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Robert Chait, M.D., F.A.C.C.

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# Expertise Contributes to Excellence

The Heart and Vascular Institute brings together years of physician experience and a variety of leading-edge procedures to deliver exceptional patient care and outcomes every day.

Clinical excellence is essential to patient care at The Heart and Vascular Institute. Many physicians boast years of both research and clinical experience, which allows The Heart and Vascular Institute to offer expertise and a strong foundation in knowledge of procedures. In addition, physicians continue to advance their learning and technical skills by participating in national clinical research trials and investigations. This therefore places The Heart and Vascular Institute on the cutting edge of cardiovascular treatment.

The physician expertise at The Heart and Vascular Institute also serves to set apart the facility through its ability to welcome and care for complex patients who might otherwise be turned away in non-university settings. This is substantiated by its statistics that often match or exceed national standards.

### On the Forefront

Physicians at The Heart and Vascular Institute have been nationally certified to use leading-edge techniques. This further enables the institute to continue to meet its goal of exceeding national standards.

For example, the Echo Lab at The Heart and Vascular Institute offers advanced noninvasive studies to diagnose these cardiovascular conditions. Echos are also used routinely during open-heart procedures, which provides a better understanding of each patient's real-time condition, enabling the surgeon to obtain the best possible outcome.

In The Heart and Vascular Institute's catheterization lab, many anatomically difficult lesions are still treated with stents obviating the need for open-heart surgery, which is often a more likely occurrence at other facilities. This too is a testament to the skills and experience of the interventional cardiologists at JFK.

> "Working hand in hand with our interventionalists and surgeons is a staff of board-certified cardiologists who diagnose and treat patients with various cardiovascular problems ranging from the straightforward to the extremely complex. This team method combines years of expertise and has always been recognized at JFK Medical Center as just another way we ensure the delivery of only the best outcomes for our patients."
>
> –Robert Chait, M.D., F.A.C.C., Medical Director of Cardiovascular Services

Except for the University of Alabama, the Electrophysiology Lab at JFK Medical Center performs the most procedures in the southeastern United States. The doctors treat all factors of electrical problems, from the relatively straightforward to the exceedingly complex and often life-threatening electrical arrhythmias. Given their expertise, it is no surprise that the electrophysiologists at JFK are recognized as leaders in the burgeoning field of atrial fibrillation ablation.

***For more information about The Heart and Vascular Institute, call (800) 848-9809.***

**Robert Chait, M.D., F.A.C.C.**

Robert Chait, M.D., F.A.C.C., Medical Director of Cardiovascular Services, is an attending cardiologist on staff at JFK Medical Center and is a clinical assistant professor of biomedical science at Schmidt School of Medicine at Florida Atlantic University in Boca Raton, Florida.

Malcolm Dorman, M.D.

# Innovations in Cardiac Surgery

Over the past several years, there have been many advances in cardiac surgery, especially in the area of valve disease. More research has been done to understand specific disease etiologies that cause valve dysfunction. I have adopted a specific disease etiology-based strategy for mitral valve surgery.

In order to provide the patient with stable long-term mitral valve repair, it is necessary to completely understand the cause of the valvular dysfunction. For example, the treatment of mitral valve regurgitation in ischemic disease is different from degenerative disease. With ischemic disease, papillary muscle displacement and the downward tethering of the posterior leaflet is the key trigger leading to mitral valve regurgitation. The restriction of posterior leaflet motion in systole, particularly in the P–3 region, results in poor leaflet coaptation and mitral regurgitation.

## Approaching Ischemic and Degenerative Mitral Valve Disease

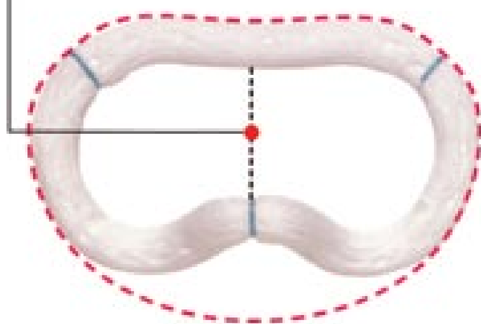
While many cardiovascular surgeons have had varying degrees of results with the treatment of ischemic MR, my strategy has been to repair IMR with a complete remodeling annuloplasty ring designed to support the posterior leaflet in the P–3 region. Rather than downsize the entire mitral annulus to restore leaflet coaptation, an asymmetric remodeling ring strategically decreases the septolateral dimension in ischemic patients without compromising the overall mitral annulus. When the posterior leaflet is supported in the P–3 region, I have found that post-procedural echocardiographs show no residual MR.

