Total Disk Replacement Offers Relief, Challenges

BY PATRICE WENDLING
Chicago Bureau

CHICAGO — The first artificial disk approved for use in the United States offers patients with chronic degenerative disk disease an alternative to spinal fusion surgery, but beware: Surgeons have a steep learning curve for placing the device correctly.

The primary advantage of the Charité Artificial Disc system by DePuy Spine Inc., a subsidiary of Johnson & Johnson, is that it offers pain relief, motion retention, and earlier return to normal function, Charité clinical trial investigator Scott Blumenthal, M.D., said in an interview.

The Charité disk, which was approved by the Food and Drug Administration in October, is indicated for patients with single-level degenerative disk disease. The device consists of two cobalt chromium end plates and a polyethylene core. There's no secondary bone graft harvesting or fixation of the spine with screws and rods to stabilize, as in spinal fusion surgery. When implanted, the device restores the natural distance between two vertebrae and allows movement at the level of implantation. And unlike the strict limitation imposed on patients who have undergone fusion surgery, when the disk is implanted successfully, there are no movement restrictions, said Dr. Blumenthal of the Texas Back Institute, Plano.

The European experience with the Charité, which dates back 2 decades, suggests it also may reduce adjacent degenerative disease better than fusion surgery, although this hasn't been specifically evaluated in clinical trials.

The FDA is requiring DePuy to conduct a long-term effectiveness and safety study of patients who have the device implanted, which will include assessing its impact on adjacent vertebrae, and on other bony structures in the back of the spine.

The artificial disk is currently being used at a handful of spine centers in the United States, and as more surgeons become trained in the procedure, it should become more widely available. Surgeon training is mandatory, and the learning curve is steep.

"This procedure is intended for experienced surgeons who already are familiar with the anterior approach to the spine," William Christianson, DePuy vice president of clinical and regulatory affairs, said in an interview. "These are for fellowship-trained surgeons who have a practice focused exclusively on the spine. We don't want knee arthroplasty guys coming to our course. They won't be able to get in."

There are about 2,000-2,500 surgeons in the United States who have the training and the experience to qualify for the course, he estimated.

A new study, evaluating the learning curve associated with Charité implantation in patients with symptomatic degenerative disk disease at L4-L5 or L5-S1, has shown that surgeons at high-volume investigational trial sites had shorter operative times (85 minutes versus 127 minutes), compared with surgeons at low-volume sites, John Regan, M.D., reported at the annual meeting of the North American Spine Society.

Patients at the high-volume sites also left the hospital 1 day earlier than patients in the low-volume group (3.5 days vs. 4.5 days). Major complications of neurologic deterioration (14.1% vs. 4.5%, respectively) and device failure (4 cases vs. 1 case, respectively) occurred significantly more often in the 85-patient low-volume group, compared with the 120-patient high-volume group.

Absolute change in visual analog scale (VAS) and Oswestry Disability Index scores was similar in both groups.

"Implant positioning is very important, and in our particular series at Cedars [Sinai Medical Center in Los Angeles] we noticed we improved from the first 10 to the last 10 cases," said Dr. Regan, who is a consultant for DePuy.

Surgeons new to the procedure should limit themselves to single-level replacement. However, two-level replacements have been implanted outside the United States, demonstrating that the technique is "very viable," said Dr. Blumenthal, who is also a consultant for DePuy and receives funds to lecture on the device.

Approval of the device was based on a 15-center study involving 304 patients who underwent back surgery for symptomatic disk degeneration that was unresponsive to 6 months of nonoperative treatment. Of the total, 205 were randomly assigned to receive a single-level Charité disk, and 99 received anterior lumbar interbody fusion using Bagby and Kuslich cages.

At 2 years of follow-up, those patients who had the artificial disk "did no worse" than those who had intervertebral body fusion with similar rates of adverse events in both groups, according to an FDA statement issued at the time of approval. There was no significant "relationship between motion at the level where the disk was implanted and the patient's relief from pain."

Mean operative time and estimated blood loss were similar in the two groups. Hospital stays were significantly shorter among Charité patients, compared with fusion patients (3.7 days vs. 4.3 days), Dr. Blumenthal reported at the meeting.

VAS scores improved significantly in both groups, although improvement was significantly greater among Charité patients at all but the 24-month follow-up. Oswestry scores, which measure disability and function, followed a similar pattern.

Among Charité patients, 73% were satisfied with their treatment at 24 months, compared with 55% in the fusion group. When asked if they would choose the same treatment again, 69% of patients in the Charité group responded "definitely yes" and an additional 13% responded "probably yes," compared with 52% and 13%, respectively, in the fusion group.

