Artificial hips corrode, poisoning some patients, lawsuits say

January 31 2013, by Stacey Singer, Palm Beach Post

Soon after Scott Ebert had his arthritic right hip replaced at 48, he felt so much better he named his new puppy Stryker, after the cool-sounding brand of his hip implant. But his relief was short-lived.

Two months after surgery, Ebert's leg started giving way. His joint began slipping. Razor blades of pain pierced his foot. An inexplicably large bruise grew along his calf. An excruciating burning feeling filled his hip. His ears rang. Doctor after doctor didn't know why. Finally, blood tests showed the metal from Ebert's artificial hip was leaching into his bloodstream.

Six months after it was installed, Ebert's new joint had to be replaced. He's left with chronic pain.

Ebert's Stryker Rejuvenate hip prosthesis was supposed to have been the latest and greatest, a new modular design fitted perfectly to his anatomy, with a choice of stems to be planted into his thigh bone and a choice of necks to support a choice of artificial balls and sockets.

Instead, Stryker's Rejuvenate and ABGII modular systems were recalled in July. They are the latest entries in a gallery of recent hip implant product failures, failures that are shining a light on the need for a system that detects quickly when medical devices go wrong.

The failures appear to have metal and friction in common: metal-on-metal balls and sockets, metal-on-metal stems and necks. Friction

appears to cause wear that exposes bare metal to blood and nearby tissues. These traveling metal ions can promote inflammation, tumor-like swellings and muscle and bone degradation, according to physicians and research reports.

An FDA panel last summer found almost no good reason to use metal-on-metal hip implants after reviewing 17,000 reports of problems in about 500,000 patients with metal balls and sockets. On Jan. 9, Stryker told shareholders it expects the recall to cost it between $190 million and $390 million.

"We have been through a rash in recent years of all these device failures," said Boynton Beach, Fla., orthopedic surgeon Dr. Gregory Martin. "All the implant companies, when it first happens, say, 'Oh, it's just their problem.' Then we come to realize that certain people don't react well to the wear particles."

For a generation of baby boomers growing old and arthritic, total hip replacement is an increasingly common need. More than 1 million of the procedures are performed in the United States every year, and the number is projected to quadruple by 2030, propelled by the graying and fattening of America. Charges can run $50,000 or more per procedure in Florida.

Research shows that for patients with severe hip arthritis, joint replacement can improve quality of life and reduce pain. More than 90 percent of new hip recipients still have their artificial joints after 10 years, the industry reports. But consumers and their doctors alike are still unclear about which materials and surgical techniques are best. Lack of data leaves marketing campaigns and paid surgeon-consultants to tout their ideas.

Modular hip joints, with their interchangeable parts, were supposed to be

a design improvement on one-piece devices, allowing for a better fit, especially for more active, younger patients. Stryker and many other joint manufacturers used alloys of titanium and chromium cobalt to combine flexibility with strength, while avoiding the breakage seen in titanium-only stems.

But the combination instead seems to have led to microscopic cracks and wear at the neck early in the life of the Stryker joint. In a notice to surgeons, Stryker used the terms "corrosion and fretting." Tiny metal ions disperse into nearby tissues. In some patients, it appears these metal wear particles cause severe inflammation and pain, and over the long term, there is a concern they could cause cancer, studies show.

Boca Raton, Fla., retiree Dianne Pingel, 66, used to exercise at the YMCA and go for long walks with her husband. Now, she said she is lucky to walk to the mailbox.

She is recovering from five surgeries related to hip implants in succession. Her left hip was replaced in July 2011 with a Stryker Rejuvenate modular stem. Her right hip was replaced 14 weeks later, in October, also with a Rejuvenate device. The right one has since been removed, but the left hip device remains. It needs to come out.

Pingel's blood cobalt levels are abnormally high and MRIs show a tumorlike swelling on the remaining Stryker hip, something that had happened with the removed joint, according to a lawsuit she has filed against Stryker. She said she should've gone into surgery right away, but her doctors told her she wasn't well enough. Her surgery is now scheduled for Feb. 4. Her right leg had to be rebuilt by a trauma surgeon last summer after her first revision surgery went badly.

Removing an existing artificial hip and putting in another one is much more extensive than a first hip replacement. It requires a larger incision,

and the sawing away of significantly more bone. Surgeons are forced to pull out a device often firmly cemented into what's left of the patient's femur, attempting to minimize damage to what bone is still there. If the problem joint is surrounded by dead muscle and tissue, that must be removed, too.

Pingel's thigh bone broke during her revision surgery. With so much tissue loss, her artificial hip dislocated repeatedly. A series of new femur fractures erupted. Her surgeon told her the cobalt poisoning and surrounding tissue destruction caused bone to die. A titanium rod now supports her right leg. Basic movements like putting on shoes, using stairs or simply using a public restroom are extremely difficult, she said.

"I just never thought this is how I would have spent my first year of retirement, in and out of hospitals," Pingel said. "It's a lot for a person to go through."

She's angry with the manufacturer.

"They have jeopardized a lot of people," she said.

The Stryker modular hips were cleared for market in February 2009. By April 2012, the company was notifying surgeons of the risk of corrosion. Recalls in Canada and then the United States followed.

Pingel is the first Rejuvenate patient in the nation to sue Stryker, but she's hardly the last. She and Ebert are both represented by West Palm Beach attorney C. Calvin Warriner at Searcy Denny Scarola Barnhart & Shipley. Pingel's suit is one of nine that have been filed in Bergen County, N.J., where Stryker is based. The company, in its court response, denied the allegations. A company spokeswoman had little to add.

"As a matter of company policy, we don't comment on legal matters," said Stryker's Jeanine Guilfoyle.

Since taking Pingel's case, the attorneys have added 300 clients, Warriner said.

