Leaving no trace

Absorbable heart stent does its job then disappears

By JoAnne Viviano
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An interventional cardiologist said he is seeing success with a new heart stent that is absorbed by the body after delivering medication and helping to strengthen arteries in people with coronary artery disease.

The stent is used to hold open arteries clogged with plaque and disappears within about three years, leaving four small platinum markers embedded in artery walls so cardiologists know where it was, according to the U.S. Food and Drug Administration, which approved its use last summer. Before dissolving, it administers a drug that inhibits the growth of scar tissue and reblockage.

The hope is to restore damaged arteries to their natural state, said Dr. Steven Yakubov, an OhioHealth interventional cardiologist.

"We've never had a stent that goes away," Yakubov said. "This is a significant change in the way interventional cardiology will be practiced eventually.

"As these products become more refined and improved, I think absorbable stents will become the mainstream for therapy."

Manufactured by California-based Abbott Vascular, the Absorb GT1 Bioresorbable Vascular Scaffold System is the first fully absorbable stent approved by the FDA.

It is made of a biodegradable polymer, similar to materials used in other absorbable medical devices, such as sutures, according to the FDA. Abbott said the polymer metabolizes into water and carbon dioxide, allowing the artery to move, flex and pulsate naturally.

Traditional stents are made of metal and can be difficult for surgeons to work around if they have to revisit that artery in the future, Yakubov said.

Yakubov served as a primary investigator during clinical trials performed at OhioHealth Riverside Methodist Hospital and the OhioHealth Research and Innovation Institute. He estimates that he's successfully inserted about 30 of the new stents and said they are ideal for relatively young patients with arteries that are larger in diameter and have plaque but little calcification.

Stents have improved tremendously since they were first used in the mid-1990s, said Dr. Hadley Wilson, chairman-elect of the American College of Cardiology Board of Governors.

The first stents, he said, were made of thick metal. Now, surgeons are using the third or fourth generation of stents, which are finely crafted devices made of hybrid or alloy metals.

Dr. Steven J. Yakubov, MD, FACC, at the McConnell Heart Hospital at Riverside in Columbus, Ohio, was involved in the trial of a new absorbable stent and implanted it in patients while it was being investigated. [COLUMBUS DISPATCH PHOTO BY FRED SQUILLANTE]

Coronary artery disease affects 15 million people in the United States and remains a leading cause of death worldwide. It is caused by the buildup of plaque along the walls of the arteries that supply blood to the heart. Plaque is made up of cholesterol deposits; too much of it along the walls of the arteries can narrow them making it harder for blood to flow through the body.
For some people, unfortunately the first sign that they have CAD is a heart attack.

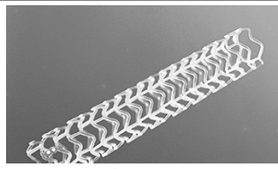
Source: Centers for Disease Control and Prevention

In 2003, drug coatings were added to the stents to prevent scarring and reblockage.

"Over the 22 years stents have been around, that's actually reduced the chance of blockage or re-narrowing from somewhere around 20 or 25 percent in all patients to sometimes 1 or 2 percent," said Wilson, an interventional cardiologist at Sanger Heart & Vascular Institute in Charlotte, North Carolina.

The incidence of clots forming at stent sites has been reduced from about 5 percent to less than 1 percent, he added.

"Stenting has revolutionized the care of patients with coronary artery disease, and we know it's dramatically reduced the need for bypass surgery," Wilson said.



The Absorb GT1 Bioresorbable Vascular Scaffold System, the first fully absorbable stent approved by the FDA, is manufactured by California-based Abbott Vascular. [ABBOTT PHOTO]

He said metal stents are still used in the majority of cases and that the use of absorbable stents is still limited to certain situations, mostly by the choice of patients who want nothing left behind that could impede natural dilation of the artery or potentially cause clots or issues with future surgery.

Coronary artery disease is the most common type of heart disease, killing more than 370,000 Americans each year. It is often treated using angioplasty, which involves sending a catheter to the blocked area, clearing the plaque with a balloon and inserting a stent to prop open the artery.

Once the artery heals, the stent is no longer needed.

In approving Absorb, the FDA referred to a trial that involved 2,008 patients and compared absorbable stents with metal stents. After one year, patients with the Absorb had a 7.8 percent rate of adverse cardiac events. That compares with a 6.1 percent rate in patients with metal stents. The FDA calls the two rates "clinically comparable."

Blood clots formed at a rate of 1.54 percent for the group with the absorbable stent, compared to 0.74 percent for those with metal stents.

Yakubov and Wilson said the increase in clots was due to patients having arteries that tend to be relatively small in diameter. Further, they said improved implantation techniques will help reduce the chance for such clots.

Wilson said such advancements should make the absorbable stent comparable to currently available metal stents.

— JoAnne Viviano writes about health for The Columbus (Ohio) Dispatch. She can be reached at jviviano@dispatch.com or on Twitter @JoAnneViviano.