HeartWATCH

FALL 2005

A Newsletter Produced by the Texas Heart Institute

Texas Heart® Institute

at St. Luke's Episcopal Hospital

Noninvasive Multidetector Computed Tomography Closes in on Traditional Invasive Coronary Angiography

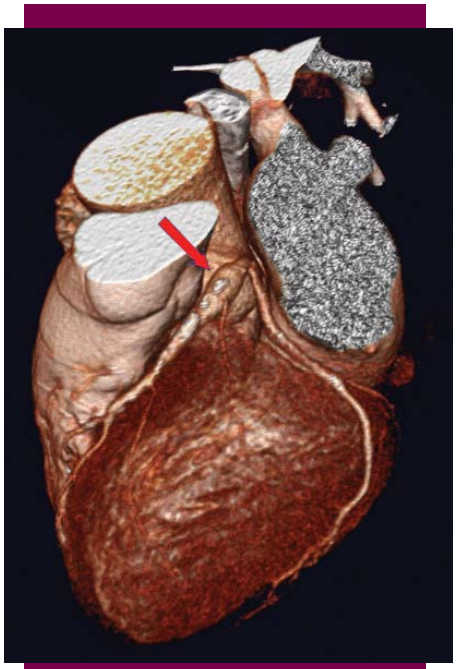
Abstract: Noninvasive multidetector computed tomography is advancing rapidly and may soon offer a safer alternative to invasive coronary angiography.

Since 1973, when computed tomography (CT) scanners were introduced into clinical practice in the United States, their speed and accuracy have improved at an astounding pace. In less than a decade, scanner computer programs that could once handle only a single channel of data have become robust enough to convert exponentially larger amounts of data—from 16 and even 64 rows of radiation detectors—into diagnostically informative 2- and 3-dimensional images. Multidetector CT (MDCT) scanners can now image peripheral blood vessels throughout the body nearly as well as catheter-based angiography can. This has raised expectations that MDCT-based coronary angiography may soon become a safer alternative to invasive coronary angiography.

"Because a catheter is not needed, MDCT doesn't carry the risks of arterial dissection, arrhythmia, stroke, or bleeding from the catheter access site associated with traditional coronary angiography," says Scott D. Flamm, MD, director of Cardiovascular Magnetic Resonance Imaging at the Texas Heart Institute at St. Luke's Episcopal Hospital (THI/SLEH). "However, MDCT scanners do expose patients to ionizing radiation and require the use of β-blockers to slow the beating heart and improve visualization of the coronary arteries."

These limitations notwithstanding, MDCT shows enormous clinical potential. One especially promising role is as a gatekeeper and, in some circumstances, perhaps even a replacement for invasive coronary angiography. Two recent European studies, conducted in nonemergency settings, compared the 2 approaches for their ability to rule out significant stenosis in patients with suspected coronary artery disease (*JAMA* 2005;293:2471–8; *J Am Coll Cardiol* 2005;45:123–7). In sensitivity, specificity, and predictive ability, MDCT neared, but did not surpass, the traditional approach, suggesting that at least in low-risk cases it might make a riskier invasive study unnecessary.

Both of the above studies used standard 16-row scanners, which even now are being nudged aside by newer, faster, and more powerful 64-slice scanners. When compared with elective catheter-based coronary angiography in 70 patients with suspected coronary artery disease (*J Am Coll Cardiol* 2005;46:552–7), MDCT with a 64-slice scanner produced clear, useful images, even in the presence of arterial calcification, high heart rates, or obesity.



Multidetector computed tomography scan showing aneurysm (arrow) of the proximal left anterior descending coronary artery. This demonstrates the exquisite detail with which the coronary arteries can be imaged, without invasive angiography, in appropriately selected patients.

