HeartWATCH

SUMMER 2004

A NEWSLETTER PRODUCED BY THE TEXAS HEART INSTITUTE

TEXAS HEART® INSTITUTE
at St. Luke's Episcopal Hospital

Innovative Device Addresses Mitral Valve Regurgitation Percutaneously

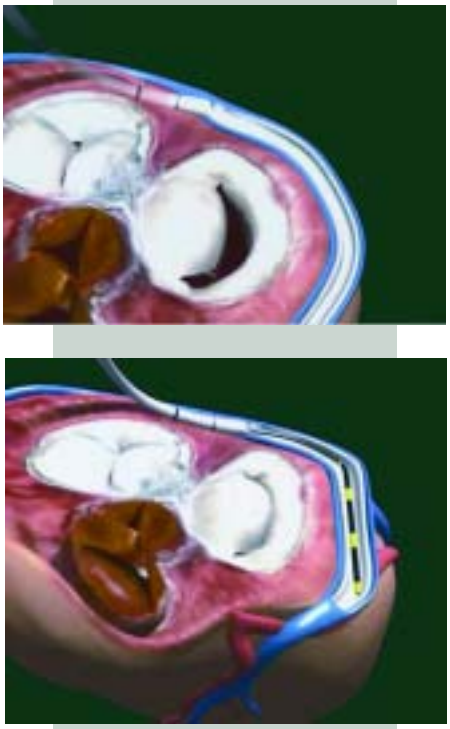
Abstract: A catheter-based device for mitral valve repair may offer a new treatment option to patients with mitral valve regurgitation and heart failure.

At present, congestive heart failure (CHF) with mitral valve regurgitation (MR) affects approximately 1 million persons in the United States alone. In patients with CHF, the heart enlarges to compensate for its decreased pumping efficacy. If this enlargement stretches the mitral valve so much that it cannot fully close, MR will result. This condition has serious implications for CHF patients; only 40% of those with both CHF and moderate or severe MR survive for more than 5 years after the initial diagnosis, as opposed to 55% of patients with CHF only (*Am J Cardiol* 2003;91:538–43). Open surgical repair with annuloplasty is the standard method of correcting dilated mitral valves, but because CHF patients with MR tend to be older and in more fragile health than other CHF patients, open surgery is not always advisable.

A new device that may present an alternative to open repair has been devised by a team of 3 heart surgeons: William E. Cohn, MD, director of Minimally Invasive Surgical Technology at the Texas Heart Institute at St. Luke's Episcopal Hospital (THI/SLEH); John Liddicoat, MD, of the Beth Israel Deaconess Medical Center in Boston; and Marc Gillinov, MD, of the Cleveland Clinic.

"Using fluoroscopic guidance, we thread a catheter into the internal jugular vein, through the right atrium, and into the coronary sinus—a large venous structure that forms a semicircle around the mitral valve," Dr. Cohn explains. "We then advance our device, a thin alloy rod, down the lumen of the catheter. The geometric and mechanical properties of the rod enable it to push the posterior portion of the mitral valve anteriorly, which may improve mitral valve coaptation and function. This approach is attractive because it can be done without stopping the heart or opening the chest."

The MR repair device (Percutaneous Transvenous Mitral Annuloplasty [PTMA™] device; Viacor, Inc., Boston, MA) is now being tested in humans in the early phase of a US Food and Drug Administration–sponsored trial at the Cleveland Clinic.



Digital rendering of a regurgitant mitral valve before (top) and after (bottom) introduction of an innovative repair device into the coronary sinus around the valve.

"The data from our short- and long-term use of the device in animals have been encouraging so far," says Dr. Cohn, "and the results of our recent clinical trials suggest that the device can be just as effective in patients. In the current pilot study, the rod is inserted briefly and then removed before the patient undergoes a standard mitral valve operation. On average, the rod decreases the diameter of the mitral valve annulus by about three quarters of a centimeter, markedly reducing MR for as long as the device is in place."

Dr. Cohn plans to conduct a clinical trial of the PTMA device at THI/SLEH in the near future. He will also continue to develop and test other cardiovascular surgery devices in both animals and humans. His previous inventions include the Cohn Cardiac Stabilizer (a frame that holds the heart in place for off-pump coronary artery bypass graft surgery and that has been used in more than 70,000 procedures) and the NextStitch heart valve implantation system.