While this strategy has been successful for ischemic MR, repair of degenerative mitral valve disease requires a completely different approach. In order to achieve a long-term stable repair in degenerative mitral valve disease, I utilize an annuloplasty ring strategy that restores the natural 3:4 ratio between the anteroposterior diameter and the transverse diameter of the mitral valve. To accomplish the perfect mitral valve repair, I utilize advanced repair techniques including quadrangular resection, chordal shortening and transfer, papillary muscle shortening and reconstruction, along with annular remodeling and decalcification.

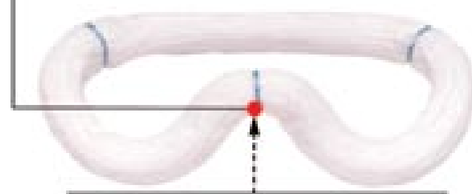
## Innovative Treatments

An exciting new treatment for chronic heart failure patients has just begun. Mitral regurgitation from dilated cardiomyopathy results from left ventricular (LV) geometrical distortion. In the past, mitral valve repair in CHF patients has had poor results. Limited LV remodeling has been noted in these patients, which has hindered long-term outcomes. By repairing MV regurgitation with a

**Reduced anteroposterior (AP) distance (41% reduction)** — brings the annulus inward to counteract the outward pull of the enlarged left ventricle



**Elevated P2 (6 mm lift)** — raises the mitral valve apparatus to counteract the downward pull of the enlarged left ventricle



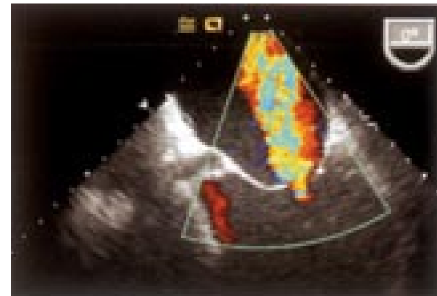
Images courtesy of Edwards Lifesciences

unique three-dimensional shaped modeling ring, LV remodeling is achieved. Early follow up has demonstrated clinical improvement with no residual or recurrent MR. An immediate favorable change in LV geometry has been noted with decreased LV volumes, a decrease in sphericity and increased ejection fractions. Many CHF patients can now benefit from surgical intervention.

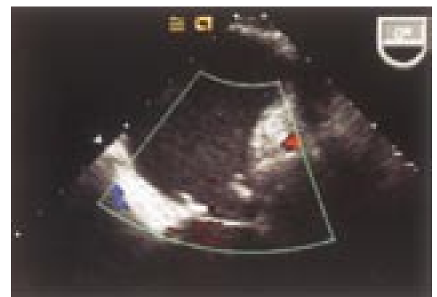
In the area of aortic valve replacement, younger patients are now benefiting from the advantages of receiving a tissue valve with long-term durability. Patients who have a mechanical valve face the risk of everyday bleeding or of a thromboembolism. Patients with a tissue valve may go a very long period of time with no problem, and may not require a reoperation.

I was one of the first to implant a new aortic bioprosthetic valve with the advanced tissue process "Thermafix." Thermafix is a new tissue processing technology that works by removing the phospholids and unstable gluteraldhyde molecules from the tissue. It is the only tissue process to remove both major calcium-binding sites. When tissue valves fail, it is most commonly due to calcification. The new Thermafix process has been shown to reduce calcium uptake by 81 percent. With this advance in bovine pericardial tissue valves, many more patients can benefit from having a tissue valve.

***For more information about cardiovascular surgery at JFK, call (561) 548-4900.***



Before
Image of patient with significant MR resulting from ventricular dysfunction.



After
Following successful mitral valve reconstruction, MR is reduced significantly.

Images courtesy of Edwards Lifesciences

## Malcolm Dorman, M.D.

Malcolm Dorman, M.D., is a world-renowned cardiovascular surgeon who was recruited to JFK Medical Center to become Medical Director of Cardiac Surgery. He was previously at Miami Heart Institute for 25 years where he served as Chairman of Cardiothoracic Surgery and Co-Chairman of the Department of Cardiovascular Medicine. In 1972 he was one of two residents selected to train with the renowned heart surgeon Michael Debakey, M.D., in Houston, Texas. In 1975 he was associated with Frank Spencer, M.D., and George Reed, M.D., as clinical research scientist at NYU Medical Center. Dr. Dorman is recognized for his research and clinical work in repairing mitral valves. He is also recognized for using all arterial conduits in bypass surgery and has demonstrated their excellent long-term results. Dr. Dorman was honored by his medical school, receiving his distinguished alumnus award in 1997. In patients who are thought to be nonsurgical candidates, he is currently involved in the angiogenesis phase one clinical trial, which uses the human growth factor to generate new blood vessels. His last 18 months at JFK placed him under 1 percent mortality rate for coronary surgery and 0 percent for straight aortic and mitral valve surgery, whether repair or replacement.