These findings point to an intriguing potential application of MDCT coronary angiography—as triage for patients with suspected coronary artery stenosis who come to the emergency department with acute chest pain. In many emergency departments, dedicated MDCT scanners are already being used efficiently and effectively to determine the extent of injuries to bone, soft tissue, and blood vessels in trauma patients (*AJR Am J Roentgenol* 2005;185:232–8). Their more specific use for cardiac triage appears inevitable (*AJR Am J Roentgenol* 2005;185:533–40; *Emerg Radiol* 2004;11:104–6). To investigate this application, Dr. Flamm and colleagues recently scanned 100 patients who presented to the emergency room at SLEH with acute chest pain and then evaluated the resulting images for diagnostic quality. They used a 16-slice MDCT scanner and took care not to administer β-blockers or add any special steps to the workup of these patients.

"We established that the smaller the patient and the slower the natural heart rate, the more accurate and more diagnostically useful the scan," says Dr. Flamm.

"And the bright side is that, as scanning technology continues to improve, the gap between MDCT and traditional coronary angiography will close even further for a broader range of patients, especially with the incoming wave of 64-slice scanners." ●

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- **Ethics: Copyright, Plagiarism, and the Internet** (CME credit available online)
- **Stem Cell Therapy for the Treatment of Heart Disease** (From Ponte Vedra Beach, Florida, May 7, 2005)
- **Cardiac Remodeling as a Therapeutic Target in Heart Failure** (From Cardiology Grand Rounds, August 2005)

texasheart.org/cmeonline.html

Total Replacement of the Heart with Dual Implantable Continuous-Flow Pumps

Abstract: Researchers at the Texas Heart Institute at St. Luke's Episcopal Hospital are testing dual implantable continuous-flow pumps for biventricular cardiac replacement.

Total artificial hearts

(TAHs) based on the pulsatile-flow principle have rescued many dying patients, mainly by bridging them to transplantation. In a recent trial of the AbioCor implantable replacement heart (ABIOMED Inc., Danvers, MA) for destination therapy, 1 patient was supported for more than 17 months. This pulsatile TAH is bulky and complex, however, and will fit only large patients.

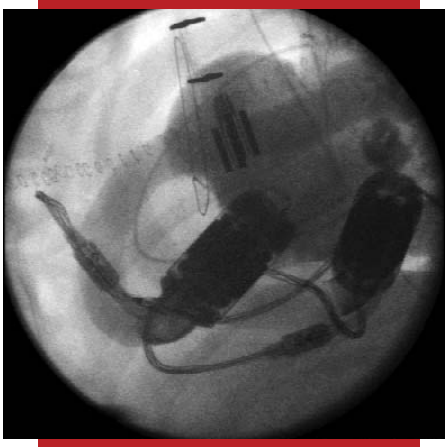
In contrast, implantable continuous-flow pumps are smaller (and therefore able to fit more patients) and simpler. For example, the Jarvik 2000 Heart (Jarvik Heart Inc., New York, NY) has only 1 moving part, which is supported by 2 bearings.

"So far, this pump has had no mechanical failures," says O.H. Frazier, MD, director of Cardiovascular Surgical Research at the Texas Heart Institute at St. Luke's Episcopal Hospital (THI/SLEH). "In fact, 1 patient has had the Jarvik device for more than 5 years without a technical problem. The bearings might eventually become worn, but this problem could be detected and the pump replaced long before it could fail."

Continuous-flow pumps are responsive to the preload, or pressure of blood entering the pump. Two such pumps used in tandem can autoregulate their output because the output pressure of 1 pump determines the input pressure of the other. The tandem arrangement is therefore potentially ideal for biventricular cardiac replacement.

Encouraged by this possibility, researchers in the Cullen Cardiovascular Research Laboratories at THI/SLEH have performed a series of preclinical studies assessing the usefulness of dual continuous-flow pumps as totally implantable ventricular assist or replacement devices. According to Dr. Frazier, initial experiments were undertaken in pigs in the mid-1980s.

"Recent technological advances have introduced newer continuous-flow pumps, such as the Jarvik 2000, which are more durable and reliable than earlier models," says Dr. Frazier. "The first dual Jarvik 2000 implants were performed in cows and sheep whose ventricles were left intact. In December 2004, however, we carried out a calf experiment in which both ventricles were excised at the level of the mitral and tricuspid annuli and their remnants were supported by circular patches of bovine pericardium. A sewing ring was sutured to each annulus, which was reinforced by the pericardial patch. After the pumps were positioned in the respective atria, the aorta and pulmonary artery were transected above the valves and sewn to the pumps' outflow grafts."



