On the Global Forefront for TAA Repair With Novel Device

Providing an important alternative to open-chest surgery, Sanger Heart & Vascular Institute, part of Carolinas HealthCare System, is the first in the world to implant a branched stent graft designed specifically for branch vessel repair of thoracic aortic aneurysm (TAA) – the first such device available in a clinical trial.

On April 11, Frank R. Arko, MD, a vascular surgeon who headed the design team for the branched stent graft – along with cardiothoracic surgeons Jeko Madjarov, MD, and Liam P. Ryan, MD – led the surgery to implant the first branched aortic stent graft device in a patient whose TAA encroached on her left subclavian artery. The trial is one of nine selected by the Food and Drug Administration for a pilot program to facilitate early feasibility studies of innovative medical devices for first-in-human trials in the United States. Only Cleveland Clinic joins Sanger Heart & Vascular Institute in investigating this device.

“We were chosen with Cleveland Clinic because we have an established practice of complex aortic surgeries and have done many procedures in thoracic aortic arch work. The FDA was looking for highly qualified and experienced surgeons to limit any sort of learning curve. Furthermore, our team approach encompasses a number of different skill sets that allow for optimal patient outcomes.”

Implanted with two catheters in the femoral and brachial arteries, the branched stent graft may potentially become an option for the estimated 40 percent of patients who have descending thoracic aneurysms who aren’t candidates for endovascular repair. The branched aortic stent graft device, Dr. Arko said, could lead to fewer complications such as blood clots, nerve injury and infections, as well as shorter hospital stays and faster recovery times.

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IMPORTANT VASCULAR SCREENINGS

To determine who may suffer from aortic aneurysms, as well as other life-threatening vascular conditions, Sanger Heart & Vascular Institute offers vascular screenings at the Charlotte, Monroe, Pineville and Rock Hill locations for $78. Screenings consist of an abdominal aortic ultrasound, which measures the size of the aorta to check for aneurysm, a carotid ultrasound to determine the amount of plaque in the carotid arteries and an ankle-brachial index to test for peripheral artery disease (PAD).

Medicare patients are eligible to receive the abdominal aortic ultrasound at no cost as a part of their “Welcome to Medicare” screenings.

Dr. Arko said patients with certain risk factors should be screened, including those who:
- Are over age 65
- Have a family history of aneurysm
- Have a history of smoking
- Suffer from PAD or another vascular disease
- Have medical conditions such as obesity, high blood pressure or high cholesterol

“If your patients have any of these risk factors, I think it’s important to get them screened. Screening can help diagnose a patient with a small aneurysm that can easily be monitored or if the patient needs more advanced care, he or she can be put on appropriate medical therapy,” Dr. Arko said. “Screening is just as important as intervention or surgery. I’d rather see patients earlier and talk about risk factor modification.”

SCHEDULE YOUR PATIENTS

For more information about scheduling your patients for a vascular screening at Sanger Heart & Vascular Institute, call the appropriate location:
- Monroe, Pineville and Rock Hill: 704-667-3840
- Charlotte: 704-373-0212

Code Rupture Protocol Saves Lives

Carolinas HealthCare System’s Aortic Center is one of a few facilities in the nation with a formal Code Rupture protocol in place to treat emergent patients with aortic ruptures and dissections, swiftly stabilizing internal bleeding and saving lives.

Procedures have been developed to efficiently treat aneurysms and other acute aortic syndromes. A select group of surgeons, anesthesiologists and other healthcare professionals is on standby when a patient arrives with one of these conditions.

“When we get that call, we are ready to take the patient up to the OR and get bleeding under control within 20 minutes,” said Frank R. Arko, MD. “This significantly increases survival rates.”

A thoracic stent graft in an aorta: The device creates a new path for blood flow through the aorta, reducing pressure on the aneurysm and the risk of rupture.