The PTMA device would not be the first tool to be evaluated at THI/SLEH for its ability to address heart valve dysfunction percutaneously; cardiologists R. David Fish, MD, and David Paniagua, MD, have designed a collapsible prosthesis for intravascular replacement of the aortic valve (see *Heart Watch*, Spring 2004).

"We're moving into an era in which surgery will be less traumatic for patients than it once was," Dr. Cohn says. "The PTMA device represents one more step in that direction." ●

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Clinical Trials Update

THI is participating in a multicenter clinical trial of the Epic heart valve, a porcine valve designed to last significantly longer than current replacement valves. Already approved for use in Europe, Canada, and parts of South America, the valve has been implanted in 32 patients at THI and in more than 300 patients nationwide. Surgeons who have implanted the device here, including Drs. Michael Duncan, David Ott, George Reul, and Ross Reul, report favorable responses and no complications so far. Study participants will be followed up for 5 years.

Nation's First Stem Cell Therapy Trial Underway for Adult Patients with Advanced Heart Failure

Abstract: A single-center stem cell trial recently approved by the US Food and Drug Administration is now underway in adult patients at THI/SLEH.

The first clinical trial

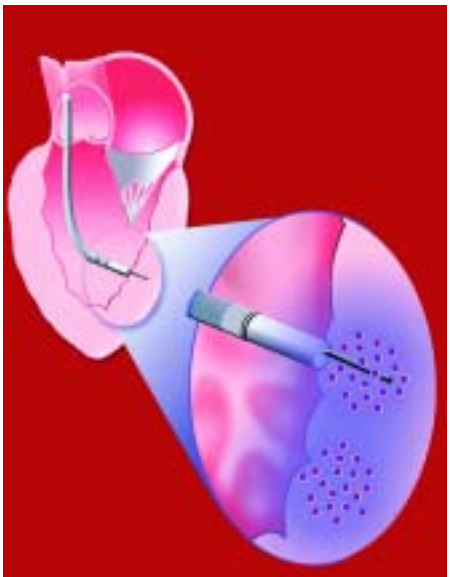
in the nation to explore the safety and efficacy of stem cell therapy for adults with advanced heart failure has begun at the Texas Heart Institute at St. Luke's Episcopal Hospital (THI/SLEH). Led by Emerson C. Perin, MD, PhD, director of New Cardiovascular Interventional Technology, and James T. Willerson, MD, medical director and director of Cardiology Research, the trial was approved by the US Food and Drug Administration in March 2004.

"In a previous trial in 21 patients at the Hospital Procardiaco in Brazil, we injected 30 million stem cells into each patient's left ventricle with the aim of inducing vasculogenesis and possibly generating new cardiac muscle," says Dr. Perin. "After 1 year, the patients who received stem cell therapy reported feeling significantly better and showed objective evidence of improvement, including longer treadmill exercise performance and enhanced myocardial perfusion on single-photon emission computed tomography."

Although it remains unclear whether the stem cells caused this clinical improvement by becoming new vascular and cardiac muscle cells or by stimulating the development of one or both types of cells, the treatment protocol itself proved safe and effective.

With the same protocol, the THI/SLEH clinicians are using an electromechanical mapping (EMM) system and a special catheter threaded through the groin for the procedure. First, they identify ischemic but still viable myocardium in the left ventricle via EMM; then they guide a specialized injection catheter to the intraventricular target site. There, they directly inject millions of autologous bone-marrow-derived mononuclear stem cells.

"Having performed more than 500 such procedures with an excellent safety profile, our team is the most experienced in the world with endocardial EMM, so we are confident that the protocol is safe," says Dr. Perin. "Consequently, the focus is now on establishing the therapy's efficacy in promoting new blood vessel formation and improving perfusion and myocardial contractility."



Technique for delivering autologous stem cells to the left ventricular myocardium via a specialized injection catheter. (From *Circulation* 2003;107: 2294–304; with permission.)