George Ebra, Ed. M.D.

# Measuring Outcomes in Cardiovascular Services

The Heart and Vascular Institute at JFK Medical Center is continuing its commitment to excellence in the provision of cardiovascular services. The administration is focused on providing unsurpassed healthcare services to consumers. This has earned them the trust of people in the community and throughout the east coast of Florida. To ensure that patients receive the highest level of care, a sophisticated outcomes database system has been implemented to carefully monitor results in a systematic manner.

## Cardiac Catheterization and Percutaneous Coronary Intervention

The number of cardiac catheterization and percutaneous coronary interventions (PCIs) continues to increase at an unprecedented rate nationwide. During 2005, The Heart and Vascular Institute at JFK Medical Center performed 4,203 interventional cardiology procedures in the Cardiac Catheterization Laboratory.

The patient population included 1,544 females (36.7 percent) and 2,659 males (63.3 percent) with an average age of 65.9 years. Almost two-thirds (65.5 percent) of the patients receiving services in the cardiac catheterization laboratory were 60 years of age or younger. This reflects a trend in the early identification and treatment of coronary artery disease. The patient's demographic characteristics are shown in **Figure 1.**

The information in **Figure 2** graphically depicts the distribution of procedures performed. In 2005, over three-fourths (77.8 percent) of the procedures were performed on inpatients. There were 362 patients (21.2 percent) transferred from other facilities to undergo PCI at The Heart and Vascular Institute.

Almost one-half of the patients (1,705; 40.6 percent) underwent some form of therapeutic interventional procedure. There were 2,502 lesions attempted in this group, and 2,476 were successfully dilated. This denotes a 99 percent success rate in treating obstructive coronary lesions. Moreover, 2,702 stents were deployed. This represents an average usage of 1.6 stents per patient.

The number of post-procedure adverse outcomes, such as myocardial infarction, chronic heart failure and stroke, experienced by patients was minimal. A significant number of patients (97.7 percent) underwent cardiac catheterization or PCI or both with no adverse outcomes. Further, 97.7 percent of the patients had no post-procedural bleeding complications.

## Cardiac Surgery

Cardiac surgery continues to flourish at The Heart and Vascular Institute at JFK Medical Center with excellent outcomes. Patients continue to receive unsurpassed care and experience favorable results. During 2005, 598 patients underwent cardiac surgery at The Heart and Vascular Institute. The demographic characteristics of the group are displayed in **Figure 3**. Moreover, the distribution of procedures is shown in **Figure 4.**

Coronary artery bypass grafting (CABG) continues to be the most frequently performed cardiac surgical procedure. During the past decade, isolated CABG procedures are being performed on significantly older and sicker patients with an increased risk of mortality. This has been well established with data from the Society of Thoracic Surgeons National Cardiac Database (STS NCD). Despite this occurrence, mortality rates for isolated CABG at JFK have declined substantially over the past four years. The observed and expected mortality rates for isolated CABG procedures by year of operation are displayed in **Figure 5**. These results clearly document the excellent care and favorable outcomes that CABG patients continue to experience at JFK.

The information displayed in **Figure 6** provides the observed and expected mortality rates for various surgical categories. The expected mortality rate has been derived from the 2005 STS NCD risk model. The observed mortality rate for each of the surgical categories presented is lower than the expected mortality rate. This information clearly demonstrates the superior outcomes achieved in the various surgical categories at JFK during 2005.

To ensure the quality and validity of The Heart and Vascular Institute data and to assess outcomes based on national benchmarks, annual harvests to the STS NCD and the American College of Cardiology Database are routinely performed. These two national databases furnish excellent benchmark measures to assess performance.

