ABSTRACTS

6th Annual NewEra Cardiac Care: Innovation & Technology

January 3-5, 2003, The Ritz-Carlton, Laguna Niguel, Dana Point, California, USA

ANASTOMOTIC DEVICES FOR CORONARY BYPASS SURGERY

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Recent developments in minimally invasive coronary artery surgery have been driven by the introduction of new enabling technologies, which facilitate the performance of precise surgical maneuvers within confined spaces and on the beating heart. Such technologies include coronary stabilizers, cardiac positioning devices and surgical robots. Despite these developments, standard suturing techniques remain a limiting factor in the surgeon's ability to perform complete revascularization with high quality anastomoses through a minimally invasive approach. Clinically validated distal anastomoses would revolutionize minimally invasive coronary surgery. Other characteristics of an ideal distal device would include applicability to all potential conduits with interchangeable proximal/distal order and a safe bail out in the case of device malfunction. The technical challenges in developing distal devices are significantly greater than proximal devices because diseased coronary arteries are much smaller, less compliant and more fragile than the ascending aorta.

The St. Jude Symmetry proximal connector is an FDA approved device with a large clinical experience. Progress in the development of distal connectors as an alternative to sutured anastomoses is now occurring in a rapid fashion and several technology companies are actively working in this area (see below). An example of interrupted clip technology is the U-clip anastomotic device (Coalescent Surgical, Inc., Sunnyvale, CA), which is based on Nitinol technology. This device eliminates knot tying and the need for suture management, and is FDA approved. Coupling devices can also facilitate distal coronary vessel anastomoses. An example is the Magnetic Vascular Positioner system (MVP™) (Ventrica Inc., Fremont, CA). This particular device creates two magnetic docking ports in the graft and target vessels, which immediately self align and magnetically couple when brought into close proximity. The MVP™ system is in European clinical trials. Other devices involving intracoronary Nitinol stents are also under development and in early clinical trials. For example, the SOLEM GraftConnector™ (JOMED, Helsingborg, Sweden) is a T-shaped PTFE connector with a self-expanding stent inside the main body. The St. Jude stainless steel connector device (St. Jude Medical, Inc., Minneapolis, MN) also utilizes an intracoronary Nitinol stent to create side-to-side distal anastomoses.

In addition to the above-mentioned devices, several others are in earlier phases of development. Promising early data from ongoing clinical trials suggest an increasing role for anastomotic technology in coronary bypass surgery. If outcomes are similar to hand-sewn anastomoses, device related costs may be the final hurdle toward wide adoption of this technology.

REFERENCES

1. Filsoufi F, Aklog L, Adams DH. Minimally invasive CABG. Current Opinion in Cardiology 2001;16:306-9.
2. Hill AC, Maroney TP, Virmani R. Facilitated coronary anastomosis using a Nitinol U-clip device: Bovine model. J Thorac Cardiovasc Surg 2001;121:859-70.
3. Shennib H. Enter the era of facilitated anastomotic devices for coronary bypass surgery. J Thorac Cardiovasc Surg 2001;121:833-4.

MITRAL RECONSTRUCTION IN HEART FAILURE PATIENTS

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Mitral regurgitation is a common finding in patients with end-stage cardiomyopathy. It is now understood that Carpentier Type IIIb dysfunction is the basis for mitral regurgitation in the setting of ventricular dilatation. Echocardiographic findings in heart failure patients include papillary muscle displacement, leaflet tethering with displacement of the line of coaptation below the annulus, and central regurgitation. Symptomatic patients are candidates for surgical therapy. 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 dilated cardiomyopathy and mitral regurgitation should receive a full remodeling annuloplasty, as opposed to a partial band restrictive annuloplasty. This approach aggressively restores the antero-posterior (eg, 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 (eg, Type II myxomatous disease), emphasis should be placed on downsizing the ring in the setting of heart failure. 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 that residual MR is a predictor of mortality and patients with complex mitral regurgitation jets and pathology may benefit from primary replacement.

Most patients with heart failure and mitral regurgitation suffer from coronary artery disease or idiopathic cardiomyopathy. The same rationale for remodeling annuloplasty should probably apply in both groups of patients. Bolling and colleagues have a large experience with mitral reconstruction and dilated cardiomyopathy, and have demonstrated improvement in end diastolic volume, EF, CO, and NYHA class in patients undergoing downsized annuloplasty. Many groups have helped show the importance of correcting mitral regurgitation in ischemic heart failure patients. Ongoing studies should help further clarify the role of mitral valve repair in patients with advanced cardiomyopathy.

REFERENCES

1. Lamas GA, Mitchell GF, Flaker GC, et al. Clinical significance of mitral regurgitation after acute myocardial infarction. Circulation 1997;96:827-33.
2. Grigioni F, Enriquez-Sarano M, Zehr KJ, Bailey KR, Tajik AJ. Ischemic mitral regurgitation: long-term outcome and prognostic implications with quantitative doppler assessment. Circulation 2001;103:1759-64.
3. Christenson JT, Simonet F, Bloch A, Maurice J, Velebit V, Schmuziger M. Should a mild to moderate ischemic mitral valve regurgitation in patients with poor left ventricular function be repaired or not? J Heart Valve Dis 1995;4:484-8;discussion 488-9.
4. Aklog L, Filsoufi F, Flores KQ, et al. Does coronary artery bypass grafting alone correct moderate ischemic mitral regurgitation? Circulation 2001;104[suppl I]:I-68-I-75.
5. Gillinov AM, Wierup PN, Blackstone EH, et al. Is repair preferable to replacement for ischemic mitral regurgitation? J Thorac Cardiovasc Surg 2001;122:1125-41.
6. Grossi EA, Goldberg JD, LaPietra A, et al. Ischemic mitral valve reconstruction and replacement: comparison of longterm survival and complications. J Thorac Cardiovasc Surg 2001;122:1107-24.
7. Hickey MS, Smith LR, Muhlbaier LH, et al. Current prognosis of ischemic mitral regurgitation. Implications for future management. Circulation 1988;78:151-9.
8. Prifti E, Bonacchi M, Frati G, et al. Ischemic mitral valve regurgitation grade II-III: correction in patients with impaired left ventricular function undergoing simultaneous coronary revascularization. J Heart Valve Dis 2001:10(6):754-62.
9. Bach DS, Deeb GM, Bolling SF. Accuracy of intraoperative transesophageal echocardiography for estimating the severity of functional mitral regurgitation. Am J Cardiol 1995;76:508-12.
10. Grewal KS, Malkowski MJ, Piracha AR, et al. Effect of general anesthesia on the severity of mitral regurgitation by transesophageal echocardiography. Am J Cardiol 2000;85:199-203.

11. Byrne JG, Aklog L, Adams DH. Assessment and management of functional or ischemic mitral regurgitation. Lancet 2000;355:1743-4.
12. Aklog L, Soltesz EG, Filsoufi F, et al. The impact of residual mitral regurgitation on survival after CABG and annuloplasty for ischemic mitral regurgitation. Abstract presented at the 2002 AATS, Washington, D.C.
13. Ellis SG, Whitlow PL, Raymond RE, et al. Impact of mitral regurgitation on long-term survival after Percutaneous coronary interventions. Am J Cardiol 2002;89(3):315-8.
14. Bolling SF. Mitral reconstruction in cardiomyopathy. J Heart Valve Dis 2002;11:S26-S31.

