

Nation's First Trans-Apical Aortic Valve Replacement at Medical City Dallas

By Tina Cauller

The most common acquired cardiac lesion in adults is calcific aortic valve disease with stenosis, a progressive condition that can eventually necessitate replacement of the diseased valve with either a prosthetic or bio-prosthetic valve. In the U.S., about 70,000 patients require heart valve repair or replacement surgery each year. The rate of aortic valve replacement increases significantly after age 75 and is becoming more common as the American population ages.

As aortic stenosis progresses, the heart must compensate by working harder to pump blood out of the heart. Ultimately, the condition results in episodes of hypotension or loss of consciousness, and fluid

may accumulate in the lungs, creating pulmonary congestion.

Similarly, when the aortic valve leaks, the heart pumps less efficiently and has to work harder. In this case, the ventricle must contract more forcefully to produce the same forward output, which results in volume overload.

The heart compensates for the inefficiency associated with a leaky or narrowed valve by working harder, which causes progressive damage to the upper and lower chambers. In time, the heart may lose the ability to compensate, causing the patient to experience angina, shortness of breath and fatigue. If the heart begins

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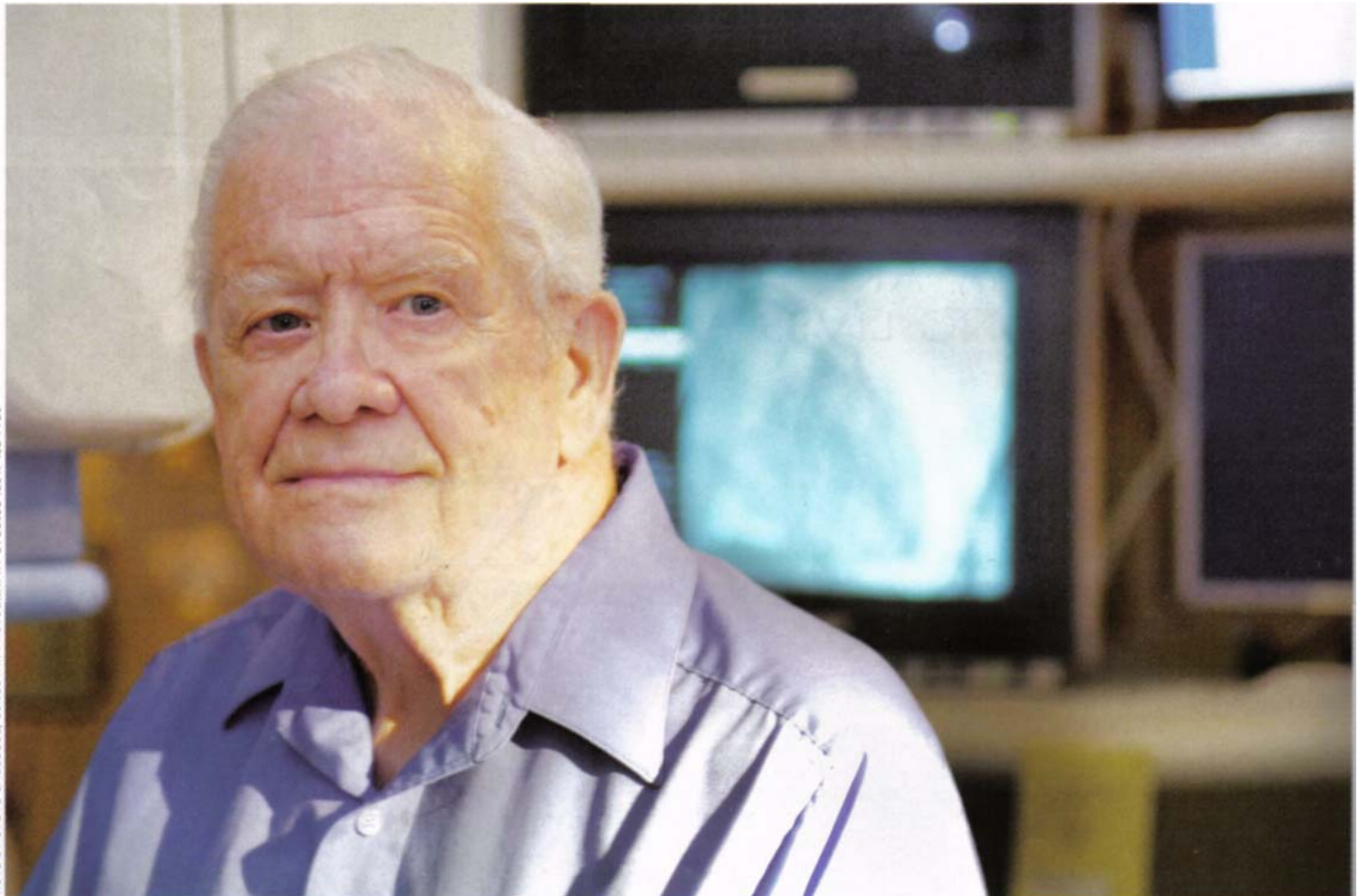


