ABSTRACTS

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SURGICAL VENTRICULAR RESTORATION (SVR) EVOLVES FURTHER WITH THE DEVELOPMENT OF AN ENABLING TECHNOLOGY IN THE FORM OF AN ENDOVENTRICULAR SHAPER WHICH SUPPORTS REPRODUCIBILITY OF OUTCOMES WITH ACCOMPANYING DECREASED MITRAL REGURGITATION

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PURPOSE: To report initial clinical and functional outcomes of patients who have undergone surgical ventricular restoration using an endoventricular shaper (Mannequin™ Chase Medical) sized based on the patient's body surface area. The polyurethane shaper is used intra-operatively to define position of a new apex, to reshape the ventricle, to correct long to short axis ratio, to reorient muscle fibers and papillary muscles to a more normal orientation, and to optimize the ventricular size.
DESIGN: A multi-center retrospective evaluation of pre-operative and post-operative functional data of 153 patients who have undergone surgical ventricular restoration with the endoventricular shaping device.
SUMMARY: Clinical research has shown that the progressive degradation of physiologic function, diminished quality of life, repeated hospitalizations and early mortality associated with CHF are a direct consequence of a dilated spherical ventricle with limited contractile and filling capacities. A variety of studies have demonstrated the success of SVR in treating dilation of the post infarction ventricle. However, restoration of normal ventricular shape presented a challenge and resulted in the introduction of secondary mitral regurgitation. Initial SVR procedures were performed using only a cardiovascular patch; the introduction an endoventricular shaping device to assist the surgeon in restoring the ventricle to its normal elliptical shape has resulted in improved functional and clinical outcome. The introduction of the elliptical shaper allows the surgeon to size and configure the ventricle, ensures a more normal short axis/long axis ratio, and identifies the correct position of the new apex. The size and shape of each shaper is based on experience with 985 patients who under went restoration beginning in 1989. As surgeons utilized the endoventricular shaper, there was an opportunity to consistently restore the ventricular shape, and to prevent incorrectly oriented ventricles that are too small, too large or too "boxy". The evolution of the procedure based on the development of the shaper may facilitate greater reproducibility of favorable outcome and predict broader acceptance of SVR as a therapy for ischemic cardiomyopathy. Patient characteristics have been identified for patients both pre and post operatively with surgical ventricular restoration. These characteristics include gender, age, and New York Heart Association Classification Function measurements demonstrated a significant reduction in degree of mitral valve regurgitation accompanied by an increase in ejection fraction.
CONCLUSIONS: Functional outcomes support continued adoption of surgical ventricular restoration with an endoventricular shaper as a therapy for selected patients diagnosed with congestive heart failure. The procedure with this methodology allows the surgeon to restore elliptical shape, to optimally resize and to reorient the ventricle in the heart failure patient. The replicable process produces consistent outcomes with a significant decrease in level of mitral regurgitation. Further studies will provide additional key indicators useful in patient selection for this procedure.
RESULTS:

Gender (n=153)
Male 82.5%
Female 17.5%
Patient Age (n = 139)
< 45 = 2.9%
45-55 = 16.5%
55-65 = 30.2%
65-75 = 33.2%
75-85 = 17.2%
Mean Age 64.12
StdDev = 10.34

MECHANISM OF ISCHEMIC MITRAL REGURGITATION: ECHO AND CLINICAL ISSUES

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The optimal management for moderate mitral regurgitation (MR) at the time of coronary revascularization remains controversial. It is well documented that even mild MR in the setting of acute or chronic myocardial infarction adversely impacts survival in patients receiving long-term medical therapy (1-3). Despite this, it is interesting to note that the AHA/ACC guidelines for the Management of Patients with Valvular Heart Disease make no comment on how to manage patients with ischemic MR undergoing coronary bypass surgery (CABG). Some still argue that revascularization alone, without correction of mitral regurgitation is adequate therapy (4-6). The rationale for this conservative approach includes potential reversibility of MR following revascularization, concern regarding increased mortality with concomitant mitral surgery, and an uncertainty that residual ischemic mitral regurgitation negatively impacts the patient. A growing number of surgeons have recently adopted a more aggressive approach which includes mitral annuloplasty at the time of coronary revascularization, based on the recognition that ischemic MR may not be reversed by CABG alone (7), that modern techniques of repair are generally effective in this groups of patients (8-9), and that residual mitral regurgitation does in fact adversely impact patient outcome (10-12).

It is now understood that Carpentier type IIIb dysfunction is the basis for ischemic MR. Echocardiographic findings in patients with ischemic MR include papillary muscle displacement, leaflet tethering with displacement of the line of coaptation below the annulus, and central regurgitation. Preload and afterload reduction due to general anesthesia downgrades the degree of MR (13-14), and provocative testing with volume loading and pharmacologic control of afterload should be utilized in borderline cases (15).

Posterior extension of the left atrial incision between the right inferior pulmonary vein and the inferior vena cava is useful to aid with surgical exposure of the valve. Segmental valve analysis should always be performed to confirm the preoperative echocardiographic findings. Patients with moderate ischemic MR should receive a full remodeling annuloplasty, as opposed to a partial band restrictive annuloplasty. This approach aggressively restores the antero-posterior (e.g. septal-lateral) valve diameter, restoring leaflet coaptation and valve competency while preserving the transverse diameter of the mitral valve. Unlike patients with other types of valve dysfunction (e.g. Type II myxomatous disease), emphasis should be placed on downsizing the ring in the setting of ischemic MR. Adjunct procedures including leaflet mobilization with secondary chordal resection, posterior leaflet extension, and subvalvular ventricular remodeling are potentially useful in addition to a downsized remodeling annuloplasty. It is important to emphasize residual MR is a predictor of mortality in these patients (16), and patients with complex mitral regurgitation jets and pathology may benefit from primary replacement (8).

Recent data confirms the presence of ischemic mitral regurgitation in patients undergoing percutaneous coronary intervention significantly decreases survival over 3 years in a grated fashion, especially for patients with ejection fraction < 40% (17). A multi-center prospective randomized trial comparing coronary artery revascularization (PCI/CABG) with or without concomitant mitral valve repair will further clarify the optimal management of patients with ischemic mitral regurgitation.

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THORACOSCOPIC TRANSMYOCARDIAL LASER REVASCULARIZATION

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Transmyocardial laser revascularization reduces angina in patients with coronary artery disease who are not candidates for coronary artery bypass surgery or percutaneous coronary interventions. When used as sole therapy, sternotomy or thoracotomy have been the traditional approaches. Advances in robotic instrumentation and intracorporeal stabilization have allowed the realization of less invasive approaches. Presented, is a video demonstration of thoracoscopic transmyocardial laser revascularization in the presence of prior coronary artery bypass surgery.

SURGICAL ATRIAL FIBRILLATION ABLATION (SAFA): THE COLUMBIA EXPERIENCE

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Introduction. Atrial fibrillation (AF) is one of the most common cardiac arrhythmias, affecting 0.4% of the general population and 5 to 10% of persons over 65 years of age. In addition, AF occurs in as many as 50% of patients undergoing cardiac operations. Patients with chronic AF may suffer from symptomatic tachycardia or low cardiac output, and have a 5-10% risk of thromboembolic complications. Compared to age-matched cohorts in sinus rhythm, patients with chronic AF are at twice the risk for death. Although electrical cardioversion, alone or in combination with antiarrhythmic therapy, is often effective in restoring sinus rhythm, recurrence rates as high as 75% have been reported. Furthermore, pharmacologic therapy is associated with adverse effects in a significant proportion of patients.

Since the initial description of the Maze procedure by Cox and colleagues, a number of surgical approaches have been devised for the treatment of AF. Although successful in the eradication of AF in a high percentage of cases, these procedures are invasive (requiring median sternotomy, cardiopulmonary bypass, cardioplegic arrest, extensive cardiac dissection, and/or multiple atrial incisions) and are associated with significant morbidity. Recent investigations suggest that in many patients, AF may be caused by reentry wavelets limited to specific areas near the origins of the pulmonary veins. In fact, several authors have reported success with more limited procedures aimed at the electrical isolation of discrete atrial regions, utilizing atriotomy, radiofrequency ablation, or cryoablation.

Columbia Experience. Since 1999, we have used a number of energy sources to perform pulmonary vein isolation for AF in patients having other cardiac operations. Over 4 years, we have performed this procedure in over 220 patients. Success rates at 6- to 12-month follow-up approach 80%. We perform the left-sided ablation by creating an encircling lesion around the four pulmonary vein orifices, as well as a lesion from this encircling lesion to the mitral annulus. Ablation is performed with one of a variety of probes, utilizing unipolar or bipolar radiofrequency, microwave, or laser energy. We have found this technique to be straightforward, reproducible, and expedient, rarely adding more than 20 minutes to the concomitant operation. Based on this experience, we now perform pulmonary vein isolation on all consenting patients with atrial fibrillation having a concurrent open-heart procedure, and have performed AF operations for atrial fibrillation as the sole indication. Described below are some important points relevant to the selection and treatment of these patients.

Patient Selection. The minimal duration of atrial fibrillation that should prompt intervention with an ablative procedure is debated. In patients with mitral valve disease and recent-onset AF (less than three months), it is believed that mitral valve repair or replacement alone is sufficient to restore sinus rhythm in most cases. In order to avoid operating unnecessarily on patients with a reasonable chance of spontaneous sinus rhythm recovery, we currently offer pulmonary vein isolation only to patients who have had AF (either chronic or paroxysmal) for at least 6 months, or to those who have failed at least two cardioversion attempts. We most frequently perform this procedure in patients undergoing mitral valve operations, but have also applied this technique in patients undergoing ASD closure, aortic valve operations, coronary artery bypass grafting, and for lone atrial fibrillation. Because of the potential to completely discontinue anticoagulation by restoring sinus rhythm, we are most aggressive about performing surgical atrial fibrillation ablation in patients undergoing valve repairs or tissue valve replacements. However, we also offer the procedure to patients receiving mechanical valves, since the elimination of atrial fibrillation may allow lower anticoagulation levels, as well as improved cardiac function and avoidance of anti-arrhythmic medications.

Operative Technique. Because our preferred approach to the mitral valve is by a left atriotomy made just medial to the right pulmonary veins, we have utilized this incision for our pulmonary vein isolation procedures. In addition to providing excellent exposure of the left atrium and mitral valve, the atriotomy serves as the right lateral component of the pulmonary vein encircling lesion. We isolate the pulmonary veins by creating a continuous endocardial lesion that begins at each end of the atriotomy. Our isolation technique includes a lesion from the pulmonary vein encircling lesion to the mitral valve annulus. There is data to suggest that this lesion is important in interrupting the propagation of atypical left-sided atrial flutter. We also believe that anatomic isolation of the left atrial appendage (either by resection or pursestring exclusion) is important to help prevent thromboembolism.

Because the majority of patients with atrial fibrillation have left-sided initiating foci, we usually confine our ablation to the left atrium. In patients undergoing a concomitant right atrial procedure and in those with a history of atrial flutter (in whom right-sided initiating foci are common), we also per-

form a limited right atrial ablation procedure. This includes a longitudinal anterolateral incision in the RA (standard right atriotomy), as well as an ablation lesion from the inferior aspect of the atriotomy to the tricuspid annulus.

The majority of these operations have been performed in conjunction with other cardiac operations (such as valve repair or coronary bypass), but the procedure has also been used for atrial fibrillation as the sole indication. In fact, we now routinely perform AF surgery via a 6 cm minithoracotomy incision, both for lone AF as well as combined AF and mitral valve surgery. We have also performed several beating heart epicardial atrial fibrillation operations, and have developed a totally endoscopic, beating heart version AF ablation procedure. In early 2003, we successfully performed the first of these in a patient with long-standing AF, and are now offering this completely closed chest minimally invasive operation for atrial fibrillation as the sole indication.

ENERGY SOURCES FOR SURGICAL ABLATION OF ATRIAL FIBRILLATION

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Other than cryoablation, the 'hot' energy sources span the electromagnetic spectrum from the large radiofrequency waves to the small near infrared laser energy. Many devices are still in their infancy clinically and others are in the pre-clinical stages. Of the many devices, only cryoablation has an indication by the Food and Drug Administration for the treatment of arrhythmias (though not AF specific). The other devices generally have approval for cardiac tissue ablation without an arrhythmia indication.

Cryoablation. Cryoablation has the longest history of surgical atrial ablation and is an important component in Dr. Cox's Maze procedures. Current modifications have been aimed at creating flexible linear probes for use in epicardial and endocardial ablation. At this time there is a lack of evidence to demonstrate the feasibility of epicardial cryoablation, though it is expected that the warming effect of the endocardial blood will make successful ablation extremely difficult. Traditional systems are nitrous based but the newer argon and helium based systems allow for much colder temperatures which may limit the ablation time.

Cryoablation has extensive clinical use and has now even been used by some to complete an entire Maze procedure. In general, cyroablation has an excellent clinical safety record, though its use in AF surgery has typically been reserved for creating spot lesions over the tricuspid and mitral valve annuli. This practice has resulted in a few cases of coronary artery stenosis, though this is a rare complication.

Due to its generally safe record and arrhythmia-specific indication, cryoablation will continue to play a role in endocardial ablation. It has been used anecdotally from the epicardium using the newer colder systems with apparently promising results. The creation of a new variable length and flexible probe has helped facilitate this approach. Its future in minimally invasive approaches has yet to be determined on a wide scale, and while an attractive energy source, its bulky nature may limit its widespread use.

Radiofrequency. Radiofrequency (RF) ablation has been available for many years, though it has not been used extensively by surgeons until recently. RF is the source most familiar to cardiologists performing catheter-based arrhythmia treatments. RF is unmodulated alternating current at 500-1000 kHz. The mechanism of heat generation with RF is by resistive or ohmic heating. The RF energy is emitted from the probe over a very small area and thus has a high current density. This high current encounters the tissue, which acts as a resistor, and heat is generated. The true resistive heating occurs only around 1 mm deep into the tissue and the remainder of ablation occurs via conductive heating from the area of resistive heating. This results in a relatively inefficient heating process, yet it provides for well controlled and generally safe ablation. In reality these lesions rarely take more than one minute to create. While there are multiple modifications of RF, there are three general methods: unipolar, bipolar and irrigated. Each has its own relative advantages and disadvantages.

Unipolar ablation relies on grounding pads to act as the other pole and is the simplest way to apply the energy. With unipolar ablation, the energy is focused at the ablating surface (highest current density) and disperses throughout the body to exit the ground. This is the slowest and most inefficient of the RF modalities but is also the most controlled method. The energy is regulated by temperature control which relies on setting a goal temperature and the RF energy is regulated such that an appropriate power is provided to maintain the goal temperature. The ideal goal temperature is not entirely clear. For endocardial ablation, experimental data has demonstrated reliable and effective ablation if ablation is performed for 60 seconds at 70°C. However, since there is greater variability in humans (particularly those with multiple pathologies), some suggest using 80°C for 60 seconds. It is also important to note that the hottest temperature will actually be achieved just below the surface. Due to this, the goal temperature is usually a few degrees cooler then the hottest tissue temperature and therefore the goal temperature should never be set at more than 95°C to avoid potential tissue disruption. Ablations must be performed for at least 60 seconds since a steady state is not achieved until 40-50 seconds of energy application.

The use of standard RF from the epicardial surface is unfortunately not as simple as from the endocardium and the heat sink effect previously discussed is a severe limitation that is probably not surmountable by standard dry unipolar RF. Some of the inefficiencies of unipolar ablation can be overcome by irrigating the active electrode with a saline solution. Irrigated or 'cooled tip' RF ablation improves efficiency. The cooling effect on the surface of the tissue actually drives the focus (hottest point) of energy deeper into the tissue, providing for both a faster and a deeper ablation. The irrigation also prevents the accumulation of char on the ablating surface as can occur with standard unipolar ablation. This char can serve as an insulator and prevent creation of an optimal lesion.

With both irrigated and standard RF, the energy disperses from a single element and there is the possibility to ablate adjacent non-cardiac tissue such as the esophagus. Adjacent damage is generally avoided provided appropriate ablation parameters are followed.

Bipolar RF is another RF modality that has the ability to make very fast and discrete lesions. This modality simply relies on having a pole on each side of the tissue to be ablated. This focuses all of the energy between the two poles and lesions can be made in less than 10 seconds. The current bipolar products also have various impedance sensors that detect when transmural ablation has occurred though clinical experience has shown this algorithm to be flawed and repeat ablation is often required. Even with repeated ablations, the lesions can still be created rapidly and appear to be electrophysiologically effective. These lesions are predominantly created from the epicardium, provided the lesion is in an area of the heart that can be opposed to itself or one of the poles can be inserted into the heart. Since both poles must be perfectly opposed to each other, there is very limited flexibility with the device and the number of appropriate lesions that can be made can be severely limited. Additonally, epicardial fat if thick may prove to be a limiting factor.

Microwave. Microwave ablation can be performed at either 915 MHz or 2450 MHz, which are the frequencies allowed by the FCC for medical microwave use. The current device uses 2450 MHz and works through dielectric heating. The microwave produces a field which causes oscillation of dipoles (water), producing kinetic energy and resulting heat generation. Not all of the ablation occurs through dielectric effects and there is a component of conductive heating.

Microwave has the advantage of creating deeper lesions than RF though in a similar amount of time. The lesions are also shorter with a maximum length of 4 cm but there is potential to make longer probes. In bench top work using 40 watts for 25 seconds with a 2 cm probe, microwave reliably ablates at 6 mm depth. Thermal profiles of these lesions demonstrated efficient and uniform penetration depth without areas of overheating and thus no char formation occurred. This effectiveness has been verified by a number of small but good clinical experience.

There are currently two main types of devices available. One is 4 cm long and flexible and can be used for both epicardial and endocardial application. The other is modified for minimally invasive application on the beating heart. This device has been successfully applied in our laboratory on animals using only ports and a mini-thoracotomy and recently with similar approaches in humans.

Due to its better penetration, microwave energy has more potential to be successful at epicardial ablation and the early clinical experience has been promising. It also deals with fat better than RF though fat continues to be a significant barrier.