SURGICAL TREATMENT OF ATRIAL FIBRILLATION: SUMMARY OF CURRENT EXPERIENCE

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To date, the results of the Cox-maze operation remain unequalled by any other surgical approach to treat atrial fibrillation (AF). Due to the complexity of the procedure and the potential for operative morbidity, other surgical approaches have been recently developed, particularly to be used in patients with associated organic heart disease requiring surgery. The ablation pattern was simplified and mostly limited to the left atrium. In addition, the use of alternative physical means to achieve atrial scars instead of cutting and suturing led to a reduction of operation time and bleeding. These developments have been shown, in an increasing number of experiences, to be highly effective in restoring the sinus rhythm in patients with AF. A left atrial procedure based on extensive use of epicardial radiofrequency ablation in an effort to reduce the aortic cross-clamping time has been used by us since 1998.

The lesion set includes separate encircling of the left and right pulmonary veins with additional lines connecting the two encirclings and the posterior mitral annulus. A total of 215 consecutive patients with chronic AF undergoing open heart surgery (mostly mitral valve repair or replacement) had combined intraoperative ablation.

The additional aortic cross-clamping time required for the ablation was 6 ± 3.5 min.

Hospital mortality was 1.4%. Freedom from AF was 78% 3 years after the operation. Of all variables analyzed, only age at surgery and early postoperative arrhythmias increased the risk of recurrent AF. Overall 3 years survival was 93%. The 3 year actuarial freedom from stroke was 98%. No patients required implantation of permanent pacemaker. Atrial contractility was recovered in all patients with stable sinus rhythm. Six months postoperatively, anticoagulation was interrupted in all patients in sinus rhythm who did not receive a mechanical prosthesis.

In conclusion, left atrial radiofrequency ablation allows recovery of sinus rhythm and atrial function in the great majority of patients with chronic AF submitted to open heart surgery without additional perioperative morbidity.

THE EDGE-TO-EDGE REPAIR OF THE MITRAL VALVE

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Mitral valve reconstruction on the basis of the approximation of the free edge of the leaflets at the site of regurgitation (edge-to-edge technique), has been carried out in 553 patients over a period of 10 years. In the last 2 years approximately one fourth of the mitral repair population had the edge-to-edge technique as part of the reconstructive procedure.

The mechanism responsible for mitral regurgitation was prolapse of both leaflets in 298 patients, prolapse of the anterior leaflet in 116, prolapse of the posterior leaflet with annular calcification or other unfavourable features in 75, and lack of leaflet coaptation for restricted motion in 64. In the latter group, patients with functional mitral regurgitation due to ischemic or idiopatic cardiomyopathy presenting with leaflets coaptation depth >1 cm are included.

Hospital mortality was 1.2%. The overall survival at 5 years was 93% ± 2.5% and freedom from reoperation was 90% ± 3.4%. Freedom from reoperation was lower in patients with rheumatic valve disease (72% ± 14.5%) and in patients who did not undergo an annuloplasty procedure (70% ± 15.0%). Since an annuloplasty was mostly avoided in patients with an extensively calcified annulus it is clear that the edge-to-edge technique although attractive in this setting, is not a panacea and can be associated with suboptimal results.

The mechanism responsible for mitral regurgitation did not affect the reoperation rate.

Follow-up information for the survivors was 100% complete, and approximately half of the patients were periodically evaluated by echocardiographic studies in our institution to assess the effectiveness and the durability of the repair. No mitral stenosis was documented and a successful repair was found to remain stable over time.

In 30 patients an exercise echo study was carried out to investigate changes in mitral valve gradient, planimetric valve area, stroke volume, pulmonary artery pressure, heart rate and blood pressure. A physiological response to physical exercise was demonstrated.

The edge-to-edge repair appears to be a useful addition to the surgical armamentarium in mitral valve reconstruction.

SURGICAL TREATMENT FOR ATRIAL FIBRILLATION: CLINICAL EXPERIENCE

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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, 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, we and others have reported success with more limited procedures aimed at the electrical isolation of discrete atrial regions, utilizing atriotomy, radiofrequency ablation, or cryoablation.

Based on this experience, we now perform pulmonary vein isolation on all consenting patients with atrial fibrillation having a concurrent open-heart procedure. We are also starting to perform these procedures minimally invasively and hope to continue the experience by using only small holes in the chest and without cardiopulmonary bypass. In effect, this could become an outpatient heart operation that is life saving and stroke reducing.

For the first time, in July 2001, we had the opportunity to extend these procedures to a less invasive dimension—epicardial delivery—with use of microwave technology. We have also utilized laser energy for the creation of hyperthermic isolating lesions. This new generation of technologies will allow physicians to eventually cure atrial fibrillation without opening the chest in a truly minimally invasive fashion.

COLUMBIA EXPERIENCE: Since 1999, we have been performing pulmonary vein isolation for AF in patients having other cardiac operations. To date, we have successfully accomplished these procedures in 81 patients, and ablation has resulted in restoration of sinus rhythm in 80% of cases with 6 months followup. In patients receiving only left-sided lesions, the success rate was 76%. 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. We use a number of energy sources, including unipolar RF, bipolar RF, microwave, and laser. In order to exclude arrhythmogenic foci within the left atrial appendage and to prevent arrhythmias based on re-entrant conduction around its base, we also isolate the left atrial appendage and add a connecting line from the pulmonary vein isolation line to the appendage isolation line. We have found this technique to be straightforward, reproducible, and expedient, rarely adding more than 20 minutes to the concomitant operation. In the last year, we have performed several such ablations in patients with lone AF as a sole indication. Most of these operations have been performed minimally invasively through a right minithoracotomy. Additionally, we have developed a totally endo-

scopic, epicardial beating heart procedure, with robotic assistance, which has been validated in animal models and will soon be utilized clinically.

TOTALLY ENDOSCOPIC, ROBOTIC CARDIAC SURGERY

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Columbia-Presbyterian is participating in all four FDA-sanctioned clinical trials of robotic cardiac surgery, and serves as the principal investigative site for two of the trials—robotic ASD repair and totally endoscopic CABG (TECAB).

ATRIAL SEPTAL DEFECT (ASD) REPAIR: On July 24, 2001, the Columbia Presbyterian Robotic Cardiac Surgery team performed the first U.S. robotically-assisted atrial septal defect repair. This represented the first totally closed-chest open-heart operation in U.S. history. The patient was discharged home on the third postoperative day. For the 17 patients who have had robotic ASD repair so far at Columbia, the median postoperative stay has been three days, and all have experienced a rapid return to their normal lives.