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Working as One

A YEAR OF CLINICAL INNOVATION AND BREAKTHROUGH RESEARCH

In 2012, Sanger Heart & Vascular Institute, part of Carolinas HealthCare System, experienced an exciting year of growth and innovation due, in large part, to the use of our collective experience and expertise to adapt and enhance standards to achieve the highest quality outcomes for all our patients.

NATIONAL RECOGNITION
The success of Sanger Heart & Vascular Institute’s pediatric cardiovascular and thoracic services was instrumental in Levine Children’s Hospital receiving a No. 37 ranking in U.S. News & World Report’s Best Children’s Hospitals list for pediatric cardiology and heart surgery.

Although Sanger Heart & Vascular Institute’s Congenital Heart Center has only been in operation for six years, it has experienced great success serving the region’s adult and pediatric patients with congenital heart disease (CHD). For example, results for the Norwood procedure to treat hypoplastic left heart syndrome show less than 3 percent mortality versus the national average of 18 percent. The healthcare team also focuses on providing care and support for adult patients who are living with CHD.

Sanger Heart & Vascular Institute’s Code STEMI metrics continually rank among the best in the nation. Coordinated care has enabled the System to reach a nearly 100 percent compliance rate with, and consistently outpace, the national 90-minute heart attack treatment time goal.

Additionally, 2012 marked Sanger Heart & Vascular Institute’s third consecutive three-star rating from the Society of Thoracic Surgeons for excellence in coronary artery bypass graft (CABG) procedures.

INNOVATORS AND COLLABORATORS
Sanger Heart & Vascular Institute physicians work together to stay at the forefront of innovative programs, procedures and treatment options.

For example, physicians collaborated to launch one of the first transcatheter aortic valve replacement programs in the region for inoperable, high-risk patients with aortic stenosis who previously had no treatment options.

The System’s Code Rupture protocol (see page 2) streamlines treatment for emergent abdominal aortic aneurysm patients. Every year, ruptured abdominal aortic aneurysms claim the lives of more than 15,000 individuals in the United States.

The Heart Success program was developed in response to the growing number of patients with heart failure who require a standardized care plan. For more information about Heart Success, call 704-373-0212.

TEAMWORK
Expertise is the foundation of our team-based culture of care. Physicians work together to ensure the highest standards of quality and safety for our patients. This cooperative work environment enables Sanger Heart & Vascular Institute to recruit physicians who are innovators in their respective fields. As a result, several pediatric and adult services have been created or enhanced, including:

- A fetal echocardiography and cardiology program created by K. Anitha Jayakumar, MD
- An expanded pediatric cardiac catheterization program led by Joseph A. Paolillo Jr., MD

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A Promising Option for A-Fib Patients

At five times the normal stroke risk, patients with atrial fibrillation (AF) face a Catch-22 when it comes to prevention: the anticoagulation medication meant to protect them also places them in danger of catastrophic bleeding. But ongoing research at Sanger Heart & Vascular Institute, part of Carolinas HealthCare System, using a device to stop clots from forming in the atrial appendage – where they can break off and trigger stroke – is proving superior to warfarin and is likely to receive Food and Drug Administration approval.

This parachute-shaped left atrial appendage (LAA) closure device was initially tested on more than 700 patients with nonvalvular AF, with four-year follow-up data from the PROTECT AF trial, demonstrating a 40 percent relative risk reduction in stroke/systemic embolism/death and a 34 percent relative risk reduction in all-cause mortality compared with those taking warfarin.

“Early LAA closure procedures, which were done percutaneously, were associated with an unacceptable bleeding risk around the heart, but improved techniques in a subsequent PREVAIL trial lowered that risk to an acceptable 2 percent,” said Michael J. Rinaldi, MD, Sanger Heart & Vascular Institute’s director of clinical research. While encouraging data continues to accrue, this procedure remains investigational. Patients only have access to this procedure through participation in the Continued Access Registry at Carolinas Medical Center, the only center in the Carolinas selected to participate.

