

The Journal of: Modern Cardiovascular Medicine

by Westside Regional Medical Center

V2N1

Experienced Team Equals Strong Patient Outcomes



At Westside Regional Medical Center, highly skilled and experienced physicians, nurses, and technologists collaborate in the comprehensive Cardiovascular Program.

Westside Regional Medical Center is committed to providing a highly skilled medical staff along with the highest quality of patient care to Broward County. The combination of experience and knowledge from our excellence-driven team of surgeons, cardiologists, anesthesiologists, radiologists, pulmonologists, internists, and clinical support staff allows Westside Regional to provide our patients with the latest scientific advances in medical technology for diagnosing and treating cardiovascular disease through our comprehensive Cardiovascular Program.

To combat heart disease, which annually claims more than 1 million lives, the comprehensive Cardiovascular Program provides a full range of diagnostic modalities, medical and surgical interventional procedures, rehabilitation, and related medical services to improve and maintain the health of people living in the heart of Broward County.

Driven for a Purpose

Westside Regional's comprehensive Cardiovascular Program facilities include dedicated operating rooms and cardiac catheterization and electrophysiology labs equipped with cutting-edge medical technology. A few of the hospital's recent

technological enhancements include the GE LightSpeed VCT XT 64-slice computed tomography (CT) scanner and the brand new GE 1.5 HDx magnetic resonance imaging (MRI) equipment.

Westside Regional also recently acquired the *da Vinci*[®] S HD Surgical System, upon which our highly skilled team of cardiovascular surgeons is trained in performing robotic minimally invasive valve repairs.

In Writing

We believe it is vital that Westside Regional's comprehensive Cardiovascular Program be known to the medical community it serves. One goal for our new publication, *The Journal of: Modern Cardiovascular Medicine*, is to provide the physicians of Broward County information and facts on our Cardiovascular Program. Westside Regional looks forward to continuing to share future journals with our medical community to communicate news of the services we offer to treat the nation's number one killer: cardiovascular disease.

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Mary Lynn Swartz, CEO
of Westside Regional
Medical Center



Leading-Edge Upgrade

A powerful software upgrade to imaging equipment is providing industry-first technology in cardiac computed tomography (CT)—outstanding image quality, at incredible speed, with less radiation exposure.

The **GE LightSpeed VCT XT** is the very latest in CT technology and scans as fast as 0.35 seconds per rotation. The 64-slice CT scanner captures sub-millimeter resolution images with minimal artifacts, such as:

- Beating hearts in five beats
- Internal organs in one second
- Full body trauma in 10 seconds

A hardware and software upgrade builds on the foundation of our already advanced technology to provide better outcomes for physicians, CT technologists, and patients.

SnapShot Pulse™

Through prospective triggered gating, SnapShot Pulse limits the patient X-ray dose by 70 percent or more. Responding to the patient's heart rate ensures the X-ray is on only during desirable portions of the scan. This new feature may extend the power of cardiac CT to patients previously excluded due to various risk factors.

The upgrade creates the first multi-slice scanner of its kind capable of performing CT angiographic (CTA) studies, converting from conventional helical acquisition to step-and-shoot. Movement of the table provides coverage of the entire volume of a patient's heart, suspending the X-ray as it moves. Again, paced by the patient's heart rate, high-quality images are obtained from the same phase of the cardiac cycle, minimizing the dose to the patient.

In Summary

As technology advances, the decision of how and when to use CTA studies still resides with physicians. According to news from the European Society of Cardiology Congress 2006, the high diagnostic accuracy of CT makes it an ideal choice when a physician is confronted with a patient with chest pain. However, if the results do not lead to an unequivocal diagnosis, physicians should follow up with a functional test.

Benefits of the Technology

Patients, physicians, and computed tomography (CT) technologists realize major benefits from the innovations in speed and quality provided by the upgraded 64-slice CT scanner. The following advances are among them:

- Patients experience reduced stress during the procedure as a result of being coached on their breathing by light cues and having to hold their breath for shorter periods of time than with the earlier version of the equipment.
- Physicians may interact with the patient while the technologist performs the scan and can also review the case within minutes.
- Pictures are clear and accurate due to the speed of the scans.
- Technologists save time and steps, thus maximizing throughput, thanks to the controls now located at the front and back of the equipment, an in-room start, and a remote gantry tilt.



Images represent cardiac computed tomography scans.

