In May, Baptist Cardiac & Vascular Institute announced a name change to Miami Cardiac & Vascular Institute. The transformation, however, goes much deeper than a simple name revision. The Institute is now extending its services, expertise and innovation across Baptist Health South Florida to bring benefits in clinical care that will enhance the Institute’s vision to become one of the leading cardiac and vascular centers in the country.

These newly integrated heart and vascular services are available at Baptist Hospital, Doctors Hospital, Homestead Hospital, Mariners Hospital, South Miami Hospital and West Kendall Baptist Hospital, along with more than 15 outpatient centers spanning three counties. Combining the unique talents and technologies of each facility and allowing for the sharing of clinical data make it possible for cardiac and vascular patients to experience consistent, exceptional, evidence-based care no matter the location.

Barry T. Katzen, M.D., who founded the Institute in 1987, remains at the helm with the title of chief medical executive. Carol Mascioli has assumed the title of chief operating officer, and Bo Boulenger, CEO of Baptist Hospital, will provide oversight for the Institute as the executive champion for Baptist Health.

“The integration involves the continued development of multidisciplinary cooperation and partnerships between physician leaders and administrators that will be based on quality and outcomes, service, efficiency and cost,” Mr. Boulenger said.

Part of Baptist Health’s commitment to the community and beyond is a $100 million expansion project that is underway on the Baptist Hospital campus. It will include the development of unique programs for aneurysms, structural heart disease and endovascular therapies, advanced procedure suites and a larger gallery where physicians can collaborate and teach the techniques they have pioneered to others from across the world. It will open in 2016.

For more than 50 years, Baptist Health has provided excellent heart and vascular care. The Institute has long been known as a pioneer in multidisciplinary, less invasive techniques. Not only has the Institute participated in hundreds of clinical trials, but its groundbreaking research has led to new approaches in medicine. Its physicians lecture around the world.

Although its name has changed, one priority of the Institute has not faltered — its desire to help patients from throughout Florida and around the world. If you have a patient who may qualify for one of our research trials, we hope you will contact Miami Cardiac & Vascular Institute at 786-596-5974.

For a full list of research trials, please visit BaptistHealth.net/Research.

James Benenati, M.D., medical director of both the Peripheral Vascular Laboratory at Miami Cardiac & Vascular Institute (formerly Baptist Cardiac & Vascular Institute) and Interventional Radiology for Baptist Health, received the honor of delivering the opening talk at the Society of Interventional Radiology’s 39th Annual Scientific Meeting in San Diego. It is the largest national meeting of interventional radiologists. The lecture is named after one of the founding fathers of interventional radiology, Dr. Charles T. Dotter, who was nominated for the Nobel Prize in Physiology for Medicine in 1978. “I am deeply humbled to be included among past Dotter lecturers — interventional radiology pioneers who solved difficult medical problems with creativity, innovation and research,” said Dr. Benenati, who is credited with developing one of the country’s most coveted and sought-after fellowships and is best known for his work to establish a nationally renowned, accredited peripheral vascular laboratory. “I have known Jim since the early days of our founding and I am pleased that he is recognized for his dedication, brilliance and ability to lead while encouraging collaboration among our teams at the Institute,” said Barry T. Katzen, M.D., founder and chief medical executive.
Assessing Potentially Safer, Faster and Easier AAA Repair

Patients with challenging infrarenal abdominal aortic aneurysms (AAA) – and the physicians who treat them – may soon benefit from a new treatment option. A clinical trial at Miami Cardiac & Vascular Institute examined the long-term safety and efficacy of completely sealing these risky aneurysms with a biocompatible polymer.

Minimally invasive repair with the Nellix EndoVascular Aneurysm Sealing System (Endologix, Inc.) was provided to appropriate candidates with an infrarenal AAA larger than 5 cm. Institute researchers plan to assess the safety of the Nellix polymer strategy relative to more-traditional shunt repairs. The Institute participated in this multicenter trial because this intervention could prove beneficial for many aneurysm patients, including those with the more-challenging aortic presentations.