Another Tool To Prevent Stroke

“This is an important technique because it is another tool to prevent stroke in patients with AF,” Dr. Rinaldi said. “There is a group of patients who can take warfarin, but have an increased risk of bleeding, who we feel are ideal for this study. The LAA closure device is associated with risk during the procedure, but once it’s implanted the patient never needs to take warfarin again.”

Leading-Edge Cardiovascular Research

Other cardiovascular research initiatives taking place at Sanger Heart & Vascular Institute include:

- EXCEL: Stenosis patients with left-main coronary artery disease receive either drug-eluting stents or open-heart surgery.
- BAXTER: Angina patients, who have exhausted options such as bypass or stents, are injected with stem cells in the heart area to grow additional blood vessels.
- CABANA: Atrial fibrillation patients receive either medication or a catheter ablation procedure that burns small areas of the atrium to potentially cure the condition.
- ABSORB: Angina patients receive either permanent metal stents or new bio-absorbable stents that eventually “melt away.”
- COAPT: Mitral insufficiency patients who are not eligible for open-heart surgery receive a device percutaneously to repair leaky valves as part of a randomized trial.

ENROLL AF PATIENTS

Ongoing research, known as CAPS2, is a Continued Access Registry that allows AF patients who can take oral anticoagulation medication and meet certain stroke risk factors to receive the left atrial appendage closure device without randomization. To learn more, call 704-355-4794 or email shviclinicalresearch@CarolinasHealthCare.org.
LVADs Change Heart Failure Outlook

With the steady growth of heart failure cases over the past decade – about half of which are managed by noncardiologists – physicians and patients may not be aware of a pivotal device that can serve as a bridge to heart transplantation or even permanently do the work of an underperforming left ventricle.

“Approximately 30 left ventricular assist devices (LVADs) are projected to be implanted in patients this year at Carolinas HealthCare System – the only healthcare system in the region offering it – and more would be possible if physicians thought about this therapy earlier in the clinical course and referred patients before the disease advances too far,” said Sanjeev K. Gulati, MD, who specializes in advanced heart failure and transplant cardiology.

“We in the heart failure community recognize that very caring physicians tend to manage it too long, so patients’ options may be limited when they get to us,” he said. “The vast majority of LVAD candidates are now chronic heart failure patients starting to fail drug therapy but who haven’t gotten to the point where death is imminent. So, we’re trying to assess who’s at high risk for progressing more quickly.”

Patients who may benefit from the palm-sized device, which requires only a small external battery pack, typically have Class 4 heart failure. “LVADs not only save lives, but also restore patients’ ability to live normally,” Dr. Gulati said.

Sanger Heart & Vascular Institute physicians also use this leading-edge therapy to treat children. In July, the pediatric cardiovascular team at Levine Children’s Hospital, led by cardiovascular surgeon Thomas Maxey, MD, was highlighted in an article in Charlotte Magazine for its highly successful work with implanted LVADs in pediatric patients. The magazine named Dr. Maxey a top doctor, acknowledging his expertise in this type of surgery.

Sanjeev K. Gulati, MD
Cardiothoracic Surgeon

Better Heart Health
Encourage your patients to join us at Freedom Park the second Saturday of each month. Visit CarolinasHealthCare.org/walk-with-a-doc for more information.

A Notable Walk
Simple things work. For the multitude of therapies we bring to the medical community, exercise is the “pill” that produces inexpensive, effective and enjoyable results.

More than 250,000 deaths annually are attributable to a lack of physical activity. Exercise has a strong effect on the prevention of cardiovascular disease. With proven reductions in blood pressure and cholesterol, regular exercise has (via risk-factor modification) been associated with a reduction in rates of heart attack and stroke.

For those with pre-existing cardiovascular disease, physical activity has been shown to alter the natural history and morbidity of their disease. Patients enrolling in a formal post-infarction exercise program return to work earlier and report increased self-confidence, lower stress and less anxiety. Via meta-analysis, post-infarct patients who participated in formal exercise programs realized a 20 to 25 percent mortality reduction.