Focus on Technique

Recent data suggest that two-thirds of late-stent thrombosis cases may be due to drug-eluting stent (DES) sizing, DES underexpansion, and technical problems post-dilation. Interventional cardiologists are addressing these concerns by refocusing on technique.

Of the patients referenced in the data, between 15 and 30 percent of those with bare-metal stents (BMS) experienced restenosis, the process by which significant scar formation at the stent site allows tissue to grow through the openings of the metal mesh. The next generation of stents—known as drug-eluting stents—was granted U.S. Food and Drug Administration (FDA) approval in 2003 and helps reduce the rate of restenosis by slowly releasing drugs that help prevent growth of scar tissue.

The two FDA-approved devices, Cordis Corporation's Cypher (which elutes sirolimus, a drug previously used to prevent organ transplant rejection) and Boston Scientific Corporation's Taxus (which elutes the cancer-treatment medication paclitaxel) have been used in more than 3 million patients since that time, with a restenosis rate of less than 5 percent.

History of Drug-eluting Stents

As far back as 2005, European researchers began noting that patients with DES had significantly higher occurrences of late-stent thrombosis than their counterparts with bare-metal stents. Additional studies—such as the BASKET-LATE study presented at the American College of Cardiology Scientific Sessions in March 2006 and the Camenzind meta-analysis presented at the European Society of Cardiology Annual Meeting/World Congress of Cardiology meeting just six months later—revealed that patients followed for 18 to 36 months after stent implantation had a slightly higher risk of myocardial infarction and death as a result of the thrombosis.

An editorial published in *Cardiosource*, an online publication of the American College of Cardiology, estimated that 45 percent of stent thrombosis events are fatal. The Cedars-Sinai physicians who wrote the editorial predicted that as many as 2,000 deaths occur each year as a result of DES.

Best Practices

To further combat problems associated with DES thrombosis, the FDA's advisory panel recommended

Key Considerations

Success of drug-eluting stent procedures depends heavily on the decisions made by the interventional cardiologists, among them:

- Correct sizing of stent length to match the length of the blocked area or lesion
- Correct sizing of stent diameter to match the healthy artery
- Sufficient deployment of the stent confirmed through real-time angiography or intravascular ultrasound imaging

extending dual antiplatelet therapy of aspirin and Plavix® (clopidogrel) for patients with off-label stent placement and requested that future clinical trials for DES specifically address stent thrombosis issues.

A *Cardiosource* editorial from September 2006 advocates the use of DES technology only in situations where benefits outweigh risks, offering the following guidelines:

1. Use DES only for patients at high risk for restenosis, such as vessels of smaller diameter or longer lesions.
2. Use provisional DES for patients who experience restenosis following BMS.
3. Avoid DES in patients unable or unlikely to comply with long-term dual antiplatelet therapy.

Revascularization vs. Medical Therapy

Findings from the COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) Trial released earlier this year revealed that percutaneous coronary interventions (PCI) plus stenting combined with optimal medical therapy was no more successful in preventing future cardiovascular events than optimal medical therapy alone in patients with stable coronary disease. The addition of PCI to medical therapy did reduce the prevalence of angina, but it did not reduce long-term death rates, nonfatal myocardial infarction (MI), and hospitalization for acute coronary syndrome.

William Boden, M.D., F.A.C.C., principal investigator of the COURAGE Trial, suggests many physicians fear the possibility of litigation if they do not perform angioplasty and a subsequent cardiovascular event occurs, therefore conducting more revascularization procedures than necessary. Dr. Boden suggests PCI is not always necessary and medical therapy may be the most efficacious for initial treatment of chronic stable angina patients.

Utilization of a closed catheterization laboratory, one dependent on referrals from cardiovascular specialists, can help to eliminate unnecessary revascularizations.

Atrial Fibrillation and Electrophysiology

Atrial fibrillation (AF) can lead to stroke, significant morbidity, and increased risk of premature death due to heart failure. Exploring effective treatment methods for AF through electrophysiology presents an opportune means for avoiding these severe complications.

AF is an extremely common disorder, particularly in the older population, where it has a prevalence of up to 10 percent. It is associated with somatic symptoms, including decreased tolerance for exercise and reduced quality of life.

“Most symptoms associated with AF are related to rapid heart rates, irregular heart rhythms, or decreased heart function,” says Bruce Perlman, M.D., board-certified cardiac electrophysiologist on staff at Westside Regional Medical Center. “One of the problems associated with atrial fibrillation is the impaired ability to regulate heart rate, resulting in inappropriately high or low rates and loss of the normally smooth increase in heart rate during exercise and stress.”