Figure 1
Interventional Cardiology Patient Demographic Characteristics

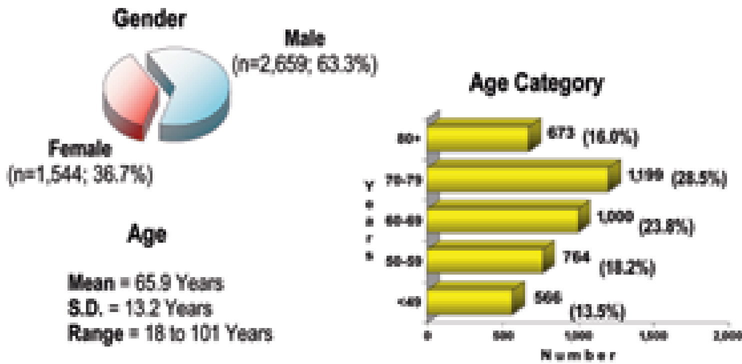



Figure 2
Distribution of Procedures

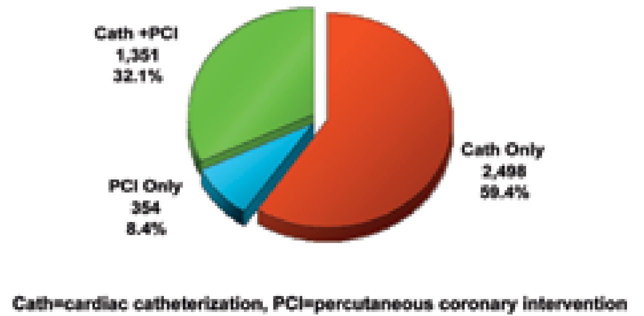



Figure 3
Cardiac Surgery Patient Demographic Characteristics

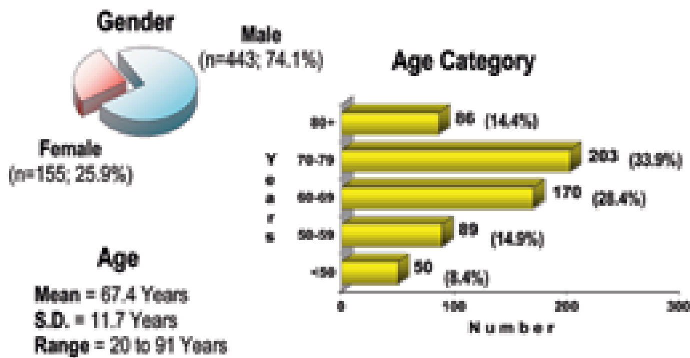



Figure 4
Distribution of Cardiac Surgery Procedures

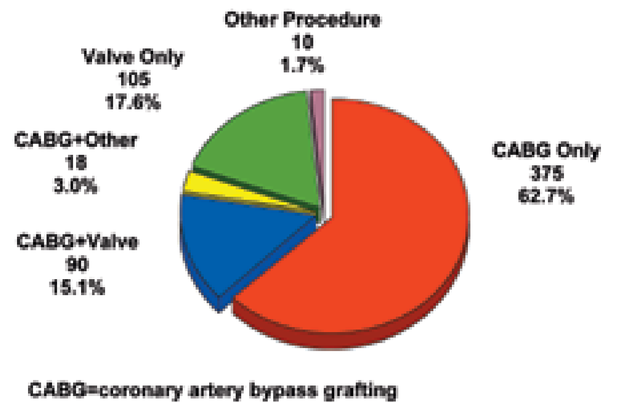



Figure 5
Observed and Expected Mortality Rate for
Isolated CABG by Year of Operation

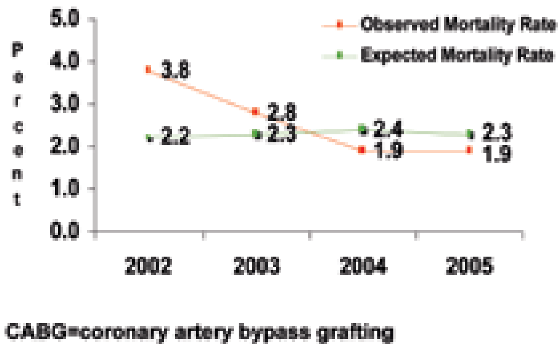
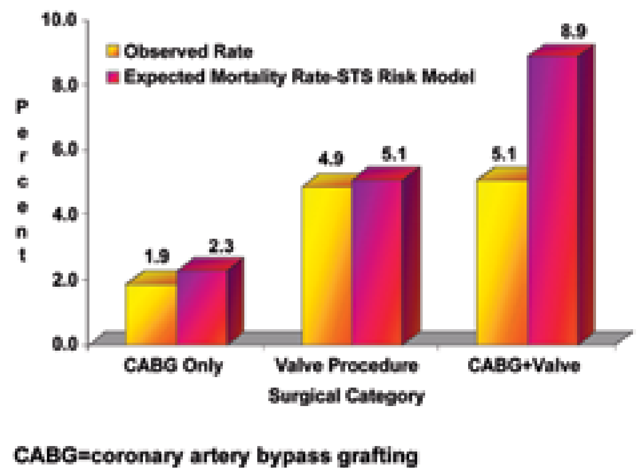



Figure 6
2005 Mortality Outcomes by Surgical Category



# Investigating New Products and Procedures in the Cath Lab

The field of cardiology is constantly evolving, and trials to develop new products, devices and medications are underway daily at the Florida Cardiovascular Research Institute at JFK Medical Center. One such trial—the tilarginine acetate injection in a randomized international study in unstable AMI patients/cardiogenic shock (TRIUMPH)—could help increase the survival rate for AMI patients.

"At any one time, the Florida Cardiovascular Research Institute can have as many as 20 clinical trials and studies underway," says Mark Rothenberg, M.D., interventional cardiologist on staff at JFK Medical Center and partner in the Florida Cardiovascular Research Institute. "Patients are constantly being recruited for the studies, and at any time those patients could have access to potentially lifesaving drugs or procedures."

