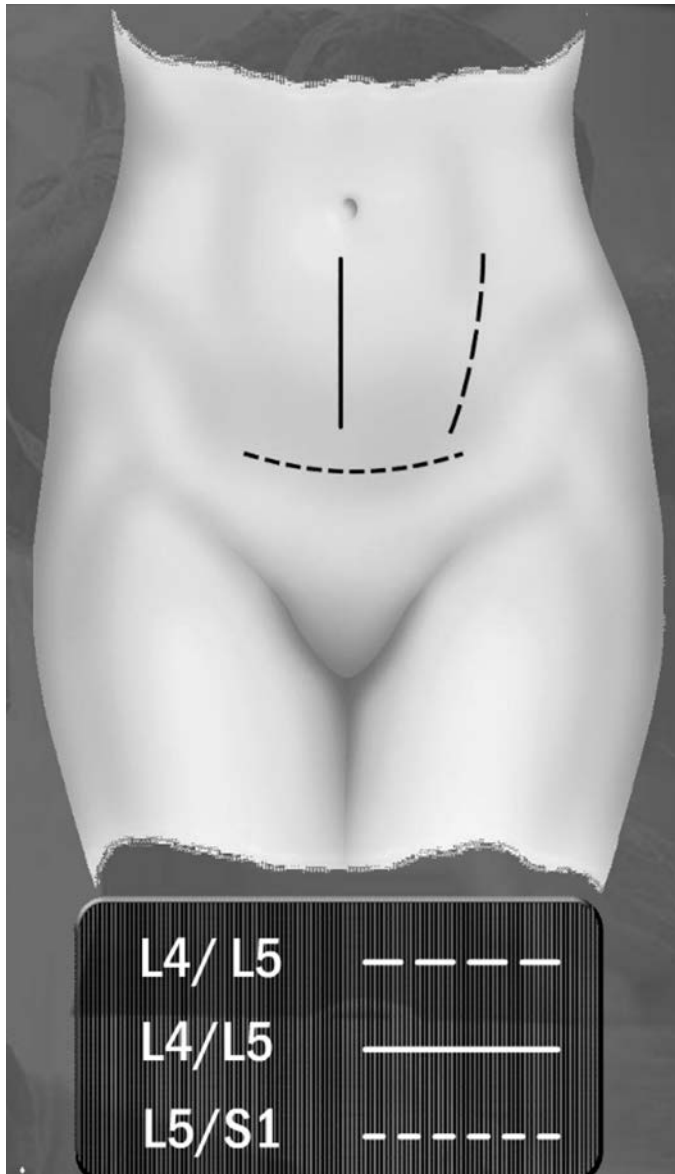


Figure 1. A left retroperitoneal approach incision (*solid line*) and dissection (*dotted lines*) carried down through the subcutaneous tissue.

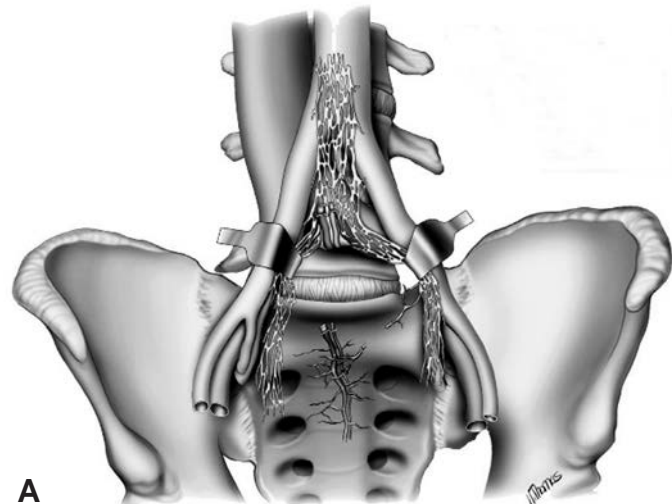
both difficult and of limited usefulness. An attempt is made to preserve the lateral portion of the annulus. A complete discectomy is performed using straight, angled, and ring curettes and Kerrison rongeurs. The cartilaginous endplates from the superior and inferior endplate surfaces also are removed. Extreme care is taken not to damage the bony endplates or encroach into the vertebral body. A rongeur is used to remove the anterior ridge of the vertebral body, the posterior ridge, and the dorsal and ventral osteophytes. A disc elevator, sharp Cobb elevator, or osteotome sometimes is used for this and also to loosen the disc material from the endplate surface and shave it down flat.