David N. Kenigsberg, M.D., a clinical cardiac electrophysiologist who recently joined the staff at Westside Regional, states that “there are many options now available to cure atrial fibrillation, including catheter-based ablative approaches and advances in surgery.”

Diagnosing AF

“AF is easy to diagnose if a patient presents symptoms while visiting a physician, because his or her heartbeat is irregular,” says Matthew L. Carr, M.D., board-certified cardiologist on staff at Westside Regional. “Palpitations, rapid heartbeat, shortness of breath, coronary plaque, and prior episodes of TIA or stroke should all cause primary physicians to seek further investigation, as AF could be the underlying cause.”

Symptoms like palpitations, dizziness, lightheadedness, loss of consciousness, or arrhythmia identified on an electrocardiogram should result in

referral to an electrophysiologist. Not everyone with AF is an appropriate candidate for catheter ablation, but many who are candidates have not been identified.

Some presumed to have AF may actually have more easily treated atrial tachycardia and atrial flutter. Patients who benefit from AF ablation are typically younger than 70 years old, are highly symptomatic, have tried and failed anti-arrhythmic medical therapy, and understand the benefits and risks of the procedure.

Treating AF

Special medications called anti-arrhythmics can often suppress or control AF. “Unfortunately, anti-arrhythmics can be difficult to tolerate and have significant short- and long-term side effects and toxicities, some of them potentially life-threatening,” says Dr. Perlman. “Intermittent episodes of asymptomatic AF are also common in people on medical therapy, and long-term blood thinners are recommended to avoid stroke.”

All blood thinners require significant patient education to avoid medication or foods that may affect these drugs and to diminish the risk of bleeding while taking them. A blood thinner does not eliminate the entire risk of stroke, and the risk of bleeding may be excessive in some patients, precluding its use.

Sometimes, when a patient’s heart rate remains difficult to control despite aggressive medical therapy, an atrioventricular (AV) nodal ablation can be performed, which cuts the normal electrical connection between the upper and lower chambers and stops the rapid rhythms, but has the downside of leaving the patient in AF with a need for blood thinners and also makes him or her dependent upon a pacemaker.

What Is a Cure?

“Curing AF is defined as absence of the condition, as verified by long-term monitoring as an outpatient,” says Dr. Kenigsberg. “Several procedures offer the possibility of curing AF, from open-chest surgeries to less-invasive catheter-based procedures. The type of procedure should be recommended based upon the underlying cause of the AF, the presence of other medical conditions, age of the patient, and presenting symptoms.”

Patients who appear to have no AF on medical therapy alone have a high incidence of asymptomatic arrhythmia and should remain on long-term anticoagulation, while those who have undergone a successful surgical or catheter ablation for AF could potentially be taken off anticoagulation in the future if aggressive follow-up testing shows no further arrhythmia.

Catheter Ablation

In a fashion similar to that of balloon angioplasty replacing a significant portion of bypass surgeries, a catheter-based procedure using the femoral vein for access to the right side of the heart has supplanted arrhythmia surgery for supraventricular arrhythmias, including AV nodal reentry tachycardia, tachycardia utilizing accessory pathways (including Wolff-Parkinson-White syndrome), and atrial tachycardia. “The cure rates for catheter-based treatment of the supraventricular arrhythmias are greater than 95 percent with a single procedure,” says Dr. Kenigsberg. “Since the discovery of pulmonary vein potentials by Dr. Haissaguerre in 1998, an improvement in the understanding of the pathophysiology of AF has transpired. Because of this discovery, there has been an increase in catheter ablations to treat and potentially cure AF, especially in patients with paroxysmal atrial fibrillation.”