Laser. Laser energy has recently received FDA approval for cardiac ablation in the U.S., and has been used clinically in a few patients. The primary enabling technology for laser ablation is the fiberoptic delivery devices rather than the laser itself. The delivery device has a diffusing tip that contains silicon particles. The silicone causes the laser to be emitted perpendicularly to the fiber direction. A mirror directs the energy so ablation can only

occur in one direction. The end result is unidirectional linear ablation of 2-5 cm with a flexible configuration. The mechanism of laser ablation is wavelength dependent but predominantly works by inducing a harmonic oscillation in water molecules with its resulting kinetic energy and heat generation. The currently used wavelength for cardiac ablation utilizes a 980 nm diode laser. This wavelength was chosen due it its good penetration of cardiac tissue with minimal pigment absorption. This wavelength reliably ablates tissue with absorption of actual laser energy as deep as 4 mm into the tissue with further ablation occurring via conductive heating mechanisms. Preliminary work in animals with epicardial ablation is very promising in that it creates transmural lesions even through epicardial fat though more data is required prior to any conclusions.

In pre-clinical work in our laboratory we have been able to create 100% transmural lesions in canines from an endocardial approach. These lesions were found to be electrophysiologically effective when subjected to pacing. The lesion times are for 36 seconds utilizing 5 W/cm but ablation can not be longer than 5 cm. The lesions can also be difficult to see immediately post procedure so careful attention must be made regarding the location of previous lesions. The initial clinical work has also been promising though the number of patients treated remains small.

Ultrasound. The mechanism for ultrasound ablation is a mechanical hyperthermia. The ultrasound wave is emitted from the transducer and the resulting wave travels through the tissue causing compression, refraction and particle movement, resulting in kinetic energy and heat. Since the mechanism is mechanical, if the wave is applied too aggressively shear stress and tissue disruption can occur. However, since the wave can be controlled via a number of different parameters, it is simple to regulate and avoid this complication. Ultrasound can either be applied in a focused (HIFU — high intensity focused ultrasound) or non-focused manner. HIFU allows for rapid, high concentration energy in a confined space. Non-focused ultrasound is a slower process but the transducer is simpler to create and may have more flexibility.

A potential advantage of ultrasound (though not yet studied extensively) will be the ability to image lesions. The transducer can be used both to image and ablate and thus it may be possible, particularly with HIFU, to determine atrial wall thickness, set the focus to ablate the appropriate amount of tissue, and then confirm that the ablation is transmural.

Summary. Energy sources for performing atrial ablation have been paramount in the resurgence of surgical treatment of AF. These energy sources permit lesions to be created without the use of incisions and allow the procedure to be performed more rapidly and by an increasing number of surgeons. Most of the energy sources for this application remain in their infancy yet they have made great strides. The future of these devices and the surgical treatment of AF will be in our ability to make rapid, safe and effective lesions from the beating heart.

MINIMALLY INVASIVE ATRIAL FIBRILLATION ABLATION COMBINED WITH A NEW TECHNIQUE FOR THORACOSCOPIC STAPLING OF THE LEFT ATRIAL APPENDAGE

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Purpose- Feasibility study of thoracoscopic microwave ablation of atrial fibrillation in conjunction with left atrial appendage (LAA) stapling.

Method- The patient is a 62 year old male with a long standing history of drug resistant paroxysmal AF for the last 10 years. He had failed multiple electrical cardioversions, as well as a percutaneous attempt at left and right superior pulmonary veins (PVs) isolation. He has been on Tikosyn for the last several months with some improvement but continued to be in AF. On October 8th 2003, he was admitted to undergo an off pump thoracoscopic epicardial microwave ablation.

After performing three port accesses on his right chest at the third, fourth and fifth intercostals spaces (IS), the pericardium was widely opened. The superior vena cava (SVC) and inferior vena cava (IVC) were circumferentially dissected to provide direct access to the transverse and oblique sinuses respectively. As shown by the video, a red rubber catheter was positioned below the SVC and advanced gently through the transverse sinus. Similarly, a second red rubber catheter was introduced below the IVC and advanced through the oblique sinus. The two catheters were retrieved on the left side after opening the pericardium using three left port accesses at the 3rd, 4th and 5th IS. The catheter tips were then tied together thus forming a guide to the FLEX 10TM microwave ablation probe (AFx) which was attached to the proximal end of the transverse sinus catheter. Traction on the proximal end of the oblique sinus catheter allowed the FLEX 10 to slide in the chest and to encircle the PVs. After visually confirming the position and orientation of the FLEX 10 ablating sheath posterior to the LAA, sequential ablation was started and continued until a continuous ablation line around the PVs was produced. A connecting lesion to the base of the LAA was then performed. The LAA was then stapled using the SurgASSISTTM computer-mediated thoracoscopic stapling system (Power Medical Interventions).

Results- The procedure was uneventful and lasted for a total of 2.5 hours. The patient was discharged home on post-operative day 2 in rate controlled AF. He was successfully electrically cardioverted to normal sinus rhythm (NSR). At latest follow up he remained in NSR and continued to take Ticosyn.

Conclusion- Thoracoscopic epicardial microwave ablation of AF is a technically feasible procedure with minimal risk. The computer deployment and motion controlled stapling system that we used in this case has the potential to become a safe and reliable alternative to conventional stapling instruments.

MINIMALLY INVASIVE PERFUSION SYSTEMS: AN UPDATE

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The movement towards minimally invasive cardiac surgery was in part stimulated by an effort to reduce the complications associated with traditional cardiopulmonary bypass (CPB). Yet efforts to primarily reduce the risks associated with CPB, including inflammation, hemodilution, coagulopathy, and emboli, remained limited during that period. The recent impetus for change has been largely driven by off-pump coronary artery bypass (OPCAB) procedures.

A host of innovative devices, circuit design and clinical technique changes are currently aimed at reducing the pathogenicity associated with CPB. This evolution of technology continues to be a joint effort of manufacturing and clinicians participating to improve patient outcomes. Manufacturers have recently designed new circuitry to address circuit performance issues such as; surface area and type, hemodilution, blood/air interface, cardiotomy suction and exposure to silicone. Clinicians are actively reassessing their conduct of perfusion including management of blood gases, coagulation, pressure, temperature, drug use, cardioplegia delivery and shed or suctioned blood handling. Many have identified this multifactoral approach as the key to handling the dilemmas posed by cardiothoracic surgery utilizing CPB.

Early use of improved and miniature devices included clinical application of the Miniature Extracorporeal Circuit (MECC) by Jostra Corp, (The Woodlands, TX) and Cardiovention CORx from Cardiovention Inc, (Santa Clara, CA). These devices utilized, closed loop bypass for reduction of blood/air interface and exposure to silicone particles, reduced prime volume and foreign surface area to mitigate platelet activation and inflammatory response coupled with clinical technique changes aimed at reducing numerous pathological conditions associated with CPB. Although initial reports looked very promising with these circuits, issues of heat exchange, volume management and venous air handling and the risk of air embolization with associated neurocognitive dysfunction continued to challenge the clinician. Currently, Jostra USA now NovaSci, (The Woodlands, TX) have incorporated a closed venous reservoir (bag) to allow air handling and volume management with their "Ready System." Cobe Cardiovascular (Arvada, CO) has developed several systems, (Ideal, Synthesis, Synthesis 4D) ranging from completely closed loop bypass circuitry with integrated components to closed and open system hybrids which allow a great deal of technique flexibility. Terumo Cardiovascular, (Ann Arbor, MI) has developed the MiniX reduced prime perfusion circuit utilizing preconnected familiar components coupled with an open reservoir system. Medtronic (Minneapolis, MN) developed a integrated, low prime system with automated venous air removal in a preconnected configuration. Each of these systems offers various improvements to current conventional bypass systems.

The perfusion and cardiothoracic community have clearly identified a host of CPB related issues including hemodilution, systemic inflammatory response, anticoagulation, platelet and formed element activation, blood loss, and neurological complications. New device technology must embody circuit performance designs which optimize sterility, sheer stress, hemodilution, air

emboli protection, areas of blood flow stasis, gas exchange and bio-friendly surfaces. Clinical practices should address changes to current techniques aimed at an overall reduction in the sequelae associated with CPB. Further analysis may prove useful in elucidating clinical and technical benefits allowing cardiac surgeons additional treatment options while improving patient outcomes.

TROUBLESHOOTING THE PUMP

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For over forty years cardiopulmonary bypass (CPB) has provided definitive or palliative surgical treatment options never before available for patients with severe cardiac pathology. Despite high complication rates, benefits outweighed risks in these otherwise doomed patients. Risks and complications associated with CPB gradually diminished with improved surgical technique and technology. Today CPB continues to be a valuable tool in the cardiac surgery armamentarium. However, situations and conditions still arise which may result in adverse patient outcomes.

In addition to emergency situation response, clinical techniques and circuit performance continue to challenge the clinician to provide the highest quality CPB. A multifactorial approach must be employed to improve CPB (i.e. "the Pump"). A combination of the best clinical practices, the right foreign surfaces and the correct circuit choice will minimize adverse outcomes and improve patient care.

The best clinical practice includes careful attention to pressure, temperature and coagulation management, comprehensive assessment of blood gas and physiologic demands as well as a thorough understanding of surgical techniques, pharmacological intervention, shed or suctioned blood handling and circuit performance. Another key area of clinical performance must address a multidisciplinary approach to communication. Open dialogue and a feedback system between Perfusion, Anesthesia and the Surgical teams must exist to ensure the best possible patient outcomes. Team interaction allows clinical issues to be addressed in a timely and appropriate fashion. The "Leave alone – Zap" method of saying nothing and then screaming when you do not get what you wanted is counter-productive. By setting clear goals and making your wishes clear, everyone is able to collectively strive for the same patient management goals. Adopting a policy of "State the Obvious" will tremendously improve team interaction and ultimately benefit quality of care.

Troubleshooting the pump must also address the question, "What is the best circuit?" Circuit configuration, i.e. choice of blood material interaction and component choices should be aimed at maintaining the highest degree of safety coupled with improving patient outcomes. Reduction of adverse sequalae associated with CPB is paramount. In order to accomplish this task; the team will need to assess the importance of circuit coatings, surface area and disposable configuration. Questions of open vs. closed, roller vs. centrifugal pumps, gravity vs. assisted drainage and a host of monitoring functions will need to be addressed.

Everyone should encourage the perfusion team to take initiative with respect to addressing these issues. Begin with a departmental policy and procedure manual where clear goals are well documented. Address issues one at a time and have all team members offer feedback. Always keep patient safety and clinical outcomes at the top of your list of desired improvements. Use open communication and a team strategy to obtain quality guidelines for improving the "Pump".

THORACIC COARCTATION-ASSOCIATED ANEURYSM WITH ANTEGRADE ENDOVASCULAR REPAIR

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Purpose: Late aneurysm formation is a well-described complication following surgical correction of aortic coarctation. Endovascular repair of such aneurysms avoids the morbidity of conventional re-operative thoracic surgery. We describe a case of endoluminal repair of a coarctation-associated thoracic aortic aneurysm with antegrade deployment of a stent graft in a patient with hypoplastic abdominal vasculature.

Materials and Methods: A patient with a large thoracic aneurysm who had undergone previous repair of a long segment, low thoracic aortic coarctation with an 18mm interposition graft was referred to our institution with claudication. A 6cm upper hemisternotomy incision was made and extended into the right third interspace. Under continuous fluoroscopy a guide wire was advanced across the aneurysm and beyond the distal anastomic stenosis. A 22 French introducer was passed into the descending aorta. 15mm AneuRX stent graft was then deployed under fluoroscopy in the distal neck. A 22mm AneuRX stent graft was deployed within the 15mm graft across the aneurysm and into the proximal neck. Completion angiogram revealed total exclusion of the aneurysm. A residual stenosis remained at the old distal anastomotic site. Intraoperative angioplasty reduced the gradient to 30 mm HG. Patient was discharged home on post-operative day 3. Persistent proximal hypertension with a residual gradient across the distal endograft was treated with an uneventful axillo-bifemoral bypass graft 2 months later.

Summary: This technique of antegrade placement of thoracic aortic stent grafts is a novel procedure for performing endoluminal repair of thoracic aortic aneurysms when the retrograde femoral, iliac and abdominal aortic vasculature will not accept an adequate sized introducer system. Cannulation of the distal aortic arch eliminates the risk of retrograde dissection and allows for the passage of significantly larger devices.

Conclusion: This is the first description of an antegrade endoluminal stent graft deployment through the open aorta with a beating heart and a minimally invasive sternal sparing incision. This and other hybrid approaches which employ open and endoluminal techniques expand the minimally invasive possibilities in patients previously without other options.

INTERLEUKIN 6 GENOTYPES DETERMINE OUTCOMES AFTER CORONARY REVASCULARISATION

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Introduction: Levels of Interleukin 6 (IL-6), a proinflammatory cytokine, increase after surgery. The functional polymorphism in the IL-6 promoter region (-174 G>C) is associated with increased risk of coronary heart disease. The relationship between different genotypes at location –174 and the IL-6 response to bypass surgery has yet to be defined.

Objectives: To assess if there is a genetically determined difference in the degree of the IL-6 response to cardiopulmonary bypass; to study the association between -174G>C polymorphism and clinical outcomes.

Methods: Genomic DNA was extracted from 96 consecutive patients who underwent elective coronary revascularisation. The DNA was genotyped for IL6 -174 polymorphism using sequence specific polymorphism (SSP-PCR). IL-6 levels were measured on serum samples taken three hours post-operatively using Enzyme linked Immuno-sorbent Assay (ELISA). IL-6 levels and genotypes (CC, CG, and GG) were correlated with peri-operative clinical data.

Results: The prevalence of CC, CG and GG IL-6 –174 genotypes was 8%, 54% and 38% respectively. IL6 levels did not significantly differ between patients with different genotypes for polymorphism -174G>C.

Carriers of allele -174C were associated with a higher post-operative serum level of IL-6, had longer ventilation time, bled more, and stayed in intensive care unit longer than patients with the allele -174 G but this was not statistically significant.

Patients with GG homozygote IL6 -174 genotype had a significantly lower incidence of post operative atrial fibrillation ($p=0.006$), and shorter hospital stay ($p=0.004$) and this remained statistically significant after adjustment for risk factors.

The severity of coronary artery disease and the higher number of bypass grafts were associated with significant increase in IL-6 levels post operatively ($p=0.005$, $p=0.007$ respectively).

Conclusion: The predominant C-allele was associated with higher postoperative IL-6 levels and less favourable clinical outcomes. The correlation with postoperative atrial fibrillation and hospital stay reached significance.

Further studies are required to investigate the relationship between chronically underperfused or damaged myocardium and post-operative increases in IL-6.

ENDOSCOPIC MITRAL VALVE SURGERY

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Several years ago the thought of endoscopic cardiac surgery was far from the minds of nearly all heart surgeons. Since 1996 a number of surgeons have accrued excellent results in large patient series in which mitral valves have been repaired or replaced using videoscopic vision and long instruments through tiny incisions. Others have said that a slightly larger incision and direct human vision is preferable but that the minimally invasive approach still should be the goal. Benefits shown for minimally invasive mitral surgery include improved cosmesis, earlier ICU and hospital discharge, faster recovery, and fewer blood transfusions. Many surgeons still disagree with either direct vision or endoscopic minimally invasive mitral surgery owing to concerns over safety and quality of the operation. Heretofore, a sternotomy approach, standard perfusion methods and direct vision have been proven to render excellent results and these remain the gold standard from which all surgeons measure their results of repairs. However, even using the traditional methods less that 35% of myxomatous mitral valves still are repaired in the United States. In comparison almost of all myxomatous and fibrous deficient mitral abnormalities can be repaired by the hands of experienced mitral surgeons using either a traditional or minimally invasive method. Thus, the questions arise - who should do mitral repairs? If all surgeons are going to attempt repairs, how can we improve the percentages and results overall? Why are surgeons not adopting endoscopic minimally invasive methods more readily when excellent results are being delivered?

Cosgrove[1,2], Cohn [3], Colvin [4], Vanermen [5,6], Mohr [7,8], and our group [9,10,11] all have shown repair results similar to that of operations done through a full sternotomy. Thus, the debate has now become whether endoscopic approaches add anything for the patient to the minimal incision and direct vision. Does video-assistance make it easier or harder? This lecture will present a compelling argument for surgeons to learn mitral repair surgery using minimally invasive methods, even aided by endoscopic vision. We will focus on the technology that enables surgeons to span the "confidence gap' and achieve comfort in performing these operations safely and with even greater accuracy than using direct unmagnified vision. To date our group had done over 300 mitral valves using video-assistance and modified shafted instruments. Many of these latter operations were done totally endoscopically, and in the others the telescopic camera was used to visualize obscure segments of the valve or other anatomy. Nonetheless, video assistance played a major role in these operations, and the results were similar to our sternotomy cases as far as safety and repair quality. More recently we have advocated using the da Vinci™ system to perform totally endoscopic repairs aided by nitinol annuloplasty ring clips. [12] To date (November 2003) we have performed 111 mitral operations with da Vinci™. The efficacy of this mitral repair technique has been supported by a recently completed multicenter trial that showed efficacy and good results at ten different cardiac centers in the United States. The author believes that these methods can be taught from the beginning as the preferred method for repairing valves. The attenuation of a learning curve can be affected through an organized curriculum-based training program.