Carefully controlled distraction is performed in a variety of ways, depending on which device is being inserted. Care is taken to achieve adequate and parallel distraction, thus restoring the height of the disc and neuroforamen. Further meticulous removal of any residual disc material is verified, with special attention paid to the posterior lateral corners. The posterior annulus usually is released using an

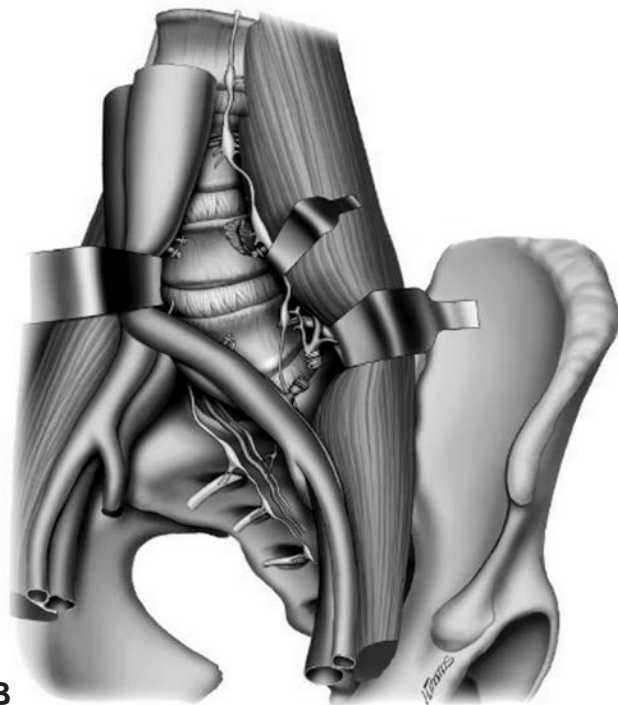
angled curette or similar instrument, with the position of the instrument confirmed on lateral fluoroscopy.

Some type of endplate sizing gauge usually is needed to size the endplates appropriately; this sizing also is confirmed using lateral fluoroscopy. Maximal coverage of the endplates should be achieved to reduce potential for subsidence. However, oversized endplates, especially those with square footprint designs, can cause neuroforaminal encroachment and postoperative radiculopathy.

At this point, it is very important to verify the precise midline of the vertebral body. Equal distances should be noted from the spinous process to the pedicles on AP fluoroscopy, and the spinous processes should be perfectly in line with one another (Fig. 3). Radiolucent trial sizers with various lordotic angles are used to select the appropriate



A



B

Figure 2. Exposure of the L5–S1 interspace at the bifurcation (*A*) and L4–L5 between vessels retracted to the right and the sympathetic chain to the left (*B*).

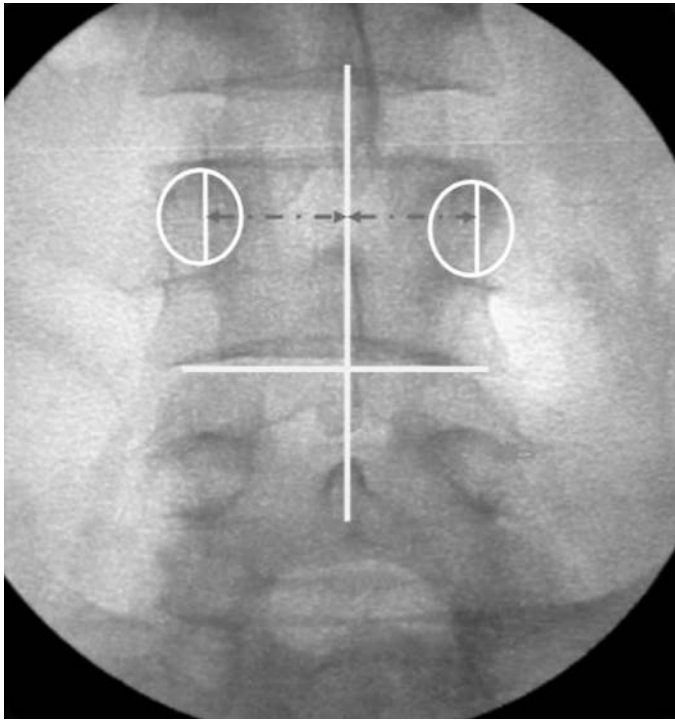


Figure 3. Anteroposterior (AP) fluoroscopic image during artificial disc replacement surgery showing equivalent distances from the spinous process to the pedicles, as used to verify that the image is truly in the AP plane. The spinous processes are perfectly in line with each other.