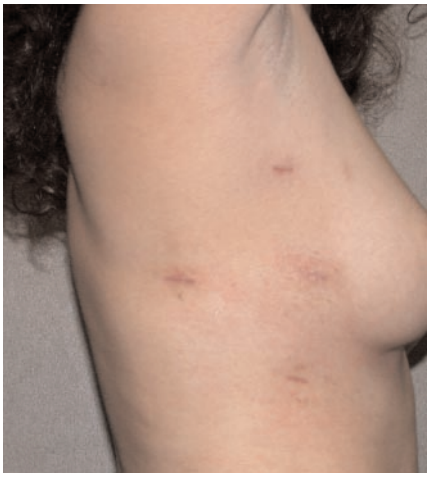

Figure 1. A patient who underwent totally endoscopic robotic ASD repair. This patient was discharged home in three days and returned to work in less than 2 weeks.

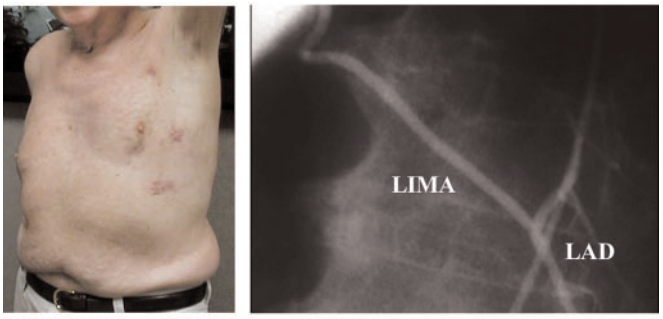

Figure 2. A patient who underwent totally endoscopic coronary artery bypass grafting (TECAB). This patient was discharged home in three days and returned to full activity within a week of surgery. The 3-month postoperative angiogram (shown) demonstrates 100% patency of the LIMA to LAD anastomosis.

TECAB (TOTALLY ENDOSCOPIC CORONARY ARTERY BYPASS GRAFTING): The nation's first robotically-assisted, totally endoscopic coronary artery bypass surgery (TECAB) was performed at New York-Presbyterian's Columbia Presbyterian Medical Center on January 15, 2002. The patient experienced virtually no post-operative pain and returned to normal activities a week after surgery. During this historic operation, three tiny holes between the ribs permitted two robotic arms and an endoscope to access the heart. The procedure was performed as part of a multicenter clinical trial sanctioned by the Food and Drug Administration. This 10-center trial is the first in the nation of totally closed chest coronary bypass surgery. Dr. Argenziano is principal investigator of this national trial. Eligible patients include those requiring single vessel surgical revascularization, either with to single vessel coronary disease, or multivessel disease approachable by hybrid (stenting + CABG) techniques. To date, over 20 TECAB procedures have been completed in the trial.

TOTALLY ENDOSCOPIC ATRIAL FIBRILLATION SURGERY: The Columbia team has performed over 150 operations for atrial fibrillation, with a success rate approaching 85% at one-year follow-up. 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 been used for atrial fibrillation as the sole indication. The Columbia team has performed several beating heart epicardial atrial fibrillation operations, and has also developed a totally endoscopic, beating heart version of this procedure. Within a few months, this minimally invasive operation will be available in the U.S. for atrial fibrillation as the sole indication.

ROBOTICALLY-ASSISTED VIDEOSCOPIC REMOVAL OF NAIL FROM HEART

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PURPOSE: The purpose of this video is to present the case of a 29 year-old Hispanic male who presented to our institution five years after suffering a nail gun injury to his heart. Robotically-assisted videoscopic techniques utilizing multiple imaging media were used to remove the nail.

METHODS: Plain radiographs and computed tomographic reconstructions were used to localize the area of right ventricular myocardium involved. A five centimeter incision was made in the right fourth intercostal space. The AESOP™ robotic system (Computer Motion, Inc., Gometa, California) was placed through this incision. The right internal jugular vein, right femoral vein, and right femoral artery were cannulated. Pericardiotomy was performed. The myocardial entry point of the nail was identified with videoscopic and fluoroscopic guidance. Grasping and magnetized instruments further localized the foreign body. Blunt and electrocautery dissection was used to remove the nail.

RESULTS: The total operative time was 2.3 hours. Cardiopulmonary bypass time was 31 minutes. There were no post-operative complications. He was discharged home on the third post-operative day.

CONCLUSION: Robotically-assisted videoscopic techniques that have been used successfully for repairing the mitral valve can be applied to unique situations such as the one presented in this video. Foreign bodies can be safely removed from the myocardium using these minimally invasive methods.

OFF PUMP MICROWAVE ABLATION OF ATRIAL FIBRILLATION USING THE FLEX 10 DEVICE: COMBINING TWO LESION PATTERNS

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PURPOSE: A new microwave ablation device, designed to ensure lesion continuity and protect the surrounding tissues, was recently used to perform a modified Maze ablation of atrial fibrillation (AF) from the epicardial surface without cardiopulmonary bypass. The purpose of this video is to illustrate a new technique to perform most of the maze ablation pattern on the beating heart.

MATERIALS AND METHODS: The patient, an 85 year old female with concomitant severe coronary artery disease, was suffering from chronic paroxysmal AF for the last 2 years. After the completion of a standard sternotomy, the FLEX 10 microwave probe (AFx, Fremont, CA) was inserted underneath the SVC, through the transverse sinus, positioned on the posterior aspect of the left atrial appendage, and brought back underneath the IVC. The ablating segments of the FLEX 10 were then activated separately (65 watts, 90 sec) to perform an isolating ablation box around the four PV's, as has been previously described. The following additional ablation lines were performed:

1. A line was performed inside of the box on the posterior aspect of the left atrium to complete an ablation loop around the right pair of PV's, thus creating a double isolation line to the RPV's.

2. The maze inter-caval line was then performed between the SVC and IVC.
3. A cruciate line was performed to connect the ablation box to the base of the right atrium, crossing the inter-caval ablation line.
4. The heart was then carefully rotated to access the left side with the help of deep pericardial sutures. A lesion connecting the box lesion at the level of the LSPV and the base of the LAA was performed.
5. An ablation line on the posterior aspect of the left pair of PV's was then performed creating a double isolation of the LPV's.

The LAA was finally excised with an endo-GIA stapling device (US Surgical, Norwalk CT) after performing a running purse string suture at its base.

RESULTS: The total ablation time was 39 minutes (not including the time required for the dissection). After the concomitant off pump 3 vessel CABG procedure, the patient received an internal cardioversion (6 joules) to restore NSR. On postoperative day 7 the rhythm was alternating between NSR and AF when a second internal cardioversion (11 joules) successfully restored NSR. The patient was discharged in NSR. At follow-up (40 days) the patient was still in NSR.

CONCLUSION: We conclude that the Flex 10 device is useful in performing most of the maze ablation lesions from the epicardial surface on the beating heart without the use of cardiopulmonary bypass.

SYSTEMIC VACSCULAR RESISTANCE DIFFERENCES BETWEEN POLY(2-METHOXYETHYLACRYLATE) AND HEPARIN COATED EXTRACORPOREAL CIRCUITS

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INTRODUCTION: Poly (2-methoxyethylacrylate) (PMEA)-coated oxygenators known as X-coating is an amphiphilic organic polymer consisting of hydrophobic backbone. PMEA is chemically inactive, thus protein denaturation and platelet aggregation is reduced.