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DEVELOPING A REGIONAL CARDIOVASCULAR INSTITUTE: "CREATING THE VISION AND BUILDING THE BRIDGE"

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To plan and develop a comprehensive cardiovascular hospital that serves a large populace, detailed background information and planning are required. Epidemiologic and service patterns must be established and the administrative skeleton must be developed well in advance of construction planning. This lecture describes how, in a very short time frame, our institution has developed the North Carolina Cardiovascular Diseases Institute conceptually and organizationally, planned the development, and gained the political and financial support to begin construction. Since 1993 our current heart center has served as the major clinical service center for the 30 counties of eastern North Carolina that have over 1.5 million citizens. This heart center has been directed singularly toward medical, interventional, and surgical services for patients primarily with heart disease. If eastern North Carolina were a state, we would rank first in cardiovascular deaths and morbidity, and we have earned the imprimatur as the "Buckle of the Stroke Belt". Heretofore, we have not focused on the multispecialty, seamless treatment of patients with vascular, thoracic, and related diseases, including stroke, complex aortic disease, hypertension, lipid modification, and diabetes. As North Carolina in general has one of the highest incidences of cardiovascular disease with concomitant mortality in the United States, the need for an organized comprehensive attack on cardiovascular diseases here is obvious. Such an effort will include both primary and secondary prevention, post-therapy rehabilitation, complex geriatric care, primary care, and epidemiologic profiling. Moreover, our university's renewed commitment to thematic disease-based education and research coapts with this public health need.

Our private, not-for profit 750 bed hospital and university medical school have been bound by an effective affiliation agreement for 30 years. Currently, our cardiology, cardiac surgery, and vascular surgery bed utilization are at near 100% weekly. Physicians practicing in our center are either in private practice or university service. Recently, the hospital has dedicated resources to develop a 150 to 200 bed cardiovascular hospital focused on state-wide patient care needs, prevention, and education related to all types of cardiovascular diseases. In parallel we are seeking public support, through the general assembly, to construct a 60 million dollar university-based research and education center that will support basic scientists, university clinicians, clinical trials, a comprehensive data center, basic research laboratories, a training center for surgical robotics and new cardiovascular technology, and a 200 seat A-V communications education center. This combined hospital and university project will constitute the North Carolina Cardiovascular Diseases Institute. The institute has a comprehensive multispecialty mandate to improve the cardiovascular health of all North Carolinians, to provide new initiatives in research, to expand knowledge in primary and specialty healthcare, to train residents, medical students and nurses, and to stimulate regional economic growth.

Both serial and parallel phases have been implemented in the planning of this center. Phase 1 of this project included a) concept development and internal marketing, B) assessment of regional demographics, patient migratory patterns, competitive services, market trends, current treatment effectiveness, current workforce issues, and financial capabilities. After the need for this center as well as potential financial resources were identified,

the most difficult parts were to follow. In Phase 2 of institute development, we have focused on hospital and university administrative "bridge-building", creation of a common vision and legislative support, as well as construction and financial planning. This lecture will focus on these aspects of development as well as potential "services of excellence", strengths and weaknesses of the current affiliation, research goals, and educational opportunities. Our next challenges relate to actual construction of the institute and then going from "building a bridge" initiatives to a "You build [built] it and they will come". By this we mean not only patients will come but our ability will be enhanced to attract "top-flight" clinical investigators, basic scientists, nursing and physician educators, engineers, PhD students, post-doctoral fellows, epidemiologists, medical students and residents. We believe that because of our indigenous regional need, our cohesive 30-year institutional record, and demonstrated quality of services, that by careful planning we have gained the "bully pulpit" toward making a major impact on mortality and morbidity form cardiovascular diseases in North Carolina by year 2015.

WHAT TO DO WHEN AND HOW TO DO IT RIGHT: AN ETIQUETTE GUIDE FOR RESIDENTS DURING THE JOB-HUNTING PROCESS.

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Etiquette is simply a guide to assist us in avoiding embarrassment. Emily Post and Amy Vanderbilt were the first to publish books on the subject. Prior to this, proper etiquette was a high society secret allowing them to separate themselves from ordinary people. Knowing the "rules" can eliminate some of the stress of the process of job-hunting.

When preparing for an interview, attire will be very important and will be dictated by time of day and location of the first meeting. Travel attire is important, too.

Lost luggage is always a possibility if traveling by air.

Being punctual is crucial. There are no acceptable excuses for being late for a job interview.

It is key to become familiar with introductions as this is part of "the first impression". A handshake is a revealing action. After the introductions, comes the conversation. Subjects not to talk about are as significant as the ones to discuss. The Top Ten Tips are helpful suggestions for conversations.

If a meal is part of the interviewing process, there are things to know to make the dining experience more comfortable. These are all simple, but significant.

Before and after the interview, there will be written correspondence. The type of stationery used is based upon the type of correspondence. It is necessary to know the proper salutations, titles, and closures when communicating in writing.

In this internet age, everyone uses e-mail and there is now e-mail etiquette. There are times to use e-mail and times when it is not acceptable. Certain subjects are inappropriate in e-mails. Caution is vital when writing e-mail and clicking the Send button. Privacy does not exist in the world of electronic mail.

Knowledge of grammar is reflected in speaking and writing. With the use of computers, grammar can be checked; however, when speaking, the brain is the computer. Therefore, it should be programmed correctly.

Finally, there are four types of books, which should be at the writing desk: a dictionary, a grammar book, an etiquette book, and a stationery book. These four tools are valuable personal and professional aids.

ORAL ANTICOAGULATION THERAPY IN CHILDREN—SUCCESSFULLY CONTROLLED BY SELF-MANAGEMENT

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Background: Children with congenital heart disease on oral anticoagulation therapy present special challenges, e.g. due to rapid fluctuations in INR-values, interruption on daily life due to frequent hospital/doctoral visits, and difficulties and pain in performing venipuncture. We hypothesize that oral anticoagulation therapy can be successfully controlled by self-management for this subset of patients. The aim of this study was to assess the treatment quality of self-managed oral anticoagulation therapy in terms of time within therapeutic INR target range in children with congenital heart disease.
Methods: Children (N=22) with a mean age of 10.6 years (range: 1.8-18.6 years) and their parents were trained in home blood analysis of INR and coumarin dosage adjustment. After training, the children were monitored by weekly INR-measurements. Therapeutic range was target INR-value +/- 0.5. The indications for initiating oral anticoagulation therapy were mechanical heart valve (N=16) and total cavopulmonary connection (N=6). The children had no physical restrictions.
Results: The mean observation time was 3.6 years (range: 0.9-5.8 years), and the total number of patient-years was 75.4. The patients were within therapeutic INR target range for a median of 73.1% (range: 30.3-91.0%) of the observation time. Two children died due to reasons not related to the oral anticoagulation therapy. None of the patients experienced thromboembolic or bleeding complications requiring doctoral intervention.
Conclusion: Self-management of oral anticoagulation therapy is safe and provides a good quality of treatment in selected children with congenital heart disease.

LEFT VENTRICULAR ASSIST DEVICE IMPLANTATION FOR POSTCARDIOTOMY CARDIOGENIC SHOCK

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Purpose: Postcardiotomy cardiogenic shock (PCCS) results in significant morbidity and mortality. Left ventricular assist device (LVAD) insertion is now a well established support option for these patients. Our institution has implemented a practice of implanting patients early and serving as a post-cardiotomy referral center for peripheral hospitals. This study reviews our experience.
Materials and Methods: Between September 1990 and February 2003, 47 patients underwent insertion of an LVAD for PCCS following cardiac surgery. Fifty patients receiving an LVAD for other indications (non-PCCS) were randomly selected from this same database to serve as a control group. The two groups were compared with regard to demographics, duration of LVAD support, total hospital length of stay (LOS), mortality rate, bridge to transplant success rate, and post-transplant survival.
Results: There were no differences in patient demographics, duration of LVAD support, and LOS between the two groups. The PCCS group experienced a greater overall mortality (46.8%) and a lower success rate of bridge to transplantation (51.1%) compared to the non-PCCS group (18.0% and 78.0%, respectively) ($p<0.01$). One- and five-year post-transplant actuarial survival rates were similar amongst the two groups (86.7% and 81.7% in PCCS, 83.1% and 83.1% in non-PCCS) ($p=0.50$).
Conclusions: These results support the continued application of implantable LVADs early in the postoperative course following PCCS. Further investigation is warranted to identify factors that may enhance the success rate of bridge to transplantation and/or explantation in these select patients.

LEFT VENTRICULAR ASSIST DEVICE IMPLANTATION IN PATIENTS WITH VIRAL MYOCARDITIS-INDUCED HEART FAILURE

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Purpose: Viral myocarditis (VM) is a disease entity that exhibits a broad range of clinical pathways to the onset of cardiac symptoms, but the progression to severe congestive heart failure, both chronic and acute, carries significant morbidity and mortality. Left ventricular assist device (LVAD) implantation has gained acceptance as a modality for providing mechanical support to the failing heart in these settings.
Materials and Methods: We retrospectively reviewed all patients who received a Thoratec Single-Lead-Vented-Electric LVAD at our institution between August 1990 and February 2003. Twenty-five patients with viral myocarditis were identified. Twenty-five patients whose primary indication for LVAD was coronary artery disease (CAD) were randomly selected from the same database to serve as a control group. Variables analyzed included patient demographics, duration of LVAD support, preoperative white blood cell (WBC) count and erythrocyte sedimentation rate (ESR) values, percent

explanted, success rate of bridge to transplantation, and post-transplant survival rates.
Results: The VM group was younger than (35.88+/-16.43 years vs. 58.88+/-4.30 years) ($p<0.01$) and consisted of a greater proportion of female patients than (36% vs. 8%) ($p=0.02$) the CAD group. Duration of LVAD support, preoperative WBC and ESR values, and percent explanted were similar between the two groups. Bridge success rates and post-transplant survival rates were also comparable (64% transplanted in VM, 60% transplanted in CAD ($p=0.86$); 1- and 5-year post-transplant survival rates of 86.67% and 72.80% in VM, 71.43% and 62.50% in CAD, respectively ($p=0.34$)).
Conclusions: These findings suggest that despite the variable clinical course of VM and the potential to rapidly progress to end-stage heart failure, LVAD implantation in these patients yields outcomes similar to those receiving LVADs for CAD. Device support permits decompression of the dilated ventricle, facilitating myocardial recovery and the likelihood of bridging successfully to transplant or explant.

LEFT VENTRICULAR ASSIST DEVICE IMPLANTATION FOR CARDIOGENIC SHOCK FOLLOWING ACUTE ANTERIOR WALL MYOCARDIAL INFARCTION

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Purpose: Left ventricular assist device (LVAD) insertion after cardiogenic shock (CS) complicating anterior wall myocardial infarction (AMI) is an accepted modality of support in select patients. Results of primary revascularization for these patients are poor. With improving outcomes of LVADs, their role as primary therapy for CS after AMI needs to be evaluated.
Materials and Methods: We retrospectively examined outcomes of 51 patients in CS following AMI who received Thoratec Heartmate LVADs. Of these, 31 underwent revascularization prior to LVAD placement (MI + CABG) and 20 underwent direct LVAD placement. Outcome variables included patient demographics, timing of LVAD after AMI, bridging to transplant and post-transplant survival.
Results: There were no differences in patient demographics between the 2 groups. The MI + CABG group had a lower survival rate to transplant (48.4%) compared to the MI-alone LVAD group (70.0%)($p= 0.13$). 1- and 5-year post-transplant survival by Kaplan-Meier analysis were 100.0% and 90.5% in the MI alone group as opposed to 86.21% and 75.43% in the MI + CABG group ($p=0.44$). There were no significant differences in rate of bridging to transplant or post-transplant survival between patients undergoing early (< 1 week after AMI) versus late (>1 week after AMI) LVAD insertion.
Conclusions: These clinical findings suggest that revascularization for CS complicating AMI adversely affects the success rate of LVAD bridging to transplantation as well as post-transplant survival. Outcomes are comparable for patients implanted either early or late after acute MI. These data support a trial evaluating implantation of LVADs as primary therapy for AMI complicated by CS.

STAGED REMOVAL OF HEARTMATE LEFT VENTRICULAR ASSIST DEVICE AFTER HEART TRANSPLANTATION

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The incidence of heart failure approaches 10 per 1000 population after the age of 65 years. Approximately 5 million Americans have CHF. The 5-year mortality rate is close to 50%. Sudden death rate is 6-9 times higher in CHF patients than in the general population. From 1979 to 1998, deaths due to CHF increased by 135%, and hospitalizations rose by 159%. The direct and indirect costs of heart failure in the US was $21 billion in 2001. The use of left ventricular assist devices (LVADs) as a bridge to transplantation is widely accepted as a standard of care for many patients with end-stage heart failure. Outcomes after transplantation in LVAD supported patients has been demonstrated to be equivalent and in many series better than non-bridged control groups. The surgical risks associated with transplantation in this patient subset are formidable. In an effort to reduce the OR time, intraoperative bleeding and need for blood product transfusion at the time of heart transplantation-LVAD explantation, we have adopted the strategy of staged explantation of the device. Our early experience with staged removal of the HeartMate LVAD is presented.

EARLY STAGE CONCEPT OF SUTURING DEVICE FOR OPEN VALVE SURGERY

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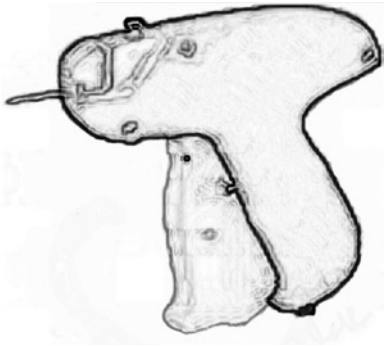
Valve procedures are well established in modern cardiac surgery. To facilitate, improve, and expedite open valve operations a new more efficient tissue approximation and adherence device is presented in its early stage of conception.

The drawing-board invention uses a one handed mechanism for engagement with a standard straight needle. Non-absorbable thread is placed into both sewing ring and endocardial tissue for firm fixation. Below is a sketch of the drawing-board device, (Figure)

With more cardiac procedures progressing toward minimally invasive approaches, novel technology to improve existing techniques must be evaluated. This new device with further development can be effective in securing the prosthetic valve-sewing ring to the valve annulus.



WHY IS OPCAB UNCOMMON IN CANADA? A POPULATION-BASED SURVEY

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OBJECTIVES: Off-pump coronary bypass(OPCAB) is proposed to improve clinical outcomes and decrease resource utilization. However, OPCAB is not widely used in Canada. The purpose of this study was to determine the current utilization of OPCAB in Canada and determine why surgeons have not adopted this technique.
METHODS: The study was a population-based survey of all adult Canadian cardiac surgeons in practice longer than one-year. Eligible surgeons were contacted by mail. Response rate was 78%(98/126).
RESULTS: Of 18,965 isolated CABGs performed in Canada last year, 2855(15.1%) were OPCAB. Over 50% of Canadian surgeons performed OPCAB in less than 5% of coronary cases, and only 12% of surgeons performed OPCAB in more than 50% of coronary cases. Only three responding centers performed beating heart surgery in more than 25% of cases.

Severe calcification of the ascending aorta, chronic renal failure, cerebrovascular disease and advanced age were associated with the selection of a beating heart operation. Diffuse distal vessel disease, emergent operation, severe left ventricular dysfunction and left main coronary artery disease were associated with the selection of a conventional bypass operation over a beating heart operation.

Respondents were divided into those who performed less than 5% of cases as OPCAB(=Non-Adopters (NON),n=52), 5-25% OPCAB (=Intermediate Users (INT), n=28) or greater than 25% OPCAB (=Enthusiasts (ENT), n=18). 82% and 79% of NON and INT surgeons felt incomplete revascularization was more uncommon in OPCAB, $p<0.001$. Mean number of distal anastomoses in OPCAB cases were 1.9±0.6, 2.2±0.6, 3.1±0.5 for

NON, INT and ENT surgeons respectively. Mean number of distal anastomoses in OPCAB cases were 1.9±0.6, 2.2±0.6, 3.1±0.5 for NON, INT and ENT surgeons respectively. 11% of NON, 55% of INT and 81% of ENT surgeons believed OPCAB improved clinical outcomes ($p<0.0001$). 13% of NON, 48% of INT and 82% of ENT surgeons believed OPCAB improved clinical outcomes ($p<0.0001$). Only 23% of all respondents felt OPCAB utilization would increase in the next five years.

CONCLUSIONS: Concerns regarding incomplete revascularization and lack of proven clinical benefit have limited OPCAB to being performed routinely by only a small number of surgeons in Canada.

MINISTERNOTOMY SINGLE VESSEL CONONARY REVASCULAIZATION WITH ROBOTIC ASSISTANCE

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Traditionally, coronary artery bypass surgery (CABG) is done through a full median sternotomy and less often through a thoracotomy. The use of manubrium-sparing ministernotomy (MSM) has the benefit of reducing surgical trauma while allowing revascularization. We describe our technique of minimally invasive CABG with the assistance of the da Vinci robot (Intuitive Surgical, Sunnyvale, CA). The left internal mammary artery (LIMA) was mobilized thoracoscopically using the robot, and a lower ministernotomy was performed to complete the off-pump coronary artery bypass grafting (OPCAB).

A 50-year-old male with history of hypertension, hyperlipidemia, and smoking developed unstable angina. A large area of anterior wall ischemia was noted on a stress test and cardiac catherization showed evidence of in-stent stenosis of the left anterior descending coronary artery (LAD). He was referred for CABG. With the patient in supine position the LIMA was mobilized with the robot. The total robot-assisted takedown of the LIMA took thirty minutes. The robot setup time was 15 minutes, and the port placement time was ten minutes. A manubrium-sparing sternotomy incision was made. The incision extended from the 4th intercostals space to the tip pf the xiphoid in an inverted L-shaped fashion. The LIMA was prepared and after heparinisation was anastomosed to the LAD on a beating heart. Transit time flow measurements were done, excellent diastolic flow with low impedance was noted. There was good wall motion on the trans-esophageal echocardiogram. Chest tubes were placed, and the chest was closed. The patient has an uneventful post-operative course. He was discharged home on the fourth post-operative day. The patient had minimal post operative discomfort and was able to return to baseline functional status in ten days.

We describe a safe minimally invasive approach when revascularization of the anterior vessels is contemplated.

RESOURCES FOR RESIDENTS IN TRAINING FOR CARDIOTHORACIC SURGERY

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Central issues of greatest concern to residents currently in training for cardiothoracic surgery include passing national board examinations, finding and securing a desirable job in the field, and learning the newest techniques and concepts in cardiothoracic surgery. Along with traditional resources, there are numerous new and innovative developments in distance-based learning, online communities, and electronic media, which are particularly applicable to the surgeon in training.