The THI/SLEH trial will enroll 30 patients younger than 70 years old who have functional class III or IV angina or heart failure symptoms, myocardial ischemia, and LV dysfunction refractory to maximal medical therapy. The trial will exclude patients whose vascular anatomy precludes cardiac catheterization; who have a recent history of cancer, high-risk acute coronary syndromes, or myocardial infarction; or whose left ventricular wall at the planned injection site is less than 8 mm thick.

To date, 3 of the planned 30 participants have been enrolled. Eventually, 20 will be chosen randomly to receive stem cell injections; the remaining 10 will undergo the mapping and injection procedures but will not receive stem cells. All will be blinded to the type of treatment they receive. For 6 months after treatment, all participants will return regularly for noninvasive tests, angiography, and neurologic monitoring for any cerebral embolic damage. Because of the frequent follow-up visits, participants will have to live or stay in the Houston area during the study period. After 6 months, patients who did not receive stem cell therapy will be told of this fact and will then be given the option to receive the therapy.

"Because 550,000 new cases of advanced heart failure are being diagnosed each year in the United States and annual health-related costs are spiraling as high as $40 billion, new treatments are urgently needed," Dr. Willerson says. "We hope to give patients with severe ischemic heart disease who have exhausted their medical therapeutic options a safe, effective alternative to standard surgical revascularization procedures." ●

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Contents

Hybrid Technique Offers Alternative to Open Repair of Thoracoabdominal Aortic Aneurysms

Abstract: Open-repair and endovascular techniques are being combined to exclude thoracoabdominal aortic aneurysms safely and effectively in certain high-risk patients.

The traditional treatment

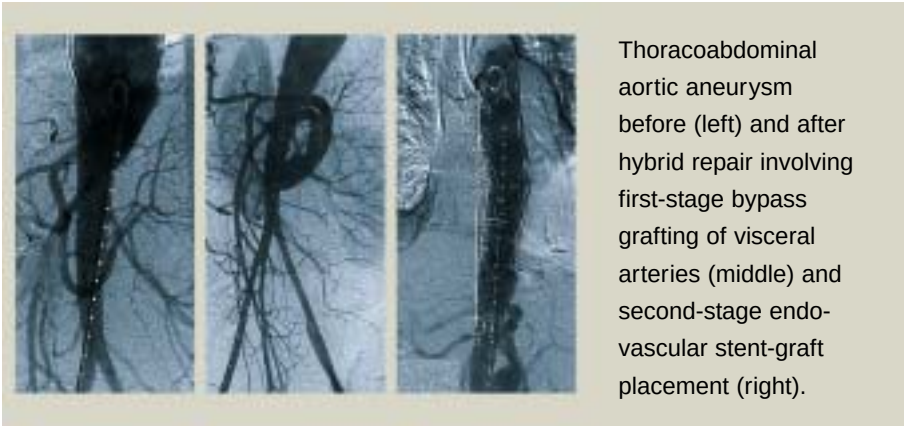
for thoracoabdominal aortic aneurysms (TAAAs) is open surgical repair. However, in high-risk patients, this approach is often associated with high morbidity and mortality attributable to the large size and location of these aneurysms, the potential involvement of other visceral arteries, the frequent presence of prohibitive comorbidities (e.g., hypertension, coronary artery disease, obstructive pulmonary disease, or congestive heart failure), and the complexity and extent of the surgical repair procedure itself.

To address this problem, cardiovascular surgeons and interventional cardiologists at the Texas Heart Institute at St. Luke's Episcopal Hospital (THI/SLEH) and elsewhere are combining less extensive open-repair techniques with new endovascular techniques to exclude TAAAs safely and effectively in certain high-risk patients.

"The risks of open surgical repair are magnified in sick or elderly patients, who would likely respond poorly to a highly invasive procedure," says cardiovascular surgeon James J. Livesay, MD. "The combined approach avoids a thoracotomy, uses a much smaller incision, and avoids cross-clamping of the aorta, thus preventing potential cardiopulmonary complications, reducing operative time, blood loss, and postoperative pain, and allowing quicker recuperation."