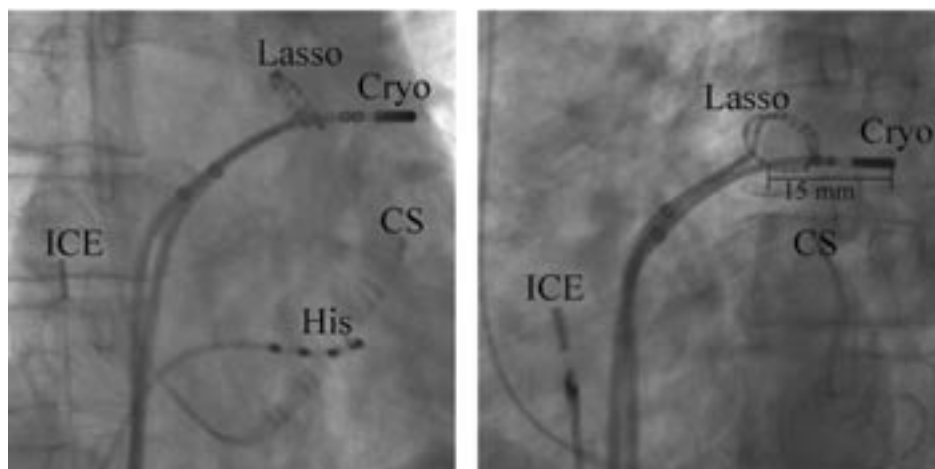
With continuous improvements in the tools and technology that are used to treat this arrhythmia, much progress has also been made toward equivalent cure rates for people with chronic AF. “In the past, it was more common for doctors to give up on converting patients with chronic AF to normal sinus rhythm,” says Dr. Kenigsberg. “However, today we can offer these patients a potential cure via a catheter-based approach. Furthermore, even patients who are not ‘cured’ typically experience improved health and fewer episodes of AF following ablation.”

New Cryoablation Option

One improvement in the catheter-based approach to treating AF is the use of an alternative energy source. Unlike radiofrequency ablation, which burns the cardiac tissue to destroy it, cryoablation freezes the tissue. Cryoablation enables curative measures to be taken for AF sufferers with reduced risk. “This technique has proven to be safer when working in areas of the heart where the tissue to be ablated is juxtaposed with tissue that should not be affected,” says Dr. Kenigsberg, a local expert in cryoablation. “Cryoablation allows the electrophysiologist to go deeper into the pulmonary vein in order to isolate it without worrying about pulmonary vein stenosis as a complication. The same is true when working inside the coronary sinus in a patient with chronic AF and when working near the esophagus.”

Referring patients to an electrophysiologist is the appropriate action for determining the best treatment options for patients with AF. At Westside Regional, medical staff with experience in complex arrhythmia cases have been recruited from around the country. In addition to cryoablation (see Figure 1 below), electrophysiology options at Westside Regional include a recently updated 3-D mapping system and the addition of intracardiac echocardiography.

Figure 1. Cryoablation catheter positioned in the PV in the RAO (right) and LAO (left) projections. The lasso catheter is positioned at the PV ostium. The coronary sinus (CS) and His bundle (His) catheters are in standard position. The ICE catheter is located in the right atrium. Note the cryoablation catheter 15 mm inside the PV ostium as defined by the lasso catheter. Cryo was delivered here to isolate the PV.



Measuring Cardiovascular Outcomes in

Over the past decade, the healthcare industry has been characterized by major changes and increased uncertainty. With the advent of managed care and a number of cost-containment initiatives, providing quality care to patients is becoming more difficult for healthcare professionals and hospitals. As the healthcare environment becomes more competitive, in order to survive and flourish, the successful hospitals of the future must demonstrate measurable differences in clinical outcomes against their competition.

There is increased recognition that the application of information processing technology is essential in the collection, storage, and retrieval of cardiovascular outcomes data. The implementation of advances currently available in information technologies is no longer a luxury in today's competitive healthcare market. These clinical database management tools have become a vital part of ensuring an enhanced level of patient services.

It is becoming a necessity in today's healthcare environment that physicians, surgeons, and service-providing institutions maintain clinical outcomes databases which provide easy access to selected patient clinical factors. The initial ingredient in quality measurement and service improvement is uniform systematic clinical data collection. To be of value, data must be collected and stored in an organized manner, employing standardized methodologies that provide for effective, efficient retrieval and reporting. Cardiologists and cardiac surgeons and the institutions in which they practice have recognized that the collection, storage, retrieval, and analysis of patient outcomes data represent an invaluable source of information for clinical decision-making.

A body of readily accessible clinical outcomes data in cardiovascular services is critical and represents a commitment to excellence in the provision of quality services to patients. It is essential to determine which therapeutic interventions and strategies are most successful in treating various cohorts of patients. It can assist in deciding among different treatment alternatives and the various effects of treatment; monitoring the success of treatment; and planning and coordinating various individualized therapeutic strategies.