Fluoroscopic angiogram of dual continuous-flow pumps used as a total artificial heart in a calf.

"To our knowledge," Dr. Frazier adds, "this was the first time both chambers of the native heart were removed with the circulation totally dependent on 2 continuous-flow pumps."

The maximal pump speed was 14,000 rpm for the left-sided pump and 12,000 rpm for the right-sided one, with a cardiac output of about 8 L/min.

"The calf had normal physiologic function," says Dr. Frazier, "and the continuous nature of the flow caused no adverse effects. Pump flows and pressures remained adequate for physiologic support. Twenty days after implantation, 1 pump accidentally became disconnected, causing acute, irreversible pulmonary edema."

Since that time, THI researchers have performed 3 more preclinical studies, confirming the feasibility of supporting the circulation for up to 3 weeks with this method. According to Dr. Frazier, the next steps are to (1) incorporate both pumps into an integrated unit with a common controller; (2) optimize the pumps' anatomic fit in the chest cavity and the design of the inlet and outlet components; (3) design the controller feedback system to keep hemodynamic values within an accepted range; (4) develop indwelling sensors to monitor tissue physiologic parameters, thus enhancing the sensitivity and responsiveness of the controller feedback system; and (5) investigate the effects of totally pulseless circulation on the recipient's physiology. Once these goals have been accomplished, the dual system may be ready for clinical testing. ●

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Contents

New Hybrid Suites Allow Simultaneous Surgical and Intravascular Procedures

Abstract: Two new suites at the Texas Heart Institute at St. Luke's Episcopal Hospital allow physicians to perform simultaneous surgical and intravascular procedures.

Recently, the Texas Heart Institute at St. Luke's Episcopal Hospital (THI/SLEH) opened 2 new suites designed to allow patients to undergo intravascular interventions and cardiac or vascular surgery simultaneously. Built with the guidance of cardiovascular and peripheral vascular surgeons, cardiologists, interventional radiologists, anesthesiologists, nurses, and technicians, these suites allow physicians to perform hybrid procedures that minimize recovery time and postoperative pain.

"This type of facility has many applications," says Ali Mortazavi, MD, an interventional cardiologist at THI/SLEH and chief of Cardiology at the Kelsey-Seybold Clinic. "For example, many patients with aortic aneurysms have too many comorbidities and other risk factors to undergo conventional bypass surgery, yet a surgical approach is necessary to provide access for the endovascular intervention."

"As the safety of minimally invasive coronary artery bypass surgery and the effectiveness of percutaneous coronary interventions such as stenting have evolved and improved, we have found ways to combine the best of what each type of intervention has to offer," says Ross M. Reul, MD, director of Surgical Innovation at THI/SLEH. "For instance, the left internal mammary artery can be used to bypass an artery on the front wall of the heart through a small incision, without the use of the heart-lung machine. Simultaneously, the cardiologist can stent narrowed arteries on the back of the heart."

Although staged hybrid procedures can be performed in conventional cardiology catheterization suites and operating rooms, simultaneous procedures require a facility with the capabilities of both settings. For some patients, the advantages of simultaneous procedures are significant.

"When both surgical and intravascular interventions are performed in a single session, the patient is exposed to less operative risk," says Dr. Reul. "A hybrid procedure can also benefit patients who would otherwise be at high risk during the interval between their percutaneous and surgical procedures—for example, patients with severe coronary artery disease or unstable angina who need percutaneous angioplasty before undergoing surgical repair of an abdominal aortic aneurysm."

Repair of a thoracic aortic aneurysm in one of the new hybrid suites.

THI/SLEH is the third heart center in the United States to open a hybrid suite, and it is the only US center to have 2 hybrid suites. Both of these facilities have advanced intraoperative imaging equipment.

"Not only can we obtain live, moving images that are extremely clear and can be displayed on flat-screen monitors anywhere in the room, but we can easily move the imaging equipment out of the way when necessary," says Dr. Reul. "This lets us operate more safely and efficiently than is possible in a conventional surgical suite. Moreover, highly mobile digital video cameras allow us to broadcast hybrid procedures to viewers here or elsewhere for educational purposes."