Preparation for the American Board of Thoracic Surgery qualifying and certifying exams is a process that ideally should begin as soon as the resident enters his or her training program. Time constraints, including both demands of a busy surgical service as well as new limitations in resident work hours, place even more of this preparation process directly upon the resident as opposed to traditional didactic teaching sessions. Cardiothoracic Surgery Notes is an online review course under the direction of the CTSNet Residents' Section, which is designed as a framework for board preparation during training. Residents and program directors can use the outline format as the sole basis for comprehensive education, or as a guideline for development of a more formal internal didactic teaching course. Multi-day review courses are also an excellent resource for intensive preparation for the qualifying exam.

Each resident that graduates from a training program must be competent to perform an ever-widening array of simple and complex operations. Real-time, continuous evaluation of resident operative experience is now possible with the CTSNet Operative Log, allowing both residents and program directors to track individual case logs to ensure that each resident will meet the criteria established by the American Board of Thoracic Surgery. Instruction in basic and advanced techniques are now available in a variety of online formats from reputable academic centers.

The search for employment should also ideally begin as soon as the resident has entered the training program, if not before. Traditional methods of finding and securing a job include using the program director and other faculty members' contacts, formal letters, national meetings, and recruitment services. Online job services are rapidly expanding, including a new effort with the CTSNet Job Center, to provide a common forum where residents can search jobs and department chairs can search candidates to find the most suitable match for both. Residents are restricted in the amount of time allowed free from clinical duties in order to attend regional or national meetings, limiting their abilities to interact with other residents and the cardiothoracic surgical community as a whole. The Internet provides an invaluable resource as a central portal for residents to exchange ideas and concerns with other residents and also with respected faculty from the international community. The Thoracic Surgery Residents Association and the CTSNet Residents' Section focus on topics of greatest interest to residents and hold conferences at the STS and AATS annual meetings to discuss these topics.

PRACTICE ENVIRONMENT: ACADEMIC VS. PRIVATE, PROS & CONS

Thomas Fogarty, MD

Stanford University, Stanford, CA

Practice environments are influenced by many factors. Regional differences are influenced by the presence or absence of managed care programs. Private pay systems dominate in some regions but are the exception in others.

Local factors are often influenced by the presence or absence of a major clinic academic medical center or a integrated healthcare system such as Kaiser Permanente.

What is clear is that increasing challenges will be presented to all those who are in the process of beginning their careers in cardiac surgery. These challenges can also represent significant opportunities.

INNOVATION AND TECHNOLOGY IN THE CARDIOVASCULAR COMMUNITY

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How one defines cardiovascular community is a matter of perspective and interpretation. I will define it for the purpose of this presentation as those specialties that cure and treat cardiovascular disease. The latter involve four specialties, cardiac surgeon, vascular surgeon, cardiologist and interventional radiologist.

The relative progress in both diagnosis and therapy has had significant contributions by all of these specialties. As one specialty creates an opportunity through innovation and technology, it often challenges and eliminates a technology of a competitive specialty. This interplay of competitive technologies is a natural product of innovation.

Numerous examples of opportunity creation have occurred during our lifetime. The current environment for the cardiovascular surgical community is challenging. Fewer procedures with diminishing levels of reimbursement for these fewer procedures have been a recurring menu. Potential avenues of addressing these challenges will be discussed. Perhaps as surgeons, we have become victims of our own success. As we honed our skills doing procedures with focus, intensity and increasing skills we lost sight of the potential for alternative approaches.

Patients are the recipients of a physician's efforts and increasingly they are becoming the ultimate arbitrator of what is appropriate treatment. Adopting a patient's perspective on what, when, and how we do procedures will give us insight into how we can influence our future in the field of cardiovascular pathology.

THE NEXT GENERATION OF VALVES

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The majority of current valvular prostheses available in the United States, especially bioprostheses, comprise of bioprostheses that have a long international experience and those that have the experience in this country that is equivalent to the international experience. The current era marks the first time in the history of bioprostheses that the United States regulatory authorities and market has afforded advanced technological stented and stentless bioprostheses for implantation in this country. The predominant mechanical prostheses available in the current era are similar in the United States as internationally.

There has been no deviation from fixation of heterographic tissue with glutaraldehyde over the past 30 years. There remains concern over the durability of both porcine and pericardial tissue as the implantation period extends beyond 10 to 12 years especially in the aortic position ″ 65 years and in the mitral positions ″70 years. The extended documentation of bioprostheses that are now available in the United States affords the opportunity to recommend bioprostheses for aortic valve replacement beyond 65 years of age and for mitral valve replacement beyond 70 years of age with the knowledge of performance to 15 and 20 years. The bioprostheses with this experience are the Carpentier-Edwards SAV, Hancock II and Carpentier-Edwards PERIMOUNT. There has remained a considerable effort to retard mineralisation of heterographic tissue with reduction of mechanical stress and calcium mitigation therapy. The calcium mitigation therapy of the Medtronic Mosaic porcine bioprosthesis requires comparison to other therapies and the different tissue preparation technologies.

The influence of hemodynamic performance as judged by degrees of patient-prosthesis mismatch remains under assessment with stentless bioprostheses, diameter enhanced stented bioprostheses and mechanical prostheses. The optimization of hemodynamic performance to avoid no more than mild-to-moderate or moderate obstructive phenomena will likely provide adequacy of left ventricular mass regression and avoid prosthesis influence on survival.

Future generations of bioprostheses may evaluate alternating collagen cross-linking technologies to avoid the compromising parameters of glutaraldehyde. Supra-annular aortic wall implantation bioprosthesis will likely be a reality to further optimize hemodynamics. The tri-composite porcine bioprosthesis manufactured in South America must be evaluated for extended durability especially in the mitral position. The future of polymer polyurethane technology may further the quest for a 25-30 years prosthesis for both aortic and mitral valve replacement, comparable to current generation mechanical prostheses. Mechanical prostheses with advanced hinge technology may reduce both thromboembolic phenomena and hemorrhage. The next generation of prosthetic valves in the United States incorporates both long-standing devices not approved in this country and new prostheses with advanced technologies.

BIOPROSTHESES AND MECHANICAL PROSTHESES

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University of British Columbia and St. Paul's Hospital

Bioprostheses have been used for thirty years for aortic and mitral valve replacement. The use of bioprostheses have only been superseded by allografts and autografts for aortic valve replacement since introduction into clinical practice forty years ago. Allografts are currently used for reconstruction of aortic valve and annular native and prosthetic valve endocarditis. Autografts are usually reserved for children and young adults active in aerobic activities and are devoid of co-morbid disease. The bioprostheses available in the United States were predominantly first generation bioprostheses that had obstructive hemodynamics and compromising durability. The last five years has seen the advent of second and third generation stented bioprostheses and stentless bioprostheses introduced into the United States market. This has brought a major shift from mechanical prostheses to bioprostheses by the United States cardiac surgeons particularly for aortic valve replacements. Mitral valve reconstruction has advanced over the use of mechanical prostheses and bioprostheses.

The bioprostheses available in the United States are the second generation stented bioprostheses, the Carpentier-Edwards supra-annular (SAV) porcine, the Hancock II porcine and the Carpentier-Edwards PERIMOUNT pericardial, and the third generation Medtronic Mosaic porcine valve. The stentless aortic bioprostheses are the St. Jude Medical Toronto SPV, Medtronic Freestyle and the Edwards Prima Plus. The stented bioprostheses dominate 92% (+12% 2000-2002) of the tissue valve market in the United States with the stentless market share diminishing at 8% (-1% 2000-2002) as 7-8 year durability results are being reported.

The University of British Columbia experience with CE-SAV porcine bioprosthesis at 15-20 years has provided recommendations for use of bioprostheses. The actual freedom from structural valve deterioration (SVD) for aortic valve replacement was 90.5% for age group 61-70 years and 98% for age group > 70 at 20 years. For the age group 65-70 years the freedom from SVD was similar to the more advanced age group. The freedom from SVD was similar at 15 years for both the Hancock II and the CE-PERIMOUNT. The actual freedom from SVD for CE porcine bioprostheses for mitral valve replacement > 70 years was 93%.

There has been limited comparison of performance of bioprostheses and mechanical prostheses. The Veterans Administration randomized trial reported 15 years results of first generation prostheses in 2000. SVD was virtually absent for mechanical prostheses and occurred more frequently for bioprostheses for AVR and MVR < 65 years than ≥ 65 years. There was no difference between the two types for thromboembolism and other valve-related complications. The use of bioprostheses resulted in lower bleeding rates. The use of a mechanical valve resulted in lower mortality and lower reoperation rate after AVR while mortality after MVR was similar with the use of the two prosthesis types.

The Edinburgh randomized trial reported in 2003 results to 20 years. The prosthesis type did not influence survival, thromboembolism or endocarditis. Major bleeding was more common with the mechanical prosthesis. Assessing mortality and re-operation, survival with original prosthesis became different at 8-10 years for MVR and 12-14 years for AVR.

The University of British Columbia has evaluated the performance of the current generation bioprostheses and mechanical prostheses to 15 years for AVR and MVR (unpublished data) for composites of valve-related complications. VR mortality was undifferentiated for AVR between BP and MP and was also not differentiated for MVR. Valve –related morbidity (permanent functional or neurologic impairment) was also undifferentiated between BP and MP for AVR and MVR for all age groups. VR reoperation for AVR was differentiated below 60 years of age favoring MP over BP and for MVR 70 years and younger favoring MP over BP. These results do not consider chronicity of care with anticoagulation or non-morbid hemorrhagic or embolic episodes.

Re-operation for structural valve deterioration for bioprostheses for both aortic and mitral re-replacements can be performed with a very low mortality if surveillance can avoid advanced functional class (NYHA IV) and emergent status at the time of re-operations.

The avoidance of severe or moderate-severe patient-prosthesis mismatch with both bioprostheses (stentless and supra-annular stented configurations) and internal-diameter enhanced mechanical prostheses will influence regression of left ventricular mass and likely survival. The surgeon can avoid PPM by always evaluating projected indexed effective orifice area from reference EOA of prosthesis choice and the patient BSA.

Bioprostheses remain recommended for the majority of aortic valve replacements, ≥ 65 years of age, and when reconstruction of the mitral valve is not feasible for the age group > 70 years of age.

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EPICARDIAL LEAD IMPLANTATION WITH ROBOTIC ENHANCED THORACOSCOPY FOR BIVENTRICULAR RESYNCHRONIZATION THERAPY: A BETTER APPROACH THAN THE PERCUTANEOUS METHOD?

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Objective. Cardiac Resynchronization Therapy (CRT) by pacing both ventricles is an emerging option for the treatment of severe heart failure with ventricular conduction disturbances. Currently, stimulation through a coronary vein is the technique of choice to achieve CRT. Unfortunately, this approach carries significant limitations and drawbacks. Therefore, we explored robotic-enhanced thoracoscopic implantation of an epicardial lead as an alternative technique to the coronary sinus technique.

Methods. Biventricular resynchronization through robotic thoracoscopy has been performed in forty two patients. After implantation of the endocardial leads in a classical way, the LV lead was sutured on the epicardium with the robotic arms. The leads were then connected to the stimulator, placed in a pectoral position.

Results. Mean duration of the procedure was 2.5 hours (28 pacemakers and 14 AICD). Mean procedural duration for the LV lead implantation was 20 minutes.

Five patients were converted into a small left thoracotomy, all for reasons unrelated to the robotic procedure (1 bleeding, 1 robotic device failure, 3 anatomic reasons).

After a mean follow up of 9.5 months, all the devices were well functioning. All the patients improved their functional capacity, except two. No major complications were observed in the early follow-up period.

Conclusions. Based on this preliminary experience, we do strongly believe that this new approach is a valid procedure for biventricular resynchronization and warrants further investigation on a larger scale basis.

RIGHT ROBOTIC-ENHANCED TOTALLY ENDOSCOPIC ABLATION OF ATRIAL FIBRILLATION WITH A CONCOMITANT SUBXYPHOIDAL APPROACH

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Purpose- To describe our robotically assisted minimally invasive surgical (MIS) ablation approach offered to patient suffering from lone atrial fibrillation (AF).

Method- Our MIS ablation procedure was performed on a 65-year-old male patient with paroxysmal AF. The patient was symptomatic with monthly episodes of AF resulting in dizziness and excessive sweating. Prior treatments included unsuccessful internal and external electrical cardioversion and multiple drugs consisting of sotalol and digoxin. Three port accesses were created on the right chest at the fourth, fifth and sixth intercostal space (IS) at the right mid-axillary line. The daVinci robot-telemanipulator (Intuitive Surgical, Sunnyvale, CA) was used for both endoscopic and manipulation. After a sharp opening of the pericardium, the superior vena cava (SVC) and inferior vena cava (IVC) were dissected circumferentially thus allowing free access to the transverse and oblique sinuses respectively. As shown by the video, a 150 cm Terumo Guidewire was used to position the FLEX 10 device (AFx, Fremont, CA) around the pulmonary veins. The confirmation of the device posterior to the left atrial appendage was successfully accomplished by introducing a VasoView endoscope through a small subxyphoid port access. After performing continuous encircling ablation line around the PVs, the device was positioned flat across the IVC-SVC where a continuous ablation line was performed.

Results- At the end of the procedure which lasted 240 minutes, the patient was in sinus rhythm (SR) and remained in SR until discharged at POD 5. At one month post-op, the patient experienced an event of AF which lasted about 30 minutes, since then the patient remained in normal SR.

Conclusion- Robotically assisted totally endoscopic microwave ablation using the FLEX 10 is technically feasible and carries minimal risk to the patient. The subxyphoid port access provided adequate exposure to confirm the accurate position and orientation of the FLEX 10 relative to the LAA.

COMBINED TREATMENT OF AORTIC TYPE A DISSECTION: ASCENDING AORTA REPAIR AND PLACEMENT OF A STENT IN THE DESCENDING AORTA

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INTRODUCTION: The established treatment modality of acute Stanford type A dissection includes repair of the ascending aorta and a variable part of the aortic arch, leaving the descending aorta untreated. We report a simultaneous approach of open repair of the ascending aorta with transluminal placement of a stent in the descending aorta to minimize the consequences of an untreated descending aorta.

METHODS: Four cases of aortic dissections type A with the entry port in the descending aorta in the aortic arch were treated by replacement of the ascending aorta and aortic arch, and placement of a stent in descending aorta with a new device under circulatory arrest and deep hypothermia.

The device consists of a stent DJUMBODIS® (Saint Come-chirurgie, Marseille, France) mounted on a compliant balloon. This stent is made of a Steel 316 L, and can be adapted to the shape of the aortic arch or descending aorta. Three different lengths are available 4, 9 and 14 cm. The device has a diameter of 9 mm.

RESULTS: The early results were satisfactory with a complete thrombosed false lumen in 3 cases, and a partial thrombosed false lumen in one case, on postoperative transesophageal echocardiography control. A follow up computed tomographic chest scan was done (between 6 month and 2 years), which confirmed the good surgical results.

CONCLUSION: This preliminary study shows that combined surgical and endovascular treatment of acute type a dissection is feasible, and at least partial thrombosis of the false lumen can be achieved, potentially minimizing the risk of further dilatation or rupture. The early results are encouraging but more cases and long-term results are warranted to demonstrate the effectiveness of this new combined treatment modality.

CAVITATION IN MECHANICAL HEART VALVE PATIENTS

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Background: Patients receiving mechanical heart valve prosthesis have an increased risk of thromboembolic complications. Those patients are therefore treated with lifelong oral anticoagulation therapy. This reduces the thromboembolic risk but may induce bleeding complications. Furthermore, in those patients fatal valve material failure has been observed. The mecha-

nisms causing those adverse effects are not yet fully understood. However, during the past decade attention has been drawn towards the valves capability of causing cavitation. Cavitation can be very devastating and is known in other industries to cause severe damage on stainless steel and other tough structures. The particular erosive pattern on such damage sites have also been found similar at explants of valves that had caused fragment or disc embolization in the patient. Strongly suggesting cavitation to occur at mechanical heart valves, in vitro studies were designed which visually demonstrated cavitation in vitro. However, in vivo measurements are sparse.

The aim of this study was therefore to apply detection schemes in vivo that had been developed and validated in vitro.

Material and methods: The study material comprised 31 patients. The prosthetic device investigated was the St. Jude Medical bileaflet valve (N = 16). As control groups, patients receiving a biological implant (Carpentier-Edwards, N = 5) as well as genuine valve patients (undergoing bypass grafting, N = 10) were included. All valves were aortic. As a quantitative measure of cavitation, high frequency pressure fluctuations were recorded intra operatively using a hydrophone positioned next to the aortic root. The data were sampled through a computer equipped with a high precision and high bandwidth data acquisition board. Besides intra operative measurements (open chest) post operative measurements were performed as well (closed chest) using the same equipment. In the latter, the hydrophone was emerged in a small waterfilled cylindric container with a latex membrane serving as its base. This ensured a good acoustic coupling to the patient. The container was positioned at the right inter costal space II.

Results illustrated that cavitation clearly could be observed at mechanical heart valves, both during intra- and post operative settings. No cavitation was seen at the biological prostheses or the genuine valves.

Conclusions: The results contribute with important knowledge that may link cavitation and the increased risk of thromboembolic complications seen at mechanical heart valves. Since it is evident that cavitation can cause structural damage on pyrolitic carbon, which is the preferred material used at mechanical heart valves today, it is most likely that it also is capable of destroying formed elements of the blood. Hence, an increased release of tissue factor from e.g. ruptured monocytes and platelets may have a central position. It is well established that the tissue factor – factor VIIa complex initiates coagulation and thereby plays an important part of thrombosis generation.

Further studies need to be carried out to elucidate those speculations in controlled settings.

IMPLANTATION OF THE MICROMED DEBAKEY VAD

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Background: Axial flow left ventricular assist devices (LVADs) offer a number of advantages over first-generation pumps, including smaller size, fewer moving parts, lower power requirements, easier implantation and explantation, and lower cost.

