

## An Alternative to Spinal Fusion

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Julie Cervinka, a 23-year-old legal secretary, had been eager for doctors at the Beth Israel Medical Center in Manhattan to implant an artificial disk called the Charité in her spine since the Food and Drug Administration approved the device on Oct. 26. Last week, Ms. Cervinka got her wish.

She was too deeply anesthetized to be aware of what she endured in her latest effort to escape the often disabling lower back pain she had suffered since age 9.

The surgeons carved carefully but relentlessly through her abdomen for nearly an hour to reach the diseased disk between her third and fourth vertebrae. Dr. Fabien D. Bitan, a spinal specialist, needed another 45 minutes to extract the compressed disk and pry apart the vertebrae into a more normal spacing. Only then, after carefully measuring the size and curvature of the cavity and selecting the version of the disk that fit most closely, did he hammer it into place, pausing frequently to check his progress on an X-ray machine.

Rough as the operation sounds, surgeons like Dr. Bitan view the implant, a sandwich of metal and plastic made by DePuy Spine, a unit of Johnson & Johnson, as a gentler and more effective alternative to spinal fusion for many patients. No one expects artificial spinal disks to spell the end of fusion, a procedure some 220,000 Americans undergo annually. But with DePuy's competitors racing to push other spinal disks through development and clinical trials, Wall Street sees the Charité (pronounced shar-ee-TAY) as the dawn of what could become another billion-dollar segment in the fast-growing orthopedics market.

"It's the first revolutionary improvement in spine surgery since Harrington in the 1950's," said Dr. Bitan, referring to Paul Harrington, inventor of the tools that made spinal fusion a common treatment for a variety of serious back ailments.

Artificial disks, which were introduced in Europe two decades ago, promise the same or better pain relief as spinal fusions, which protect degenerating natural disks from pressure by joining the vertebrae above and below the disk into a single immobile segment of bone. Their real advantage though, according to Dr. Bitan and other researchers, is that patients recover more quickly from insertion of disks, retain far more flexibility and are less likely to need further surgery than spinal fusion patients.

The Johnson & Johnson disk consists of cobalt-chromium endplates around high-density polyethylene. It is named Charité after the hospital in Berlin, where the first version of the device was created 20 years ago by Dr. Karen Buttner-Janzen, a former East German Olympic medalist in gymnastics.

Some of the anecdotal evidence for the Charité is impressive. The first European recipient of a Charité disk is still playing tennis 20 years later, according to Dr. Bitan. And Jeffrey Lee Gibson, a 46-year-old stunt man who received a disk two years ago as part of the trial of Charité in the United States, said he left the hospital the day of the surgery and was able to perform a four-story stomach-first fall for the television show "Third Watch" 12 weeks later.

But many American health insurers remain unpersuaded by experiences cited in Europe, where more than 6,000 patients have received disks over the years. Many doctors helping American insurance companies assess new technology say that the European studies do not rigorously track results in enough patients to know how long the disks last. Nor, they say, is there comprehensive data that clearly predicts what happens when they fail.

The main clinical trial data submitted to the F.D.A. by DePuy Spine tracked the outcomes for patients in the United States two years after receiving Charité disks or fusions.

"We are concerned about the quality of the long-term data," said Dr. Robert McDonough, medical director for the clinical policy unit of the giant insurer [Aetna](#). "The durability of the result is the most important factor in evaluating orthopedic technologies."

Still, the Charité sounded promising to Ms. Cervinka. Dr. Bitan had told her that her condition would otherwise eventually require the fusing of two joints. "I don't want to be limited," she said a few days before her operation, referring to the extreme stiffness that would have accompanied such extensive fusion. She underwent fusion two years ago to combat pain from degeneration of the lowest disk in her spine and obtained only temporary relief.

But the insertion of an artificial disk is not cheap - or easy on the patient. DePuy's list price for each disk and specialized instruments to insert is \$11,500, although hospitals ordering in quantities receive discounts. Depending on the complexity of the insertion, total costs run from \$30,000 to more than \$50,000 - a range that is comparable to spinal fusions.

Ms. Cervinka's doctors managed to squeeze between her intestine and major muscles in their approach to the disk, but still needed to cut and cauterize many other tissues. They had to slice ligaments covering the front of the disk, and they severed small blood vessels connecting a short stretch of Ms. Cervinka's spine to the two major circulatory pathways- the aorta and vena cava - so they could be moved out of the way.