METHODS: During the period between March and June 2002, 30 patients who underwent coronary artery bypass grafting were divided into two equal groups randomly. Preoperative characteristics of the patients revealed no significant difference. Capiox RX 25 X-coating oxygenator was used in group I (n = 15 patients) and Baxter spiral gold heparin coated circuit was used in group II (n = 15 patients). The same tubing system without heparin coating was used in both groups. Perioperative systemic vascular resistance (SVR) was obtained and compared between two groups.

RESULTS: Preoperative mean SVR was 923 ± 37 dyne-sec/cm^5 in group I and 941 ± 34 dyne-sec/cm^5 in group II ($p>0.05$). Following cross-clamp mean SVR was slightly decreased in group I (827 ± 32 dyne-sec/cm^5) whereas significantly decreased in group II (718 ± 28 dyne-sec/cm^5) ($p < 0.01$). During the weaning period mean SVR was 862 ± 35 dyne-sec/cm^5 in group I and 781 ± 33 dyne-sec/cm^5 in group II ($p < 0.01$). According to significant decrease in SVR and increased pressure drop in group II inotropic support (> dobutamin 10 µg/kg/min) was necessary in 8 patients during postoperative mean 8.3 ± 1.7 hr.

CONCLUSION: PMEA oxygenators reduce platelet aggregation and adhesion and protein denaturation. We suggest PMEA oxygenators are preferable because of slighter decrease in SVR and lower necessity for inotroppic support when compared to heparin coated extracorporeal circuits.

OFF-PUMP VS ON-PUMP CORONARY ARTERY BYPASS

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OBJECTIVE: Results of off-pump coronary artery bypass (OPCAB) surgery have demonstrated a trend towards fewer complications, faster recoveries and lower costs as compared with on-pump coronary artery bypass. We review the morbidity and mortality of consecutive on and off pump coronary artery bypass patients.

METHODS: From a total of 452 consecutive CABG patients, 229 (51%) underwent OPCAB (group A). In the OPCAB patients there were significantly more octogenarians 13.5% (n = 31), and preoperative renal failure 12.2% (n = 28). The prevalence of these preoperative risk factors in the on-pump patients (group B) was 4.5% (n = 10, $p < 0.001$), and 5.8% (n = 13, $p = 0.018$), respectively. There was a trend towards higher preoperative CVA 10.9% (n = 25) in group A as compared to group B: 6.7% (n = 15, $p = 0.12$).

RESULTS: The mean number of grafts per patient in group B was 3.0 as compared to 2.4 in group A ($p < 0.05$). In group A, 69.9% of patients received blood products as compared to 89.7% in group B ($p < 0.001$). The re-exploration rate due to bleeding in group A was 1.75% as compared to 3.14% in group B (NS). In group A no post-operative CVAs were reported, as compared to five CVAs (2.24%) in group B ($p = 0.02$). There was no difference in the mortality and postoperative renal failure between the two groups.

CONCLUSIONS: Though the OPCAB patients in our institute are at higher surgical risk, there was no difference in mortality and postoperative renal failure. Moreover, significant reduction in post operative CVAs, and the use of blood products was documented.

VIDEO-ASSISTED MITRAL VALVE REPAIR AND LEFT ATRIAL ABLATION THROUGH A RIGHT MINI-THORACOTOMY

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ABSTRACT: We present a video-assisted combined mitral valve repair and left atrial ablation through a right anterior mini-thoracotomy, in a 51 year old male with severe mitral regurgitation and a six month history of atrial fibrillation. The procedure was performed through a five cm right anterior mini-thoracotomy. Voice-activated robotic camera control (AESOP 3000™, Computer Motion, Inc., Santa Barbara, CA) was employed. The Medtronic Cardioblate™ Surgical Ablation System (Medtronic, Minneapolis, MN) was used for left atrial ablation that included: the left atrial appendage that was later oversewn, the left upper and lower pulmonary veins, the right upper and lower pulmonary veins, connection between the pulmonary veins, and finally a lesion line from the mitral valve annulus to the right pulmonary veins. The mitral valve repair consisted of a P2 quadrangular resection, annular compression sutures in a figure, and 4-0 cardionyl interrupted sutures to re-approximate leaflet edges. A #38 Cosgrove anuloplasty band (Edwards LifeSciences, LLC, Irvine, CA) was used. Postoperative echo showed no mitral insufficiency. The postoperative recovery was uneventful. In three month follow up the patient has had no complications and maintains normal sinus rhythm.

ARTICULATING ARTERIOTOMY KNIFE FOR MODIFIED END-TO-SIDE CORONARY ANASTOMOSIS CONSTRUCTION

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INTRODUCTION: In search of new approaches towards closed-chest, beating heart CABG, novel facilitated anastomosis techniques are currently developed. Ideally, the partitioning wall between the recipient coronary artery (CA) and bypass conduit is removed after the bonding procedure has been completed thus avoiding blood loss and myocardial ischemia (non-occlusive technique). We present an articulating arteriotomy knife (AAK) that facilitates and accelerates performing the arteriotomy in the construction of a modified non-occlusive end-to-side anastomosis.

DESIGN: A dedicated tissue cutter was designed which creates a controlled arteriotomy of standardized length within the limited space of the vessel lumen (diameter 2.0–3.0 mm). After the graft and CA have been linked in a side-to-side configuration, the guiding tube which houses the articulating knife is introduced in the distal end of the graft, which concurs with the introduction of a slotted needle into the lumen of the CA (Figure 1A). By translating the knife over a fixed distance an arteriotomy of pre-set length is created (Figure 1B).

RESULTS: A working prototype was constructed (Figure 2A). Construction and assembly of the knife and axle was cumbersome due to the small dimensions (Figure 2B). In the ex vivo porcine coronary artery, three attempts were made to created an arteriotomy using the AAK prototype.

The needle could be inserted in the CA in an easy and controlled manner. The cutting process was not perfect owing to a relatively blunt standard knife blade.

CONCLUSIONS: A first generation standardized vessel wall cutter was tested to create without visual control of its size an arteriotomy of a standardized length. The performance was not perfect owing to insufficient knife sharpness. Provided that improvements are made, this tool may be helpful in developing alternative approaches to facilitated coronary anastomosis

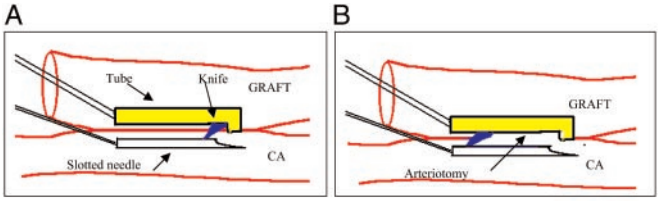

Figure 1. A,B, Schematic representation of AAK working principle.

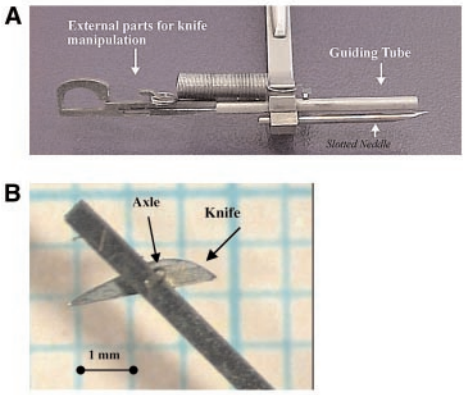

Figure 2. A, Working prototype. B, Knife with axle and strip, normally housed in tube.

