For arthritis in the big toe, surgeons offer new option

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The big toe on Pattie Bostick-Winn's right foot was excruciatingly painful, likely the result of her 10 years as a professional dancer in Broadway-style shows. Often, she had to wear heels on the stage, and by

age 48, the cartilage had worn away between the bones connecting her big toe to the ball of her foot.

One option was to have a surgeon fuse the bones together with metal plates, but she worried that would limit her flexibility when she taught at her family's dance studio. Instead, she opted to have a new type of implant inserted between the bones, cushioning the aching joint.

The size and shape of a miniature marshmallow, the implant is made from saline solution and polyvinyl alcohol—the same material as in soft contact lenses. The material compresses slightly under pressure, much like real cartilage.

The type of cartilage on the ends of bones enables them to move with low friction, but when the smooth, whitish tissue wears away, the result is arthritis. For years, biomedical engineers have been exploring ways to regenerate that lost cartilage, with limited success, so device makers began to pursue synthetic alternatives. The one Bostick-Winn was considering, called Cartiva, is the first of its kind, approved in the United States in 2016 and used in Europe for years before that. So far, the material has held up well in the big toes of thousands of patients, and now is being tested in the thumb and knee. Other synthetic implants are on the horizon, including one in development by Kevin Mansmann, of Premier Orthopaedics in Paoli, Pa.

Bostick-Winn sought multiple opinions before deciding to move forward with the Cartiva implant, getting a thumbs-up from three out of four physicians she consulted.

On Dec. 3, she walked into an operating room at Pennsylvania Hospital, and a team led by orthopedic surgeon Keith Wapner went to work.

'Keep going!'

Bostick-Winn had no idea anything was wrong until one day last January, after she led a fitness class through an hour's worth of muscle-toning moves. When she stepped out of her car back at home, she felt a sudden stab of pain.

Always an active person, she had run both a 5K and a 10K race the week before with no ill effects, but now she could barely put any weight on the ball of her right foot.

"Something kind of triggered it for me," she said.

Her physician thought it might be a stress fracture or a sprain, but as the weeks went by, the pain did not get better. An MRI revealed that in addition to suffering from arthritis, she had developed a painful cyst in one of the bones.

She came to Philadelphia to discuss the Cartiva implant with Wapner, chief of foot and ankle services at Penn Medicine. He told her that the implant significantly reduced pain for most people. And even if it did not offer her relief, she could still come back and have the bones fused together.

On the day of the operation, the team started her on anesthesia at about 1:30 p.m.

The first incision was made a few minutes later. Wapner bent the toe back to expose the end of the patient's first metatarsal—the bone just behind the big toe—and trimmed away excess bone.

A surgical resident inserted a guide wire in the center of the end of the bone, then used that to position a reamer—a tool that would hollow out a round cavity for the implant to sit in. Little flakes of bone flew off to the side as the whirling device did its work.

The reamer had a ridge around its edge to tell the surgeons when to stop—a hole 10 millimeters deep, so that the 12-millimeter implant would protrude from the bone by 2 millimeters. Still, Wapner kept a close eye on his colleague.

"Keep going, keep going," Wapner urged. "Stop!"

The surgeon then used a plunger-like device to insert the implant, which expanded slightly to press against the sides of the bone cavity, holding it in place. The team sewed up Bostick-Winn's toe, and that was it.

Total elapsed time: less than 15 minutes.

Pain free?

Bostick-Winn was on her feet again within a few days, wearing a hard boot. It is too soon to tell how well it worked, as full recovery can take several months, but a 2016 study suggests that most patients have success.

Six months after getting the implant, patients reported an average pain score of 28.9 on a scale of zero to 100, down from 68 beforehand. By two years, the average pain score dropped to 14.5—virtually pain-free.

A second group of patients was randomly assigned to have the traditional approach—fusing together the bones in the big toe with plates. Their pain scores were even lower, though the joints were less flexible.

In 9.2 percent of implant cases, patients were not satisfied, coming back to have the device removed in order to undergo fusion. And 12 percent of the original fusion patients also required follow-up surgery.

In cases where the implant fails to provide relief, the issue is not the

device itself, said Judith F. Baumhauer, a professor and associate chair of orthopedics at the University of Rochester School of Medicine and Dentistry, who has done consulting work for the implant maker. Implants removed from patients years later have shown no signs of wear and tear.

Instead, one of three problems can occur, said Penn's Wapner:

The patient's bone is soft, allowing the implant to subside so that the two bones once again are jammed against each other.

The "capsule" of tissue surrounding the joint is stiff and fibrotic, preventing the patient from moving it without pain.

The patient has undetected arthritis in small bones beneath the metatarsal, called the sesamoids, which becomes apparent only after the implant is inserted.

Or, as Jane Langille learned, arthritis can develop in adjacent bones after getting the implant. A freelance health journalist who lives near Toronto, the 55-year-old had implants placed in both big toes, and had a split experience.

The left one worked like a charm. "I wouldn't even know I had an implant in there," she said.

But the right one was slower to heal, still somewhat painful after six months. And in follow-up visits, she discovered that arthritis had developed in adjacent bones in the foot.

"I was told: 'You have an arthritic foot. We bought you some time.' " Langille said.

Insurance companies reimburse about $8,000 for both the fusion and implant procedures, including anesthesia and surgeon fees, according to James Laskaris, a senior clinical analyst at MD Buyline, a subsidiary of Dallas-based TractManager, a purchasing and contract manager for hospitals. But some do not cover the cost of the implant itself—an additional $3,500 or so, said Michelle Ostrander, a product manager at Hayes Inc., another TractManager subsidiary.

Wapner said he still thinks of fusion as the gold standard, given its long track record. Though the joint is no longer movable, patients can compensate by flexing other joints in the foot—as tennis star Lleyton Hewitt did in 2012 after undergoing fusion.

But when flexibility is paramount—whether for sports, dancing, or simply wearing heels—Cartiva is an increasingly popular choice. Langille, for one, said her left foot is now entirely free of pain.

"It went back to feeling like a foot again," she said.