disc size, depending on the patient's anatomy and sagittal alignment. It is important to select the proper disc height and sagittal angle. Overdistraction of the disc space can have far worse consequences than loss of disc space height and could make it necessary to abandon the entire procedure and perform an anterior-posterior fusion. Degenerated discs usually are collapsed, and the vertebral column adapts to these new conditions over a period of time. If the selected disc height is too high, it could cause overstretching of the surrounding structures and lead to root stretch injuries, annular laxity, or implant failure in the long term. On the other hand, insufficient restoration of disc height can lead to overloading of the facet joints, with continued pain and, possibly, instability of the spinal column. All of the trial sizers have some type of marker to verify proper orientation both within the disc space and radiographically. For example, the Charité has a lateral "o" marker that represents the center of rotation and should be aligned on lateral fluoroscopy as a full circle 2 mm dorsal to the lateral midline (Fig. 4A) and a "+" sign that should align with the spinous process on AP fluoroscopy (Fig. 4B). The reasoning for this relates to the fact that the natural center of rotation in the spine lies at the two-thirds points of the disc space. Please see Part I of this article for more information.

After the correct size, angle, and position are ensured and the midline is verified, proper placement of the endplates of the artificial disc is ensured using a pilot driver. This step is important for all types of implants, but especially with the midline keel designs, because with this design the surgeon usually has only one chance to position the disc

correctly. Parallel positioning of the pilot driver and, ultimately, the implant is required to restore normal biomechanics. The selected endplates are loaded and inserted into the disc space. FlexiCore and Maverick prostheses are inserted in one piece, which reduces placement error possibilities and lessens the amount of distraction required because with these ADRs, it is not necessary to implant the inner core separately after placement of the metal endplates. The posterior position of the device is verified again on lateral fluoroscopy. For three-piece implant devices, sliding cores are then correctly sized and placed under careful distraction. Adequate positioning of the entire prosthesis

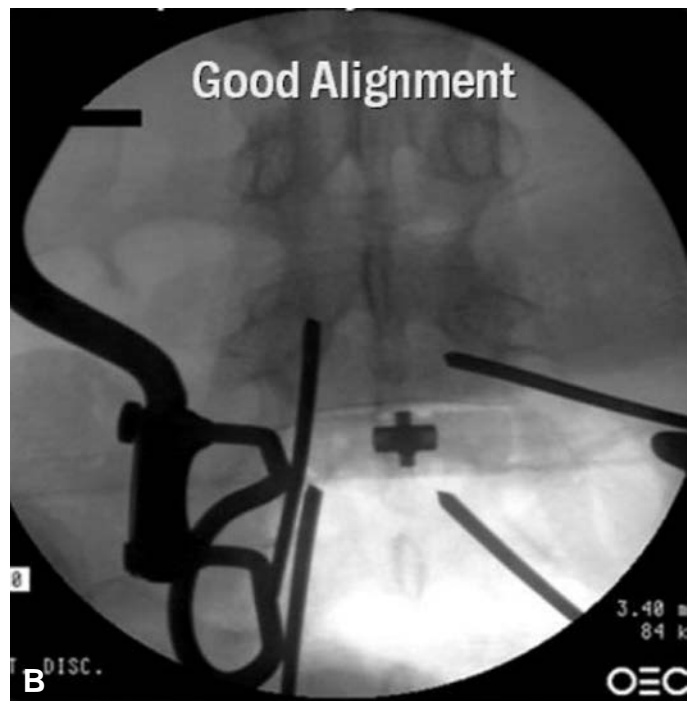
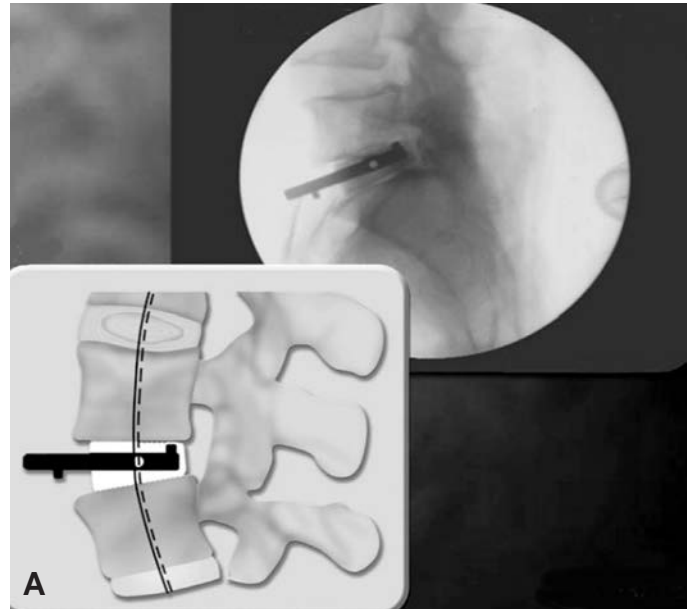