ROBOTIC MITRAL VALVE SURGERY

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ROBOT-ASSISTED CARDIAC SURGERY (AESOP™): In 1997 Mohr first used the Aesop 3000™ voice-activated camera robot in minimally invasive videoscopic mitral valve surgery. Six months later we began using the Aesop 3000™ robotic arm to perform both video-assisted and video-directed minimally invasive mitral valve repairs. We have continued to use this device during most isolated mitral valve surgery. This instrument provides surgeon camera site voice activation, precluding translation errors, inherent with verbal transmission to an assistant. Camera motion has been shown to be much smoother, more predictable, and requires less lens cleaning than during manual direction. Currently, if necessary we are able to do over 90% of a mitral repair under video-direction with the Aesop 3000™. Mohr first termed this method "solo mitral surgery" and reported 8 patients undergoing successful mitral repairs using this robotic technique. Since these early procedures, over 1500 videoscopic and robot-assisted mitral valve repairs have been done worldwide with excellent results.

In early 2001 the East Carolina University (ECU) group reported their 128 successful video-assisted mitral valve operations. At first patients with anterior leaflet pathology and annular calcification were avoided. However, now we consider these patients within the realm of video-assisted surgery. The majority of patients had myxomatous disease and 61% of the total group underwent a repair. When the early series is combined with the subsequent 100 video-assisted mitral operations, repairs have been done in 81% of patients at ECU. The operative and 30-day mortalities for our entire series have been 0.4% and 1.7% respectively. After implementing the Aesop 3000™ robot to voice-direct the endoscopic camera, cross clamp, and perfusion times fell secondary to improved visualization and reduced lens cleaning. However, in the latter half of the early series cross clamp (90 minutes) and perfusion times (143 minutes) still remained longer than conventional operations. Currently, cardiac arrest and perfusion times have fallen to 70 and 100 minutes, respectively. Interestingly, we have seen no difference in bleeding and transfusion requirements between our conventional and minimally invasive patients. However, the hospital lengths of stays have averaged 4.9 days compared to 8 days for conventional operations. Of these 228 patients there have been two conversions to a sternotomy, two strokes, and no aortic dissections. We have had one vena caval injury during cannulation. Included in this series are 28 patients having had either prior coronary or mitral surgery. These patients underwent video-assisted re-operations with a 3.5% mortality and markedly less blood loss than conventional re-operations.

Mohr and associates reported 154 video-assisted mitral valve operations using Aesop™ 3000 robotic camera control. In these patients the aortic cross clamp and perfusion times were similar to his conventional operations, and the operative mortality was 1.2%. He considered three-dimensional visualization to be the key to excellent results during videoscopic valve reconstructions. In a study comparing the Port-access™ technique to trans-thoracic clamping, Wimmer-Greinecker obtained similar repair results but with faster operations, less technical difficulties, and lower cost using the clamping method. In early 2002 Vanermen reported success in 187 patients undergoing totally endoscopic repairs using the Port-access™ method and no rib spreading. He used a holder-mounted, two-dimensional endoscopic camera and performed complex repairs with excellent results at follow-up 19 months later. The hospital mortality was 0.5%, and there were two conversions to a sternotomy for bleeding. Freedom from re-operation was 95% at four years. Over 90% of patients had minimal postoperative pain. Although, this and other series have not been randomized, there are strong suggestions that mitral valve surgery has entered a new era and that video techniques can facilitate these operations.

DA VINCI™ MITRAL VALVE SURGERY: In June of 1998 Carpentier and Mohr did the first true robotic mitral valve operations using the da Vinci™ surgical system. In May of 2000 the East Carolina University group performed the first da Vinci™ mitral repair in the United States. This system provides both tele- and micro-manipulation of tissues in small spaces. The surgeon operates from console through end-affecter, micro wrist instruments, which are mounted on robotic arms that are inserted through the chest wall. These devices emulate human X-Y-Z axis wrist activity throughout seven full degrees of manipulative excursion. These motions occur through two joints that each affect pitch, yaw, and rotation. Additionally, arm insertion and rotation, as well as variable grip strength give additive freedom to the operating "wrist". Mohr and Chitwood have the largest experiences in this area and independently have determined this device effective for performing complex mitral valve repairs. Using the Zeus™ system, Grossi and associates performed a partial mitral valve repair but had limited ergonomic freedom. Lange and associates in Munich were the first to perform a totally endoscopic mitral valve repair using only 1-cm ports and da Vinci™.

At our institution, as part of a *Food and Drug Administration* trial, mitral repairs have been performed in 51 patients using the robotic da Vinci™ Surgical System. The device was recently approved for general open cardiac surgical usage in the United States. Since then we have done an additional four mitral operations including the world's first replacement using da Vinci™. Quadrangular leaflet resections; leaflet sliding plasties, chordal transfers, PTFE chord replacements, and annuloplasty band insertions have been done with facility. Difficult commissural and trigone sutures dissolved into simple efforts using da Vinci™. Robotic repair and total operating times decreased from 1.9 and 5.1 hours, respectively, from the first 21 patients to 1.5 and 4.4 hours, respectively, in the last 21 patients. Excepting times required to place annuloplasty bands, all time intervals decreased significantly with experience. In the last cohort cross clamp and perfusion times were 1.8 and 2.7 hours, respectively. This time course paralleled improvements experienced with our videoscopic series reported above. We have had no major complications and the mean length of stay has been 3.8 days. Two valves were replaced either because of hemolysis (19 days) or a new grade 3 leak (2 months). Mohr successfully has completed 22 mitral repairs in Leipzig with da Vinci™. Lange in Munich has performed a totally endoscopic mitral repair using only 1-cm port incisions. A multicenter da Vinci™ trial, enlisting approximately 122 patients, is completed and to date demonstrates efficacy and safety in performing these operations by multiple surgeons at various centers. Operative times at other centers parallel our times and there were no deaths or robot related complications in this

trial. To date aortic and tricuspid valves have not held widespread interest for robotic surgeons.

CONCLUSIONS: Although operative philosophies, patient populations, and surgeon abilities differ between centers the compendium of recent results remains very encouraging. The advent of true three-dimensional vision with tactile instrument feedback will be the major bridge to truly "tele-micro-access" operations. Also, to perform these operations optimally, "extracorporeal" surgeons and engineers will need to improve methods by which instrument are directed by computers. Recent successes with direct vision, videoscopic, and robotic minimally invasive surgery all have reaffirmed that this evolution can be extremely fast, albeit through various pathways. In fact catheter-based technology is even moving toward treating aortic valve disease, and mitral annuloplasties have been done experimentally through the coronary sinus.

Patient requirements, technology developments, and surgeon capabilities all must become aligned to drive these needed changes. In addition we must work closer with our cardiology colleagues in these developments. This is an evolutionary process, and even the greatest skeptics must concede that progress has been made. However, curmudgeons and surgical scientists alike must continue to interject their concerns. Caution cannot be over emphasized. Traditional valve operations enjoy long-term success with ever-decreasing morbidity and mortality, and remain our measure for comparison. Surgeons and cardiologists must remember that less invasive approaches to treating valve disease cannot capitulate to poorer operative quality or unsatisfactory valve and/or patient longevity.