Doctors at THI/SLEH have begun using and refining a hybrid technique that is especially suited for high-risk patients whose TAAAs involve one or more visceral arteries. The two steps of the hybrid procedure can be performed in a synchronous or staged manner. In either case, the involved arteries are first bypassed with woven Dacron grafts, and then the TAAA is excluded with a catheter-delivered stent-graft. So far, only the staged procedure has been performed at THI/SLEH, but a special operating suite is being equipped to handle the synchronous operation.

One potential problem with the hybrid approach to TAAA repair is the need for adequate landing, or attachment, zones for the endovascular stent-graft.



Thoracoabdominal aortic aneurysm before (left) and after hybrid repair involving first-stage bypass grafting of visceral arteries (middle) and second-stage endovascular stent-graft placement (right).

"Without such landing zones, the stent-graft may not be able to extend far enough away from the aneurysm and remain securely in place after deployment," says interventional cardiologist Neil E. Strickman, MD. "This poses a special problem if the planned landing zone includes the origins of one or more visceral arteries. In such cases, the deployed stent-graft might block blood flow to those arteries, leading to life-threatening abdominal ischemia."

During the hybrid procedure, surgeons circumvent this problem by creating visceral artery bypasses, which divert arterial blood flow to organs downstream (e.g., the kidneys or intestines) while simultaneously creating a suitable landing zone for the distal end of the stent-graft.

The first patient to undergo the hybrid procedure at THI/SLEH was an 85-year-old woman with a TAAA and abdominal pain related to intestinal artery occlusion. The procedure, performed by Dr. Livesay and interventional cardiologist Zvonimir Krajcer, MD, involved bypassing the intestinal and renal arteries first, then placing a stent-graft several months later. One week after the first-stage operation, the patient returned home symptom-free; 2 days after the second-stage procedure, she resumed normal activity.

"More recently, we performed this hybrid procedure in a severely ill, alcoholic patient with cardiopulmonary and liver disease, whose aneurysm stretched from the supraclavicular to the infrarenal region and involved both the superior mesenteric and celiac arteries," says cardiovascular surgeon Igor D. Gregoric, MD. "We bypassed both arteries via a laparotomy. Six weeks later, after the patient had fully recovered, we excluded the aneurysm. The patient went home the next day, and the endovascular exclusion remains intact 6 months later."

"Despite the hybrid procedure's newness and technical requirements, we are encouraged by the short-term results thus far," notes Dr. Krajcer. "It safely and effectively addresses a complicated and otherwise potentially untreatable disease while decreasing the operative risk and recovery time. Thus, the hybrid technique appears to be a promising alternative to traditional open repair of TAAAs." ●

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Gender-Related Differences in Cardiovascular Disease Prompt Clinical Initiatives

Abstract: Gender-related differences in patients with cardiovascular disease are prompting the establishment of gender-based clinical studies and programs.

Cardiovascular disease (CVD) is the leading cause of death in women of all ages, killing more women than cancer, accidents, and diabetes combined. It also affects women more often and more severely than it does men. Since 1980, according to the American Heart Association, CVD-related mortality has generally been decreasing for men but increasing for women. Therefore, the role of gender-related differences has become an important issue.

Although the principal risk factors for CVD (smoking, high cholesterol, diabetes, high blood pressure, and family history) are the same for men and women, women tend to be older when they first experience cardiovascular problems and tend to have different signs and symptoms. In a recent study of 500 women who had an acute myocardial infarction (*Circulation* 2003;108:2619–23), most patients did not experience chest pain, a traditional warning sign of heart attack in men; instead, the most frequent premonitory symptoms—fatigue and sleeplessness in the month preceding the infarction—were nonspecific.

Cardiovascular disease–related mortality by gender, 1979–2001. (*Source*: American Heart Association.)

"More and more, we're finding that men and women differ in the way they experience CVD and respond to treatment," says Nancy A. Nussmeier, MD, director of Cardiovascular Anesthesia Research at the Texas Heart Institute at St. Luke's Episcopal Hospital (THI/SLEH) and editor of an ongoing series of articles in the *Journal of Thoracic and Cardiovascular Surgery* concerning gender-related issues in cardiovascular surgery. "For example, women with coronary artery disease tend to present later and with more advanced disease and more comorbidities than do men, and they tend to have poorer postsurgical outcomes."