Methods: Implantation of the DeBakey VAD can be performed via either median sternotomy or left lateral thoracotomy. After initiating cardiopulmonary bypass, the apical fixation ring is sewn in place at the site of insertion for the inflow cannula. A cruciate incision is made inside the apical ring, and a round bladed couring device is used to extract a core of the left ventricular apex. The inflow cannula is then inserted and sewn in to place. A partial occlusion clamp is placed on either the ascending or descending aorta. The outflow graft is sewn in end-to-side. The heart is filled with blood and de-aired, the clamp is removed, and the VAD is started. The driveline is tunnelled to the right side of the abdomen and connected to the controller and Clinical Data Acquisition System (CDAS). Pump flows are begun at 7,500 rpm and adjusted for a cardiac index of 2.0 L/min/meter squared or greater.

Results: The MicroMed DeBakey VAD has been successfully implanted in over 200 patients with similar survival characteristics to other VADs. Complications are comparable to first-generation pumps and include hemorrhage, infection, thrombus formation, and right ventricular failure.

Conclusions: As the first axial flow pump to be successfully implanted in a human being, the MicroMed DeBakey VAD is easy to implant. It offers an excellent alternative to first-generation devices, particularly in patients with a smaller body surface area (BSA) who may not tolerate a larger pump. Currently, the only contraindications for implantation include those factors which exclude a patient from cardiac transplantation.

DOR PROCEDURE

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It has been well known that left ventricular aneurysm repair can successfully treat heart failure. Several innovators have demonstrated that an endoventricular repair of left ventricular aneurysms (Cooley) achieves the best results due to the fact that it creates a more elliptical ventricle. The breakthrough for this technique occurred when Dor demonstrated that in patients who had akinetic ventricles endoventricular repair would provide equivalent results to patients undergoing left ventricular aneurysm resections (Dor). Dor demonstrated clearly that reducing the size of these ventricles improved symptoms of heart failure.

The converse of this was demonstrated by Yamaguchi (Yamaguchi). These investigators noted that patients who underwent coronary by-pass and had large ventricles did far worse than patients with smaller ventricles despite both groups having equivalently poor ventricular function.

Our group has studied this topic as well. We knew that Dor had demonstrated good results in patients with akinetic ventricles. We also had studied Yamaguchi's results. We compared two groups of patients treated at our institution for ischemic cardiomyopathy. Both groups had very large ventricles. One group received the Dor procedure and the other received coronary by-pass alone. We noted that the operative mortality in both groups was the same, at 0. However, at the end of one year the readmission rate for heart failure in the patients who did not have the Dor procedure was significantly higher than those that had the Dor procedure (Kron). This is a subject of some interest to the NHLBI as well. The STICH Trial has been organized, in part, to study this topic.

Finally, the issue is how to best perform the Dor procedure. Buckberg and colleagues has suggested that this procedure is best performed in patients whose hearts are beating (Buckberg). The surgeon can delineate where the beating stops and put the patch in at that site. Our belief is that this is not necessary. The beating heart approach may be hazardous in that it would potentially allow for the showering of clot from inside these diseased ventricles. We have switched to a cross-clamp no-touch technique (Maxey). We believe the most important place to put the stitch is where one can optimally change the size of the ventricle. This should be decided preoperatively with the use of echocardiography. There are also devices available such as that manufactured by CHASE that can help determine the appropriate size ventricle to leave behind.

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THE PRO/CON: OPCABG

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OPCAB is a technique that allows one to avoid the cardiopulmonary bypass. The few randomized studies out there show advantages from OPCAB compared to normal CABG in only a few situations. It is clear that patients who have OPCAB likely are in the hospital approximately a day less than people who have cardiopulmonary bypass. There is some evidence that there is less incidence of blood transfusion. There is no evidence that there is less atrial fibrillation, renal insufficiency, or fewer strokes. The only exception, to fewer strokes are on patients who truly have atherosclerotic aortas.

Unfortunately, there are disadvantages as well. If one has to revert to cardiopulmonary bypass in an urgent fashion the mortality is extremely high. There are clearly fewer less anastomoses per patient with off-pump than on pump. Finally there are no large studies on graft patency. Since this is the heart and soul of what we do this clearly needs to be verified before off-pump is used universally as compared to on-pump procedures.

GETTING IDEAS PUBLISHED AND BUILDING AN ACADEMIC CAREER

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There is no one formula for developing an academic career. Everyone has his or her own way to do this but certainly an essential is finding the right job. The essentials of the right job include a good institution, an active surgical division with adequate patient volume, and a decent boss. Once you have such a position available you must get a mentor. That mentor may or may not be your Division Head. The mentor doesn't even necessarily have to be in the same institution. However, that individual should have an interest in your career and be an advisor both professionally and academically. You may require both a basic science mentor as well as a clinical one depending on the type of career you develop.

You then must decide what your interests are. It is much easier to write about things you are interested in than things you are not. Therefore, if you develop a laboratory effort related to a specific clinic issue you would be thinking about this as you are doing clinical work. Developing a laboratory is a major proposition. You have to have some protected time, some research support, and stay focused. You will want to have very specific goals and you can't spread your efforts too thin. Sooner or later you will have to gain funding. Likely you will be turned down several times before you are successful in this. You will need collaboration, but remember your collaboration is likely with a basic scientist. You do have one major advantage for funding. You know what is essential for patient care and usually the basic scientists don't. The 'buzz' word at the NIH is translational research and you by definition do that.

Whether or not you have a laboratory, if you are in an academic situation, sooner or later you must write. You could either write about your laboratory efforts or your clinical efforts or preferably both. You should start with a specific hypothesis before you develop a laboratory experiment or any clinical study. Once you find an answer to your question that is exactly the time to write the first draft. The first draft is the hardest thing to do and you must be efficient to do this. You may have to learn to dictate your publications. This will save you tons of time unless you are truly an expert typist. Once you have your manuscript or abstract completed that is the time to submit it to a journal or meeting. This is where peer review comes into play. Remember, beauty is in the eye of the beholder. Just because someone dislikes your work does not mean they are bad people. You will have papers turned down, even if they truly are a cure for cancer or the meaning of life. Pay attention to the critiques. Some are legitimate, some are not. Ignore the illegitimate ones. Sooner or later, if your concept is sound it will be published.

HOW TO EXPAND AN ACADEMIC CAREER

Basically, once you have written a certain amount and appeared at some national meetings the positions will come to you. You don't have to be any more proactive than that. If someone asks you to do something and you accept, do it. This includes writing a chapter or moderating a session at a national meeting. The worst hit you can take is offering to do something and not coming through. If you do your work well for a society then you will likely move up the ladder in that society. Finally, it's helpful to stay put in one academic situation unless the next job truly is an advantage. Most people only have one or two moves in their career. Moving sideways is no help to you and you can lose time academically. Once asked to do a division or department head job be certain it is a doable job. The Dean and hospital CEO's will be very interested in talking with you but they are not the ones you will be working with every day. Get to know the individuals who you will work with on a daily basis.

In summary, developing an academic career really is a fun thing to do. You will meet wonderful people and you will make things better for patients. You need most importantly to enjoy what you do. If you don't then you are in the wrong venue.

OFF PUMP LEFT ATRIAL ABLATION FOR ATRIAL FIBRILLATION TREATMENT THROUGH A LIMITED STERNOTOMY ACCESS

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Purpose- Feasibility of limited access incision via lower partial sternotomy using off pump technique for surgical ablation of atrial fibrillation (AF).
Method- Between August 1, 2002 and March 1, 2003, six patients underwent off pump left atrial ablation for isolation of pulmonary veins (PVs) (3 standalone pts and 3 concomitant to MV repair in 2 patients and to an ASD repair in one patient). The mean age was 49 years within a range of 27 to 64 years. Five patients had paroxysmal AF and one patient had persistent AF. A lower partial sternotomy incision with a "T" into the fourth inter-costal space was performed. After widely opening the pericardium, the superior vena cava (SVC) and the inferior vena cava (IVC) were dissected circumferentially to provide free access to the transverse and oblique sinuses respectively. A FLEX 10 device (AFx, Fremont, CA) was used to encircle the PVs (as shown in the video). After confirming the position of the ablating sheath posterior to the left atrial appendage, serial ablation on the beating heart were performed. This resulted in an encircling ablation line around the PVs. After completing the ablation, electrical isolation of the PVs was assessed with inability to capture the body of the atrium by pacing inside the isolated segment. Left atrial appendage was ligated in all patients. Patients were discharged on anti-arrhythmic drugs and anti-coagulant for 3 months.
Results- All procedures were completed uneventfully. All patients were able to be discharged on the fourth post-operative day. As of the latest follow up (over 6 months), all patients were in normal sinus rhythm and were off anti-arrhythmic drug and anti-coagulant.
Conclusion- Lower partial sternotomy can provide adequate exposure and cosmesis to successfully perform off pump left atrial ablation to treat atrial fibrillation.

PERFUSION FOR MINIMALLY INVASIVE CARDIAC SURGERY

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Cardiac surgery has traditionally been performed through a median sternotomy, providing ample access to all cardiac structures for cannulation and institution of cardiopulmonary bypass. Recently, advances in intracardiac visualization, instrumentation, and robotic telemanipulation have hastened a shift toward efficient and safe minimally invasive cardiac surgery (MICS). However, only after modifications in cardiopulmonary bypass, reductions in the size of incisions, and alternate incision site usage, were the possibilities of MICS realized.

Traditional cannulation techniques can no longer be applied to MICS. Endovascular cardiopulmonary bypass systems (Cardiovations, Inc., Somerville, NJ) have been developed that do not require a median sternotomy (1). Specialized catheters and cannulas provide either antegrade and/or retrograde cardioplegic arrest. Aortic clamping can be done with a multipurpose endovascular balloon catheter, which is usually placed through the femoral artery into the ascending aorta. When integrated into a modified cardiopulmonary bypass circuit, this system creates a platform that facilitates both epicardial and intracardiac procedures done through alternative incisions. Ultimately, these methods will facilitate performance of operations in a closed chest environment using robotic assistance.

In median sternotomy-based cardiac surgery, gravity venous drainage has been the mainstay of cardiopulmonary perfusion. In MICS, access for direct insertion of large-bore cannulas is not feasible. Augmented venous return with kinetic or vacuum assistance is used to provide total cardiopulmonary support. Cannulation methods are governed by the incision selected. Upper or lower hemi-sternotomies can allow for direct arch cannulation. We rely on the Seldinger technique to place a Biomedicus™ coaxial dilator cannula in the distal aorta. The Cardiovations Endodirect™ arterial cannula can be placed across the chest wall with direct aortic cannulation. Venous return is kinetically augmented and both percutaneous internal jugular and femoral vein cannulation are used instead of placing the venous cannula directly in the atrium. Others directly cannulate the atrium through the incision. For the minimally invasive thoracotomy incision, most cannulate the femoral artery and vein. We use the Seldinger method to perform an open direct femoral cannulation. Generally, a 17 or 19 Fr arterial and 23 Fr venous cannula is adequate. We prefer to use an additional percutaneous 17 Fr internal jugular vein cannula for upper body and head drainage (2).

Direct aortic occlusion using specialized flexible-handle clamps have been developed for minimally invasive valve surgery. For mitral operations, done through a minithoracotomy, we developed a percutaneous transthoracic aortic cross-clamp. This clamp is inserted percutaneously through a 4-mm incision in the right lateral 3rd intercostal space (3). In contrast, the balloon clamp is introduced through a channel in either the peripheral or central arterial perfusion cannula. The occlusive balloon is positioned, under transesophageal echocardiographic (TEE) control, just above the tubulosinus ridge in the ascending aorta. Balloon pressures must be continuously moni-

tored and antegrade cardioplegia is given via a central catheter lumen. Continuous TEE monitoring is important to detect balloon migration.

Myocardial preservation in MICS is similar to sternotomy-based operations, but limited exposure makes retrograde coronary sinus catheter insertion more difficult and under less control should complications arise. Generally, for aortic and mitral surgery, an initial dose of antegrade cardioplegia is given via the occluded aortic root. For supplemental cardioplegia, doses are administered either into the coronary ostia for aortic surgery or the aorta for mitral operations. With our "micromitral" mini-thoracotomy, we insert the cardioplegia needle directly into the ascending aorta through the incision, under videoscopic control.

Air removal is difficult in MICS. The cardiac apex cannot be elevated, and difficulty exists in manipulating the heart. Air is often sequestered in pulmonary veins and along the interventricular septum. Carbon dioxide infusions have been particularly helpful for air removal (4). This gas is much more soluble in blood than air and displaces it. After atriotomy closure, we suction vent the aortic root and compress the right coronary artery upon cross-clamp release. As the heart beats, we gently reclamp the aorta to expel the residual air into the vent suction. With the balloon clamp, similar maneuvers can be applied to remove residual cardiac air. TEE monitoring should assure adequate air removal before weaning the patient from cardiopulmonary bypass.

In summary, MICS allows the surgeon to perform operations through much smaller incisions. Modifications in cardiopulmonary perfusion have become necessary as the surgeon is removed from the operative field. MICS requires TEE expertise and a team approach with the anesthesiologist and the perfusionist performing a similar critical role as the surgeon. Data suggest that these minimally invasive operations can be done in a safe manner (5). Further study is needed to analyze the outcomes, long-term efficacy, recovery times and cost-effectiveness of minimally invasive cardiac surgery.

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THE NEW HEART INSTITUTE

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Disease specific point of service venues such as heart institutes, neurologic institutes, etc. are being created with increasing frequency due to compelling driving forces in medicine. These forces include improved outcomes, greater profit margins, and benefits from the economy of scale, health professionals' esprit de corps, greater patient satisfaction, opportunity to acquire costly technologies and support highly focused sub-specialists. Lastly, the magnitude of cardiovascular disease and our attention to it makes the heart institute an excellent venue for teaching, for education of health professionals and the public, a superb marketing arena.

Although these programs can be free standing, they most commonly are attached to or affiliated with a general medical facility to call upon other specialty expertise. The extant Heart Institute model usually takes one of three forms: The first is a public not-for-profit entity that has either private practitioners or salaried physicians. The second is a for profit institute that is owned by investors, some of which may be the practicing physicians or employees. Lastly, the joint venture model where the practicing physicians and the institute can joint venture for a profit or not-for-profit program depending on the structure and objectives.

Each of these arrangements has specific advantages and pitfalls. The primary concerns being avoidance of legal issues, conflict of interest, patient "churning", unnecessary procedures, medical liability, investment return, institutional compensation for the physician and vulnerability to a physician exodus. The construct of the Heart Institute depends on what best fits the patient needs, region, economic feasibility and institutional desire and physician leverage.

OFF PUMP CABG: PRO

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Off pump coronary artery bypass (OPCAB) surgery was re-introduced into coronary artery bypass grafting in the mid-1990s and in the seven years since, the percent of coronary artery bypass procedures performed off-pump has increased to approximately 25%. However, over the past 1-2 years we have seen a relative plateau effect in the adoption rate of off-pump surgery by cardiac surgeons. Numerous factors play a role in the adoption rate of any new technology or techniques including the demonstration of benefit, the ease of use, and effective education methods. All of these play a significant role in the adoption rate of OPCAB. My bias (but not without some merit) include the following:

- All other things being equal, OPCAB is better than on-pump CABG for patients
- Specific groups of patient i.e., patients that are particularly high risk for surgery with significant comorbidities are those that benefit the most from off-pump techniques.
- OPCAB is not necessarily for all patients by all surgeons at the present time
- OPCAB is a different operation requiring a different mind set and different skill set and commitment than on-pump surgery. It doesn't necessarily require more *technical* skill
- Surgeons should not be pushed too hard or too quickly out of their comfort zone

Over 90% of hospitals in the United States currently perform off-pump procedures. However, this ranges from virtually none in some institutions to virtually 100% in others. Projections are that over the next five years the percent of CABG procedures performed on the beating heart will increase from 25% to 45%. This will be due to a gradually increasing adoption rate but also to a relative decrease in the total number of CABG procedures performed.

In a hierarchy of evidence of benefit, the prospective randomized trail reigns supreme. There are four randomized trials published comparing on and off-pump CABG. Meta-analysis shows that although there is less mortality in the off-pump surgery group, it is not statistically significant. The same holds true for neurologic complications. However, with an expected incidence of an end point of 1%, even a meta-analysis is underpowered to show a difference between the two groups in randomized studies. However, in end points in which there is greater incidence, including the need for blood transfusions and atrial fibrillation, there is a clear cut benefit to off-pump surgery.

The retrospective analyses of large outcome databases hold the next level in the hierarchy of evidence. In review of the STS database, the HCA System Hospital database, MedPar data, and our practice there is a statistically significant mortality benefit to off-pump surgery compared to on-pump surgery. Similarly, major complications in cardiac surgery in all instances are less off-pump compared to on-pump.

A recent survey on CTSNet regarding adoption rates of surgeons revealed that the reasons more CABG surgery is not done off-pump includes: patient selection, lack of demonstration of benefit, anesthesia issues, and lack of training. Issues that would increase the adoption rate were recommended to be more data showing benefit, better tools, better training of anesthesiologists, and more training of surgeons. New technology on the horizon that would significantly facilitate both beating heart surgery and minimal access surgery include distal anastomotic connectors. Further significant growth is dependent upon this enabling technology that will make the operation less technically challenging and more adaptable to a wider group of surgeons.

