Artificial Lumbar Disks Not Yet Widely Adopted

BY ALICIA AULT
Contributing Writer

Although the SB Charité III artificial lumbar disk has been available commercially in Europe since 1987 and in the United States since last November, some surgeons are reluctant to adopt the technology. And some American insurers still regard it as experimental.

The Food and Drug Administration approved the disk for 18- to 60-year-old patients with degenerative disk disease at one level, either L4/L5 or L5/S1. Contraindications include spondylothesis and osteoporosis.

Several surgeons, however, say they are cautious because few long-term outcomes have been published on the disk's durability, and few data support its hypothetical advantage: By preserving motion at the affected level, it will protect adjacent levels from further degeneration.

'I think there is use for this device, and I think there are potential benefits down the line.' But, 'we do not know the long-term complications.'

The SB Charité III was developed by two orthopedic surgeons in Berlin. Eventually, after a third design revision, the technology was acquired in 2003 by DePuy Spine, a division of Johnson & Johnson.

According to DePuy, 200,000 Americans undergo spinal fusion for degenerative disk disease each year. Surgeons say that so far, few patients seem to be candidates for the disk. "There are no real good indications for this product," said Greg Graziano, M.D., a professor in the departments of neurosurgery and orthopedic surgery at the University of Michigan.

Dr. Graziano told this newspaper that he believes the ideal candidate is someone who is young, has arthritic degenerative changes, and exhibits minimal posterior arthritis. A patient who needs spinal canal work or decompression surgery isn't suitable, he said.

The University of Michigan Hospital told insurers it was willing to reduce the surgical costs for 20 patients as a means of getting the procedure off the ground at the facility, Dr. Graziano said. But the disk itself is still in the $11,000-$12,000 range, and insurers have balked, he said.

In April, the Blue Cross and Blue Shield (BCBS) Association's Technology Evaluation Center issued a report stating that "current evidence supporting the effectiveness of the artificial vertebral disk is insufficient." The organization said there were methodologic flaws with the single randomized study used to win FDA approval, and it noted that the study only proved noninferiority to fusion with a Bagby and Kuslich (BAK) cage.

The technology assessments are meant as scientific opinions—although they sometimes form the basis for coverage decisions, a BCBS spokeswoman said. Individual BCBS plans are not under any obligation to follow the recommendations, she added.

DePuy Spine is working with the BCBS plans to provide further evidence that it is a superior technology, said Richard Toselli, M.D., vice president for research and development at the company. In an interview, Dr. Toselli said that several individual BCBS plans, along with Aetna, Kaiser Permanente, and 62 small regional carriers, are paying for implantation of the Charité disk.

"Some evidence shows that it's as good as standard fusion and perhaps better, but we don't know that yet," Ziya Gokaslan, M.D., vice chairman of the department of neurosurgery at Johns Hopkins Hospital in Baltimore, told this newspaper. Dr. Gokaslan said he has not yet implanted a Charité disk at Hopkins, but he has participated in the implantation of the device in Germany and Brazil.

"I think there is use for this device, and I think there are potential benefits down the line," he said. But he added, "We do not know the long-term complications of the implantation of this device," such as whether the plastic core will wear out. If early hip and knee implants are any indication, revisions and replacements could be required within 15-20 years of the original implantations, he said.

DePuy acknowledged that getting at the Charité disk for a revision can be difficult. The company said that if the disk has migrated from the disk space, it needs to be removed through an anterior approach and replaced with another disk or

via a fusion done either anteriorly and/or posteriorly. "If the device has not migrated, and the patient continues to complain of pain, then the revision strategy is to do a posterior fusion alone and leave the disk in place," Dr. Toselli said.

But the company said there's no indication the disks will have a short life span and that there have been few reports of complications in the 10,000 devices implanted worldwide. Dr. Toselli also cited a 10-year follow-up report on 100 cases, published in 2002 by one of the Charité pioneers, J.P. Lemaire, M.D. In that study, "no significant migration of the polyethylene" occurred in any of the implants, and there were only 2 cases (2%) of adjacent functional overload (Rachis [The Spinal Column] 2002;14:271-85). Overall, 62% of the patients had excellent results.

Surgeons need more experience in choosing the correct disk size and placing it properly. "There's an art to placing these things," Dr. Graziano said, adding that "the reproducibility between surgeons is not there yet."

DePuy has trained about 2,200 surgeons at its Center for Spine Arthroplasty at the Endo-Surgery Institute in Cincinnati. Surgeons can also train with or observe colleagues who have Charité experience at 50 regional sites.

Dr. Gokaslan and Dr. Graziano agree that artificial disks are at the stage interbody fusion cages were 10 years ago. An initial burst of enthusiasm was followed by the recognition that cages were not a panacea.

"It took 5 years to figure out who should get cages and who shouldn't," Dr. Graziano said.

Although patients are asking for the Charité disks, surgeons will likely resist the pressure, Dr. Gokaslan said. "It's hard to change the habits of surgeons when there is no serious evidence showing this is better than what they've done in the past," he said. ■

VERBATIM

'We saw one patient with ascites and one with congestive heart failure. We had enough Lasix for only one and had to make an ethical choice.'

Dr. Mark D. Dressner, on his first volunteer mission in Honduras, p. 62