Several reasons for these findings have been proposed. One is that women generally have a smaller body surface area and smaller arteries, which may complicate treatment of coronary, carotid, and infrainguinal arterial disease and treatment of abdominal aortic aneurysms. Another proposed explanation is that women may be more likely than men to develop diastolic dysfunction and periprocedural congestive heart failure.

However, firm evidence for these and other gender-related differences in CVD is generally lacking. According to Dr. Nussmeier, only 25% of patients enrolled in cardiovascular research studies are women, despite greater efforts since the early 1990s to include them in sufficient numbers to address gender-related differences. Moreover, current guidelines for the care of women with CVD are derived from studies conducted primarily on middle-aged men. Therefore, some diagnostic tests and procedures may not be as effective or accurate in women.

THI/SLEH is now addressing gender differences through clinical research and care. Dr. Nussmeier is leading 2 clinical studies that specifically target women undergoing coronary artery bypass grafting. One study is evaluating the safety and efficacy of a recombinant complement receptor designed to inhibit complement activation associated with cardiopulmonary bypass and thereby reduce morbidity. The other study is investigating whether estrogen administration during and after surgery can reduce transfusion requirements and improve surgical outcomes.

Recently, a THI/SLEH task force led by Dr. Nussmeier; cardiologists Stephanie Coulter, MD, and Amy L. Woodruff, MD; Sharon Broussard, RTR, assistant director of Non-Invasive Cardiology; and Kristen Turner, RN, MSN, assistant vice president of SLEH, was appointed to establish a multidisciplinary cardiovascular care program aimed specifically at women.

"The program, called *HerHealthyHeart*, aims to educate women about the prevalence of CVD, identify those at risk and offer them appropriate interventions, and recommend ways to lower their risk," says Ms. Turner. "Another important aim is to stimulate gender-based CVD research regionally and nationally by assembling a large database of relevant clinical information."

"Regardless of the approach, it is important that women be treated as aggressively as men," says Dr. Woodruff, "and that primary care physicians, emergency department staff, and women themselves recognize the risk factors and symptoms of CVD early, so that referrals can be made while intervention is still feasible. It is also important to urge women to modify their lifestyles by exercising regularly, following a heart-healthy diet, and, if applicable, quitting smoking." ●

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Training Program Focuses Attention on Overlooked Peripheral Arterial Disease

Abstract: Training clinicians and nurses to promptly diagnose and treat peripheral arterial disease should enhance the overall management and care of cardiovascular patients.

Approximately 8–12 million Americans have peripheral arterial disease (PAD), an obstructive disease of the aorta and its branches, including the iliac arteries and the femoral, popliteal, and distal tibial arteries in the legs. The most common form of PAD is caused by arteriosclerosis. Blood flow is obstructed not only to the distal arterial system but also to the nerves and tissue, which may result in limb loss.

Peripheral arterial disease is a marker of coronary artery disease, cerebral vascular artery disease, and abdominal aortic aneurysm and a powerful predictor of myocardial infarction, stroke, and death. According to one study, severe, symptomatic, large-vessel PAD may increase the risk of cardiovascular mortality as much as 15-fold (*N Engl J Med* 1992; 326:381–6). Thus, early diagnosis and treatment of PAD may help reduce morbidity and mortality in patients undergoing cardiovascular procedures such as coronary artery bypass grafting and carotid endarterectomy and improve cardiovascular outcomes in general.

The most common symptom of PAD is intermittent claudication (i.e., leg pain with exercise that is relieved at rest). The final stage of PAD is gangrene, characterized by ulceration, tissue ischemia, and loss of sensation, but not all patients progress to this stage. Unfortunately, as many as half of all persons with PAD have no symptoms at all.

"Early identification would be straightforward if leg pain were always present when walking," says Maria Henderson, RN, MSN, CVN, RVT, advanced practice nurse and supervisor of the Peripheral Vascular Laboratory at the Texas Heart Institute at St. Luke's Episcopal Hospital (THI/SLEH). "However, the clinical reality is that PAD is asymptomatic in many patients and is often not revealed by pulse assessment as routinely performed in the emergency department or patient care unit. This may lead hospital physicians and nurses to inadvertently overlook PAD in the absence of classic signs and symptoms."