Figure 4. A, Lateral "o" marker used for the Charité represents the center of rotation, which should be aligned on the lateral fluoroscopy as a full circle 2 mm dorsal to the lateral midline. B, "+" sign on AP fluoroscopy verifies proper alignment with the spinous process in the AP plane.

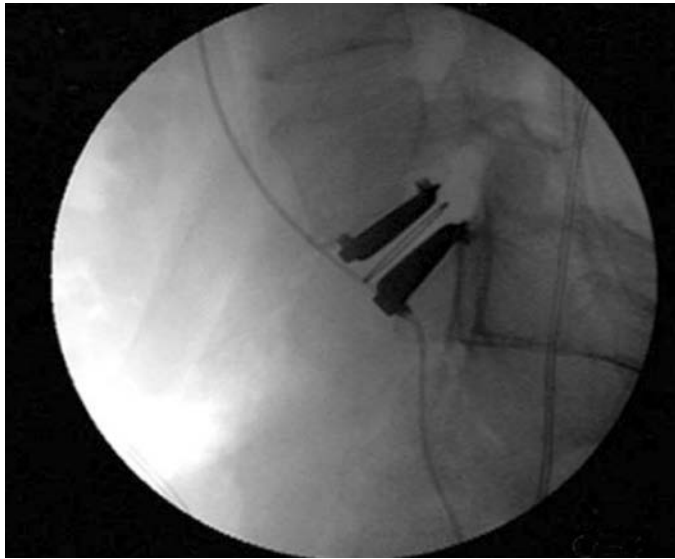


Figure 5. Intraoperative fluoroscopy confirming adequate positioning of the entire prosthesis.

(Fig. 5) is confirmed using intraoperative fluoroscopy. An impactor occasionally is used to make small adjustments and set the final location of the system at both upper and lower levels. Before the incision is closed, the status of the ureter and vessel should be verified.

Risks and Complications

Severe complications such as death, major bleeding, or severe nerve injury may be encountered. The risk of other complications, such as infection, minor bleeding, deep vein thrombosis, thrombophlebitis, ileus, or urinary retention, is approximately 5% to 10%. Male patients have a 2% to 10% risk of developing retrograde ejaculation, even when the operation is performed by an experienced surgeon.

Postoperative Management

Recuperation time after the arthroplasty procedure is comparatively short. In the multi-institutional FDA prospective randomized Charité artificial disc clinical trial, the mean hospitalization time was 3.4 days, and patients were able to return to work in 6 weeks, on average.

Physical therapy begins after the immediate postoperative period. Patients should begin to walk as soon as possible. Rehabilitation begins with abdominal flexion and active and passive hip and knee flexion exercises. After 4 weeks, physical therapy is directed toward maintaining mobility of the affected spinal levels, general conditioning,

and strengthening. Lumbar spine rotation, side bending, and abdominal strengthening can begin at 6 weeks.

Some surgeons advocate that patients wear a lumbar corset for 3 months after Charité ADR and for 2 weeks after implantation of the ProDisc. This measure usually is not required after Maverick device implantation, because the Maverick has a large central keel. Patients should avoid lumbar hyperextension, heavy lifting, impact-loading activities, and twisting after implantation of the Charité and should avoid mechanical vibration or shock for about 3 months when the ADR has been performed with the Maverick device. Jumping, running, or contact sports are not recommended for 3 months, but swimming usually can begin after 4 weeks. The patient should be weaned from narcotic medication as early as possible.

