Concerns Over 'Metal on Metal' Hip Implants

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By Barry Meier
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Gregory Smith was in severe pain after getting a hip implant and had it replaced two years later. He said it was "like having a fire taken out of your body."

Some of the nation's leading orthopedic surgeons have reduced or stopped use of a popular category of artificial hips amid concerns that the devices are causing severe tissue and bone damage in some patients, often requiring replacement surgery within a year or two.

In recent years, such devices, known as "metal on metal" implants, have been used in about one-third of the approximately 250,000 hip replacements performed annually in this country. They are used in conventional hip replacements and in a popular alternative procedure known as resurfacing.

The devices, whose ball-and-socket joints are made from metals like cobalt and chromium, became widely used in the belief that they would be more durable than previous types of implants.

The cause and the scope of the problem are not clear. But studies in recent years indicate that in some cases the devices can quickly begin to wear, generating high volumes of metallic debris that is absorbed into a patient's body. That situation can touch off inflammatory reactions that cause pain in the groin, death of tissue in the hip joint and loss of surrounding bone.

Doctors at leading orthopedic centers like Rush University Medical Center in Chicago and the Mayo Clinic in Rochester, Minn., say they have treated a number of patients over the last year with problems related to the metal debris.

Artificial hips, intended to last 15 years or more, need early replacement far more frequently for reasons like dislocation than because of problems caused by metallic debris. But surgeons say that when metal particles are the culprit, the procedures to replace the devices can be far more complex and can leave some patients with lasting complications.

"What we see is soft-tissue destruction and destruction of bone," said Dr. Young-Min Kwon, an orthopedic surgeon at Massachusetts General Hospital in Boston.

A recent editorial in a medical journal for orthopedic surgeons, The Journal of Arthroplasty, urged doctors to use the metal-on-metal devices only with "great caution, if at all."

The limited studies conducted so far estimate that 1 to 3 percent of implant recipients could be affected by the problem. Given the large number of people who have received metal devices, that could mean thousands of patients in the United States. Reports suggest that women are far more likely than men to be affected.

All the major orthopedics makers sell these devices. Several companies said in statements that the implants did not pose a significant risk and that the incidence of metal debris problems was extremely low.

For example, Zimmer Holdings, one of this country's biggest producers of artificial joints, said in a statement that published data "suggests that ion release levels from Zimmer's metal-on-metal hip systems are commensurate with other metal-on-metal systems in the industry, and are not associated with significant risk to patients."

But some surgeons are concerned that they may only now be seeing the leading edge of a mounting problem. The current generation of metal-on-metal devices is still relatively new, having been used increasingly over the last decade.

Studies show that the devices can shed atomic-size particles of metals like chromium and cobalt that can be readily absorbed by tissue or enter the bloodstream.

Surgeons at Rush University Medical Center have performed about two dozen replacement procedures because of metal debris over the last year, said Dr. Joshua J. Jacobs, the head the orthopedic surgery department there. A similar number of patients have had metal-on-metal hips removed at the Mayo Clinic, according to Dr. Daniel J. Berry, Mayo's head of orthopedic surgery.

Dr. Berry added that surgeons at the Mayo Clinic had reduced by 80 percent their use of metal-on-metal implants over the last year in favor of those made from other materials, like combinations of metal and plastic. Other doctors said that to be cautious they were also scaling back their use of the all-metal implants until the scientific evidence became clearer.

It is not clear whether some makers' devices are more prone to the debris problem than others. But some experts argue that some manufacturers, in a rush to meet the demand for metal-on-metal devices, marketed some poorly designed implants and that some doctors fail to properly implant even well-designed ones.

"It is a sad travesty," said Dr. Harlan C. Amstutz, an orthopedic surgeon in Los Angeles who helped pioneer hip resurfacing. "It is design-related and it is technique-related."

Dr. Amstutz, who developed a hip-resurfacing system sold by the Wright Medical Group, said he believed that resurfacing, which typically uses all-metal components, was safe. The procedure, which preserves more thigh bone than in a conventional hip replacement, is aimed at younger, more active patients who may need several hip replacements in their lifetimes.

Several orthopedic surgeons agreed that the procedure was generally safe. But those doctors said they were limiting resurfacing procedures to men under 55 with strong bones because other patients, including women, did not have good outcomes.

One hip device company, Smith & Nephew, which markets an implant called the Birmingham hip resurfacing system, said that data from an implant registry in Australia showed that fewer than 1 per-

cent of patients using that product had reactions to metal.

Another major producer, the DePuy Orthopaedics division of Johnson & Johnson, said that, “as with other materials, metal-on-metal wear debris may cause soft tissue reaction in the area of a hip implant in a small percentage of cases.”

All hip devices, regardless of the material, create debris as the ball rotates and rubs against the cup-like socket. But in metal-on-metal hips, either because of poor design or poor implant technique, the ball can sometimes press against the cup’s edge. This creates a chisel-like effect referred to as “edge-loading” that produces large volumes of microscopic metallic particles that can cause havoc in some patients.

Three years ago, for example, Gregory Smith, 35, of Milan, Ill., got a metal-on-metal joint to correct a congenital hip disorder. Mr. Smith, an unemployed heavy-equipment operator, said that he began experiencing severe pain almost immediately.

Finally, last year, he went to Rush University, where an orthopedic surgeon, Dr. Brett Levine, removed the device and replaced it. The soft tissue surrounding Mr. Smith’s left hip was severely inflamed, and some of it had died.

“It was like having a fire taken out of your body,” Mr. Smith said of the removed joint.

Dr. Levine said he was now replacing metal-on-metal devices at the rate of one a month. He said that the surgeon who had implanted Mr. Smith’s artificial hip had installed the cup component slightly askew. The misalignment, he said, probably would not have created a serious problem if the device had not been metal on metal.

“These implants are less forgiving,” Dr. Levine said.