> *"The sooner we can identify the disease, the sooner we can intervene in its progression,…thus providing a better outlook for all of our cardiovascular patients."*
>
> *—George J. Reul, MD*
> *Co-Director*
> *Peripheral Vascular Disease Service*

Recently, THI/SLEH began an educational program to focus attention on PAD and increase its early recognition in at-risk and asymptomatic patients by both clinicians and nurses. Spearheading this effort are George J. Reul, MD, and Zvonimir Krajcer, MD, co-directors of the Peripheral Vascular Disease Service; Mark Skolkin, MD, chief of Radiology; and Ms. Henderson.

The initial phase of the educational program has focused on training nurses in the emergency department and in patient care units to know the risk factors for PAD and to identify its signs and symptoms, according to guidelines developed by the nationally based Vascular Disease Foundation. The risk factors include hypertension, diabetes, smoking, hypercholesterolemia, increasing age, and cardiovascular disease. In addition, the trainees are being taught to measure blood pressure at the ankle, using a handheld Doppler device, and then calculate the ankle-arm systolic blood pressure ratio for all at-risk patients, especially those who are more than 40 years old. This ratio, called the ankle-brachial index (ABI), is an established, sensitive, noninvasive, and cost-effective diagnostic test for PAD; values less than 0.90 are considered abnormal. The second phase of the training program will target hospital clinicians.

Once diagnosed, PAD is usually treated first with aggressive lifestyle modifications. Medications, including some antiplatelet drugs, can also have a beneficial effect. In some patients whose symptoms persist, reconstructive vascular surgery or endovascular interventions may be needed. Surveillance programs offering follow-up examinations after intervention are also important.

"The sooner we can identify the disease, the sooner we can intervene in its progression," says Dr. Reul. "By addressing the issue in the emergency department or soon after the patient is admitted to the hospital, we can order the right tests and initiate appropriate treatment early, thus using our healthcare resources more effectively and providing a better outlook for all of our cardiovascular patients." ●

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Implantable Left Ventricular Assist Devices Become Smaller, Simpler, and Potentially More Durable

Abstract: Over the last 40 years, implantable left ventricular assist devices have become smaller, simpler, and potentially more durable.

Over the last 40 years, a variety of implantable left ventricular assist devices (LVADs) have been developed to support patients with terminal heart failure. Initially, these pumps necessitated that patients be hospitalized for the duration of support. Since 1991, however, patients with implantable LVADs have been discharged home, often returning to active lives and even employment. Meanwhile, researchers have continued to reduce the size of these pumps in order to improve their safety and durability and enhance quality of life.

"At present, 3 generations of implantable LVADs have either been approved or are being developed for clinical use," says Kamuran A. Kadipasaoglu, PhD, assistant director of Cardiovascular Surgical Research at THI. "The generations are differentiated mainly by how their rotating elements are supported and by the types of flow they produce."

First-generation implantable pumps have sealed, lubricated mechanical bearings and provide pulsatile (i.e., valved) flow. The pulsatile HeartMate XVE (Thoratec Corp., Pleasanton, CA), approved by the US Food and Drug Administration for both bridge-to-transplant and destination therapy, is a first-generation pump. Second-generation implantable pumps lack valves and use blood-lubricated bearings to support a continuously spinning rotor. Examples are the MicroMed DeBakey (MicroMed Technology, Inc., Houston, TX), Jarvik 2000 (Jarvik Heart Inc., New York, NY), and HeartMate II (Thoratec Corp.), all currently in clinical trials. Third-generation implantable pumps also lack valves but rely on hydrodynamic or electromagnetic forces instead of mechanical bearings to support the rotor. Examples are the HeartWare (HeartWare, Inc., Durham, NC) and HeartMate III (Thoratec Corp.) rotary pumps now being tested preclinically in the Cardiovascular Surgical Research Laboratories at THI/SLEH. Both second- and third-generation pumps produce nonpulsatile, continuous flow.

