A new artificial spinal disc for patients with lower back pain is generating a buzz. In October, the Food and Drug Administration (FDA) approved the first disc of this kind, the Charité Artificial Disc, manufactured by DePuy Spine, Inc, Rayn-ham, Mass.

This is the first of a wave of artificial discs for the lumbar and cervical spines that are expected to enter the market over the next decade as an alternative to spinal fusion. Unlike a spinal fusion, the artificial disc allows the spine to bend and twist after surgery.

Spinal surgery programs are gearing up for the new procedure, which has a steep learning curve for surgeons and requires new instrumentation and training for the staff. They also are investigating reimbursement for the procedure.

The disc consists of a plastic core of ultra-high molecular weight polyethylene sandwiched between 2 metal endplates made of a cobalt chromium alloy. The device helps restore the natural distance between the 2 vertebrae and preserves motion at the level where it is implanted.

The Charité disc was approved for use in patients who have degenerative disc disease at 1 level in the lumbar spine (from L4-S1) and who have had no relief from low-back pain after at least 6 months of nonsurgical treatment. The Charité disc has been used in patients in Europe for more than 17 years and is in use in more than 30 countries.

Orthopedic and neurosurgeons and medical device companies say artificial discs have strong potential because patients recover more rapidly and have more freedom of movement.

Three more discs with slightly different designs are expected to become available in the next couple of years. Artificial discs are projected to generate billions of dollars in revenue for medical device companies.

“Many enthusiasts for the artificial disc point to an increasing market for patients who will be eligible for spine surgery. Some who may not have been eligible for a fusion in the past may now qualify for a disc replacement,” says Stan Mendenhall, editor and publisher of Orthopedic Network News, Ann Arbor, Mich, a long-time observer of cost and quality issues in orthopedics.

Questions remain about artificial discs, he adds, including how long the implants will last and how well the procedure will be reimbursed.

How the disc is implanted

Implantation of the artificial disc is much more difficult than a fusion and should be performed only by the most experienced spine surgeons, says Fred H. Geisler, MD, PhD, a neurosurgeon at the Illinois Neuro-Spine Center, Rush-Copley Medical Center, Aurora, Ill, one of the lead researchers in the FDA trial. He has implanted more than 100 Charité discs in the past 4 years.

“We are recommending that surgeons be experienced with anterior spinal procedures, having done several hundred cases,” he says.

Complications can occur in the initial cases as a result of the disc not being seated properly, and the surgeons must go back and readjust it. There also can be nerve root injury or temporary nerve paralysis because of distraction of the disc space when the surgeon is preparing the vertebral bodies for the endplates and inserting the device.

Overall, the complication and reoperations rates with the Charité disc were no higher than with the BAK fusion control group, he says.

The disc is placed anteriorly through a 3-in to 6-in incision just below the
navel, depending on the patient’s size. Because the disc is inserted in the anterior column in the disc space, there is no way of placing it posteriorly, notes Dr Geisler. The anterior approach also is key to the quick recovery because when the back muscles are severed, as they are in a posterior lumbar fusion, it takes them 3 months to rebond to the bone.

The procedure involves a complete discectomy of the diseased disc and meticulous bone preparation for the endplates. Special attention must be paid to placing the implant’s endplates so they are parallel.

A set of custom instruments, which Dr Geisler helped develop, is used for cleaning the disc space and placing the implant. New instruments are needed because a discectomy is not normally performed from the front, and the surgeon must scrape the bone with a different type of precision, he explains.

In the clinical trial, the rates of adverse events from use of the artificial disc were comparable to those from conventional fusions. The trial involved 375 patients at 15 centers. After a 2-year follow-up, patients who received the artificial disc had similar outcomes to patients treated with anterior lumbar fusion.

With FDA approval, Dr Geisler expects the clinical inclusion criteria to broaden beyond the strict criteria used in the trial (sidebar), expanding to 2-level disc disease. But patients with spinal diseases such as osteoporosis, which can weaken the spine, and patients whose spines are severely damaged probably never will be eligible for the artificial disc because the spine would be too weak to hold the device.

Postoperative care is similar to that for abdominal surgery. Artificial disc patients don’t have a bone graft incision to recover from, and they don’t need a brace. They are not limited in mobility other than by their abdominal incision.

The hospital stay after an artificial disc procedure is about 4 days, whereas fusion patients are in the hospital about 5 days. Disc patients typically return to work in 4 to 12 weeks, while fusion patients usually do not go back to work for 4 to 6 months.

**Training for surgeons**

Only a few dozen surgeons in the US are qualified to implant the disc presently, though DePuy Spine’s parent company, Johnson & Johnson, plans to train about 2,500 surgeons during the next year. Currently, 15 centers in the US offer artificial disc replacement, but many more are expected to join in the next several months as surgeons are trained.

Surgeons attend a 2-day course at the DePuy Spinal Institute in Cincinnati. Surgeons who were involved in the FDA investigations participate in the training, which is both didactic and hands on. Afterward, newly trained surgeons visit and observe the investigational surgeons. The investigational surgeons then observe and assist the newly trained surgeons on their first cases.

“This is a brand-new technique, and we are trying to roll it out in a responsible manner,” says Dr Geisler.

Johnson & Johnson currently does not have training sessions for nursing personnel.