Benchmarking on a national as well as regional and local level is also essential if hospitals are to have a better understanding of their performance. The Society of Thoracic Surgeons (STS) and the American College of Cardiology (ACC) have each established national databases for their respective specialties. These two national initiatives represent a cooperative program with practitioners throughout the nation in which clinical data are harvested

periodically to a central site for processing, analysis, and reporting. Participants can then compare their outcomes with those achieved by similar entities in their region and across the country. Participation in these standardized and monitored clinical databases serves to foster a culture of quality as well as the basis for the implementation and maintenance of a continuous quality improvement program. Historically, the collection and sharing of clinical outcomes data have been shown to lead to significant program improvements and an enhanced level of quality.

An integrated cardiovascular outcomes clinical database (Figure 1) is the cornerstone of a comprehensive outcomes management system in the delivery of healthcare services. Outcomes management is the key to effective, efficient resource allocation and utilization. This type of information architecture supports the design and implementation of a continuous quality improvement program within an institution. A well-designed clinical outcomes management program offers a number of tangible benefits to participants. It allows physicians and the institutions in which they practice to monitor and facilitate the development of "best practices" and focus on providing an improved level of quality to patients in the most cost-effective and efficient manner.

Healthcare organizations, including third-party payers, medical societies, and regulatory agencies, are using clinical outcome data to monitor quality assurance, establish practice guidelines, and evaluate new and emerging medical and surgical technologies. Outcomes evaluation can be used by physicians, surgeons, and other healthcare professionals within institutions to select the most appropriate cost-effective management strategies for patients and support ongoing research initiatives.

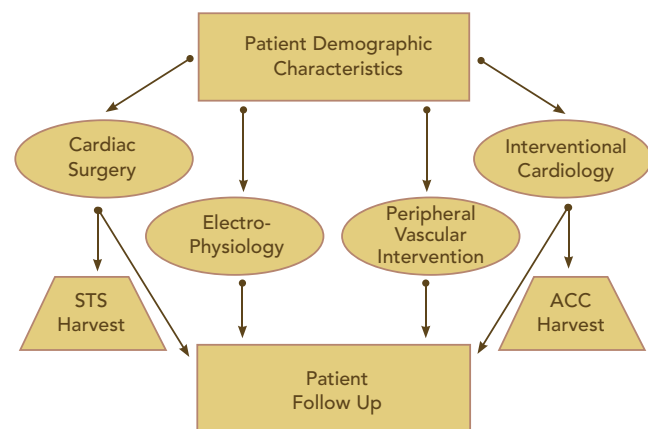


Figure 1 – Integrated Cardiovascular Outcomes Clinical Database

Today's Competitive Healthcare Market

In today's healthcare environment, patients/consumers are demanding more clinical outcomes data for informed decision-making concerning their healthcare needs. They are asking for information on morbidity, mortality, long-term results, and costs for various types of therapeutic interventions. Moreover, group benefit purchasers/insurers are using clinical outcomes data to determine which physicians and hospitals provide quality care for their employees, subscribers, participants, etc. These groups often question why differences exist in the quality and efficiency of care provided by various physicians and institutions. Moreover, the federal government, state regulatory agencies, private entities, and healthcare consumers are pushing for a greater degree of "data transparency" on hospital and physician practices.

As patients become more conversant with accessing the information highway and utilizing the capabilities of the Internet, consumers can retrieve a broad array of data on hospital quality. As a result, it is critical that institutions be able to respond to the informed patient. Moreover, legislatively mandated public disclosure of data by physician and hospital will require the continuous monitoring of clinical outcomes data. These comprehensive information management resources are an essential ingredient for addressing patient concerns in today's competitive healthcare environment.

The current healthcare payment system is "dysfunctional" and often fails to recognize the process of furnishing quality care to patients and rewarding providers accordingly. With the advent of pay-for-performance, an opportunity exists to realign incentives in a way that rewards physicians and hospitals for the delivery of cost-effective quality care. Pay-for-performance is rapidly gaining momentum as a method to raise the bar on quality and as a means of ensuring that, given the money spent, the best care is provided to patients.

The current healthcare payment system must be reengineered using appropriate quality metrics as the foundation for creating a fair and credible pay-for-performance environment. It is important that the right measurements to assess quality of care be collected in an accurate, valid, and reasonable manner. While there is a concentrated effort to tie performance to payment, it is essential that appropriate and adequate incentives be used to determine how compensation for services will be linked to improvements in patient care.