Sanger Heart & Vascular Institute, part of Carolinas HealthCare System, launched Walk with a Doc on April 30, 2011, as a way to engage and educate our community about the benefits of physical activity. The program operates in 24 states and five countries, and has been recognized by the United Nations.
Making Summer Camp a Reality for Cardiac Kids

Sanger Heart & Vascular Institute employees, including physicians and nurses, worked behind the scenes at the first annual charity bike ride that raised close to $10,000 to support Camp LUCK (Lucky Unlimited Cardiac Kids). “The fundraiser, called Bike LUCK, promoted Camp LUCK within the community and raised awareness about heart disease in kids,” said J. René Herlong, MD, director of pediatric cardiology at Sanger Heart & Vascular Institute and a member of the camp’s board of directors.

LETTING KIDS BE KIDS
Camp LUCK provides a medically supervised camp experience for children, ages 7 to 14, with congenital heart defects. One week in August, the children are transformed into “regular campers” by programs designed to nurture, educate and support them and their families. Donations help sponsor kids who attend free of charge at Camp Cherokee, located at Kings Mountain State Park in Blacksburg, SC.

“Many thanks to Hendrick Honda, our presenting sponsor, and to everyone who participated in the event,” said Dr. Herlong.

SUPPORTING CHILDREN AND THEIR FAMILIES
Camp LUCK is free of charge to all campers. For more information, visit campluck.com.

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• An enhanced expertise in atrial fibrillation and ablation of complex arrhythmias brought by Brian Powell, MD
• A cardiac MRI program led by Michael Elliot, MD, who joined the team in June.
• A complex aortic program spearheaded by Liam P. Ryan, MD, in collaboration with Frank R. Arko, MD, and the vascular surgery team.

ONGOING RESEARCH
Sanger Heart & Vascular Institute’s participation in national clinical trials and groundbreaking research allows us to share innovative techniques and therapies with the community. Charles R. Bridges, MD, ScD, is making great strides in the field of gene therapy through the development of patented molecular cardiac surgery with recirculating delivery technology – a surgical technique used to reduce heart failure that is more efficient at delivering therapeutic DNA sequences to the hearts of large animals than any other method currently available.

The dedicated and dynamic physicians of Sanger Heart & Vascular Institute strive for excellence in providing compassionate, high-quality care. While 2012 was an exciting year, filled with many firsts, the team continues to build on its successes. Our physicians are committed to engaging with the community and with each other, and to using evidence-based measures to improve patient outcomes in the remainder of 2013 and well into the future.
Recent News

Charles R. Bridges, MD, ScD, participated in the 2012 ACCF/AHA Focused Update of Guidelines for the Management of Patients with Unstable Angina/Non-ST-Elevation Myocardial Infarction. The guidelines were published in the Journal of the American College of Cardiology.

Joseph A. Paolillo Jr., MD, implanted one of the first GORE® septal occluders in the nation. The device is intended for secundum atrial septal defects as an alternative to the HELEX® device, providing improved apposition to the septum and more rapid endothelization. Sanger Heart & Vascular Institute was one of 10 sites chosen for this US clinical trial.

Alan M. Thomley, MD, presented an abstract at the International Society for Heart & Lung Transplantation in April. His abstract was titled “Allomap Gene Expression Profiling in Lieu of Routine Endomyocardial Biopsy (EMB) at 6 Months Post Transplant.”

Frank R. Arko, MD, presented “The Optimal Strategy in Type B Aortic Dissections is for More Extensive Stent Graft Coverage to Minimize Reentry,” at the 2013 Southern Association of Vascular Surgery meeting. Dr. Arko also presented “Comparison of Acute Versus Chronic Dynamic Intimal Flap Movement in Stanford Type B Aortic Dissections (ATBD) and the Effects of Thoracic Endovascular Stent Grafting,” at the 2013 Peripheral Vascular Surgery Society meeting. His article, “Left Subclavian Artery Coverage During Thoracic Endovascular Aortic Aneurysm Repair Does Not Mandate Revascularization,” was published in the Journal of Vascular Surgery. This research has led to improvements in the care of patients with acute Type B dissections.