REFERENCES

Chitwood WR, Elbeery JR, Moran JM. Minimally invasive mitral valve repair: Using a mini-thoracotomy and trans-thoracic aortic occlusion. Ann Thorac Surg 1997;63:1477-9.

Chitwood WR, Elbeery JR, Chapman WHH, Moran JM, Lust RL, Wooden WW, Deaton D. Video-assisted minimally invasive mitral valve surgery: The "Micro-Mitral" operation. J Thorac Cardiovasc Surg 1997;113:413-4.

Chitwood WR Jr, Wixon CL, Elbeery JR, Moran JF, Chapman WH, Lust RM, Video-assisted minimally invasive mitral valve surgery. J Thorac Cardiovasc Surg 1997;114:773-80.

Carpentier A, Loulmet D,Aupecle B, Kieffer JP, Tournay D, Guibourt P, Fiemyer A, Meleard D, Richomme P, Cardon C. Computer assisted open-heart surgery. First case operated on with success. CR Acad Sci II.1998;321:437-42.

Casselman FP, van Slyche S, Dom H, Lamberrecths Y, Vermulen Y, Vamermen H. Endioscopic mitral valve repair: feasible, reproducible, and durable. J Thorac Cardiovasc Surg 2003;125:273-82.

Chitwood WR, Nifong LW, Elbeery JE, Chapman WH, Albrecht R, Kim V, Young JA. Robotic mitral valve repair: trapezoidal resection and prosthetic annuloplasty with the da vinci surgical system. J Thorac Cardiovasc Surg 2000;120:1171-2.

Falk V, Walther T, Autschbach R, Diegeler A, Battellini R, Mohr FW. Robot-assisted minimally invasive solo mitral valve operation, J Thorac Cardiovasc Surg 1998:115:470-1.

Felger JE, Chitwood WR, Nifong LW, Holbert D. Evolution of mitral valve surgery: toward a totally endoscopic approach. Ann Thorac Surg 2001;72:1203-8.

Grossi E, Lapietra A, Applebaum RM, Ribakove GH, Galloway AC, Bauman FG, Colvin SB. Case report of robotic instrument-enhanced mitral valve surgery J Thorac Cardiovasc Surg 2000;120:1169-71.

Mehmanesh H, Henze R, Lange R. Totally endoscopic mitral valve repair. J Thorac Cardiovasc Surg 2002;123:96-7.

Mohr FW, Onnasch JF, Falk V, Walther T, Diegeler A, Krakor R, Schneider F, Autschbach R. The evolution of minimally invasive valve surgery—2 year experience. Eur J Cardiothorac Surg 1999;15: 233-8.

Mohr FW, Falk V, Diegler A, Walther T, Gummert JF, Bucerius J, Jacobs S, Altshulbach R. Computer-enhanced "robotic" cardiac surgery: experience in 148 patients. J Thorac Cardiovasc Surg 2001;121:842-53.

Nifong LW, Chitwood WR, Chu VF, Bailey BM, Maziarz DM, Sorrell VL, Holbert D. Robotic mitral valve repair: experience with the da Vinci™ system. Ann Thorac Surg 2003;75:438-42.

Ribikove GH, Steinberg BM, Piedad B, Tunick PA, Kronzon I. Minimally invasive aortic valve replacement: echocardiographic and clinical results. Am Heart J 2001;142:476-81.

Schoeyers P, Wellens F, De Geest R, Degreick I, Van P:raet F, Vermuelen Y, Vanermen H. Minimally invasive video-assisted mitral valve surgery: our lessons after a 4 year experience. Ann Thorac Surg 2001;72:S1050-4.

ETHICS OF APPLYING NEW TECHNOLOGIES TO PATIENTS

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Cardiothoracic surgery has been fortunate enough to be born in a technologic age. However, from the beginning ethical dilemmas have vexed surgeons, their patients, and the lay public. No surgical procedures have created greater ethical dilemmas than the first closed mitral commisurotomy, the first atrial septal defect closure under deep hypothermia, the first congenital operations using parent cross-circulation, or the first use of primitive cardiopulmonary bypass. Advances in performing new operations and applying unproven devices for the treatment of cardiac disease will always generate discussions related to the ethical application. Newly invented or applied devices, drugs, and procedures may have far reaching improvements compared with current or past therapy. However, patients and surgeons are relying on the "may" and "possibly be better" scenario rather than the "is" or "proven result". At the same time the risks are often undefined and can be greater than the current standard of care. What are risks and ethical considerations of applying early innovations in taking care of patients?

This discussion will address the appropriateness of applying unproven new technology to the care of our patients. Moreover, oversight mechanisms, to assure the most appropriate application of new devices and drugs, will be discussed. Informed patient consent has become a catch phrase for telling the patient what operation a surgeon is planning and the risks. However, when new devices and therapies are being tested a higher level of consent must be given. Patients must really understand the difference in traditional operations and the therapy to be used, which may have ill-defined risks. Thus, the true understanding becomes the ethical frontis piece rather than what the surgeon delivers verbally or otherwise. Lastly, the discussion will center on how the surgeon views him or herself when applying new technology. How does one deal with the uncertainties of a new device or application, and how does a surgeon mentally handle complications that might arise from the use of unproven technology? These complex questions require surgeons to joust with their inner homunculus to provide improving care through new technology within the constrained realm of "doing the right thing for the patient and still provide future care."

TIPS FOR THE YOUNG CARDIAC SURGEON

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Despite the lengthy residency training of a cardiothoracic surgeon, young surgeons have no experience in entering a new practice or academic department. Early interactions with patients, referring doctors, partners, staff, and hospital administrators in these early years set the stage for overall perceptions, referral patterns, and even one's efficiency in patient care. Most of us have learned much more about the specialty and ourselves after leaving the postgraduate training "nest", through experience, which often has been built on trials and tribulations. Although many training programs offer excellent technical training, it is the early practice years that vulcanize this knowledge into expert technical application and fruitful wisdom. Experienced surgeons may not seem to have much to offer to the young surgeon, who is well equipped with greater new knowledge and more modern training. Nevertheless, many of us can offer suggestions that may help the introspective, young cardiothoracic surgeon to avoid many of the "boulders" and "sink holes" in the river of experience … that many of us have already "fished". These tips come in all forms and are often a compendium gathered from fellow surgeons, nurses, perfusionists and even residents, whom we have taught. This lecture will be comprised of tips to recognize and avoid both the obvious technical and biopolitical mistakes, but also how to paint one's self in the best light during these early years of practice. These most important years become the opinion makers for life.

BIOPROSTHETIC VALVES

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A formidable amount of knowledge has been accumulated during the past three decades of clinical use of glutaraldehyde-fixed porcine and pericardial

valves. The clinical experience far exceeds our knowledge of the interactions between the xenograft tissue and the host. Based more on this experience than on our understanding of the biophysics and biochemical properties of the xenograft cusps, newer valves were designed to be less obstructive to blood flow and to reduce the mechanical stress on the cusps. In addition, because calcification of the first generation porcine and pericardial valves was a major cause of premature failure in young patients, the new bioprosthetic valves are chemically treated to retard or prevent calcification, and hopefully extent their durability in the young.