Also available in the hybrid suites is the da Vinci surgical robot. The robot enables the performance of minimally invasive procedures by copying, in miniature, the movements of the surgeon, who sits in a control booth with a magnified, 3-dimensional view of the surgical field.

"By using the robot, we can perform parts of some procedures through a much smaller incision than in conventional surgery," says Dr. Reul. "The robot also gives us a better view of the surgical field than an endoscope could. Together with the endovascular equipment, the robot enables us to access much more of the heart than before."

With this advanced technology, the new hybrid suites allow certain cardiovascular diseases to be treated more safely and successfully.

"Traditionally, when either a surgical or transcatheter technique performed in isolation failed, we had to fall back on the other technique," says Dr. Mortazavi. "With the hybrid suite, we have a new paradigm: surgeons and interventionalists working in the same place, at the same time, on the same case to achieve the maximum benefit for the patient." ●

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Matrix Metalloproteinases May Contribute to the Development and Expansion of Thoracic Aortic Aneurysms

Abstract: Ongoing research underway at THI/SLEH suggests that increased production of matrix metalloproteinases contributes to the development and expansion of thoracic aortic aneurysms.

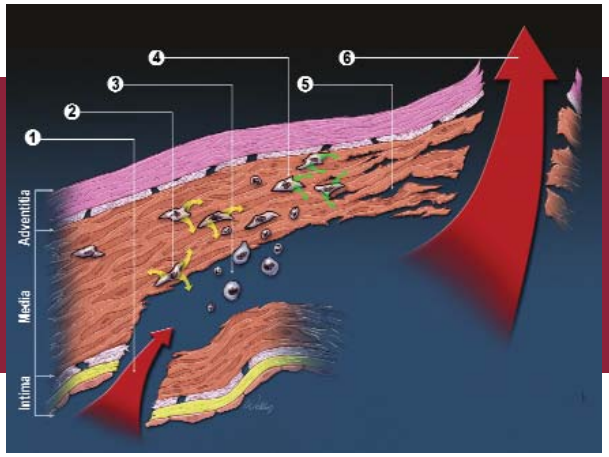
According to the Centers for Disease Control and Prevention, aortic aneurysms and dissections are among the 15 leading causes of death for Americans aged 50 to 84. Recently, the development and expansion of some types of aortic aneurysms have been linked to the overproduction of proteolytic enzymes called matrix metalloproteinases (MMPs). Generated by macrophages and smooth muscle cells within the aortic wall, MMPs can degrade proteins such as collagen and elastin and weaken the aortic wall.

Ever since he was a resident, Scott A. LeMaire, MD, cardiovascular surgeon at the Texas Heart Institute at St. Luke's Episcopal Hospital (THI/SLEH) and associate professor of surgery at Baylor College of Medicine, has collaborated with Joseph S. Coselli, MD, chief of Adult Cardiac Surgery at THI/SLEH, on research projects in thoracic aortic disease.

"Recent research has shown that abdominal aortic aneurysms (AAAs) are related to an increase in MMPs, including MMP-2 and MMP-9, within the aortic wall," says Dr. LeMaire.

These findings have led Drs. LeMaire and Coselli to theorize that an abnormally high ratio of MMPs to the tissue inhibitors of MMP (TIMPs) contributes to degeneration of the aortic wall in other types of aortic aneurysms. In support of this concept, they have already shown that increased MMP levels and increased MMP/TIMP ratios are associated with the development of degenerative ascending aortic aneurysms (*J Surg Res* 2004;123:40–8).

"In that study, patients with ascending aortic aneurysms and trileaflet aortic valves had higher MMP-9 levels and MMP-9/TIMP-1 ratios than did control patients," says Dr. LeMaire.



Paradigm for the role of proteases in aortic dissection. Dissection (1) causes local release of chemokines (2) and recruitment of inflammatory cells (3). Proteases, especially MMPs, are then released by macrophages and smooth muscle cells (4). Degradation of the aortic matrix follows (5), leading to aneurysm expansion and rupture (6).