## TRIUMPH

One such study for which Florida Cardiovascular Research Institute is currently recruiting patients is the tilarginine acetate injection in a randomized international study in unstable AMI patients/cardiogenic shock, also known as TRIUMPH. In this international, multi-center study, patients who experience cardiogenic shock (CS)—as between 5 and 14 percent of AMI patients do—are given an injection of tilarginine acetate to inhibit inducible nitric oxide synthase (iNOS) from causing the toxic levels of nitrous oxide that can lead to numerous negative effects.

Single center studies have demonstrated that nitric oxide synthase (NOS) inhibitors might reduce mortality substantially in patients with refractory CS.

Patients who are potentially candidates for TRIUMPH will be identified from the hospital, CCU, ED or Cardiac Catheterization Laboratory. If all the inclusion requirements—including shock symptoms following revascularization, ASBP support and resuscitation with vasopressors—he or she will be randomized, tested again for shock and then given the medication if shock is confirmed within five minutes of the administration of the drug.

The 120 worldwide centers currently participating in TRIUMPH are evaluating the effectiveness of tilarginine acetate injection 1.0mg/kg IV bolus followed by 1.0 mg/kg/hr five-hour infusion as compared to placebo. Researchers will evaluate the effectiveness of reducing mortality of patients with cardiogenic shock complicating AMI at 30 days. The study will continue until 658 patients worldwide have received the medications.

"The TRIUMPH trial could have a huge impact on reducing the high mortality rate of cardiogenic shock," Dr. Rothenberg says. "The trials that come through here are exciting because they could change the way heart disease is treated."

# Inclusion Criteria for TRIUMPH

**1.** Diagnosed acute MI confirmed by both ischemic symptoms of 30 minutes or more and electrocardiogram changes with at least one of the following:

- ST segment elevation or depression of $\geq$ 2mm in two or more contiguous leads
- Q-waves that evolve
- Left bundle branch block (LBBB)

**2.** Confirmed persistent cardiogenic shock at the time of randomization with all of these criteria met:

- Peripheral symptoms of tissue hypoperfusion
- SBP<100mm Hg after vasopressor therapy with dopamine, norepinephrine/epinephrine or phenylephrine
- Elevated LV filling pressures that indicate the patient is not hypovolemic
- Left ventricular ejection fraction (LVEF) <40 percent

**3.** Confirmed persistent cardiogenic shock within five minutes of the administration of the study drug. Confirmation is made after all these shock criteria have been met:

- Continuous tissue hypoperfusion
- SBP<100mm Hg after vasopressor therapy with dopamine, norepinephrine/epinephrine or phenylephrine
- No post-randomization intercurrent volume loss

**4.** Patency of the infarct related artery ($\leq$70 percent stenosis with TIMI flow grade) confirmed.

**5.** Cardiogenic shock must be less than 24 hours before the randomization, which lasts at least one hour after infarct related artery patency is confirmed.

***For more information about the TRIUMPH trial, call (561) 548-3440.***

# TRIUMPH Exclusion Criteria

If any of the following criteria apply, patients are excluded from the study:

1. Infection (either suspected or documented)
2. Shock caused by any other reason (septic, hypovolemic, hemorrhagic, anaphylactic, etc.)
3. Acute severe mitral regurgitation (MR) and/or mitral apparatus rupture that results in secondary shock
4. Aortic stenosis, mitral stenosis, aortic insufficiency or any other severe underlying form of valvular heart disease
5. Cardiogenic shock caused by predominant RV failure or severe RV dysfunction
6. Cardiogenic shock caused by rupture of the ventricular septum or ventricular free wall
7. Cardiogenic shock caused by bradyarrhythmia or tachyarrhythmia
8. Aortic dissection
9. Serum creatinine > 3.0 mg/dl
10. End-stage renal disease that requires dialysis
11. Adult respiratory distress syndrome (ARDS)
12. Severe brain damage that will prevent survival (even if normal cardiovascular status is present)
13. Irreversible multi-system failure
14. Abdominal or intra-thoracic surgery within 30 days
15. Primary pulmonary hypertension
16. Under the age of 18
17. Emergency coronary artery bypass grafting (CABG) is necessary
18. Infarct related artery occlusion
19. Participation (either concurrent or prior) in another clinical trial where the last study drug dose was within five half-lives of that drug
20. Prior enrollment in TRIUMPH
21. PCI (iatrogenic shock) that causes cardiogenic shock if the IRA can't be demonstrated as patent
22. Cardiogenic shock that is rapidly resolved between the time of randomization and the administration of the study drug
23. Women who are breastfeeding or confirmed to be pregnant

## Mark Rothenberg, M.D., F.A.C.C.

Mark Rothenberg, M.D., F.A.C.C., interventional cardiologist on staff at JFK Medical Center, earned his medical degree from the Medical College of Pennsylvania. He then went on to complete his internal medicine internship, internal medicine residency and cardiology fellowship at Temple University Hospital in Philadelphia, Pennsylvania.