Shorter procedure time could be a benefit for both patients and physicians. The Nellix permits easier endovascular delivery and deployment compared to many existing devices for aneurysm repair.

Once injected in the aneurysm sac, the biocompatible polymer hardens in three to five minutes. Researchers hope that complete sealing of the sac will preclude the need for any secondary interventions.

PENDING RESULTS OF THIS AND OTHER TRIALS SET TO EVALUATE NELLIX IN UP TO 180 PATIENTS AT 30 SITES IN THE UNITED STATES, CANADA AND SOUTH FLORIDA, THIS STUDY COULD BE EXPANDED TO ANYONE WITH A TREATABLE SIZE AAA.

The study duration is 24 months. Institute physicians plan to evaluate participants twice in the first year post-intervention and then annually for life.

Taking a New Route to Aneurysm Repair

A young woman with a large intracranial aneurysm and bad headaches came to Miami Cardiac & Vascular Institute for consultation. Having met the criteria for an innovative, minimally invasive new trial of flow diverter technology, she underwent the procedure and fared well. Noteworthy, yes; but her story also represents hope to other high-risk patients with giant irregular aneurysms and few options.

Large or giant brain aneurysms can be deadly if left untreated. Although some people remain untreated, they experience debilitating symptoms when the aneurysms grow so large that they compress on nerves or other structures in the brain. Large or giant aneurysms are difficult to treat with traditional “open” surgery due to the high mortality rate. Smaller aneurysms elsewhere in the body are commonly repaired through conventional endovascular or surgical approaches. However, internal carotid artery aneurysms larger than 10 mm come with bigger challenges.

Intra-luminal catheterization of the aneurysm in the abdominal aorta.

b) Covered stent-grafts placed inside the aneurysm to preserve the intraluminal flow.

Endovascular aneurysm sealing with polymer to minimize risk of leaking.

The Perceval S device is placed through a minimally invasive procedure in combination with more-conventional heart surgery. People experiencing symptomatic aortic valve stenosis and small annuli and/or calcified annuli could benefit from this valve procedure. Additionally, the Perceval could be appropriate for some patients who require redo valve procedures.

Medium-to-high-risk patients over the age of 60 who require aortic valve replacement were considered for the trial.

The Perceval S is a collapsible profile valve positioned and secured without the need for sutures. Commissural, straight struts hold the valve to the heart anatomy and unossualized strutts attach the valve to the sinus of Valsalva. By making this new technology available for aortic valve replacement, the Institute remains on the forefront of providing innovative technology for our patients.

Institute researchers plan to specifically assess the five-year results for improved gradients across the valves, a decreased heart size over time and a lower rate of overall complications, including the incidence of perivalvular leak.

Ideally, investigators would like to see fewer patients returning because of complications, a reduced need for pacemaker placement and improved five-year survival.

Potential problems for some patients with traditional pacemakers include the risk of infection and the need to retrieve and replace the leads over time.

New technology offers a possible solution. Miami Cardiac & Vascular Institute physicians are enrolling candidates in a Phase I clinical trial to assess the safety and efficacy of a leadless, single-chamber ventricular pacemaker system.

Study participants will be among the first humans worldwide to undergo implantation with the Micra Transcatheter Pacing System (Medtronic). The miniaturized pacemaker is about the size of a vitamin, making it about 10 times smaller than a traditional pacing system. Physicians deliver the device directly into the heart using a catheter inserted in a femoral vein. They attach the pacemaker to muscle wall using only a few millimeters long. A tiny electrode then delivers electrical pulses to pace the heart.

Because the Micra device does not require leads that communicate with the heart, researchers hope patients will experience fewer complications. For example, although risk of infection is low with current lead-based devices, many do occur, infections can be devastating for patients.

In addition to potentially safer pacing, patients are likely to be more comfortable and experience fewer limitations on activities of daily living immediately post-procedure and over the long term.