Laboratory research is also underway to determine whether thoracic aortic aneurysms are associated with abnormal MMP levels in patients with aortic dissection. Drs. LeMaire and Coselli hypothesize that the initial dissection injures the aortic wall, causing an inflammatory response that leads to the production of proteases—including MMPs—which then break down the wall, resulting in expansion and rupture of the aneurysm.

Additionally, Drs. LeMaire and Coselli are investigating whether MMPs play a role in aortic aneurysms that are caused by genetic defects. For example, the fibrillin-1 defect in patients with Marfan syndrome produces an abnormal matrix of aortic elastic fibers that may be especially susceptible to degradation.

For patients, the potential link between MMPs and thoracic aortic aneurysms holds the promise of new and better treatments. Protease inhibitors such as doxycycline have already been shown to limit expansion and prevent rupture of aortic aneurysms in animal models.

"Prospective clinical trials are underway to determine whether protease inhibitors can be used to prevent AAA expansion pharmacologically," says Dr. Coselli.

Adds Dr. Coselli, "If MMPs are implicated in the expansion of thoracic aortic aneurysms, treatments involving protease inhibitors may also be developed for patients with these potentially fatal lesions."

"Recent evidence has shown a quantitative difference in MMP gene expression in different areas of the aorta," explains Dr. LeMaire. "Therefore, all forms of aortic aneurysm need to be studied to determine whether aortic inflammation and MMP expression vary among aneurysms of different type and extent."

Much remains to be learned about the mechanisms underlying thoracic aortic expansion. Because Drs. LeMaire and Coselli have the largest collection of thoracic aortic tissue anywhere in the world, they are ideally equipped to perform such studies. ●

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Texas Heart Institute's Heart Information Center Website Becomes a Prominent Heart-Health Resource

Abstract: As more patients seek health information online, the number of visitors to the website of Texas Heart Institute's Heart Information Center continues to grow.

According to a May 2005 report by the Pew Internet and American Life Project, 80% of Internet users have searched online for information about at least 1 health topic, and 66% of Internet users have searched for information about a specific disease or condition. This year, approximately 95 million American adults will use the Internet to find health information.

The website of the Texas Heart Institute at St. Luke's Episcopal Hospital (THI/SLEH), texasheart.org, gives THI's community outreach program, the Heart Information Center (HIC), an effective way to reach thousands of patients. Website visitors can find lay-oriented cardiovascular information concerning medical conditions, diagnostic procedures, treatments, medications, nutrition, exercise, fitness, and cardiovascular anatomy. Visits to the HIC's health-topic pages account for approximately 90% of all pages viewed on the THI site.

"The number of visitors to the THI website has risen steadily since the site went online in June 1996," says Ken Hoge, manager of Visual Communication Services at THI and webmaster for the site. "One important measure of website activity is the total number of 'unique visitors,' or the number of different people who have visited a particular site in a given period. In 2003, the THI website had approximately 900,000 unique visitors; in 2004, it had more than 1.3 million."

The Pew study also indicates that the reason many health-information seekers go online is to address a pressing medical situation in their own lives, such as a new diagnosis or the need to prepare for a medical appointment or surgery. The HIC site caters to this need by providing, for example, step-by-step explanations about what to expect before heart surgery and a list of questions to ask before entering a clinical trial. Many patients print out the information and take it to appointments.

The HIC website now contains 140 cardiovascular topics, including a glossary and an anatomy section, in both English and Spanish. In fact, approximately 20% of visitors use Spanish browser settings while viewing the site. Many of the Spanish pages rank among the site's most popular.

> *"Our success in making the HIC website clear, comprehensive, and unbiased is reflected in the number of other sites and search engines that link to it for authoritative health information."*
>
> *Ken Hoge*
> *Manager, Visual Communication Services*
> *Texas Heart Institute*

"Our success in making the HIC website clear, comprehensive, and unbiased is reflected in the number of other sites and search engines that link to it for authoritative health information," says Mr. Hoge. "For example, our heart anatomy page is currently ranked number 1 out of 3.19 million Web pages listed for that term on the popular search engine Google. Our site has high rankings for other topics as well, including congestive heart failure (3 out of 1.4 million pages) and β-blockers (1 out of 788,000 pages)."

