Surgeon Creates Relief Device For Back Pain

Jon Walker

SIOUX FALLS, S.D. (AP) — Jackie McNamara has a bullet in her back.

A surgeon put it there.

Dr. Wilson Asfora calls the little device a bullet cage. It wasn't his idea, but he's refined the science and now has the federal government's blessing to use it in his corner of neurosurgical medicine at Sanford Health in Sioux Falls.

Asfora, 54, a native of Brazil, is a one-man conglomerate. He landed in Sioux Falls in 1991 by way of Harvard, Yale, San Francisco, Oxford and two universities in Canada. He's a father of two who plays guitar and soccer, owns a Brazilian grill, runs several businesses and has 33 engineers in Silicon Valley working on his inventions.

One such invention was his version of the bullet cage with supporting tools to drill into a patient's spine and relieve back pain. He used a model other medical investigators helped design and began serving patients with it in a trials starting in 1999. This August, the U.S. Food and Drug Administration gave its official approval.

McNamara went to Asfora in fall 2006 with recurring pain that followed the sciatic nerve into her right leg. "It got to be I couldn't stand and I couldn't sit," said McNamara, 48, principal at Cleveland Elementary School. "I had to ask, how was I ever going to be able to sit through a meeting or walk down the hall?"

Asfora drilled into her lower back, hollowed out a place in her spine and inserted the bullet cage. The device is so named for its bullet shape, an inch-long piece of titanium with screw threads that let it bore into bone and stay secure.

McNamara has an inch-tall vertical scar on her lower back as a reminder of the experience. But her problem is solved. "I seriously have not had any pain," she said.

Asfora said the bullet cage goes back to a doctor who grew up in Hawaii in the early 20th century. After the Pearl Harbor attack in 1941, the doctor repaired many backs of wounded men who would help rebuild the island. A veterinarian used a similar device on a horse in the 1980s, leading into a period where neurosurgeons began looking more intently at human applications.

A healthy spine is the key to a person's posture but also the nerve pathway from the brain to the body. Its bone structure is a succession of vertebrae cushioned by soft, intermittent discs that, if worn down or misshapen, lead to friction that can radiate extraordinary pain. The bullet cage replaces a worn out disc by restoring proper spacing between vertebrae.

The science led some surgeons to a frontal approach through the abdomen to reach

the lower back. Asfora looked for a rear approach.

"With my system, I can do the entire surgery through a minimally invasive procedure through the back," he said. "This way, I minimize nerve injury and I don't have to open the belly."

He uses a set of drills that look fit for an afternoon of picture hanging or bolting two-by-fours to build a shed. But they are part of the hardware that let him dial down the procedure to what he calls a minimal disruption of the nerves. "I do the entire surgery under the microscope," he said.

The procedure, including hospital care, can run $65,000 to $70,000 in fees before insurance, Asfora's office said.

Barriers of time, effort and FDA concerns Securing the government's approval was not without its bumps. The FDA issued a warning letter to Asfora in 2008 concerning his reporting on patient enrollment and complications in his trial surgeries. One study monitor was fired. Asfora said such letters from the FDA are not unusual in medical research, and he responded to the agency's concerns. "And that was the end of it," he said.

Another concern came years earlier as he began his trials. He needed 250 test-case surgeries as evidence of his method's worth. He found a group of physicians in Chicago who said they would use his instruments in trial surgeries but charge him $1,700 each time to record data. That would have cost Asfora $400,000 for the paperwork alone. He decided to do it himself, starting in 1999 on a trail that would take almost 10 years. He was an independent Sioux Falls surgeon then. He joined Sanford in 2007.

Clearance for market granted Last month, the FDA granted market clearance for the Asfora Bullet Cage, which specialists call a lumbar intervertebral body fusion device. Medical Designs, a Sioux Falls company Asfora owns, will manufacture and sell it.

McNamara was one of his 250 test cases. "I had tried physical therapy, cortisone shots, all the steps, and then was referred to Dr. Asfora," she said. She has a doctorate herself in education and said she was happy to be part of the surgeon's research.

Another case provides validation of device Another test case was Tom Lambert, a hospital worker who went to Asfora because of recurring lower back pain. Injections at the time were giving Lambert temporary relief.

"I'd be relieved but not pain free. As time went on, I wanted a permanent solution," he said.

That time was a day at work when he turned to speak to someone and had a pain so sharp that he fell to his knees. He went to the emergency room. The next day specialists took a magnetic resonance image, and the day after that Lambert was in

surgery with Asfora. Asfora stuck four bullet cages into Lambert's lower back along with two metal plates.

The bills for Lambert totaled $73,000 before insurance, but the procedure ended a problem.

"The only thing I notice now is if I lift something incorrectly, I'll get a little zing," he said.

Lambert, 47, is 5-foot-8 and 180 pounds. He works as a patient family advocate at Sanford Hospital in a job where he meets patients before surgery, measures vital signs, helps them dress and talks with their families. Much of that is hands-on work. "I'm lifting 150 pounds. If I lift it correctly I don't have any pain at all," he said.

Lambert's surgery was in summer 2003, four years before Asfora would join Sanford and the two men would be co-employees. The surgery was on a Friday. He was home that Sunday and would miss 12 weeks of work. His only rehabilitation assignment was to walk. He began with a cane but soon was on his own. He worked up to four miles a day walking around his neighborhood. "I think I even grew taller," he said.

McNamara, who lives in Harrisburg, said her one limitation is that she's not supposed to lift anything heavier than a gallon of milk. She had never been a runner but began training and ran the Sioux Falls half-marathon in fall 2007, a year after her surgery.

"It was just because I wanted to push myself," she said.

She now jogs 10 miles a week, does landscaping and other physical labor in her free time. During Labor Day weekend, she helped paint a house. She thought carrying around a metal bullet in her spine would mean she'd need to carry a card in order to get past airport scanners. But it's never been an issue.

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