Dr. Bitan was able to quickly cut away the nucleus of the disk, but scraping off the tough outer ring of cartilage took half an hour. "Because Julie's young, this stuff is tenacious," he said.

Most insurers are at least several months away from coming up with general policies on when they will cover the Charité, according to DePuy. For now, they are reviewing applications case by case - and denying many requests. Ms. Cervinka's operation is being covered primarily by Blue Cross Blue Shield of Illinois, her employer's insurer. Dr. Bitan said the insurer gave its

approval reluctantly, after long arguments on his part that multiple fusions were the alternative. The company said it did not comment on individual cases.

Dr. Robert Haralson, executive director of medical affairs with the American Academy of Orthopedic Surgeons, in Rosemont, Ill., said that as many as five more years of study might be necessary to answer the insurers' questions about durability.

DePuy says that despite the limited insurance coverage, demand for the Charité has outstripped the availability of the doctors trained to insert it. About 200 of the nation's 6,000 spine surgeons have made the trip to Blue Ash, Ohio, the Cincinnati suburb where the company runs its three-day training sessions. But 2,000 have signed up to attend. "We are booked for the next year," said William R. Christianson, vice president for clinical and regulatory affairs for DePuy.

Wall Street analysts say Charité may contribute around \$100 million to Johnson & Johnson's revenue next year - a pittance for a company expected to have total revenue of \$50 billion in 2005. But some predict \$1 billion in worldwide sales of artificial disks by 2010 when companies like Medtronic, Stryker, and Synthes of Switzerland are expected to have competitive products in the lumbar, or lower back, market that Charité is intended for, and once disks have been introduced for the cervical, or upper, spine.

Even advocates of artificial disks acknowledge that the devices are not likely to be a useful treatment for a majority of the tens of millions of Americans who report that they suffer from back pain, which has myriad causes. The sole back problem the new devices address is disk degeneration, which afflicts virtually everyone as they age but is also caused by disease and accidents. Replacing degenerating disks can be pointless or even counterproductive for patients who also have other back ailments.

"I've received over 500 calls since the F.D.A. approval, and over half are from people who aren't good candidates," said Dr. Scott Blumenthal, a surgeon at the Texas Back Institute in Plano, Tex., who participated in the clinical trials. DePuy has estimated that the F.D.A. approval will allow it to offer Charité as an alternative to 5 percent to 25 percent of the 220,000 Americans who receive spinal fusions annually. The approval covers replacement of one of the two lowest of the five lumbar disks in adults up to age 60 with degenerative disk disease and no past fusion operations. But the approval, like any such F.D.A. action on a drug or device, does not bar surgeons from "off label" uses that they believe are medically sound.

Ms. Cervinka, who DePuy estimated was among the first 30 patients to receive a Charité in the United States since it was approved, may be a harbinger of the developing off-label market. Not only had she already undergone a fusion, but the diseased disk Dr. Bitan replaced was further up her spine than the disks allowed for in the F.D.A. approval.

Tom Collins, a 63-year-old Montana rancher, had an off-label Charité procedure last week, having two disks replaced in one operation. The surgery was performed in Dallas by Dr. Stephen Hochschuler, a Texas Back Institute surgeon who had been one of the lead investigators in the clinical studies.

Mr. Collins said his back problems began in 1991 but that he did not view fusion as an option. "I know ranchers who have had fusions," he said. "Some worked, but others have had to go back for more operations."

Even seemingly ideal candidates may not benefit from the Charité. The clinical trial data DePuy submitted to the F.D.A. to prove that the device is at least as successful a therapy as fusion tracked just over 300 patients, concluding that 12 percent of Charité patients reported only minor pain relief after two years and 13 percent said their pain was the same or greater.

"They compare it to fusion, but the data we have on fusion isn't all that great," Dr. Haralson said.

Such failure rates explain why many medical device companies are working on less invasive alternatives to total disk replacement. Raymedica, for example, is a start-up in Minneapolis developing a plastic-encased protein gel that is injected into the nucleus of a degenerating disk to restore its shock-absorbing capability. The device is being marketed in Europe and is undergoing clinical trials in the United States.

Ms. Cervinka is recuperating at her mother's home in New Jersey, enduring back spasms and post-operative soreness, but happy that one familiar pain is missing - the one emanating from her diseased disk.

"I'm optimistic this is going to work," she said.