According to Mr. Hoge, these high rankings are largely due to the increasing number of links to the HIC pages on other high-quality sites, including MedlinePlus.gov.

"The validity of online information is a concern for health care consumers, so we provide terms of use and a privacy policy and subscribe to the Health On the Net Foundation code of conduct for medical and health websites," says Mr. Hoge. "In addition, all topics are reviewed by THI physicians and are frequently revised to remove outdated information." ●

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Clinical Trials Update

THI/SLEH is participating in a pair of clinical trials in patients undergoing major cardiac surgery while on cardiopulmonary bypass (CPB). One of these trials is a multicenter randomized phase II study of human recombinant soluble complement receptor type I (TP10) in high-risk women. A previous placebo-controlled trial revealed that TP10, a potent and effective inhibitor of complement activation, had a statistically significant beneficial effect on morbidity and mortality in men but not in women undergoing CPB (*Circulation* 2004;110:II-274–9). The new study, being performed here and at 24 other centers, will enroll approximately 300 women aged 18 years or older; half of the women will receive TP10 and the other half, placebo. Nancy A. Nussmeier, MD, director of Cardiovascular Anesthesia Research, is leading THI/SLEH's efforts in the trial.

In a second trial, THI/SLEH investigators led by Alina Grigore, MD, are studying the effects of an antiinflammatory intravenous drug known as CTI-01 in patients undergoing CPB. The aim of this multicenter randomized proof-of-concept study is to determine whether CTI-01, a small molecule known to block the systemic release of a number of inflammatory-response mediators, can prevent the inflammation-related end-organ damage that can occur after CPB. The trial, being conducted at a total of 18 centers, will enroll approximately 150 patients aged 18 years or older.

Improved Delivery Becomes a New Goal in Cardiac Stem Cell Therapy

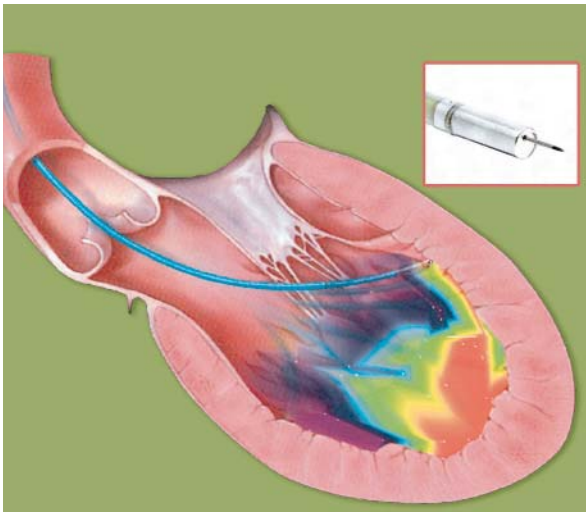
Abstract: Fast, 3-dimensional electromechanical mapping, remotely controlled catheters, and other automated techniques should improve the delivery of cardiac stem cell therapy.

Recently, physicians at the Texas Heart Institute at St. Luke's Episcopal Hospital (THI/SLEH) reported that they had directly observed new blood vessels and evidence of cellular regeneration in the heart of a patient who underwent stem cell therapy but later died of unrelated causes (*Circulation* 2005;112: 521–6). The patient had been taking part in a 4-year-old collaborative Brazilian study (*Circulation* 2003;107:2294–302) that eventually led to THI/SLEH's initiating the first FDA-approved clinical trial of adult stem cells for the treatment of severe heart failure.

"This observation adds to the growing evidence that cardiac stem cell therapy works," says Emerson C. Perin, MD, PhD, director of New Interventional Cardiovascular Technology and co-principal investigator of the trial at THI/SLEH. "A main challenge now is to improve the delivery techniques so that this therapy can be administered easily and repeatably."

"In cases of acute ischemia, when cellular homing signals are relatively strong, it may be best to administer stem cells peripherally or locally through the circulation," says Dr. Perin. "On the other hand, when homing signals are weaker, as in chronic end-stage heart failure, direct injection into the myocardium seems more logical."

