# Diseased heart valve replaced through small hole in the leg

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Physicians at the Methodist DeBakey Heart & Vascular Center in Houston implanted a new investigational heart valve in a patient through a small puncture hole in the leg.

Mr. Dale Wilber, 69 year old retiree from Arkansas, had the new valve implanted in Houston on Feb. 16, 2011. The disease restricted blood flow from his heart to his vital organs. This can weaken the heart over time and cause chest pain, fatigue and heart failure. By having a valve implanted through a small hole in the leg, he hopes to shorten his recovery time and prevent complications that sometimes occur after major heart surgery. Wilber is recovering comfortably in his hospital room, hoping to be on the road in his 40-foot motor home exploring the country with this wife soon.

The new procedure is part of a clinical trial designed to evaluate the safety and efficacy of the investigational valve as a treatment for aortic stenosis, a life threatening narrowing of a heart valve. Aortic stenosis occurs when the valve that controls the flow of blood out of the heart becomes hardened and narrowed. The condition is progressive and is seen more frequently as patients age. As the valve becomes narrow, the heart has to work harder, and eventually becomes unable to pump enough blood to supply the body's needs, a condition known as congestive heart failure.

The only treatment available in the United States is a form of open heart surgery in which the diseased valve is removed and replaced with a new

one. In patients with severe aortic stenosis who are fit enough to tolerate the surgery, the operation is life saving.

Worldwide, approximately 300,000 people have been diagnosed with this condition. However, in approximately one-third of patients who have aortic stenosis, the risk of open-heart surgery is too high, largely as a result of advanced age or other medical conditions. Traditionally, a valve is replaced with a tissue or mechanical valve during open-heart surgery, which requires a surgical incision in the chest and is usually followed by a recovery period that lasts several months.

The trial being performed at Methodist is studying transcatheter aortic valve implantation (TAVI). TAVI is being studied in part to evaluate whether recovery times can be shortened and whether the side effects of major surgery can be avoided, all while producing an outcome that is as good as that which results from traditional open heart operations. The trial incorporates expertise of both cardiac surgeons and interventional cardiologists.

"Using this technique, we make a small puncture hole in the individual's groin and thread a catheter through the femoral artery into the heart," said Dr. Michael Reardon, cardiac surgeon at Methodist and surgical principal investigator on the trial. "We deliver the valve to the site of the diseased aortic valve through the catheter, then deploy the new valve inside the individual's original valve, thus providing the patient with a functioning valve to allow for effective blood flow."

"It is very important that we find new ways to treat severe aortic stenosis, and to extend it to people in whom the current treatment options are limited," said Dr. Neal Kleiman, director of the catheterization labs at Methodist and cardiology principal investigator for the trial. "As the population ages, the need for this procedure will grow, as aortic stenosis develops with age."

In the U.S., this system, called the Medtronic CoreValve System will not be commercially available until the successful completion of this clinical trial and approval by the U.S. Food and Drug Administration (FDA). The CoreValve System received CE (Conformité Européenne) Mark in Europe in 2007.

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