As healthcare costs continue to escalate, commercial payers and/or government agencies are demanding

greater accountability from healthcare providers for the financial resources being expended. The key to establishing increased accountability is the objective assessment of quality of care. This assessment process can best be accomplished through the implementation of standardized performance measures. An outcomes clinical database management system is the cornerstone of a data-driven quality improvement program that guarantees each patient the highest quality of care in the most cost-effective manner.

Dr. George Ebra and Associates



Dr. George Ebra and Associates is a cardiovascular outcomes research and information management organization. The founder, Dr. George Ebra, has been involved in cardiovascular outcomes research and data management for over 30 years. Dr. Ebra received his bachelor's degree from the University of Tampa, master's degree from the University

of South Florida, and doctorate from Nova Southeastern University. He has held academic appointments at several institutions of higher learning.

Dr. Ebra has participated in numerous peer-review journal publications over the years including long-term studies of valve repair and replacement, valve durability, myocardial revascularization using arterial conduits, coronary artery bypass grafting in women, and the long-term benefits and quality of life of cardiac surgery in the elderly. More recently, he has addressed surgical intervention outcomes in the treatment of atrial fibrillation.

The group focuses on the application of informatics technology including the design, development, implementation, and support of cardiovascular database systems. Moreover, the organization provides data auditing services, research design, statistical analysis, and outcomes evaluation. As a consultant, methodologist, and statistician, Dr. Ebra has provided a broad array of clinical data management and analytical services to physicians, surgeons, hospitals, and cardiac device manufacturers in the design and conduct of numerous medical/surgical research projects throughout Florida.

Mitral Valve Repair Made Easier and More Effective

The surgical treatment techniques for mitral valve prolapse are constantly improving, and Westside Regional Medical Center is one of about 300 hospitals worldwide to offer the latest advancement—the robotic *da Vinci*® S HD Surgical System.

The *da Vinci S HD Surgical System* is a dramatically different surgical technique that utilizes a set of robotic instruments and cameras placed at the surgical site through tiny incisions, some no longer than the diameter of a pen. Under the surgeon's control, the arms of the *da Vinci* are more flexible and stable than a human hand. Further, the surgeon's ability to see the operative site is vastly improved by the pair of tiny high-resolution cameras that magnify the visual field up to 10 times its actual size in three dimensions.

All of this makes heart surgery easier and less painful for patients than traditional surgery. In fact, patients who undergo surgery with the *da Vinci* system may return home as soon as two days following the procedure and resume normal activities in two to three weeks. Additionally, the precision of robotic surgery reduces pain, blood loss, and scarring.

"Before robotic surgery, I had to open the patient's breast bone through a 12- to 18-inch incision," says Harold G. Roberts, Jr., M.D., F.A.C.S., Senior Cardiothoracic Surgeon at Westside Regional, who, as of last year, had performed more mitral valve repairs than any other surgeon in Florida. "Using the *da Vinci* technology, I've been able to repair mitral valves with much less surgical trauma."

Benefits with Scientific Backing

In one study cited by the *Annals of Thoracic Surgery* (2003; 75: 438–443), all patients who underwent robotic mitral valve repair had successful operations. Many of the surgeries were complex and entailed quadrangular resections, sliding plasties, edge-to-edge approximations, or chordal transfers and replacements.

Participants in the study had nonischemic, moderate to severe mitral insufficiency prior to surgery. In all cases,

robotic repair decreased total operating times and lengths of stay following surgery, allowing most patients to return home in four days or less.

"I have used the *da Vinci* system for numerous mitral valve surgeries," Dr. Roberts says. "So far, my repair rate has been 100 percent with the use of this equipment. The outcomes have been excellent, and my patients have been pleased."

"The da Vinci® S HD Surgical System provides a way for us to minimize the recovery time, disfigurement, and blood loss associated with standard open-heart surgery. Having this surgical tool speaks volumes about Westside Regional's commitment to staying on the leading edge of quality cardiothoracic surgical care."

—Harold G. Roberts, Jr., M.D., F.A.C.S., Senior Cardiothoracic Surgeon at Westside Regional Medical Center

An Array of Robotic Procedures Available

Surgeons at Westside Regional Medical Center have received in-depth training for using the *da Vinci* S HD Surgical System for a variety of cardiothoracic procedures, including:

- Closure of atrial septal defects
- Insertion of pacemaker leads
- Minimally invasive coronary bypass
- Mitral valve repair
- Removal of tumors from the chest
- Treatment of atrial fibrillation using the Cox-Maze approach

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