Therapeutic cells can be delivered to ischemic sites by surgical, intravenous, intracoronary, or transendocardial means. Surgical injection, the most invasive approach, allows ischemic areas to be visualized and treated directly through an incision but also entails many of the risks and complications of surgery. Intravenous, or peripheral, infusion is much less invasive, but the injected stem cells must take a circuitous route through the bloodstream to reach the damaged myocardium; some of the cells may become trapped in other organs and never reach their target. Intracoronary delivery into an infarct-related artery entails the low-pressure infusion of stem cells through a percutaneous transluminal catheter. Despite encouraging initial results with this approach, recent preclinical and clinical studies suggest that it may cause an acute myocardial infarction (*Lancet* 2004;363:751–6) and exacerbate restenosis (*Lancet* 2004;363: 783–4).



Transendocardial route for electromechanical mapping of damaged but viable myocardium and injection of therapeutic stem cells (inset).

"The intracoronary technique seems well suited to the treatment of specific coronary regions, especially because coronary artery disease is often segmental," Dr. Perin says, "but careful monitoring is required to prevent coronary flow impairment and resulting cell necrosis."

Transendocardial injection, the route used in the Brazilian trial, is now being applied at THI/SLEH. With angiographic guidance, the physician advances a needle-tipped catheter through a femoral artery into the heart; presses the catheter against damaged, but viable, myocardial regions previously identified by electromechanical mapping (EMM); and then injects millions of stem cells. This technique has proved safe and effective despite the long learning process associated with EMM. Nevertheless, there is room for improvement.

"Delivering stem cells to ischemic tissue is like landing a plane on an aircraft carrier," says Dr. Perin. "Both require a highly complex yet delicate blend of human and computerized control. Just as modern fighter pilots depend on real-time data and computerized displays, cardiologists will come to rely on fast 3-dimensional EMM, remotely controlled catheters, and other automated techniques for stem cell delivery."

"In the near future," he predicts, "we should be able to remotely steer an automated catheter to ischemic sites while adjusting the catheter's torque and angle of attack, then map the sites and inject them with therapeutic stem cells."

Still farther off, but already under development, are nanotechnology and microelectromechanical systems that will make direct contact between catheter and target unnecessary. These and related topics were discussed by Dr. Perin on May 7, 2005, at a THI/SLEH-sponsored symposium, Stem Cell Therapy for the Treatment of Heart Disease, in Ponte Vedra Beach, FL (texasheart.org/cmeonline_ stem_ cell_therapy.html). ●

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Cover: Detail of artwork donated by Dr. & Mrs. James T. Willerson and family 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

American Heart Association Scientific Sessions 2005 Satellite Symposium

Evolving Standards in Cardiovascular Care: What Have We Learned? Where Are We Going?
Program Directors: James J. Ferguson III, MD; James T. Willerson, MD; R. David Fish, MD; Zvonimir Krajcer, MD
November 12, 2005 • Dallas, Texas

Texas Heart Institute 7th Symposium on Cardiac Arrhythmias

New Pharmacologic and Interventional Strategies
Program Director: Ali Massumi, MD
February 18, 2006 • Houston, Texas

Selected Upcoming National and International Meetings

American Heart Association Scientific Sessions 2005

November 13–16, 2005 • Dallas, Texas

Society of Thoracic Surgeons 42nd Annual Meeting

January 30–February 1, 2006 • Chicago, Illinois

American College of Cardiology 55th Annual Scientific Session

March 12–15, 2006 • Atlanta, Georgia

International Society for Heart and Lung Transplantation 26th Annual Meeting and Scientific Sessions

April 5–8, 2006 • Madrid, Spain

For information about the CME activities listed above, please e-mail cme@heart.thi.tmc.edu or call 832.355.2157.
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The Texas Heart Institute at St. Luke's Episcopal Hospital has been ranked among the top 10 heart centers in the United States by *U.S. News & World Report's* annual guide to "America's Best Hospitals" for 15 consecutive years.

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FALL 2005

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