Most bioprosthetic heart valves are tricuspid and basically the same valve is used for replacement in all positions in the heart. Current knowledge of blood flow through the human heart suggests that the shape and function of the native valves are needed to maintain a laminar flow throughout the cardiac cycle. It is likely that future bioprosthetic valves will be designed to allow normal flow through the cardiac chambers and a valve used for aortic valve replacement will be different from a valve used for mitral valve replacement.

Currently there are basically two types of bioprosthetic heart valves commercially available in North America: porcine and pericardial valves. There are numerous reports on the longitudinal outcomes of aortic and mitral valve replacement with the first generation bioprosthetic valves and a few on the second-generation bioprosthetic valves (Carpentier-Edwards porcine supra-annular, Carpentier-Edwards Perimount, and the Hancock II). There the durability of the Carpentier-Edwards Perimount and the Hancock II bioprostheses, the two most commonly used bioprosthetic valves in North America, is similar. They are most durable in the aortic position in older patients. Actually, there have been very few valve failures after aortic valve replacement in patients 65 years of age and older. They are not as durable in younger patients. At 15 years, the failure rate is approximately 15% for patients aged 50 to 64 years, and 30% to 40% in those younger than 50 years. Failure rates are significantly higher in the mitral position for both valves with no difference between them.

During the past decade there has been a rather limited interest in stentless porcine aortic valves for aortic valve replacement, possibly because of the difficulty in implanting them. The two commercially available stentless valves, the Medtronic Freestyle and the St Jude Toronto SPV have excellent hemodynamic performance and are unparalleled by any stented bioprosthesis, particularly during exercise.

REFERENCES

Jamieson WR, David TE, Feindel CM, et al. Performance of the Carpentier-Edwards SAV and Hancock II porcine bioprostheses in aortic valve replacement. J Heart Valve Dis 2002;11:424-30

Banbury MK, Cosgrove DM 3rd, Thomas JD, et al. Hemodynamic stability during 17 years of the Carpentier-Edwards aortic pericardial bioprosthesis. Ann Thorac Surg 2002;73:1460-5.

Dellgren G, David TE, Raanani E, et al. Late hemodynamic and clinical outcomes of valve replacement with the Carpentier-Edwards Perimount pericardial bioprosthesis. J Thorac Cardiovasc Surg 2002;124:146-54.

Dellgren G, Feindel CM, Bos J, et al. Aortic valve replacement with the Toronto SPV: long-term clinical and hemodynamic results. Eur J Cardiothorac Surg 2002 21:698-702.

Bach DS, Cartier PC, Kon ND, et al. Impact of implant technique following Freestyle stentless aortic vavle replacement. Ann Thorac Surg 2002;74:1107-13.

Banbury MK, Cosgrove DM 3rd, Lytle BW, et al. Long-term results of the Carpentier-Edwards pericardial aortic valve: a 12-year follow-up. Ann Thorac Surg 1998;66:S73-6.

David TE, Ivanov J, Armstrong S, et al. Late results of heart valve replacement with the Hancock II bioprosthesis. J Thorac Cardiovasc Surg 2001;121268-77.

CARDIAC CARE IN CANADA

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Canada is a large country with a relatively small population of 31 million, spanning 10 provinces and 3 territories from coast to coast. Health care in Canada is mandated nationally through the Canada Health Act, which outlines the fundamental principles that the country's health care system must embrace. The system provides access to universal comprehensive coverage for medically needed hospital, in-patient and out-patient physician services. It is a publicly funded and administered system, and is privately delivered. The system upholds five key principles:

1. Public administration: non-profit basis by a public authority
2. Comprehensiveness: insures all needed services by hospital and physicians
3. Universalitly: every resident is eligible
4. Accessibility: no barrier, no user fees
5. Portability: coverage throughout Canada

Canadians who require health care services go to a physician or hospital of their choice. They make no direct payments and there are no insurance forms to fill, no deductibles, co-payments, or cost limit for any insured service. Patients are initially seen by a primary care physician who assesses and, when required, refers them to specialists. Most doctors are private practitioners who work independently or in group practice. They are paid on a fee-for-service basis directly by a provincial health insurance plan.

Patients requiring cardiac care are initially referred to a cardiologist who investigates and establishes diagnosis. There are more cardiologists in private than academic-affiliated practice. If the cardiologist deems that surgical treatment is an option, either the cardiologist or the family doctor refers the patient to a cardiac surgeon. The patients can choose their physicians. However, most patients accept the advice of the primary care physician to a see a cardiologist, and the cardiologist to see a surgeon.

There are 31 cardiac surgical centers across Canada. The Province of Ontario has 9 open-heart units to serve a population of 12 million. Two more are to be opened in 2003. The average reimbursement for a CABG in Canada is US $1,300.00.

The outcomes of angioplasty and CABG for coronary artery disease are comparable to those of the United States. The results of heart valve surgery tend to be better than the results reported in the Society of Thoracic Surgeons Database.

Patients and physicians alike were very satisfied with their health care system until late 1980s when waiting lists for diagnostic procedures, operations, and even access to specialists began to increase. At the same time, hospitals began to have increasing financial difficulty in maintaining equipment and acquiring new technology. The quality of care, however, has not changed and remains very high. Accessibility is the main problem and federal and provincial governments are trying to find alternatives to increase funding of health care and the consensus is that personal income taxes will rise in a country where most people feel already over-taxed. But the Canadian Medicare will likely remain intact and as the sole payer of health care.

ROBOTICALLY-ASSISTED LEFT VENTRICULAR LEAD PLACEMENT FOR VENTRICULAR RESYNCHRONIZATION THERAPY

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PURPOSE: Approximately 10% of patients undergoing biventricular pacemaker insertion have a failure of coronary sinus cannulation. We hypothesized that biventricular pacing could be performed in these patients using a robotically assisted, direct left ventricular (LV) epicardial approach.

METHODS: Eight patients with congestive heart failure (NYHA class 3.4 ± 0.5) and a widened QRS (175 ± 20 msec) underwent robotic LV lead placement following failed coronary sinus cannulation. Mean patient age was 68 ± 12 years, LV ejection fraction (EF) was 13 ± 6% and left ventricular end diastolic volume was 6.3 ± 0.5 cm. Two patients had prior cardiac surgery and 5 patients had a prior device implanted. All patients were placed in the left posterolateral thoracotomy position, and the posterolateral LV surface was exposed by opening the pericardium posterior to the phrenic nerve. Lead placement was targeted by intra-operative mapping of the LV and by transesophageal echocardiography.