RESIDENT CROSS-TRAINING

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The specialty of cardiac surgery is in a state of significant flux at the present time and a paradigm shift in disease treatment modalities is occurring before our eyes. The demands and opportunities of cardiac surgery practice recently time have significantly changed, and they will in all likelihood dramatically shift again in the next five years. Today, there is a relative over supply of cardiac surgeons in the marketplace due to a recent relative decrease in procedural volumes and to practice issues such as declining reimbursement, loss of valuation of retirement funds as well as a relative surplus of recent trainees. However, due to the large number of practitioners anticipated to retire within the next five years, as well as decreasing enrollment in cardiac and thoracic surgery residency programs as medical students and residents pursue specialties more adaptive to different lifestyles (0.7 FTE), there is expected to be a relative shortage of cardiac surgeons within the next decade. However, in the interim, because of these marketplace issues as well as the change in the nature of the specialty, alternatives to traditional cardiac surgery training need to be seriously considered. The current structure of the graduate medical education programs makes pursuing alternative training somewhat problematic. However, in order to adopt to change and emerge optimally position to best address cardiac intervention over the next 20 years, cross-training should be actively pursued. (Viz. vascular surgery)

Today's world certainly does not need another traditional CABG surgeon (or for that matter, interventional cardiologist either). A recent trainee is much better positioned for success if they have had additional training in specific "niche" procedures including:

- Beating heart surgery
- Transplant/ assist devices
- Advanced valve techniques
- Thoracic oncology

Emerging areas in which sub sub-specialization would be beneficial include:

- Congestive heart failure
- Atrial fibrillation

Because of the increasing permeation of minimally invasive and catheter based techniques in all aspects of intervention, training in catheter based technology is extremely desirable. In a special millennium edition of JAMA in which medicine in the 21st century was forecast, I wrote in 2000 that the most desirable therapeutic interventions were projected to be those that could be performed through a blood vessel or a natural orifice. I feel even stronger today that such is the case. The current practice of endovascular therapy for abdominal aortic aneurysms to be followed soon by the widespread application of carotid stenting and soon after that, percutaneous aortic and mitral valve therapy predicates skill and expertise in endovascular therapeutic applications. Although formal training with these specialties is still somewhat problematic, it would be advisable to pursue these options to be able to have the ability to adapt to the future.

Besides endovascular therapy, other areas of cross training that offer significant opportunities include:

- Tissue engineering
- Cell transplantation therapy
- Thoracic oncology
- Advanced imaging techniques including MRI, ultrasound, CT, and echo

The traditional cardiac surgery training alone is not sufficient for the recent trainee to adapt to the rapidly changing aspects of patient care to be required in the upcoming years.

MINIMALLY INVASIVE CORONARY BYPASS SURGERY IS FACILITATED BY ROBOTIC TECHNOLOGY AND A NOVEL THORACOSCOPICALLY DEPLOYED CARDIAC STABILIZER (VIDEO ABSTRACT)

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Background: The recent evolution of minimally invasive techniques has allowed less traumatic approaches to open heart procedures such as mitral valve and atrial septal defect surgery. However, despite the maturation of off-pump coronary bypass grafting (OPCAB) procedures, the surgical treatment of coronary artery disease still remains quite invasive, requiring a sternotomy or large thoracotomy in the majority of patients. We have utilized a robotically assisted technique to perform LIMA-LAD OPCAB through a left minithoracotomy, and herein report our technique.
Methods/Results: Over 2 years, we performed 25 OPCAB operations via left minithoracotomy (MiniThoraCAB) utilizing the DaVinci robotic surgical system and a novel minimally invasive cardiac stabilizing device. We have designed this device to be deployed through a thoracoscopic port incision, so as to maximize exposure without requiring a larger incision. There were 16 men and 9 women in the series. Mean age was 65.4 $\pm$ 12.7 years, and all patients had single vessel coronary artery disease for which they received a LIMA-LAD bypass without extracorporeal circulatory support. The LIMA harvest was performed thoracoscopically with robotic assistance, through three 1 cm ports in the left chest. The robotic system was then used to open the pericardium, identify the target vessel, and select the appropriate minithoracotomy location. Next, a 6 cm minithoracotomy was made in the anterolateral left chest, and our minimally invasive stabilizer was positioned through one of the thoracoscopic port sites. This allowed the performance of a hand-sewn, off-pump LIMA-LAD anastomosis in all cases.
Conclusions: Minimally invasive, off-pump coronary artery bypass surgery is greatly facilitated by the use of robotic technology for IMA and target vessel preparation, and particularly by our specially designed OPCAB stabilizing system which can be deployed through a thoracoscopic port incision.

A MODIFIED MINITHORACOTOMY APPROACH FOR MITRAL VALVE AND ATRIAL SEPTAL DEFECT SURGERY: COMPARISON TO MEDIAN STERNOTOMY

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Background: Many non-sternotomy open-heart approaches are complicated by the need for femoral arterial cannulation and prolonged operative times. We have utilized a modified minimally invasive approach that avoids these disadvantages.
Methods: Over two years, we performed over 235 minimally invasive cardiac operations, and utilized a modified right minithoractomy approach (7 cm incision, central aortic cannulation, percutaneous SVC/IVC drainage, transaxillary crossclamp) in 50 isolated mitral valve operations (RMT-MVS) and 18 isolated atrial septal defect repairs (RMT-ASD). These were compared to a concurrent, matched case-control group of mitral (STER-MVS, n=50) or ASD operations (STER-ASD, n=18) done by median sternotomy.
Results: There were no deaths or major complications in either ASD group. Crossclamp time was slightly shorter in STER-ASD than RMT-ASD (14+/-5 vs 20+/-14 min, p=.002), but cardiopulmonary bypass (CPB) time (43+/-19 vs 57+/-27 min), transfusion incidence (0 vs 2 patients), length of stay (5.5+/-2.2 vs 6.2+/-3.2 vs days) and all other postoperative parameters were similar in both groups. In mitral valve procedures, mortality (2% vs. 0%), CPB time (112+/-33.2 vs. 128+/-34.5 min), crossclamp time (77+/-27 vs. 80+/-24 min), and transfusion incidence (11 vs. 9 patients) were similar for STER-MVS and RMT-MVS, respectively, while morbidity (22% vs. 8%, p=.045) and length of stay (8.1+/-5.2 vs. 6.5+/-2.9 days, p=.007) were higher in the STER-MVS group.
Conclusions: Our modified right minithoractomy approach is safe and effective for mitral valve and ASD surgery. For mitral valve surgery, this technique was associated with a shorter length of stay and lower incidence of complications than the sternotomy approach.

COMPLEX SECOND REPAIR OF MITRAL VALVE USING TWO ANNULOPLASTY BANDS: A CASE REPORT

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Background:
As mitral valvuloplasty has demonstrated significant benefits over valve replacement, an increasing number of repairs and in some cases, second repairs are being performed with durable outcomes. We describe the case

of a second repair in a patient with atrial fibrillation, bileaflet prolapse, commissural clefts and an extremely dilated mitral annulus, after having undergone a quadrangular resection of the posterior leaflet seven years prior to presentation. The patient underwent cryoablation of the left atrium, a complex bileaflet repair and a Cosgrove-Edwards ring annuloplasty with two serial rings to subtend the posterior annulus.

Case Report:

A 68-year-old male was diagnosed with symptomatic severe mitral regurgitation and atrial fibrillation. Seven years earlier, he had undergone P_2 quadrangular resection with sliding plasty at an outside institution. Because of the large size of the annulus, a pericardial strip plication of the posterior annulus was performed instead of a ring annuloplasty. His most recent transesophageal echocardiogram (TEE) revealed leakage at both commissures and an anteriorly and another posteriorly directed regurgitant jet from a prolapsing posterior and anterior leaflets respectively. The annulus was massively dilated with a diameter of over 50mm. The ventricular function was preserved with ejection fraction of 65-70%.

The patient underwent video-assisted mitral valve repair and cryoablation of the left atrium. The repair consisted of bilateral commissuroplasty, Goretex neo-chords to the prolapsing A_2 and the P_2 segments. To reduce the annulus, a #38 Cosgrove-Edwards ring was placed around two-thirds of the posterior annulus. A #26 Cosgrove-Edwards ring was then placed around the remaining one-third of the posterior annulus after some trimming. Saline test was then performed to confirm the competence of the repair. Post-operative TEE revealed no mitral regurgitation. His postoperative course was uneventful and he was discharged home on the fifth postoperative day.

Conclusion:

This is the first reported use in literature, of two annuloplasty bands for repair of a dilated mitral annulus. Despite the complexity of the leak, a successful second repair of the mitral valve was performed with construction of multuple neo-chords and reduction of posterior annulus. The durability of the repair remains to be seen. However, this technique might be useful to a surgeon dealing with a massively dilated mitral annulus.

COMPARISION OF ANGIOGENESIS INDUCED BY VEGF GENE WITH METALLOPROTEINASE AND PHOSPHOLIPASE A2 DERIVED FROM VENOM OF NAJA NAJA SAGGITEFERA IN A RAT MODEL OF HIND LIMB ISCHEMIA

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One of the shortcomings of strategies designed solely to stimulate proliferation of endothelial cells (ECs) such as VEGF therapy, is the fact that only capillary (<40mm) networks are formed. Instead, formation of large conductance arterioles require a series of sequential steps involving EC migration, adhesion and differentiation and smooth muscle cell (SMC)migration. Venom from Indian cobra contain several potent enzymes including metalloproteinases (MP). We undertook the present study to test efficacy of MP and phospholipase A2 (PLA2) derived from venom of Indian cobra and compare it with plasmid VEGF 165 (ph VEGF 165) gene.

Methods : Twenty four male Wister albino rats (6 in each group) were randomized to receive MP 1mg/kg, PLA-2 2.5mg/kg, ph VEGF 165 400mg or normal saline (control), 2 days after left femoral artery division. Fifteen days after injection of active principal / control, digital subtraction angiography (DSA) was performed and muscles of thigh distal to the site of division subjected to histopathological examination.

Results : On DSA there was a mild increase in number of large arterial collaterals both in MP and pH VEGF 165 groups as compared to PLA-2 or saline groups (statistically not significant). Morphometric analysis revealed that there was a marked stimulation of neo-angiogenesis in the MP group and ph VEGF group as compared to PLA-2 or the saline group. Capillary density was : saline 4.6 ± 1.4; PLA-2 5.2 ± 2.2; MP 8.8 ± 2.1($p<0.05$ vs saline group) ph VEGF 9.2 ± 2.8 ($p<0.05$ vs saline group). Capillary myocyte ratio was : saline 0.20 ± 0.14; PLA-2 0.16 ± 0.07, MP 0.35 ± 0.16, ($p<0.05$ vs saline group) ph VEGF 0.36 ± 0.10 ($p<0.05$ vs saline group).

Conclusions: Metalloproteinase derived from Venom of Indian Cobra can produce angiogenesis of efficacy equivalent to VEGF Gene and thus may be useful in endstage ischemic peripheral and coronary artery disease

SURGICAL ATRIAL FIBRILLATION ABLATION (SAFA) IN PATIENTS WITH ATRIAL FIBRILLATION

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Introduction

Atrial fibrillation (AF) is one of the most common cardiac arrhythmias, affecting 0.4% of the general population and 5 to 10% of persons over 65 years of age. In addition, AF occurs in as many as 50% of patients undergoing cardiac operations. Patients with chronic AF may suffer from symptomatic tachycardia or low cardiac output, and have a 5-10% risk of thromboembolic complications. Compared to age-matched cohorts in sinus rhythm, patients with chronic AF are at twice the risk for death. Although electrical cardioversion, alone or in combination with antiarrhythmic therapy, is often effective in restoring sinus rhythm, recurrence rates as high as 75% have been reported. Furthermore, pharmacologic therapy is associated with adverse effects in a significant proportion of patients.

Since the initial description of the Maze procedure by Cox and colleagues, a number of surgical approaches have been devised for the treatment of AF. Although successful in the eradication of AF in a high percentage of cases, these procedures are invasive (requiring median sternotomy, cardiopulmonary bypass, cardioplegic arrest, extensive cardiac dissection, and/or multiple atrial incisions) and are associated with significant morbidity. Recent investigations suggest that in many patients, AF may be caused by reentry wavelets limited to specific areas near the origins of the pulmonary veins. In fact, several authors have reported success with more limited procedures aimed at the electrical isolation of discrete atrial regions, utilizing atriotomy, radiofrequency ablation, or cryoablation.

Columbia Experience

Since 1999, we have used a number of energy sources to perform pulmonary vein isolation for AF in patients having other cardiac operations. Over 4 years, we have performed this procedure in over 240 patients. Success rates at 6- to 12-month follow-up approach 80%. We perform the left-sided ablation by creating an encircling lesion around the four pulmonary vein orifices, as well as a lesion from this encircling lesion to the mitral annulus. Ablation is performed with one of a variety of probes, utilizing unipolar or bipolar radiofrequency, microwave, or laser energy. We have found this technique to be straightforward, reproducible, and expedient, rarely adding more than 20 minutes to the concomitant operation. Based on this experience, we now perform pulmonary vein isolation on all consenting patients with atrial fibrillation having a concurrent open-heart procedure, and have performed AF operations for atrial fibrillation as the sole indication. Described below are some important points relevant to the selection and treatment of these patients.

Patient Selection

The minimal duration of atrial fibrillation that should prompt intervention with an ablative procedure is debated. In patients with mitral valve disease and recent-onset AF (less than three months), it is believed that mitral valve repair or replacement alone is sufficient to restore sinus rhythm in most cases. In order to avoid operating unnecessarily on patients with a reasonable chance of spontaneous sinus rhythm recovery, we currently offer pulmonary vein isolation only to patients who have had AF (either chronic or paroxysmal) for at least 6 months, or to those who have failed at least two cardioversion attempts. We most frequently perform this procedure in patients undergoing mitral valve operations, but have also applied this technique in patients undergoing ASD closure, aortic valve operations, coronary artery bypass grafting, and for lone atrial fibrillation. Because of the potential to completely discontinue anticoagulation by restoring sinus rhythm, we are most aggressive about performing surgical atrial fibrillation ablation in patients undergoing valve repairs or tissue valve replacements. However, we also offer the procedure to patients receiving mechanical valves, since the elimination of atrial fibrillation may allow lower anticoagulation levels, as well as improved cardiac function and avoidance of anti-arrhythmic medications.

Operative Technique

Because our preferred approach to the mitral valve is by a left atriotomy made just medial to the right pulmonary veins, we have utilized this incision for our pulmonary vein isolation procedures. In addition to providing excellent exposure of the left atrium and mitral valve, the atriotomy serves as the right lateral component of the pulmonary vein encircling lesion. We isolate the pulmonary veins by creating a continuous endocardial lesion that begins at each end of the atriotomy. Our isolation technique includes a lesion from

the pulmonary vein encircling lesion to the mitral valve annulus. There is data to suggest that this lesion is important in interrupting the propagation of atypical left-sided atrial flutter. We also believe that anatomic isolation of the left atrial appendage (either by resection or pursestring exclusion) is important to help prevent thromboembolism..

Because the majority of patients with atrial fibrillation have left-sided initiating foci, we usually confine our ablation to the left atrium. In patients undergoing a concomitant right atrial procedure and in those with a history of atrial flutter (in whom right-sided initiating foci are common), we also perform a limited right atrial ablation procedure. This includes a longitudinal anterolateral incision in the RA (standard right atriotomy), as well as an ablation lesion from the inferior aspect of the atriotomy to the tricuspid annulus.

The majority of these operations have been performed in conjunction with other cardiac operations (such as valve repair or coronary bypass), but the procedure has also been used for atrial fibrillation as the sole indication. In fact, we now routinely perform AF surgery via a 6 cm minithoracotomy incision, both for lone AF as well as combined AF and mitral valve surgery. We have also performed several beating heart epicardial atrial fibrillation operations, and have developed a totally endoscopic, beating heart version AF ablation procedure. Earlier this year, we successfully performed the first of these in a patient with long-standing AF, and are now offering this completely closed chest minimally invasive operation for atrial fibrillation as the sole indication.

HEART SAVING DRUGS

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Many of the high risk CABG procedures that we perform annually are complicated by renal dysfunction and challenging post operative courses resulting from heart failure or post operative bleeding. Use of mechanical support devices, including balloon pump have been life saving, but also result in significant morbidity. As our heart failure cardiology colleagues learn more about the neurohumoral mechanisms underlying heart failure, the surgical community should embrace therapies that facilitate recovery of the critically ill post cardiotomy patient. These range from intelligent use of products to limit hemorrhage to agents that address the pulmonary component of our challenges.

In this spirit, a large multicenter study seeks to demonstrate the impact of brain naturetic peptide (BNP) on patient recovery in the postoperative period, specifically on patients with heart failure and poor left ventricular function as evidenced by a left ventricular ejection fraction (LVEF) of less than 35%. These patients are most likely to have a significant and demonstrable benefit from BNP, as previous studies have shown that this drug can reduce PCWP and act as a diuretic while maintaining glomerular filtration rate.

Equally importantly, large studies on heart failure patients undergoing CABG are lacking. The NIH funded STICH trial will address some factors, but enrollment is slow and years will pass before this data will be available to drive clinical decision making. The BNP trial will provide this information within a year.

REMATCH FOLLOW UP

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The Randomized Evaluation of Mechanical to medical therapy for congestive heart failure (REMATCH) trial established that left ventricular assist devices could prolong the life of critically ill patients. In addition, quality of life was improved in the device group compared to medical therapy. As a result, the FDA granted approval for use of VADs for destination therapy in March of 2002. Over the ensuing 18 months, follow up research on cost implications, complications, and long term durability have produced more profound insights into this technology. We estimate that the average pump implantation procedure will cost $200,000, which is similar to other solid organ replacement procedures. Cost efficacy data is still pending; however, a sensitivity analysis of the cost drivers revealed the reducing infections could almost half the overall costs of these procedures. Device durability has been acceptable although confounding factors such as infection or patient death due to other morbidities have limited the number of 2-year survivors.

On the basis of available data, CMS approved payment for destination VADs in September 2003. Advances in the device powering system including battery technology and drive lines will improve the ease of patient use. Understanding the biology of the device and its impact on the host will also reduce infections and immune complications. Finally, improved device durability and minimally invasive approaches to implantation could lead to improved long term results.

LEARNING CURVES ASSOCIATED WITH ROBOTIC MITRAL VALVE REPAIR

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Introduction: Eighty robotic mitral valve repairs (RMVR) using the da Vinci™ Surgical System have been done by a single surgeon. RMVR learning curves can prove advancement in skill and speed to validate new technology. This information may be applicable to a variety of robotic surgical procedures.