Dr. Rothenberg is board certified in internal medicine, cardiovascular disease and interventional cardiology, and is a fellow of the American College of Cardiology and a member of the American College of Physicians. He has published in the *Journal of American Cardiology*.

Vladimir Rankovic, M.D., F.A.C.C.

# Cardiac Resynchronization Therapy: New Hope for Heart Failure Patients

The toxic effects of chemotherapy used to treat breast cancer had left Diane, a 48-year-old real estate agent, with a severe cardiomyopathy (CM) and symptomatic congestive heart failure (CHF). Her functional capacity and quality of life had significantly deteriorated. Simply walking across a room resulted in fatigue and shortness of breath. She often woke up at night gasping for air. She was unable to continue her job, and she could no longer participate in routine family activities.

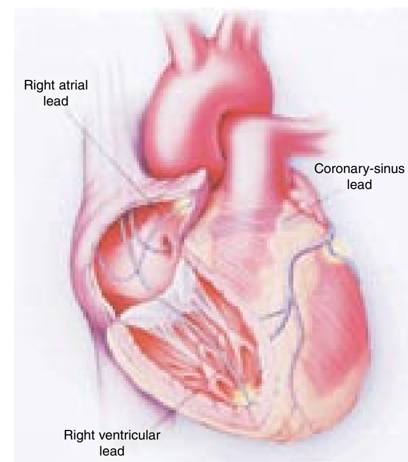
Diane was treated with all the appropriate medications including a beta-blocker, ACE inhibitor and a diuretic with only minimal improvement in her condition. Diane also had a left bundle branch block (LBBB), a cardiac electrical abnormality causing the right side of her heart to contract earlier than the left side. The resultant dyssynchrony between the cardiac chambers acted to further decrease the efficiency of her cardiac pump.

For patients like Diane, their only treatment options until recently were lifestyle changes, medications and sometimes heart surgery. Patients with severe symptoms are often refractory to these approaches.

In addition, up to 40 percent of CHF patients have an interventricular conduction delay (IVCD), further reducing the efficiency of the heart pump. A delay in the electrical signal transmission through the LBBB causes the right ventricle (RV) to contract a fraction of a second earlier than the left ventricle (LV), leading to dyssynchrony of the contraction pattern of the left atrium (LA) and LV. The contraction of the lateral LV wall is delayed compared to the septum, further reducing the efficiency of the contraction.

## What is CRT?

Cardiac resynchronization therapy (CRT) has emerged over the past several years as a new and innovative treatment that can relieve CHF symptoms by improving coordination of cardiac contractility. By simultaneously pacing both the RV and LV, synchrony can be restored. Several large clinical trials are demonstrating the benefits of CRT, including PATH-CHF, MUSTIC-SR, MIRACLE, MIRACLE-ICD, COMPANION, CARE-HF, PATH-CHF II and CONTAK-CD.



CRT lead placement

All of these trials show an improvement in exercise capacity, a decrease in CHF symptoms and an overall improvement in quality of life. Several of these studies have also shown an increase in LVEF (ejection fraction). The COMPANION and CARE-HF trials in particular demonstrated a clear survival benefit after CRT as compared to optimized medical therapy alone.

Data from these trials have been published in a number of medical journals including the *New England Journal of Medicine* and the *Journal of American College of Cardiology.* Although 20 to 30 percent of patients do not respond to CRT, it is the only current treatment that can correct the adverse effects of an IVCD.

## Help Is on the Way

Diane was referred to Florida Electrophysiology Associates for cardiac resynchronization therapy. A CRT device, also referred to as a biventricular pacemaker/defibrillator, involves the implantation of a special pacemaker, which triggers both the right and the left sides of the heart to squeeze simultaneously.

A traditional pacemaker has one or two leads placed in the right side of the heart. A CRT device is implanted in the same manner as a traditional pacemaker with the exception that an additional lead is also placed on the left side of the heart. Implanting a CRT device is often more challenging than a regular pacemaker, but with operator expertise, the procedure

is only slightly longer in duration and patients generally go home the following day.

Florida Electrophysiology Associates at JFK Medical Center performed some of the original investigations with CRT devices, which led to the FDA's approval of the devices. Florida Electrophysiology Associates implant more CRT devices annually than any other medical group in Florida.