"Despite technological improvements," says Dr. Kadipasaoglu, "the challenge in developing any new pump is to minimize thrombogenicity, maximize durability, and normalize end-organ perfusion. When operating properly, the continuous-flow pump functions throughout the cardiac cycle, thereby dampening pulsatility but enhancing diastolic blood flow, resulting in normalized cardiac output."

Thrombogenesis was a problem in the initial clinical trial of the second-generation HeartMate II in Europe, as thrombus formed in the pump near its inflow and outflow stators.

First-generation HeartMate XVE (left) and second-generation HeartMate II (right).

"In the original design," says O.H. Frazier, MD, director of Cardiovascular Surgical Research and chief of Cardiopulmonary Transplantation at THI/SLEH, "the stators as well as the inflow and outflow cannulas had textured surfaces designed to capture blood cells that would form a thin, nonthrombogenic cellular lining. Such surfaces have been very successful in the pulsatile HeartMate XVE pump. However, the narrow clearance inside the smaller, nonpulsatile HeartMate II promoted obstruction and thrombosis."

"The problem was solved," explains Dr. Frazier, "by limiting the textured surfaces in the HeartMate II to the inflow and outflow cannulas, thus minimizing the risk of obstruction and thrombosis."

The second-generation continuous-flow LVADs offer some potential advantages over the earlier pulsatile LVADs. The newer pumps are smaller, simpler (thus less prone to mechanical problems), quieter, and less intrusive surgically and biologically. They promise a better quality of life and the possibility of use in smaller patients, including children. On the other hand, the second-generation devices are less reliable than the pulsatile pumps at producing a normal cardiac output and are more likely to interfere with right ventricular function.

Thus far, however, the clinical experience with second-generation implantable pumps has been promising.

"In Europe, the first Jarvik 2000 implanted in a patient, over 4 years ago, remains fully operational," notes Dr. Frazier. "The recipient, homebound for more than 2 years before device implantation, is now fully active with New York Heart Association class I functional status. No device failures have occurred in the Jarvik 2000 experience at THI, and infections have been rare and easily treated. And the first recipient of the redesigned HeartMate II was ambulatory within days after the device was implanted in November 2003; he has not experienced any complications and is now home awaiting a heart transplant."

"The third-generation, bearingless devices promise to be even more durable," says Dr. Frazier, "but this advantage remains theoretical at the moment." ●

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Cover: Artwork donated by comedienne Phyllis Diller for the Celebration of Hearts display in the Wallace D. Wilson Museum of the Texas Heart Institute at St. Luke's Episcopal Hospital—The Denton A. Cooley Building.

Calendar of Events

Texas Heart Institute Continuing Medical Education Symposia

Denton A. Cooley Cardiovascular Surgical Society 14th International Symposium: A Homecoming
October 7–10, 2004
Houston, Texas
Program Directors: Francis Wellens, MD; James J. Livesay, MD; O.H. Frazier, MD; Michael J. Reardon, MD; Denton A. Cooley, MD

Texas Heart Institute Fourth Symposium on Congestive Heart Failure
October 21–22, 2004
Houston, Texas
Program Director: Sayed Feghali, MD

Texas Heart Institute Heart Failure Summit
November 4, 2004
Houston, Texas
Program Director: James T. Willerson, MD

American Heart Association Satellite Symposia
November 6, 2004
New Orleans, Louisiana
Program Directors: James J. Ferguson III, MD; James T. Willerson, MD; R. David Fish, MD; Reynolds M. Delgado III, MD

Selected Upcoming National and International Meetings

American Heart Association Scientific Sessions 2004
November 7–10, 2004
New Orleans, Louisiana

Society of Thoracic Surgeons 41st Annual Meeting
January 23–26, 2005
Tampa, Florida
Abstract submission deadline: August 20, 2004

American College of Cardiology 54th Annual Scientific Session
March 6–9, 2005
Orlando, Florida
Abstract submission deadline: September 8, 2004

International Society for Heart and Lung Transplantation 25th Annual Meeting and Scientific Sessions
April 6–9, 2005
Philadelphia, Pennsylvania
Abstract submission deadline: September 17, 2004

For information about Texas Heart Institute CME activities, please contact cme@heart.thi.tmc.edu or call 832.355.2157.

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