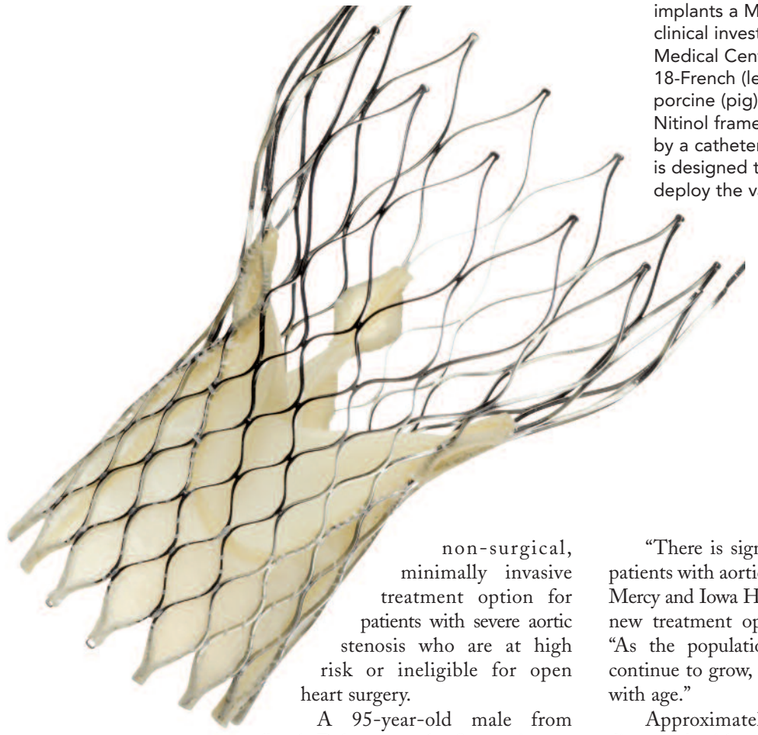
CoreValve Clinical Trial

Evaluating Alternative to Open-Heart Surgery

By Amy Bentz

Norma Smith can walk by herself for the first time in eight years after having a procedure currently under clinical investigation at Mercy Medical Center.

Mercy is just one of 40 clinical sites in the U.S., and the only one in Iowa, participating in a clinical trial to evaluate a revolutionary treatment for severe aortic stenosis, a common form of heart disease. Led by primary investigators Dr. Atul Chawla, an interventional cardiologist, and Dr. David Hockmuth, a cardiothoracic surgeon, Mercy and Iowa Heart Center are evaluating the Medtronic CoreValve System as a non-surgical, minimally invasive treatment option for patients with severe aortic stenosis who are at high risk or ineligible for open heart surgery.



Opposite page: Dr. Atul Chawla, interventional cardiologist, implants a Medtronic CoreValve system, currently under clinical investigation, in Norma Smith on July 15 at Mercy Medical Center. **Left:** The CoreValve System is sized at 18-French (less than 1/4 of an inch). It is made from porcine (pig) cardiac tissue fixed to a self-expanding, Nitinol frame and is delivered through the femoral artery by a catheter (long thin tube). The self-expanding frame is designed to help physicians control and accurately deploy the valve.

A 95-year-old male from South Dakota was the first patient at Mercy to receive the CoreValve replacement valve on July 15. He suffers from aortic stenosis, which prevents the heart's aortic valve from opening completely, thereby preventing healthy blood flow from the aorta to the rest of the body. Left untreated, aortic valve stenosis can lead to serious heart problems.

The second recipient of this treatment — Norma Smith, a 78-year-old female from Des Moines — also underwent the procedure the same day. She returned home three days later — compared to five to six days with traditional surgery. She will return in three and six months for follow-up appointments to make sure her heart is functioning properly and her blood thinning medication is adequate. Smith says she can't remember when she felt so good.

"I fee so much better," Smith said. "Not feeling good came on me little by little. The feeling good came all at once."

In the clinical trial, physicians channel a catheter with a prosthetic valve through a small opening in the patient's femoral artery in the leg to reach the heart. The physician then guides the CoreValve System to the aortic valve, where it self-expands (like a balloon) to replace the diseased aortic valve. Once the catheter is removed, the valve opens up so blood can pump through. The procedure is completed without open-heart surgery or surgical removal of the native valve and is typically referred to as transcatheter aortic valve implantation (TAVI).

"There is significant need for a new treatment option for patients with aortic stenosis, and it is enormously rewarding that Mercy and Iowa Heart can be part of evaluating this revolutionary new treatment option in our community," says Dr. Chawla. "As the population ages, the need for this procedure will continue to grow, as aortic stenosis is a condition that develops with age."

Approximately 300,000 people worldwide have been diagnosed with aortic stenosis. Of those, approximately one-third are deemed at too high a risk for open-heart surgery, the only therapy with significant clinical effect that is currently available in the United States.

"Because open-heart surgery is currently the only available treatment option for these patients, and because the risks of surgery can be significant for many patients, the medical community is enthusiastic about having a less-invasive option for these patients," says Dr. Chawla.

The procedure can be important for even the most senior patients – like the 95-year-old farmer from South Dakota.

"It's not necessarily the lifespan we're changing, but their quality of life and their ability to be productive in society," he said.

Two weeks after her procedure, Smith shopped with her daughter at the mall for the first time in a few years. Previously, she limited herself to her home and only went to stores with wheelchair carts or scooters.

The CoreValve System was first approved for use in Europe in 2007. Physicians there are training U.S. cardiologists on the first few cases. CoreValve is not yet approved for commercial use in the U.S. ✦

Learn more. For more information on the CoreValve clinical trial, visit www.aorticstenosistrial.com or call Mercy at 515-802-4057.