After being evaluated by Florida Electrophysiology Associates, Diane underwent successful implantation of a CRT device. Almost immediately, she noted an improvement in her breathing and a decrease in fatigue. Over the next few months, she was gradually able to resume many of her normal activities. She was able to perform low-intensity exercise and even started working again. Her kidney function also normalized over time. The improvement in the quality of Diane's life as a result of CRT was dramatic.

### On the Horizon

Biventricular pacing can be a life-changing therapeutic modality in patients with IVCD, cardiomyopathy and refractory CHF. It has been extremely gratifying to observe the benefits CRT has had for heart failure patients that simply were not available in the past.

Florida Electrophysiology Associates has received numerous letters from patients thanking us for the improvement in the quality of their lives. Although not a current indication for CRT, several patients have also had refractory angina resolve after the procedure.

In the future, with further clinical studies and newer technology, we hope to be able to better select patients who will benefit from CRT and also expand the patient inclusion criteria for biventricular pacing.

***For more information about CRT, call (561) 548-3440.***

## Patient Selection

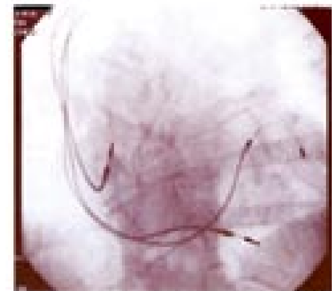
The current American College of Cardiology/American Heart Association Class I Heart Failure Guidelines Recommendations state that patients qualify for cardiac resynchronization therapy if:

—Ejection fraction (LVEF) is less than or equal to 35 percent.

—They are in sinus rhythm.

—They possess New York Heart Association (NYHA) Functional Class III or Ambulatory Class IV symptoms despite recommended, optimal medical therapy.

—They have cardiac dyssynchrony, which is currently defined as a QRS greater than 120ms.



**Slide shows CRT lead placement within the heart**

## Vladimir Rankovic M.D., F.A.C.C.

Vladimir Rankovic, M.D., F.A.C.C., cardiac electrophysiologist on staff at JFK Medical Center, received his B.S. in electrical engineering, his M.S. in biomedical engineering and his medical degree from The Ohio State University in Columbus, Ohio. He then went on to complete his internal medicine residency and cardiology and cardiac electrophysiology fellowship at Northwestern Memorial Hospital in Chicago, Illinois.

Dr. Rankovic is board certified in internal medicine, electrophysiology and cardiology, and is a member of the American College of Cardiology. He has published in the *American Journal of Cardiology* and has presented at the American Heart Association Annual Scientific Session.

James Jaffe, M.D.
Jack Zeltzer, M.D.

# Carotid Stenting Trials Help High-Risk Patients

Patients whose carotid stenosis was previously considered too high risk for surgery now have a unique opportunity to participate in clinical trials at JFK Medical Center comparing carotid stenting with carotid surgery.

The carotid stenting trial tests the Xact® Rapid Exchange Carotid Stent System and Emboshield® Embolic Protection System. The Xact stent is designed to avoid snagging during retrieval, a high-coverage ratio intended to reduce the release of stroke-generating plaque and constructed to tightly conform to the artery. The Emboshield filter opens like an umbrella downstream from the stenting procedure to protect the patient's brain by catching any plaque dislodged by the procedure.

The trial will enroll 50 patients who will be monitored for six months to a year following their procedures. JFK is one of only 50 hospitals with 1,500 patients participating in the study.

"This trial will help researchers learn if carotid stenting can have outcomes equivalent to surgery," says James Jaffe, M.D., neurointerventional radiologist on staff at JFK who has been performing carotid stenting since 1998. "Thus far our equivalency results have been similar to surgery. In 4 to 10 years, carotid stenting could become the standard of care."

## Candidates for Carotid Stenting

Those considered at high risk for carotid surgery include those who have had radiation treatments, stroke or mini-stroke symptoms or who have developed new narrowing after previous carotid surgery. If a patient were symptomatic, 50 percent stenosis or more in the carotid artery, or in an asymptomatic patient, 80 percent or more would also place the patient at high risk for a carotid endarterectomy. Because the procedure is performed without anesthesia, patients with lungs or hearts too weak to undergo surgery may qualify for carotid stenting.

In addition to being an attractive choice for high-risk patients, recovery time from carotid stenting is a matter of hours and can offer a reduced risk of morbidity.

"From a vascular surgeon's perspective, we are entering a new era of knowledge on managing this disease," says Jack Zeltzer, M.D., vascular surgeon on staff at JFK Medical Center. "We have a responsibility to learn new techniques such as carotid stenting and adopt new tools in order to stay current in the cardiac care field."

## Revolutionizing the Standard of Care

The Xact trial at JFK hopes to demonstrate the lasting potential of carotid stenting. With carotid stenting, researchers need to determine if the morbidity rate is less than with surgery and if the procedure offers less nerve damage and better results in the long term than surgery.