Appropriate candidates for the trial need ventricular pacing and must be capable of walking one to three minutes on a treadmill during evaluation. In addition, people must be able to return for follow-up evaluation during the trial in order to be considered for enrollment.

Physicians will use radiofrequency technology to communicate with the implanted pacemaker. This allows them to noninvasively calibrate and communicate with the device. Morbidly obese patients are not candidates for the trial because of the small chance that physicians will be unable to properly communicate with the device.

The Institute is the only site in South Florida enrolling patients in this international trial.

Demonstrating the safety of the Micra system is the main objective of the trial. It’s also a non-inferiority study, meaning researchers at the Institute hope to show that the device is as good as, if not better than, commercially available pacemakers.

The retrieval device is designed to last at least seven years. Retrieval, if any, will depend in part on how patients fare over the duration of study follow-up. As engineering and technology progress, the next generation of miniaturized technology may be wireless, dual-chamber devices.
Leading the Way on Lipid Management

**The Role of PCSK9 in the Regulation of LDL Receptor Expression**

Cholesterol travels inside lipoprotein particles. The main way excess cholesterol is removed by the body is by these cholesterol containing particles to fit a receptor in the liver and the entire particle and receptor is taken in by the liver. The cholesterol is removed in the bile and the receptor is recycled to pick up another particle. PCSK9 is a protein that prevents the receptor from recycling. Blocking PCSK9 increases the receptors and, thus, particle and cholesterol removal.

Clinical trials underway at Miami Cardiac & Vascular Institute explore the promise of a new strategy to treat people with lipid abnormalities. This novel treatment takes advantage of the body’s own mechanism for removing LDL cholesterol from the bloodstream.

For some people, favorable genes enable them to live with naturally lower levels of LDL cholesterol. For others who are not so fortunate, an antibody therapy could provide the same advantage.

By harnessing and enhancing the liver’s own cholesterol-clearing action, inhibition of PCSK9 (proprotein convertase subtilisin/kexin type 9) could revolutionize how physicians prevent cardiovascular events. This approach may even help people with lipid abnormalities who do not respond or who respond only partially to traditional cholesterol-lowering medication. In fact, some initial PCSK9 inhibitor trials demonstrated benefits for patients with elevated cholesterol despite statin therapy.

Institute physicians are on the forefront of this research and conducting multiple Phase 3 studies to further evaluate PCSK9 inhibition, including:

**Statin Intolerant Trial.**
Patients who cannot tolerate statins because of side effects or a relevant family history may be candidates for this research. A sizable minority of people cannot tolerate statin therapy (approximately 10 percent to 15 percent of Caucasians, for example). Participants will be evaluated for response to PCSK9 treatment over 24 months.

**The FOURIER Outcomes Trial.**
People with elevated LDL cholesterol despite statin treatment (including partial responders) and those with diabetes and/or a history of myocardial infarction might be suitable candidates for an outcomes trial. This international, double-blind, placebo-controlled study is called the Further Cardiovascular Outcomes Research with PCSK9 in Subjects with Elevated Risk (FOURIER) trial. Researchers hope to demonstrate that PCSK9 inhibition is associated with a decrease in “hard events,” including heart attack and stroke. They also plan to track secondary outcomes, such as the incidence of stent placements and hospitalizations.

Consider referring your patients to the Institute if they meet the criteria for these PCSK9 Phase 3 trials. Thought leaders and experts in multiple areas of cardiovascular medicine collaborate in research and clinical treatment at the Institute for the benefit of patients.

**Cholesterol travels inside lipoprotein particles. The main way excess cholesterol is removed by the body is by these cholesterol containing particles to fit a receptor in the liver and the entire particle and receptor is taken in by the liver. The cholesterol is removed in the bile and the receptor is recycled to pick up another particle. PCSK9 is a protein that prevents the receptor from recycling. Blocking PCSK9 increases the receptors and, thus, particle and cholesterol removal.**