Benjamin B. Peeler, MD, and K. Anitha Jayakumar, MD, had an article titled “Head and Neck Vessel Size by Angiography Predicts Neo-Aortic Arch Obstruction after Norwood/Sano Operation for Hypoplastic Left Heart Syndrome” published in the Journal of Invasive Cardiology in February.

Patrick Anonick, MD, participated in “Cooking with the Cardiologist” at Carolinas Medical Center-NorthEast in February, where he educated the public about heart health.

The following physicians participated in and/or presented at the American College of Cardiology Scientific Sessions in San Francisco in March:


- Michael J. Rinaldi, MD, who presented an abstract, titled “Impact of Point-of-Care Platelet Function Testing Among Patients with and without Acute Coronary Syndromes Undergoing PCI with Drug Eluting Stents: An ADAPT DES substudy.”

- Sherry J. Saxonhouse, MD, who participated in several presentations, including “Maintenance of Certification ABIM Recertification Made Easy – Clinical Cardiac Electrophysiology and Cardiovascular Diseases.” She also served as an abstract session faculty member and abstract reviewer.

- A. Resai Bengur, MD, who presented an abstract, titled “Mitral Regurgitation in Congenital Heart Disease: When to Intervene.”

Congratulations to Melony K. Covington, MD, for being voted No. 1 Cardiologist in Gaston County by voters from the Gaston Gazette.

Cheryl A. Russo, MD, was interviewed for the website “MyFit50.com,” a women’s health and wellness site.

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Matthew J. Levinsky, MD, successfully enrolled the first patient in the ATTAIN study at Carolinas Medical Center-NorthEast. This is a safety and efficacy trial, evaluating a new quadripolar left-ventricular pacing lead for cardiac resynchronization therapy.

Brian Powell, MD, published four articles that appeared in *Europace Heart Rhythm*, and the *Journal of Innovations in Cardiac Rhythm Management*. Titles included: “Impact of shock energy and ventricular rhythm on success of first shock therapy: The ALTITUDE First Shock Study” and “Atrioventricular node ablation in atrial fibrillation patients with cardiac resynchronization therapy: Benefits beyond rate control.”

Frank R. Arko, MD; A. Resai Bengur, MD; Amanda L. Cook, MD; William E. Downey, MD; John Fedor, MD; Theodore A. Frank, MD; Sanjeev K. Gulati, MD; J. René Herlong, MD; John W. Holshouser, MD; Benjamin B. Peeler, MD; Mark K. Reames, MD; Michael J. Rinaldi, MD; Donald A. Riopel, MD; Geoffrey A. Rose, MD; Eric R. Skipper, MD; John D. Symanski, MD; Larry T. Watts, MD; B. Hadley Wilson, MD; and Samuel H. Zimmern, MD, have been chosen Best Doctors in America 2013, North Carolina Hospital List, by *U.S. News & World Report*.

A. Resai Bengur, MD; Amanda L. Cook, MD; William E. Downey, MD; John Fedor, MD; Theodore A. Frank, MD; Sanjeev K. Gulati, MD; J. René Herlong, MD; John W. Holshouser, MD; Benjamin B. Peeler, MD; Mark K. Reames, MD; Michael J. Rinaldi, MD; Donald A. Riopel, MD; Geoffrey A. Rose, MD; Eric R. Skipper, MD; John D. Symanski, MD; Larry T. Watts, MD; B. Hadley Wilson, MD; and Samuel H. Zimmern, MD, were selected as Best Doctors in America 2013 by *U.S. News & World Report*. 

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