Artificial disc replacement surgery represents an exciting area of rapidly advancing spinal technology. However, spine surgeons should be aware that definitive evidence of motion preservation at the operated level and protection of adjacent levels from increased degeneration await long-term outcomes from the prospective clinical studies. Patient selection criteria and skilled surgical technique will have a significant impact on results, now that artificial disc devices are becoming available for widespread use in the United States.

Readings

- Bertagnoli R, Kumar S: Indications for full prosthetic disc arthroplasty: a correlation of clinical outcome against a variety of indications. *Eur Spine J* 11(Suppl 2):S131, 2002
- Delamarter RB, Fribourg DM, Kanim LE, et al: ProDisc artificial total lumbar disc replacement: introduction and early results from the United States clinical trial. *Spine* 28:S167, 2003
- Geisler FH: Surgical technique of lumbar artificial disc replacement with the Charité Artificial Disc. *Neurosurgery* 56(1 Suppl):46, 2005
- Geisler FH, Blumenthal SL, Guyer RD, et al: Prospective, randomized, multicenter, trial of artificial disc versus fusion for a single-level lumbar degenerative disc disease: a 2 year follow-up investigational device exemption study. *Neurosurgery* 55:453, 2004
- Mathews HH, Lehuoc JC, Friesem T, et al: Design rationale and biomechanics of Maverick Total Disc arthroplasty with early clinical results. *Spine J* 4(6 Suppl):268S, 2004
- Szpalski M, Gunzburg R, Mayer M: Spine arthroplasty: a historical review. *Eur Spine J* 11(Suppl 2):S65, 2002
- Tropiano P, Huang RC, Girardi FP et al: Lumbar total disc replacement. Seven to eleven-year follow-up. *J Bone Joint Surg Am* 87:490, 2005
- Valdevit A, Errico TJ: Design and evaluation of the FlexiCore metal-on-metal intervertebral disc prosthesis. *Spine J* 4:276S, 2004
- van Ooij A, Oner FC, Verbout AJ: Complications of artificial disc replacement: a report of 27 patients with the SB Charité disc. *J Spinal Disord Tech* 16:369, 2003
- Zigler JE: Lumbar spine arthroplasty using the ProDisc II. *Spine J* 4:260S, 2004

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 Wolters Kluwer Health by **September 29, 2006**. At the end of each quarter, all CME participants will receive a progress report detailing their activity. This report will contain the volume and issue numbers, issue dates, credits earned, and participant answers and correct answers to quizzes submitted. In addition, all participants will receive an annual certificate in February awarding the total credits earned during the previous year. 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: Wolters Kluwer Health **will not** mail certificates to online participants.

Wolters Kluwer Health is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

Wolters Kluwer Health designates this educational activity for a maximum of 1.5 category 1 credits toward the AMA's Physician Recognition Award. Each physician should only claim those credits he/she actually spent in the educational 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. Wolters Kluwer Health 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.

1. The ideal candidate for Charité artificial disc replacement surgery has single-level degenerative disc disease, disc height greater than 4 mm, osteoarthritic changes of the facets, no adjacent level degeneration, and intact posterior elements.
True or False?
2. CT or MRI is used to select appropriate footprint sizes before implantation of artificial discs.
True or False?
3. The ProDisc artificial disc is the only device that may be considered for implantation at two levels.
True or False?
4. Patients are required to undergo at least 6 months of conservative treatment with unsuccessful results to be eligible for artificial disc replacement surgery.
True or False?
5. The joint space of the L5–S1 vertebral bodies is accessed using the Omni retractor and retracting the iliac vessels to the right and the sympathetic chain to the left.
True or False?
6. Maximal coverage of the endplates should reduce potential for subsidence.
True or False?
7. Overdistraction of the disc space during insertion of the device has far better consequences than loss of disc space.
True or False?
8. FlexiCore and ProDisc prostheses are inserted in one piece, which reduces the amount of distraction required.
True or False?
9. Patients should wear a lumbar corset for at least 2 weeks after implantation of the Maverick device.
True or False?
10. The average time to return to work reported in the multicenter FDA prospective randomized Charité artificial disc clinical study was 6 weeks.
True or False?

Important Notice

We are pleased to announce that you can now take your continuing medical education quiz online and immediately print out your certificate. Please refer to the online instructions printed above the quiz in this issue.