

# **A Government-Approved Artificial Disc Brings Only Mixed Results for People Suffering From Lower-Back Pain**

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Hratch Vranian's lower-back pain landed him in a study designed to test an artificial disc that his surgeon promised would be the cure he was searching for.

Before the experimental surgery, he rated his pain as three on a 10-point scale. Today, three years after the surgery to place the Charité artificial disc into the lumbar part of his spine, Vranian's pain scores have almost reached 10. The 49-year-old California man can no longer work, and lives on daily doses of morphine to alleviate pain.

Vranian is one of 3,000 Americans who have undergone surgery to implant the Charité artificial disc, made by DePuy Spine, a division of Johnson & Johnson with headquarters in Raynham, Mass. Last October, the Food and Drug Administration approved the device, the first of its kind for the lumbar spine. More than a dozen other companies are developing similar devices.

But a growing number of surgeons are concerned that the studies conducted on the Charité artificial disc were fraught with problems.

"I'd like people to really understand the risks and the limited benefits," said Dr. Sohail Mirza, associate professor in the department of orthopedic and neurological surgery at the University of Washington in Seattle. Two papers outlining the results of a study used to gain FDA approval were published last month in the journal Spine. Mirza wrote an editorial in that issue outlining concerns about the artificial disc. Several other surgeons worried about the Charité artificial disc wrote online commentaries for the journal.

"If you are doing it to treat back pain, it didn't show much effect," Mirza said. The one study reviewed by the FDA followed 205 patients with the implanted disc and compared them with 99 others who had a spinal fusion with a device called a BAK cage that was popular in the 1990s. "The BAK is no longer being used today because it didn't work," Mirza said.

## **57 percent success rate**

**The latest study in Spine reported a 57 percent success rate for the Charité. That meant no major complications, no surgery to remove the device and patients reported a 25 percent improvement in daily function. Pain itself was not something the researchers took note of. "Most people still had pain after two years," Mirza said. "Most people were still taking narcotics."**

"In any other surgical procedure a 57 percent success rate is nothing to be proud of," Mirza added.

He and others are concerned that millions of people suffer from chronic lower-back pain and lumbar disc degeneration, and that surgeons may be too quick to offer the artificial disc option without questioning the benefits and risks of long-term problems. The same artificial disc has been used in Europe for almost 20 years, but follow-up information on these patients is not readily available, Mirza said. One group in the Netherlands reported on complications in 27 patients, ranging from abdominal wall bleeding to erectile dysfunction and migration of the device that required surgery to move or remove it.

About 200,000 people in the United States undergo spinal fusion for lower-back pain every year. Since

federal approval last October, the company has been hosting training sessions for surgeons. The Charité device itself costs around \$12,000; surgery and hospital fees cost about \$30,000.

Dr. Richard Toselli, worldwide vice president for research and development at DePuy Spine, said 3,000 people in the United States have had the disc surgically implanted since last fall. As with all new federally approved devices, the FDA keeps track of adverse reactions.

"There have been issues related to the disc and its adoption," Toselli said. "But it is safe and effective when used in the proper patients."

#### Problems with early study

Like most surgeons, Dr. Charles Rosen, an associate clinical professor at the University of California at Irvine, was initially intrigued by the new technique. But when he began reading the fine print on the study results, he saw red flags everywhere. First, he said, the company failed to include the first 75 patients enrolled in the experimental surgical study. "These were called 'training' patients," said Rosen. "This represented 25 percent of their sample." An FDA bio-statistician, Jianxiong Chu, agreed at a public hearing that "excluding patients biased the results."

Then Rosen began seeing patients, including Vranian, who were having problems with the disc.

"Patients want these discs," said Dr. Robert F. Heary, a neurosurgeon at the Spine Center of New Jersey and a professor at UMDNJ-New Jersey Medical School in Newark. "They see artificial hips and knees and assume it falls into the same category. But they are very different joints. That is a very big leap of faith."

The surgery itself is also riskier than hip or knee procedures. The device is put in through a small opening in the abdomen, a technique to gain access to the spine and avoid direct contact with the nerves. But if something happens - if the device slips or wears down - surgeons can't go through the abdomen again without risking life-threatening bleeds, Rosen said.

"Revisions are considered a nightmare," Heary added.

"Patients need to think carefully about this device," said Mirza. "This is not like getting a new car part, where it's in and you are set to go. This is a big deal, and it's not something you can undo without great risk." He also worries that surgeons are operating on people who are a decade or so younger than those who have been seeking spinal fusion. It's not clear how long the disc will last.

"I am not sure I would put it in me," Mirza added. "So I would have a hard time putting it in one of my patients."

Rosen said he asked the company and the FDA for supplemental reports on disc complications, but the FDA viewed those numbers as proprietary and the company also said no.

Mirza, who sat through an intensive training program for surgeons, said the complications with the disc were covered in a talk over dinner, rather than in the course itself.

#### Surgery requires great skill

Dr. Fabien Bitan, chief of spine surgery at Lenox Hill Hospital in Manhattan, has probably done more Charité implants than anyone in the country, around 200. His first experience was as a resident in France in the 1980s, when the disc first came out. Later, he was recruited to help design the U.S. trial.

"Is it the final product? Probably not," he said. "The problem is that whatever you say works today is going to be wrong in 10 years. But this is most likely the future."

He said that the device is difficult to implant, and surgeons do have better outcomes the more operations they do with it. "You need a lot of skill in anterior spinal surgery," he said. He's satisfied with the results in his hands. So are most of his patients, he said: 60 percent of them are almost pain-free.

Vranian said he was drawn to the experimental surgery because of the enthusiasm of his surgeons. "It sounded too good to be true," Vranian recalls. "My expectations were so high because of what my surgeons told me."

Doctors agree that surgery should not be the first treatment option for lower-back pain from disc degeneration. Three new European studies show that patients do just as well with aggressive rehabilitation.

#### A SPINAL SUCCESS STORY

For the first time in years, 50-year-old Amy Ruth of Huntington Station can turn over in her bed at night without waking up.

A decade ago, Ruth was pulling up carpet when she fell backward and damaged her lumbar disc. She spent years swallowing over-the-counter pain medicines. Nothing worked to alleviate the pain. In 1999, the disc ruptured, and surgeons went in to clean up the debris. Still, the pain persisted.

Last January, her surgeon, Dr. Arnold Schwartz, who has a Melville practice, suggested the artificial Charité disc. She had avoided fusion, the mainstay for lumbar surgery, because she heard that the recuperation was long and the surgery didn't always work. She had the procedure done in June, after months of phone calls and letters to her insurance company to get the surgery approved. Finally, her husband's insurance came through.

"Now, I can sit and stand without a problem," she said. In fact, she's back to living. While it once took her four hours to get dressed, today she only needs a few minutes. "The pain I had lived with for years is gone," she said, adding that she has a new pain that travels down her leg every so often. Her surgeon said it will go away in time. "I'm very happy I had this done," she added.