**Getting ready**

HealthEast, a Minneapolis-based health system, expects its surgeons to perform their first Charité artificial disc cases within the next month. HealthEast’s surgeons were in the first group of surgeons being trained in December. The hospital and physicians already have been receiving phone calls about the procedure and have patients waiting, says Julie Blatnik, RN, BSN, CNOR, the system’s program director for spine care.

Blatnik has talked with Johnson & Johnson about setting up a program at their hospital to train the nursing staff and physician assistants.

“The success of our program will be greatly influenced by the training of our nurses as well as surgeons,” she says. Because of the learning curve associated with the procedure, she plans to assign the same nursing personnel to work with the surgeons for their first 10 cases.
HealthEast is working on a contract with DePuy Spine on the cost of the implant. The company has proposed to provide the custom instruments if the hospital purchases a certain number of discs. This is similar to contracts for total joint replacements in which the instruments are provided with the implants.

Costs and reimbursement

HealthEast is beginning to talk with payers about coverage of this new procedure. A DePuy reimbursement specialist is working with them and has met with personnel from physicians’ offices and the hospital’s coding and billing staff, and the person who negotiates insurance contracts.

The cost of the surgical procedure plus implant is between $35,000 and $45,000, according to the Wall Street Journal. The list price of the three components of the disc is $11,500, says Blatnik.

Kathy Killeen, HealthEast’s orthopedic service line manager, thinks more insurance companies will begin to cover the procedure because patients are in the hospital a shorter time, and recuperation time is about half as long as that for spinal fusion.

Medicare presently covers the procedure under DRG 499 and 500 (back and neck procedures except spinal fusion), with a payment of between $4,700 and $7,200, which is less than the device alone. Killeen thinks the artificial disc warrants a DRG of its own. It has been given an ICD-9-CM procedure code.

Killeen says HealthEast is fortunate to have surgeons who are careful in patient selection and who make sure there is insurance coverage before they perform the procedure.

“I think it is fair to say that what is going to happen to reimbursement is not really worked out at this time,” Dr Geisler says. He notes the hospital was reimbursed during the FDA trial, and he is optimistic about receiving reasonable reimbursement for his future cases. He adds that he has a long list of patients waiting for the artificial disc. If their insurance will not pay for the procedure or they are unable to pay for it themselves, they will need to be treated with other methods.

How many fusions will be replaced?

The extent to which artificial disc replacements will replace spinal fusion procedures has been estimated to be between 0% to 50%, “with the higher estimates coming from those who have the most to gain from introducing new discs,” Mendenhall comments.

Industry analysts estimate that in 2005, the percentage of patients who may receive an artificial disc instead of fusion, will be less than 10% of fusion cases. About 200,000 lumbar fusions are performed each year in the U.S.

Dr Geisler predicts that in his practice, the disc will replace 10% to 15% of fusion cases. He says his personal results are better with the Charité artificial disc than with fusion in patients who meet the FDA trial criteria.

Long-term issues

How well will artificial discs hold up?

Revision surgeries after artificial discs have been rare in Europe where large numbers of patients have had the procedure and there are many years of experience, says Dr Geisler.

An FDA panel, while unanimously endorsing the Charité disc in June 2004, expressed several concerns, which Mendenhall says also were discussed at the meeting of the North American Spine Society this fall:

• how long the discs will last
• the ability to perform successful revision surgery
• prevention of adjacent segment disease.

Because the average age of a lumbar disc replacement patient is 35 years, the discs need to last 40 years. Some experts think there is no long-term survivorship data on polyethylene, and that it could fail, he notes. Another concern is particulate debris.
“We know about wear debris in total joints, and it took manufacturers 10 years to figure out that the plastic that came off from the metal rubbing against the head was causing some osteolysis and loosening of the stem,” says Mendenhall. In a long-term laboratory test of cyclical motion simulating more than 11 years of use with the Charité disc, no clinically significant wear debris particles were identified.

Revision surgery for artificial discs is complex, and there are questions about its safety. There have been 12 revisions performed in Europe, so they appear to be possible. Still, the FDA panel expressed concern.

Though it is believed artificial disc replacements, unlike spinal fusion, will not cause adjacent segment disease, panel members noted there was no evidence to support this belief.

—Judith M. Mathias, RN, MA

References


Patient selection for artificial disc

These are the criteria for patients in the clinical trial for the Charité artificial disc:

Inclusion criteria

Patients who:
• suffer low back pain
• are between 18 and 60 years of age
• have a diagnosis of degenerative disc disease at the L4-L5 or L5-S1 level
• have had at least 6 months of conservative treatment.

Exclusion criteria

Patients who:
• have had any previous back fusion surgery
• have multiple levels of degenerative disc disease
• suffer from osteoporosis, osteopenia, or other metabolic bone disease
• suffer from infection, spinal stenosis, spondylolisthesis, scoliosis, or spinal tumor
• have a history of chronic steroid use
• are pregnant or morbidly obese.
Artificial discs

Charité Artificial Disc: DePuy Spine
First artificial disc approved by the FDA in October.

FlexiCore: Stryker SpineCore
Clinical trials were initiated in August 2003 and are expected to last 2 years. The company should present data to the FDA in late 2005 and receive clearance in 2006.

Maverick: Medtronic Sofamor Danek

ProDisc: Synthes-Stratec
The ProDisc is expected to be the second artificial disc to reach the U.S. market. Clinical trials began in October 2001, and FDA clearance is predicted within 18 months.