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The Cribier-Edwards percutaneous aortic heart valve (Edwards LifeSciences Corporation, Irvine, CA) is a balloon-mounted tissue heart valve that is compressed to about 8 mm diameter and delivered percutaneously through the patient's circulatory system directly into the heart. The surgical technique for implanting the experimental device was developed over the past three years by Medical City physician/researchers in partnership with colleagues at other sites in Leipzig, Frankfurt, Vienna and Vancouver.

to enlarge or the patient begins to experience symptoms, valve replacement may be performed to lower the risk of future heart failure and improve life expectancy. Left untreated, aortic valve disease eventually leads to death.

Traditional valve replacement surgery is a major, invasive procedure that requires thoracotomy and cardiopulmonary bypass. Unfortunately, a high percentage of the patients who need valve replacement are elderly or have other medical conditions that make them poor candidates for open thoracic surgery, leaving them with few options for effective treatment and a dramatically shortened life expectancy.

That disheartening scenario was personal for Isaac Phillips. At 79, Mr. Phillips was feeling so weak that the short walk to his mailbox left him breathless. He had already undergone two heart bypass operations and suffered from coronary artery disease and aortic valve disease. Doctors at Medical City believed that implantation of an experimental heart valve using a minimally invasive procedure known as trans-apical heart valve replacement surgery was Phillips' only realistic hope for survival.

The aortic valve implant was developed in conjunction with professor Alain Cribier, M.D., Chief of Cardiology at the University Hospital in Rouen, France. The device was specially designed to provide hemodynamic improvement in patients with severe aortic valve disease who are considered to be too high risk to tolerate conventional open-heart valve replacement surgery. The Cribier-Edwards percutaneous aortic heart valve (Edwards LifeSciences Corporation, Irvine, CA) is a balloon mounted tissue heart valve that is compressed to about 8 mm diameter and delivered percutaneously through the patient's circulatory system directly into the heart. The surgical technique for implanting the experimental device was developed over the past three years by Medical City physician/researchers in partnership with col-

During the trans-apical aortic valve replacement surgery, the replacement tissue heart valve is compressed, loaded onto a balloon-expandable stent, and delivered to the patient's malfunctioning heart valve through a percutaneous catheter under fluoroscopic guidance. Once positioned within the existing aortic valve, the new valve is expanded by the balloon. The replacement valve pops open, pushes the diseased valve's leaflets against the aortic wall, and immediately takes over its function.