"Our studies are now putting people into a current timeline, and outcomes for risk of stroke and recovery are promising," says Dr. Zeltzer. "However, we are unsure of the long-term results regarding the removal of the stent, making those who have a 20-year timeline a less likely choice for surgery."

Through continued research and study, those at JFK hope to determine if carotid stenting is the best choice for all patients—not just those at high risk for surgery.

"With the understanding that some people have vessels that cannot be stented, we want to determine on which candidates can it be done safely with long-term effectiveness," says Dr. Jaffe. "We want to be able to say that if a stent is just as good as surgery and with shorter recovery times, then the stent should be the new standard of care."

*For more information about vascular disease treatments at JFK Medical Center, call Dr. Jaffe at (561) 548-3621 or Dr. Zeltzer at (561) 964-2211.*

## James Jaffe, M.D.

After graduating from Temple University magna cum laude, James Jaffe, M.D., neurointerventional radiologist on staff at JFK Medical Center, remained at the school to receive his medical degree before completing his residency in diagnostic radiology and a fellowship in angiography/interventional radiology at Temple University as well. In 2003, Dr. Jaffe completed an additional fellowship in neuroradiology at the University of Pennsylvania Health System.

Dr. Jaffe, who is certified by the American Board of Radiology in diagnostic radiology with added qualifications in vascular and interventional radiology, was a participant in both the Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) and Maverick studies. He currently serves as a proctor for Acculink, the only FDA-approved carotid artery stent placement tool.

## Jack Zeltzer, M.D.

Jack Zeltzer, M.D., a vascular surgeon on staff at JFK Medical Center, is currently the Chairman of the Department of Surgery at JFK. Dr. Zeltzer is a member of the Florida Vascular Society as well as the President of the South Florida Society for Vascular Surgery.

# Current Clinical Trials at JFK Medical Center

## The Heart and Vascular Institute at JFK Medical Center remains on the leading edge of medical options and treatments through continued participation in clinical trials.

"As one of only a few centers in Palm Beach County involved with clinical trials, we feel we're giving patients who meet the criteria the highest level of excellence," says Joshua Kieval, M.D., board-certified cardiologist and Codirector of the Cardiovascular Laboratory at JFK Medical Center. "In addition, the advantage of our expertise allows us to go above and beyond what others may offer."

The Heart and Vascular Institute is excited to be part of the following clinical trials:

### Cardio Vascu-Grow™

The last issue of *The Journal of Cardiovascular Care* outlined The Heart and Vascular Institute's involvement in Cardio Vascu-Grow, an angiogenic approach to growing new blood vessels where needed. As we approach the end of Phase I, two patients have been enrolled and are experiencing optimal results following the injection of the growth factor directly into heart tissue. Looking forward to the next phases, The Heart and Vascular Institute may consider enrolling a third patient.

### CoStar™

Beginning this spring, The Heart and Vascular Institute will join a randomized, multi-center study, CoStar. This trial will compare Paclitaxel-Eluting Coronary Stent (a reservoir-based DES system) by Cortis and TAXUSTM Express2™ Paclitaxel-Eluting Coronary Stent (surface coated DES stent) in the treatment of single-vessel and multi-vessel coronary artery disease. The study is aiming for 1,500 participants. The Heart and Vascular Institute is accepting as many as possible.

### TRIUMPH

With the knowledge that the body produces a large quantity of nitric oxide during a heart attack, which can develop into cardiogenic shock, TRIUMPH will investigate the use of medication to inhibit the production of nitric oxide and reduce the risk of blood vessel dilatation and resulting low blood pressure. The Heart and Vascular Institute is currently approved to begin the study.

### SYNTAX

The Heart and Vascular Institute looks forward to its involvement in SYNTAX. This groundbreaking and controversial trial is randomized and designed to determine the best treatment for patients with complex coronary disease. Patients will receive either a percutaneous coronary intervention with polymer-based paclitaxel-eluting TAXUS stents or coronary artery bypass surgery (CABG). The study will review the benefits of bypass over stenting and vice versa and will determine if outcomes are comparable.

***For more information on clinical trials at JFK, call (561) 548-5538.***

## Joshua Kieval, M.D.

A cum laude graduate of Harvard University, Joshua Kieval, M.D., board-certified cardiologist and Codirector of the Cardiovascular Laboratory at JFK Medical Center, went on to earn his doctor of medicine degree at the University of Rochester School of Medicine in New York. Dr. Kieval underwent fellowship training at the University of Miami School of Medicine in Florida and has been a diplomate of the American Board of Internal Medicine, American Board in Cardiovascular Diseases and Subspecialty Board—Interventional Cardiology. He is a fellow of numerous associations and has taught up-and-coming cardiologists at the University of Miami School of Medicine since 1979.

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