Warriner blames the product recalls on two factors: First, an approval process at the U.S. Food and Drug Administration that allows new medical devices into the market with minimal testing if they claim to be improvements on already approved devices. And second, government's lack of an independent and transparent system for tracking medical devices.

"What we need is a national device registry. They have it in Australia and Europe. Every single device implanted in a patient gets listed in a registry and they track these devices," Warriner said. "It is embarrassing that a country as advanced as ours doesn't have that."

The problems with Stryker's Rejuvenate and ABGII modular hip joints were revealed first not in the United States, where at least 20,000 were implanted over almost three years, but in Australia, where far fewer were implanted.

Australia picked up the problems first because of its national joint replacement registry, said Dr. Art Sedrakyan, director of the Comparative Effectiveness Research Program at Weill Cornell Medical College's Public Health Department in New York. Sedrakyan served on the FDA panel that reviewed metal-on-metal joints.

"We really need that large data capture system that goes back to regulatory agencies," Sedrakyan said. "Without information, we cannot inform patients."

A national joint registry could enable doctors to know with certainty that they were matching the right type of prosthesis to the appropriate patient because they could sort data based on patient characteristics. They could then assess product life and revision rates for their type of patient. Regulatory agencies such as the FDA could move quickly when problems arose. And it would cover not just artificial hips, but knees and other joints, too.

Now, the FDA asks companies to track their products and report back. But there is a lag time, and it's unclear what the failure rate is, because the data doesn't include the total number sold.

Medical device makers argue that a voluntary product registry is the right approach. The American Academy of Orthopedic Surgeons has given seed money to launch a nonprofit, the American Joint Replacement Registry.

The voluntary registry's executive director said the goal is to create the largest registry in the world, one similar to Australia's mandatory system. But the project has been thwarted by the lack of a uniform method for hospitals to scan data, such as a bar code. Instead, hospitals must assign a staff person to enter data. In 18 months, 116 hospitals have agreed to participate. The group hopes to attract more than 3,000. In addition, device makers need to develop a plan for adding serial numbers to actual devices without increasing risk of corrosion or metal exposure.

"Everybody says, 'Why haven't we done this in the past?' But really technology is just being brought up to speed where we can do it," said Jeffrey Knezovich, executive director of the Rosemont, Ill.-based registry.

Faced with a barrage of liability lawsuits, Stryker isn't saying what percentage of its joints have failed.

"Our decisions are based on evaluation of post-market surveillance data," Guilfoyle said in an emailed response to questions.

Boynton Beach retiree Branko Obradovic, 73, is also suing Stryker through Warriner. One of the facts that bothers him is his first surgeon's relationship with the company.

Dr. Robert B. Zann is listed as a consultant to the firm, a fact Obradovic said he didn't know. Company records show Zann was paid in the range of $225,000 to $250,000 for his consulting services in 2011, before the modular joint recall, plus between $25,000 and $50,000 for other services and less than $25,000 for research services.

Stryker's spokeswoman would not reveal the nature or length of Zann's consulting arrangement other than to confirm that there is no exclusivity requirement, and "absolutely no requirement for our consultants to use or refer others to use any Stryker products."

Zann did not return repeated calls requesting comment.

Stryker was one of five companies cited by the U.S. Department of Justice for having improper consulting arrangements with physicians in 2007. Stryker agreed to a monitoring program, and it was deemed compliant in 2009.

Obradovic asked another surgeon, Dr. Gregory Martin, to do the second revision surgery. He said he's doing somewhat better now that the joint is out, although he still suffers pain if he stays in one position too long, and he suspects the effects of cobalt poisoning are lingering.

"I'm very angry about the whole thing," he said. "They should know what they are putting in someone's body."

Ebert also was a patient of Zann's. He said it took Zann months to accept his complaints of slippage and pain and order a cobalt test. The cobalt test showed his joint was failing. When his surgeons finally opened his leg up, they found dead muscle tissue around the joint, and fluid-filled tumor-like growths. He said Zann apologized to him afterward for not listening sooner.

Ebert of Deerfield Beach, Fla., believes his case may have been the one that caused the company to finally take its problematic joint off the market, because Zann told him he sat a company executive down over dinner and told him the modular joints needed to be recalled. Stryker issued its product warning two weeks after Ebert's revision surgery, and the recall came shortly after Zann's dinner, which was over Father's Day weekend, Ebert said.

"It has totally ruined my life," said Ebert, a master automotive mechanic who works on semitrailer-tractor rigs. "I got pain in my leg all the time, my leg always gives out. I used to run all the time. I can't run. I can't play with my dog anymore."

Ebert's wife, Molly, pleads for answers about what to do now, because her husband's pain is still extreme.

"Who is working on this or finding out how to fix my husband and all of these other people who had the misfortune to get this hip?" Molly Ebert asked. "It's very disconcerting to hear your doctor say, 'I don't know.' We've gone to the Cleveland Clinic, Holy Cross, seen specialists. No one can give us any answers. I'm frightened for my husband."

—-

RECENT PROSTHETIC HIP RECALLS

The FDA encourages patients who have metal-on-metal hip replacements to follow up with their surgeons and seek regular blood tests.

2008 - Zimmer Durom Acetabular Component ("Durom Cup") label recall, because of surgical technique instruction issues. On the market with updated instructions, but, according to a company spokesman, no longer for sale in the United States due to lack of demand.

2010 - DePuy ASR Total Hip System, because of higher-than-anticipated revision rates according to non-U.S. joint registries. Off the market.

2012 - Stryker Rejuvenate and ABGII modular neck-stems because of corrosion. Off the market.

2012 - DePuy Orthopaedics unused custom hip and knee replacement implants; a warning letter from the FDA said that they had not been properly approved for use in patients, DePuy disagreed. Off the market.