Methods: Data were gathered prospectively including both valve resection (RST) and repair (RPT) times; number of annuloplasty sutures (#SU); band placement (BPT), individual suture placement (SPT), and knot tying (KTT) times; total robotic (TRT), cross clamp (CCT), bypass (CPB), and total procedure times. Since every patient had a band inserted, #SU, BPT, SPT, and KTT were analyzed in all 80 patients and then subdivided into 8 equal chronologic cohorts. Remaining variables were analyzed for quadrangular resections (N=40) and placed in 5 similar cohorts.

Results: Data were compared using ANOVA (Kruskal-Wallis) and shown as mean±SEM. Significant reductions were evident between subsequent cohorts except #SU which increased with larger annuloplasties. However, BPT decreased despite additional sutures. SPT and KTT decreased until the 3rd cohort with no improvements until the 8th cohort, coinciding with a change from suture to U-clips for band approximation.

Conclusions: Intraoperative times with RMVR improve and variability decreases as more procedures are performed. The learning curve for all variables except SPT and KTT is most evident through the first 20 cases with incremental improvements thereafter. After approximately 20 cases, KTT does not improve significantly, revealing limitations of robotic knot tying. However, novel tissue approximation devices help to reduce KTT by 65%, shortening the time required to place a suture robotically by approximately 30%.

	RST (n=40)*	RPT (n=40)*	#SU (n=80)	BPT (n=80)*	SPT (n=80)*	KTT (n=80)*	TRT (n=40)†	CCT (n=40)†	CPB (n=40)†
1st	8.8±2.5	54.9±2.8	7.8±0.51	45.6±4.2	2.7±0.27	1.9±0.11	2.1±0.15	2.7±0.07	3.4±0.10
2nd	5.6±1.0	52.2±8.2	9.6±0.50	45.5±3.7	1.9±0.11	1.7±0.09	2.0±0.50	2.7±0.16	3.4±0.17
3rd	4.7±0.8	38.1±5.4	9.8±0.33	41.7±3.6	1.5±0.08	1.5±0.08	1.5±0.33	2.1±0.13	2.7±0.14
4th	2.9±0.4	29.1±2.9	10.0±0.39	41.0±3.9	1.5±0.09	1.5±0.08	1.5±0.17	2.1±0.10	2.7±0.15
5th	2.6±0.6	27.8±3.1	10.1±0.59	37.6±3.9	1.3±0.09	1.5±0.07	1.4±0.17	2.0±0.09	2.5±0.13
6th			10.4±0.47	37.0±2.6	1.3±0.08	1.5±0.07			
7th			11.7±0.31	37.0±3.0	1.3±0.09	1.4±0.06			
8th			10.3±0.77	28.4±2.3	1.4±0.10	0.5±0.05			
p	0.005	0.001	0.01	0.001	0.001	0.001	0.001	0.001	0.001

*minutes (mean±SEM) †hours (mean±SEM)

CONSIDERATIONS FOR MINIMALLY INVASIVE MITRAL VALVE SURGICAL ACCESS AFTER BREAST RECONSTRUCTION

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Introduction:

Minimally Invasive Mitral Valve Surgery (MIMVS) using AESOP or da Vinci (Intuitive Surgical, Sunnyvale, CA) has transformed the way patients and surgeons are viewing mitral valve surgery. Through a 5cm mini-thoracotomy,

these complex surgeries have significantly reduced blood loss, ventilator time, and hospital length of stay. Initially, not all patients were deemed suitable for MIMVS, with contraindications including prior thoracotomy, morbid obesity, breast reconstruction, and chest radiation. However, continued success with MIMVS has forced re-evaluation of prior contraindications.

Materials and Methods:

We present a MIMVS performed on a 55 year old white female who underwent right radical mastectomy, post-mastectomy radiation therapy, implant placement, and nipple reconstruction fifteen years prior to presentation. The usual right infra-mammary mini-thoracotomy incision was changed so that the prior mastectomy incision could be used for thoracic access. The implant capsule/pectoralis muscle was dissected free from the lateral latissimus dorsi muscle and raised superiorly so that the fourth intercostal space could be entered. Radiation had caused intra-thoracic lung adhesions and these were dissected free. The atrial retractor was placed through the mini-thoracotomy and not trans-thoracic to avoid the implant capsule. All other maneuvers were identical to conventional MIMVS. A Jackson-Pratt drain was placed under the implant capsule/pectoralis flap and the incision was closed in two perpendicular layers to ensure capsular protection and strength.

Results:

The patient underwent an uncomplicated quadrangular resection of P2, sliding plasty of P1 on P3, transfer of P2 chords to A2, and insertion of #36 Cosgrove-Edwards (Edwards Lifesciences, Irving, CA) annuloplasty band. The implant capsule was never violated. Trans-esophageal echocardiography showed no post-repair mitral regurgitation. Post-operative transfer from the ICU was on day one, while chest tubes and JP drain were removed on post-operative day number two. The patient was discharged from the hospital on day number four.

Conclusions:

The major tenant of MIMVS after breast reconstruction is implant capsule avoidance for fear of serious infectious risk. However, surgeons performing MIMVS should not exclude these patients based on implant presence. With diligent dissection and adaptable incision location, patients with prior histories of breast reconstruction can reap the benefits of MIMVS.

CURRENT STATUS OF CARDIAC TRANSPLANTATION

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Cardiac transplantation continues to be the best treatment option for patients with end- stage myocardial failure. There have been over 61,000 cardiac transplant operations performed in over 223 centers in 18 countries over the past thirty-six years. Currently, approximately fifty percent of cardiac transplant recipients will survive for ten years following transplantation with the longest survivors living for twenty-five years. Allograft coronary artery disease, a form of chronic rejection, is the primary cause of long-term cardiac failure with infectious complications being the second most common cause of death following cardiac transplantation. There has been an evolution toward considering older, sicker patients for cardiac transplantation and the criteria for the use of marginal donor hearts has been liberalized over the past five years. The use of newer immunosuppressive drugs, such as Rapamycin, that may have an effect on the rate of post transplant coronary artery disease is commonplace in most centers. Less than 2,500 cardiac transplants are performed in the United States annually despite intensive public education efforts to increase organ donation.

The lack of a sufficient number of donor hearts represents one of the major limitations to cardiac transplantation. There has been a recent interest in increasing the utilization of donor hearts by establishing guidelines for the assessment and management of potential donors.[1] Several centers have documented excellent results with the use of "marginal" donor hearts.[2] Approximately ten percent of the patients listed for cardiac transplantation will die while waiting for a donor heart and the expansion of the donor pool would permit the treatment many of these patients.

The long-term success of cardiac transplantation is limited by the development of graft coronary artery disease or cardiac allograft vasculopathy. This is a process that is thought to be a form of chronic rejection for which there is currently no prevention or treatment. The incidence of graft coronary artery disease is approximately 50% five years following transplantation.[3] Coronary artery stent placement and coronary artery bypass operations have been utilized in selected cases of graft coronary artery disease. However, the disease process is typically diffuse and not amenable to conventional treatment. Cardiac re-transplantation represents the definitive treatment for this group of patients but the results are clearly inferior to the outcomes with primary transplantation.[4] Several investigational strategies are in development for the treatment of graft coronary artery disease but the most efficacious solution will likely be the induction of tolerance.[5]

Despite advances in cardiac transplantation, this therapeutic option is limited to a small percentage of the nearly five million United States patients that currently suffer from congestive heart failure. The aggressive use of traditional cardiac surgical procedures such as mitral valve repair, left ventricular remodeling, and myocardial revascularization is increasing being considered for patients referred for cardiac transplantation. Moreover, the promise of permanent mechanical circulatory support and cellular myocardial restoration will continue to receive intensive investigation for the treatment of congestive heart failure.

An estimated 5 million Americans suffer from congestive heart failure. There are approximately 550,000 new cases diagnosed each year and the incidence continues to increase. There are more annual hospitalizations for congestive heart failure in the United States than for all combined cancer diagnoses. Congestive heart is the most common diagnosis for hospitalized patients over 65 years of age. The five year mortality for end stage congestive heart failure is 50%. Approximately $40 billion is spent for the treatment of congestive heart failure annually. Medical therapy effectively treats most patients with congestive heart failure. The utilization of high risk surgical myocardial revascularization and mitral repair operations has recently increased for patients refractory to medical therapy or ventricular resynchronization. Cardiac transplantation remains the treatment of choice for patients who have exhausted all other treatment options. However, the shortage of suitable donor hearts continues to limit this treatment option to approximately 2000 patients per year. The results of the REMATCH trial established the concept that long-term mechanical support of patients with end stage congestive heart failure is efficacious compared to medical therapy. There remain several issues concerning the dissemination of this treatment option. One of the most important factors involves proper patient selection for this expensive therapy. Additionally, refinement of the device technology will continue to be critical. The goals will be to develop smaller, fully implantable pulsatile devices with 5-10 year reliable function. There are several devices in development that will potentially reduce the current incidence of infection, thromboembolic complications, and device failures. There are estimates that approximately 10,000 patients per year will be candidates for long-term mechanical support for the treatment of congestive heart failure. Not only do mechanical devices for end stage heart disease still hold promise for the treatment of these patients, these devices are beginning to be used for this group of patients and will likely permit the use of scarce donor hearts for the most optimal candidates for cardiac transplantation in the near future.

The long-term objective for the treatment of patients with refractory congestive heart failure is to customize the use of the limited number of donor hearts for the candidates that may derive the most long-term benefit from cardiac transplantation. This objective will be achieved by the aggressive use of long-term mechanical support and standard cardiac surgical procedures such as valve repair, high-risk myocardial revascularization, and ventricular remodeling.

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CORRECTION OF FUNCTIONAL ISCHEMIC MITRAL INSUFFICIENCY WITHOUT THE USE OF CARDIOPULMONARY BYPASS

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INTRODUCTION:

Although perioperative morbidity and mortality are increased when mitral valve procedures are performed with concomitant coronary revascularization, recent data shows improved long-term outcomes after ischemic mitral regurgitation is corrected. Currently, there is great interest in less-invasive methods of addressing functional ischemic mitral regurgitation, which can result from both annular dilation and leaflet retraction due to papillary muscle displacement.

METHODS: The Coapsys Annuloplasty System, developed by Myocor, Inc., is designed to correct ischemic mitral regurgitation without the need for atriotomy or cardiopulmonary bypass. The device has been implanted in over 20 patients in clinical trials worldwide and is currently the focus of a multicenter FDA randomized trial. Using intraoperative, epicardial echocardiography, a needle is delivered through the subvalvular apparatus allowing a PTFE suture 'chord' to be placed across the ventricle. Anteriorly and posteriorly placed epicardial pads provide external attachment points. As the suture is tightened, the posterior pad elevates the mitral annulus, decreases annular AP diameter, and corrects left ventricular wall displacement. These geometric changes improve mitral leaflet coaptation and thereby correct the insufficiency.

RESULTS: This video presentation demonstrates the operative positioning and placement of this device and its elimination of ischemic mitral regurgitation.

CONCLUSIONS: This new technique allows for the off pump correction of ischemic mitral insufficiency. Randomized studies are currently underway to document the short- and long-term efficacy of this procedure.

MECHANICAL HEART VALVES – CURRENT STATUS

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There has been steady incremental improvement in design of prosthetic heart valves over the past 30 years, but the choice of valve type still depends on relative risks of structural valve failure of bioprostheses versus the hazards of chronic anticoagulation with mechanical valves. In many circumstances, such as elderly patients or those who require chronic anticoagulation for other reasons, valve choice is straightforward. For other patients, mainly those whose life expectancy is greater than 12 to 15 years, choice of a prosthetic heart valve presents a dilemma.

There are no randomized trials with currently available prosthetic valves to guide decision making. Clinicians and patients should be aware, however, that two large randomized comparisons of tilting disc prostheses versus first generation bioprostheses now have follow-up of 15 to 20 years. In the VA study, 575 patients undergoing aortic or mitral valve replacement at 13 medical centers were randomized to receive a bioprosthetic or mechanical valve. At 15 years, all-cause mortality after AVR was lower with the mechanical valve versus a bioprosthesis (66% vs. 79%, $P = 0.02$) but not after MVR. There were no statistically significant differences for other complications, including thromboembolism and all valve-related complications between the two randomized groups. Valve failure occurred mainly in patients <65 years of age (bioprosthesis vs. mechanical, 26% vs. 0%, $P < 0.001$ for AVR and 44% vs. 4%, $P = 0.0001$ for MVR), and bleeding occurred more frequently in patients with mechanical valve.

In the Edinburgh study, there was no difference in 20-year survival comparing the Bjork-Shiley versus the porcine prosthesis, but risk of reoperation was 4 times higher among patients with bioprostheses. Major bleeding was more common in patients with mechanical valves, but there was no significant difference in major embolism or endocarditis.

Thus, better outcome following mechanical valve replacement depends upon improved regimens for anticoagulation. Important steps in optimizing anticoagulation for heart valves include adjunctive antiplatelet therapy, following lower INRs for patients with bileaflet aortic valve prostheses, and self-management of Coumadin. For example, in the Early Self-Controlled Anticoagulation Trial (ESCAT I), patients in the self-management group had 80% of their measured INR values within the therapeutic range compared with only 65% in those managed by their primary physicians, and bleeding complications were similar in patients managed by the local doctor (3.0% ppy) and the group with INR self-management (3.8% ppy).

Furthermore, the ESCAT II trial demonstrated that early onset INR self-management of oral anticoagulation after mechanical heart valve replacement enables patients to maintain within a lower and smaller INR target range. The reduced anticoagulation level resulted in fewer serious bleeding complications (0.56% in the low-dose regimen group vs. 0.91% in the conventional group) without increasing thromboembolic event rates (0.21% for both groups).

This presentation will summarize the currently available data on optimal anticoagulation of prostheses as well as future approaches that may avoid Coumadin completely.

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CONVENTIONAL MAZE FOR ATRIAL FIBRILLATION

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The Cox-maze operation corrects atrial fibrillation in 90% of patients, and successful operation restores sinus rhythm, thereby, reducing risks of thromboembolism and anticoagulant-associated hemorrhage. Symptoms of palpitation and fatigability also improve with restoration of atrioventricular synchrony. At Mayo Clinic, 437 Cox-maze operations have been performed from March 1993 through December 2002. Over 75% of patients have had associated cardiac disease and have had concomitant operations, including 203 who have had cardiac valve repair or replacement. Overall early mortality for 327 patients having biatrial maze procedures has been approximately 1.5%, and incidence of postoperative pacemaker implantation has been 8.7%. The conventional biatrial procedure has been modified in two ways to facilitate the procedure. First, the medial incision from the cut edge of the right atrial appendage to the tricuspid valve annulus is replaced with a line of cryolesions to avoid permanent injury to any sizeable coronary branches supplying the sinoatrial node. Secondly, the left atrial appendage is inverted and amputated from within the left atrium, and the orifice is incorporated into the pulmonary vein encircling incision. With experience, the conventional maze procedure can be performed expeditiously; for combined mitral valve repair and maze procedures, durations of cardiopulmonary bypass and aortic cross-clamping average 89 and 52 minutes respectively. Limiting incisions to the right atrium simplifies operation for patients who primarily have tricuspid valve disease, and, in early follow-up, outcome appears to be as good as that achieved with biatrial incisions. The Cox-maze procedure has proved particularly useful for patients with preoperative atrial fibrillation who require valvuloplasty for acquired mitral valve regurgitation; over 130 patients have had this combined procedure, and there have been 2 early deaths. Further, our experience indicates that ventricular dysfunction is not a contraindication for operation, and, indeed, restoration of sinus rhythm after the Cox-maze operation improves left ventricular ejection fraction in most patients. This presentation will summarize experience at Mayo Clinic with the Cox-maze procedure and present details of our analysis of outcome of the operation

in selected patient groups, including patients with severe mitral valve regurgitation having mitral valve repair and patients with atrial fibrillation and left ventricular dysfunction having the Cox-maze operation.

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A LONG-TERM PORCINE MODEL FOR EVALUATION OF PROSTHETIC HEART VALVES

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Objective: Preservation of the native valve leaflets and chords during mitral valve replacement (MVR) is known to preserve or even enhance left ventricular function. However, this option is often prohibited by pathological conditions in the leaflets as well as potential technical difficulties of the procedures. Since there is still a lack of overall concensus as to which structures to preserve and how, a long-term human compatible animal experimental model would constitute a valuable tool for further investigation of this. Though many groups use canine or bovine species for mitral valve investigation, studies of human and pig mitral valves have shown remarkable anatomical similarity, rendering the porcine species superior with respect to human compatibility.

Aims: Our aims were to develop an animal experimental model for MVR with mechanical prostheses and furthermore to investigate the practical feasibility of three different concomitant procedures.

Methods: 16 consecutive 60 kg pigs were allocated to procedures i) preservation of the entire subvalvular apparatus (n=8), ii) preservation of the secondary chordae only (n=4) or iii) excision of the native valve and papillary resuspension with sutures (n=4). 29 mm St. Jude Medical valves were implanted during cold cardioplegic arrest and extracorporeal circulation. Postoperative anticoagulation was administered by subcutaneous heparin injections.

Results: 14 animals survived one month, thriving and without any signs of heart failure and were hereafter excluded from the study. One animal was euthanized before extubation due to irreversible bleeding in the tracheal tube while another animal died on postoperative day three due to thrombus formation on the prosthetic valve. Overall mean cross clamping time (CCT) was 35.6 minutes (range 24-55 minutes). Procedure i) (mean CCT 31.1 min. (range 24-40 min.)) had significantly shorter CCTs than procedures ii) and iii) combined (mean CCT 41.6 min. (range 28-60 min.)($p<0.005$ by Mann-Whitney U test).

Conclusion: A practically feasible long-term porcine model of MVR has been established. Not surprisingly, complex procedures ii) and iii) had significantly longer CCTs than procedure i). However, CCTs were still safely within clinically acceptable limits. Furthermore, we conclude that the anatomy of the pig mitral valve is well suited for studies of chordal preservation and substitution during MVR. Further studies will investigate long-term global and regional left ventricular function after MVR with total, partial or no subvalvular apparatus preservation.