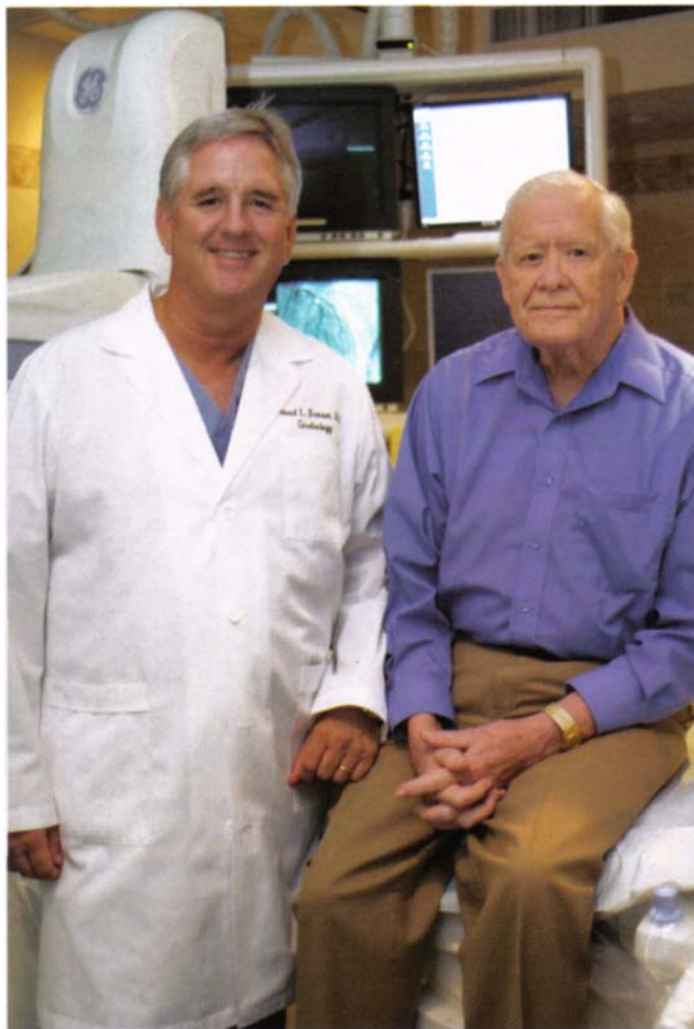


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Once animal studies were completed, Todd Dewey, M.D., Surgical Director of Heart Transplantation and Mechanical Circulatory Support at Medical City Dallas and active researcher with the Cardiopulmonary Research Science and Technology Institute (CRSTI) in Dallas, along with Michael Mack, M.D., Medical Director of Cardiovascular Disease and Transplantation and CRSTI Chairman, and David Brown, M.D., a leading cardiology researcher with CRSTI, trained for two years alongside German surgeons to perform the procedure.

Since the trans-apical heart valve replacement surgery had not yet been performed in the U.S., Medical City's team of cardiac surgeons and cardiologists requested special permission from the Food and Drug Administration for "compassionate use" of the procedure to treat Mr. Phillips. Taking into consideration the team's extensive training abroad, the FDA granted permission to use the device outside the clinical protocol. Drs. Dewey and Brown implanted the device in Isaac Phillips on August

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Conventional valve-replacement surgery is a four- to six-hour procedure that requires opening the patient's chest, stopping the heart and using a cardiopulmonary bypass machine to manage circulation for a minimum of an hour. In comparison, the trans-apical procedure takes about two hours and is performed on a beating heart using local anesthesia. No cardiopulmonary bypass machine is required.

That fact, in combination with the minimally invasive trans-apical surgical approach, represents a significant decrease in complications

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Ten days after surgery, Mr. Phillips (pictured here with David L. Brown, M.D., Todd M. Dewey, M.D., Mrs. Phillips and Michael J. Mack, M.D.) was released from the hospital and continues to do well. He walks one mile on an indoor track every day and is steadily regaining strength and vitality. For him, the innovative procedure has meant a world of difference.

and mortality for high risk patients, a shorter hospital stay and faster recovery. Although its long term durability is unknown, the replacement valve is expected to last 10 years or more.

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Dr. Dewey notes, "The complexity of the trans-apical aortic valve replacement surgery demands a collaborative effort between surgeons and cardiologists to plan treatment and bring their collective expertise to the operating room."

In the near future, this minimally invasive, beating-heart valve-replacement procedure may provide an alternative to traditional open-heart valve surgery and offer new hope to other high-risk patients for whom traditional surgery is not an option. Dr. Dewey notes, "This procedure is sure to revolutionize the way we think about thoracotomy in cardiovascular surgery and to transform the way we perform valve replacement surgery. We look forward to its continued evaluation and eventual release to the medical marketplace, because of the significant number of patients who can be expected to benefit."

Medical City Dallas is now screening patients for a national research trial planned to begin in mid-October. Medical City Dallas is one of the initial sites enrolling patients for the implantation of this valve, using not only a trans-apical approach but also a percutaneous trans-femoral approach. At present, other participating sites include Cleveland Clinic and Columbia-Presbyterian Hospital in New York.

For more information about Medical City Dallas or the trans-apical aortic valve replacement procedure, call (972) 566-7000 or visit www.medicalcityhospital.com.