The device will be sold only to surgeons who have been trained by DePuy, and its Web site clearly states that patients should discuss with their surgeon whether they are candidates for the device, Mr. Christianson said. ■

Senior Writer Elizabeth Mechcatie contributed to this report.

Other Cervical Arthroplasty Options

The Charité Disc System might have made it to the market first, but several other cervical arthroplasty options are in the developmental pipeline. Here's a look at some of those devices under investigation in the United States and elsewhere:

► Bryan Cervical Disc System (Medtronic Sofamor Danek) was approved for use outside the United States in 2002, and is now being investigated in the United States.

Results from a multicenter prospective study of the Bryan disk showed positive clinical outcomes in both single-level and bilevel treated patients with disk herniation or spondylotic changes at the C3-C7 levels with radiculopathy and/or myelopathy.

At 2 years, 62% of 98 single-level patients and 59% of 41 bilevel patients were "excellent" according to modified Odom's criteria, Jan Goffin, M.D., reported at the meeting. At 2 years, 86% of single-level patients and 96% of bilevel patients had preserved motion of more than 2 degrees.

However, paravertebral ossification was observed on x-ray in 4 of the original 25 study patients at 4 years. The use of NSAIDs postoperatively seems to reduce this phenomenon, said Dr. Goffin, of University Hospital Gasthuisberg, Leuven, Belgium.

There was no evidence of adjacent-level degeneration in 15 of the 25 patients, although long-term follow-up of more than 5 years will be necessary to address this issue, Dr. Goffin noted.

In a separate yearlong study of 90 patients with radiculopathy and/or myelopathy, 16 patients or 18% had signs of heterotopic ossification following implantation of the Bryan disk, reported Clarence Leung, M.B., London.

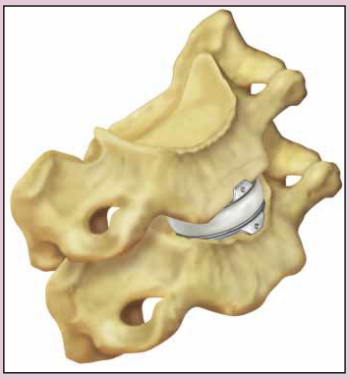
"In 10 patients, the artificial disk actually stopped moving at 1 year," Dr. Leung said.

Based on the McAfee classification, six patients had grade III and IV heterotopic ossification, which was strongly associated with loss of movement. Older males were more likely to develop heterotopic ossification, he said.

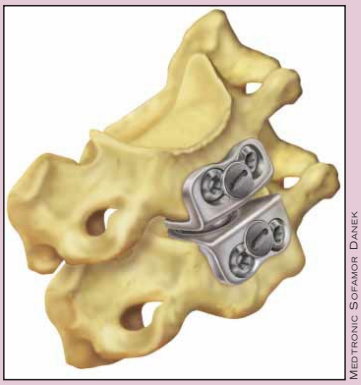
► PCM cervical artificial disk (Cervitech) is not yet in U.S. clinical trials.

In a study comparing the Bryan system with PCM or porous coated motion disk, the Bryan group had longer incisions and operative times, compared with the PCM group, reported lead investigator Luiz Pimenta, M.D., of the University of Sao Paulo (Brazil).

Both groups had minimal blood loss of less than 50 cc.



The Bryan cervical disk was approved for use outside the United States in 2002.



MEDTRONIC SOFAMOR DANEK

The Prestige cervical disk is now being tested in U.S. clinical trials.

Range of motion averaged about 8.3 degrees for flexion and extension in the PCM group vs. 4.5 degrees in the Bryan group.

Heterotopic ossification, which is strongly correlated with loss of movement, was present in 19% of Bryan patients, and in none of the PCM group.

In the Bryan group, there were no cerebral spinal fluid leaks, one anterior device migration, two postoperative cases of kyphosis, and three cases of fusion. By comparison, in the PCM group there were two intraoperative leaks, two device migrations, no kyphosis, and no cases of fusion.

► Prestige Artificial Cervical Disc (Medtronic Sofamor Danek) has been studied in clinical trials outside the United States and is currently in trials in the United States. In a small, prospective study, there was no statistical difference in any clinical outcomes at 1 year among 22 patients randomized to receive the Prestige disk and 48 patients who received anterior cervical diskectomy and fusion using cortical allograft and a cervical plate.

Patients treated with the Prestige disk showed improvement in all outcomes and maintenance of motion on x-ray, reported J. Kenneth Burkus, M.D., of the Hughston Clinic in Columbus, Ga.