STROKE: THE ACHILLES' HEEL OF PERFUSION

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Cardiac surgery and the use of cardiopulmonary bypass (CPB) are associated with damage to end organs. Brain injury during surgery is relatively common with 6.1% of patients suffering a major neurological event [1]. Two-thirds of patients experience brain dysfunction following surgery, which persists in up to 20% of patients at three months [2]. Perioperative renal impairment of varying severity occurs in 7.7% of patients with the development of severe renal dysfunction requiring supportive therapy resulting in an increase in mortality to over 60% [3]. Lung injury and damage to the splanchnic viscera [4] during CPB are well documented and similarly increase morbidity and mortality.

The etiology of the above injuries is varied and probably multifactorial [5]. However, there is substantive evidence, particularly with regard to brain injury [6], implicating emboli as a cause of organ damage during CPB. Emboli may be gaseous, liquid, or particulate, and they may originate in the circulation or be introduced into the circulation. Gaseous microemboli (GME) may either be entrained into the CPB circuit [7], or they may be generated by the circuit components, such as the oxygenator [8], venous reservoir, or roller occlusive pump [9]. Circuit design and CPB technique are directed toward eliminating the generation of GME. The risk of inadvertent air embolism will always be present and the circuit components should be able to significantly reduce and preferably stop any GME from reaching the patient.

There is increasing evidence that contact between embolic material (including microbubbles) and the vessel wall disrupts the blood brain barrier via irritation of the endothelium and thereby causes both acute and chronic neurologic injury (9). The traditional model of focal ischemia secondary to embolic occlusion of the capillatory bed is not the only and may not be the best model of neurologic dysfunction associated with cardiopulmonary bypass. Just the passage of embolic material through the vascular system may precipitate a cascade of events leading to chronic neurologic dysfunction.

Emboli can originate from both the surgical field and the CPB apparatus. The GME handling characteristics of an oxygenator can be reduced in the blood circuits because gas bubbles develop a platelet, lipoprotein capsule when exposed to blood [10,11]. The formation of the capsule increases the residence time of the bubble [12] and may reduce the ability of CPB components to remove GME.

The association between intraoperative emboli and brain injury during cardiac surgery has been established [2] but our inability to identify the type of embolus has made it difficult to study the precise role of GME in postoperative brain injury. The optimal method for counting, sizing, and identifying different types of embolic material remains controversial [13]. Different techniques and equipment produce markedly different embolic counts [14]. The most common technique used is ultrasound. Increasingly, the frequency, amplitude, intensity, and spectral array of the reflected signal are being analyzed to make assumptions about embolic numbers, size, and material; however, most systems have never been validated. In our laboratory, Deal et al. [15] investigated the reliability of pulsed and continuous wave Doppler to count emboli in both *in vitro* and *in vivo* models. They noted that detectors from the same and different systems placed in series on a tube did not count the same number of emboli. Detectors are easily "tricked' by artefactual noise arising from tapping the tubing or from bubbles trapped in connectors or bifurcations. Similarly, the angle of orientation, coating of acoustic gel, and application and reapplication of the transducer will influence the GME count. Changing ultrasound settings, such as gain and power, between recordings will result in changes in sensitivity and specificity making it difficult to compare GME counts. A consistent finding is the presence of GME in the arterial line following

the introduction of air into venous line independent of the method of venous drainage. Clinically, air is frequently introduced into the venous line due to non-occlusive arterial purse-strings or caval snares, during blood sampling, injecting drugs [7], and at the initiation of CPB. Traditionally, it has been assumed that entrained venous air will be removed by the CPB circuit components. All studies to date have demonstrated this assumption to be incorrect.

The best neuroprotection is prevention. Embolization should be avoid via careful blood management, the use of improved CPB apparatus and minimal manipulation of the aorta.

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MEDICAL DEVICE DEVELOPMENT: FROM RESEARCH TO FDA APPROVAL

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Food and Drug Administration

Medical device development and FDA approval differs from that of drugs in several ways. The studies are generally much more difficult and costly to carry out, it is often impossible to blind the patient or evaluating physicians, they are conducted by companies with far less resources than big pharmaceutical firms, and design changes often occur during the trial. The trial size for pharmaceutical studies is often 10,000 or more patients versus 200-500 patients for most cardiovascular device trials.

The challenge faced by the FDA is to obtain valid scientific data on the safety and efficacy of devices in the most expeditious and least costly way. Good clinical trial design is the key to getting devices approved. It is important for companies to have consultants or employees who are knowledgeable and experienced in clinical trial design to propose the best trial for the least money. It is also important to start working early with the FDA to get a trial design that has the best chance of succeeding.

How does one begin to design a clinical trial? The initial step is to decide how the device will be used (Indications for Use), then design a trial that will support the labeling of the device for the desired marketing. The safety and efficacy endpoints of the trial must be consistent with the desired Indications for Use.

Endpoints determine the sample size needed for the study. For PMA devices, a device must be shown to have a clinically relevant endpoint. For example, the primary endpoint for a circulatory assist device cannot be "pumps blood", but must be a clinically relevant endpoint such as "increases survival". Surrogate and composite endpoints may be used in many instances to decrease sample size and time of the trial.

The type of trial used depends on the type of device studied. A randomized, controlled, blinded trial is the gold standard. Trials of this type have recently been done for cardiac resynchronization therapy. The REMATCH trial of left ventricular assist devices for destination therapy is a good example of a randomized, controlled, unblinded trial. For unique, first-of-a-kind devices, a randomized trial will often be required. When several devices of a similar kind have been approved, the FDA tries to develop Objective Performance Goals so that single-armed studies can be used for device approval. The classic OPC is that developed for prosthetic heart valves.

The most common problems with clinical trials submitted to the FDA will be discussed.

AMIODARONE REDUCES THE RATE OF PERIOPERATIVE ATRIAL FIBRILLATION FOLLOWING SURGICAL ATRIAL FIBRILLATION ABLATION

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Background: Although surgical ablation of atrial fibrillation (AF) results in success in the majority of patients, these procedures are associated with high rates of perioperative AF. We assessed whether implementation of a standardized prophylactic postoperative amiodarone protocol will increase maintenance of perioperative sinus rhythm (SR).

Methods: Over three years 141 surgical atrial fibrillation ablation procedures were performed. During this period, amiodarone was used in varying doses or not at all for perioperative AF prophylaxis, based on physician preference, until a standardized dosing regimen was implemented. Seventeen patients were excluded due to incomplete followup and 29 did not have complete documentation of amiodarone dosing. Patients who received no or low dose amiodarone (< 4gm over 7 days) [Group 1, n=91] were compared to those receiving a complete dosing regimen (> 4gm/7 days) [Group 2, n=18]. Continuous rhythm monitoring was performed during the postoperative stay. Perioperative SR was defined as the absence of AF or other atrial arrhythmia during the first 14 postoperative days.

Results: Perioperative SR was maintained in 26% of patients in Group 1 and 56% of patients in Group 2 (p=0.02). After 3 months, 59% of patients in Group 1 and 69% of those in Group 2 and were in SR (p=0.48).

Conclusions: In patients undergoing surgical atrial fibrillation ablation, a short prophylactic course of amiodarone significantly improves maintenance of sinus rhythm during the perioperative period. This effect does not, however, influence the eventual success rate of these procedures.

INITIAL CLINICAL USE OF BOSTON SCIENTIFIC COBRA® BIPOLAR CLAMP IN TREATMENT OF ATRIAL FIBRILLATION: A VIDEO DEMONSTRATION

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Background: It is estimated that over 2.2 million Americans have atrial fibrillation (AF). This number rises annually by 160,000 new cases. Surgical atrial fibrillation ablation (SAFA) is increasingly performed as a concomitant and lone cardiac procedure to cure atrial fibrillation. This video was prepared to illustrate the clinical utilization of a bipolar radiofrequency (RF)-enabled clamp system designed to create epicardial linear lesions on the beating heart.

Methods: A set of differently shaped clamps modified to deliver bipolar RF energy (Boston Scientific/EP Technologies, San Jose, CA) were used to create epicardial right- and left-sided pulmonary vein encircling lesions. Temperature controlled RF energy was delivered to maintain a tissue

temperature of 80oC for 30 seconds. Epicardial beating heart SAFA was performed on three patients scheduled for elective aortic valve replacement (n=2) and CABG (n=1). Success of SAFA was based upon evaluation of postoperative electrocardiograms for freedom of AF and atrial flutter. Results: There were 2 females (67%) and 1 male (33%) with mean age of 64.0 +/-11.5 years. The mean left atrial diameter was 4.6 +/- 1.8 cm. Mean SAFA procedure time was
12.0 +/- 7.1 minutes and required 3 +/- 1 lesions for bilateral encirclement of the pulmonary veins. With a mean postoperative period of 36.3 +/- 4.0 days a 67% freedom from AF was documented.
Conclusion: This video demonstrates that epicardial beating heart surgical atrial fibrillation ablation can be performed rapidly utilizing a novel bipolar radiofrequency clamp system. Further clinical evaluation is necessary to determine the long-term success rate of this lesion pattern.

TRANSTELEPHONIC MONITORING OF CARDIAC ARRYTHMIAS FOLLOWING SURGICAL ATRIAL FIBRILLATION ABLATION

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Background: Transtelephonic monitoring (TTM) has been shown to be useful and efficient in detecting cardiac arrhythmias in the outpatient setting. We evaluated the effectiveness of the LifeWatch TTM device to provide enhanced postoperative monitoring and to assess freedom from AF following surgical ablation.
Methods: From September 2002 to March 2003, 41 patients underwent surgical atrial fibrillation ablation. During discharge from the hospital patients received a LifeWatch device with instructions to perform a recording and transmission monthly, or upon experiencing sensations of an arrhythmia, for one year. We analyzed 1, 3 and 6 months postoperative transtelephonic reports for rates of follow-up and freedom from AF. Three patients declined enrollment, and of the 38 patients enrolled, there were 2 early postoperative deaths. Final analysis included 36 patients.
Results: There were 21 males (58%) and 15 females (42%) with mean age of 68.8 +/-11.0. Patients' compliances with TTM device use were 75%, 85% and 93% at 1, 3 and 6 months, respectively. They transmitted 238 recordings with a mean follow-up time of 131 +/- 76 days. Freedom from AF at 1, 3 and 6 months were 67%, 82% and 86%, respectively. Interestingly, of 4 transmissions made by patients during "symptomatic" periods, only one documented AF (the others were sinus rhythms).
Conclusions: Transtelephonic monitoring provided closer postoperative monitoring compared to routine ambulatory follow-up after surgical atrial fibrillation ablation, and allowed for enhanced documentation of postoperative arrhythmias. Our experience also suggested that patients' subjective assessment of symptoms is not predictive of the presence or type of atrial arrhythmia present.

THE PRIVATE HEART HOSPITAL: FROM CONCEPT TO REALITY

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In the United States, specialty hospitals per se are not new. Childrens, lying-in and eye hospitals, among others, have been present for decades. Specialty hospitals in Britain go back to the mid-nineteenth century. The National Hospital for Diseases of the Heart and Paralysis in London dates from 1857 and is the progenitor of the National Heart and Lung Hospital of today. A recent volume on British cardiology noted: "Special hospitals sprang up either because a physician felt his career was thwarted or there was an unmet need not covered by the general hospitals". (1) (A circumstance perhaps not unlike that which motivates American doctors of today to embrace the specialty hospital concept).

In the United States, the heart hospital may be viewed as a phase in the inexorable progression of specialization in practice since World War II. Advances in science and technology in cardiovascular medicine and surgery have created synergies between these specialties which are enhanced in the heart hospital environment, leading to a systems approach more difficult to achieve in a general institution. In addition, the rise of the private heart hospital was stimulated by a convergence of events in the United States which gained momentum during the 1980s, and by the mid 1990s had changed irrevocably the character and economics of medical practice. Ostensibly to control rising health care costs, an ever more powerful "managed care-insurance complex", had gained substantial domination of the entire medical enterprise, imposing control and severe financial restraints on both doctors and hospitals. Under these circumstances, relationships between doctors and hospital administrators became more and more adversarial, and as their interests diverged, doctors began to lose virtually all decision making influence. Frustration and hopelessness began to pervade the profession. It was in this environment that the Medcath Corporation of North Carolina, developer of a successful proprietary heart hospital joint venture with a group of cardiologists and cardiovascular surgeons in McAllen, Texas, introduced its concept of a free standing heart hospital with joint ownership by the corporation and doctors. This concept gave doctors a major role in all aspects of decision making as well as financial participation. In a word, the interests of doctors and administrators had finally become aligned, which is the sine qua non in the success of the proprietary heart hospital. The Medcath heart model has found expression in a number of joint ventures between other corporations and doctors and also in free standing units developed by subsidiaries of non profit hospitals and physician investors.(2)

Creating a proprietary heart hospital begins with strong cardiac, surgical and experienced management groups, working as a team, with mutual confidence, and dedicated to the mission of providing patient centered, quality oriented, integrated medical and surgical care. From the moment of deciding to go forward, this team works together.to select location, architectural design, equipment and staff and in defining hospital goals and policies.(3)

Updated performance data on proprietary heart hospital performance will be presented which appears favorable in comparison with general institutions with regard to mortality, length of stay, severity index, cost, patient satisfaction and percent of patients dismissed directly home rather than to intermediate care facilities. Nevertheless, controversy persists regarding physician financial participation, based largely on complaints by competing non profit general hospitals. (4) Legislation is currently before Congress and some state legislatures to limit physician financial participation in specialty hospitals.

It is of interest, however, that the heart hospital concept per se, has been embraced by academic centers as in the Ohio State University Medical School model and by general hospitals in modifying facilities and building new wings to create a more patient friendly and a more efficient integrated cardiovascular medical and surgical service line approach.

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EXCELLENT HEMODYNAMIC PERFORMANCE OF A STENTLESS TRI-LEAFLET VALVE CONSTRUCTED FROM DECELLULARIZED PORCINE SMALL INTESTINAL SUBMUCOSA (SIS)

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Tissue implants constructed from SIS have demonstrated the ability to encourage seeding and growth of autologous cells, while providing initial material strength until remodeling occurs. We hypothesized that by using an involuted cylinder method of valve construction, the in vivo performance of a stentless heart valve made entirely from porcine SIS would approach that of a native valve. A cylinder of porcine SIS was created by suturing a 20 mm wide by 62 mm long sheet along its width. A valvee construct was formed by involuting the cylinder inside itself and suturing the free edge at points 120 degrees apart. Extensions of tissue at either end of the valve construct were created by suturing a 2 cm wide cuff of SIS along the superior and inferior aspects of the valve construct. In four anesthetized sheep, cardiopulmonary bypass was instituted, the pulmonary trunk was transected 1 cm above the pulmonary valve, and the native pulmonary leaflets were excised.

The valve construct was sutured to both ends of the pulmonary trunk. After separation from bypass, valve function was assessed using echocardiography, and transvalvular gradients were determined by pressure measurements across the valve construct. All animals were successfully weaned from bypass. Systolic peak-to-peak gradient of the replacement valve was 0.74 +/- 0.73 mmHg. Echocardiography demonstrated symmetrial leaflet closure without regurgitation. In conclusion, a method of involuting tissue to create a trileaflet valve from a sheet of SIS created a functional valve with low gradient in live animals. Further studies are necessary to demonstrate autologous cell seeding and growth on this SIS construct and characterize the effects of tissue remodeling on hemodynamic performance.

ANASTOMOTIC DEVICES: REPLACING SUTURES IN CABG?

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In the last six years there has been a tremendous and unprecedented interest in the development of anastomotic devices for coronary surgery. Looking at the big picture, one might ask what fueled this surge in anastomotic devices for vascular anastomoses. There appear to be two main forces: The first is that it was difficult to perform a vascular anastomosis in an endoscopic environment using conventional suturing techniques and conventional materials. The second is the large world-wide anastomotic market which accounts for over 5 million anastomoses annually in the world. Industry has become interested in providing an anastomotic device which would have market share and provide significant benefits to patients, physicians and anastomotic device companies.

Proximal and distal anastomotic devices have different value. The goal of proximal anastomotic coronary devices is to reduce neurological deficits by eliminating the side biting clamp and in beating heart cases and also to improve the ease of use of performing an proximal anastomoses. On the distal side, the goal is enablement of minimally invasive coronary surgery procedures as well as time savings, consistency and repeatability. Proximal connectors theoretically have advantages over conventional suture construction of vein to aortic anastomosis. Automatic proximal connectors are more likely to result in a geometrically perfect anastomosis.

There have been benchmarks for which anastomotic devices are tested. These include reproducibility, ease of use, a short anastomotic time (<than 1 minute). The anastomotic device ideally would work with either vein or artery and the proximal or distal order of anastomoses would be interchangeable. The device should facilitate a broad range of surgical access and should have comparable patentcy compared to hand-sewn techniques. Additionally, there must be a reasonable bail-out option.

In summary there are five proximal automatic anastomotic devices, four which have been implanted clinically and provide a proximal aortic anastomosis for coronary revascularization with minimal aortic manipulation. The Symmetry™ device has raised questions regarding patency, but this is clouded by the issue of the known pre-existing patency issues with saphenous vein grafts.

Proximal and distal anastomotic devices will play different roles in advancing minimally invasive cardiac surgery. With some of the St. Jude Symmetry TM rumors, data will be needed to support new technology adoption. The value of anastomotic technology will be greater in the off-pump and small access coronary techniques. When coronary vascular connectors work cardiac surgeons will use them for most cases because they will be faster and more reliable. This burgeoning field of anastomotic connectors is already beginning to spill over into other specialties. There is promise for these devices in vascular procedures. It is predicted that similar devices will also be used for bowel anastomoses. With continued evolution of these devices, it is easy to visualize that in the near future the majority of anastomoses may be performed with a manual or automatic device as opposed to the current conventional suture technique. This indeed will be a disruptive change. However, I believe Alexis Carell would be proud of the advances that researchers and clinical surgeons have realized in the recent development of anastomotic devices.

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