RESULTS: Fifteen epicardial leads were successfully placed on the posterolateral surface of the LV. Intraoperative lead threshold was 1.0 ± 0.5 V at 0.5 ms, R-wave was 18.6 ± 8.1 mV, and impedance was 1160 ± 266 ohms at 0.5 V. Complications included one post-operative pneumonia and one episode of ventricular tachycardia in a patient with an AICD. There were no deaths, myocardial infarctions or post-operative bleeding. Improvements in exercise tolerance (6 of 8 patients), ejection fraction (19 ± 10%) and QRS duration (152 ± 16 msec) have been noted at 20 ± 8.0 weeks fol-

low-up. Lead thresholds have remained unchanged (1.8 ± 1.1 V at 0.5 ms, p = NS), and a significant drop in impedance (310 ± 54 ohms, p = 0.005) has been measured.
CONCLUSIONS: Robotic LV lead placement is an effective and novel technique which can be used for ventricular resynchronization therapy in patients with no other minimally invasive options for biventricular pacing.

EXPERIENCE WITH PATIENT SELECTION, IMPLANTATION AND MRI FOLLOW UP OF THE CORCAP™ CARDIAC SUPPORT DEVICE

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BACKGROUND: Left ventricular remodeling is a hallmark for heart failure progression. Passive ventricular containment has been shown to mitigate disease progression and allow for beneficial reverse remodeling in pre-clinical studies in heart failure animal models. Patient selection is likely to be important in optimizing therapeutic effect of the CorCap™ device.
METHODS: A series of 10 patients have been entered as part of an on-going multi-center randomized trial of the Acorn CorCap™ Cardiac Support Device. The two main study groups were distinguished on the basis of whether mitral valve surgery (repair or replacement) was required. Within these two groups, patients were randomized for implantation of the CorCap™ device. Echocardiography was used to evaluate baseline cardiac structure and function for all patients in the study, as well as during device implantation. Some patients were also evaluated by cardiac magnetic resonance imaging (MRI).
RESULTS: Mitral valve surgery was required in 5 patients, whereas the remainder did not have concomitant surgery. Two patients in each group were randomized to receive the CorCap™ device. Patients were primarily idiopathic, and in NYHA functional class III (2.9 ± 0.3). Left ventricular end diastolic dimension (LVEDD) was 73.6 ± 12.2 mm, with ejection fraction (LVEF) of 18.8 ± 6.7%. Implantation time for the CorCap™ device averaged 42 ± 22 minutes, and was accomplished on beating hearts for the two patients implanted with the CorCap™, who did not require concomitant valve surgery. LVEDD decreased acutely by an average of 6% following CorCap™ device implantation. MRI showed good correlation to echo, and provided additional information on right heart structure and function not available from echo. There were no complications with CorCap™ device implantations.
CONCLUSIONS: The CorCap™ device can be implanted safely, with or without concomitant cardiac surgery. Also, it is feasible to perform CorCap™ device-only implantations on beating hearts. Finally, MRI may have additional value for baseline and follow-up evaluations.

"CLAMPLESS" PROXIMAL ANASTOMOSIS

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Hundreds of thousands of coronary artery bypass operations (CAB) are performed yearly in the world. Even though the left internal thoracic artery has been shown to be the conduit of choice for the left anterior descending artery, in multivessel grafting other conduits have to be used to bypass the remaining coronary arteries. Arterial and venous conduits are used to bypass these other vessels and many are anastomosed to the intact LITA to derive their inflow. However, the majority of proximal anastomoses are still performed to the ascending aorta. Occlusion of the aorta is necessary during the anastomoses and this is accomplished by the use of a side biting clamp (SBC) for off pump revascularization (OPCAB) and a SBC or single aortic cross clamp (SAC) for on pump CAB.

There are risks associated with the use of the large clamps for partial or total occlusion of the aorta, most devastating of which are aortic dissection or emboli.

We will describe the use of a novel device to allow for a minimally invasive less traumatic approach to perform the proximal anastomosis without the use of these clamps. The Novare Enclose™ is very intuitive and allows for a bloodless field to perform the proximal anstomosis to the aorta using arteries or veins. It also allows for the surgeon to perform his customary graft sequence performing the distal anastomoses first if that is his preference.

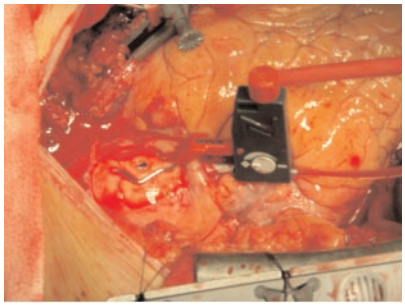

Figure 1. Aortotomy performed.

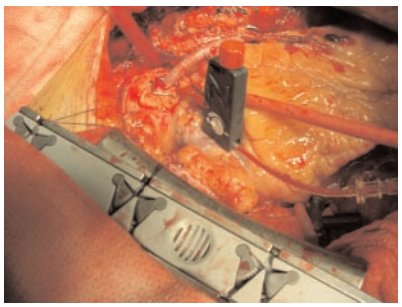

Figure 2. First graft completed and perfused.

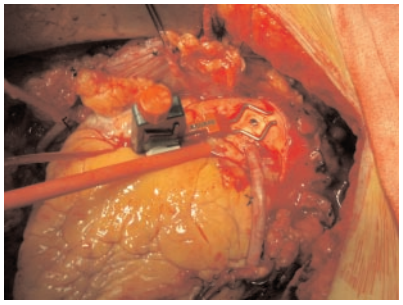

Figure 3. Second aortotomy performed.

HEART FAILURE: CARDIAC RESTRAINT THERAPY

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Heart failure is still the leading cause for hospitalization in the U.S. with increasing numbers annually. There are many causes of myocardial dysfunction in heart failure including coronary artery disease, hypertension and idiopathic primary cardiomyopathy. The final result is progressive ventricular dilatation and remodeling. This altered LV geometry causes further LV dysfunction, mitral regurgitation, and continual dilatation resulting in differing degrees of diastolic and systolic dysfunction with a spiraling downhill course for the patient. Medical management of symptoms of heart failure has been the mainstay of treatment but frequently without the reversal of the underlying process. There have been improved medical therapies.for heart failure including medications and biventricular pacing. Surgical therapies for heart failure are evolving and there are now many more surgical options for heart failure management in the form of destination therapy pumps and cardiac restraint devices.

Ventricular containment decreases wall stress, arrests the remodeling process and provides an environment for reverse remodeling of the ventricle. These containment devices can be applied to the ventricle either early after the initiating injury to prevent the cycle of ventricular dilatation with resultant LV dysfunction or later in the cycle when ventricular remodeling is still reversible.

To obtain optimal results adjunctive procedures in combination with cardiac restraint devices may be necessary for treatment of heart failure. These would include coronary revascularization, mitral valve surgery, cell

therapy or ventricular manipulation. The management of cardiomyopathy should incorporate all modalities available to reverse the remodeling process to improve the quality of life and outcome of these patients The various cardiac restraint options and timing of therapy will be discussed

OPCAB RANDOMISED TRIALS

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OPCAB has been shown to be associated with improved outcomes in elective coronary revascularization as well as safe and effective in high risk groups In addition, off-pump surgery significantly reduces transfusion needs and shows a consistent trend in reducing morbidity and mortality overall for high-risk patients. OPCAB has been shown to be safe in women patients with low ejection fractions and safe and effective for patients with critical left main disease. Proper patient selection and the use of adjunctive measures such as the IABP and positioning techniques are crucial for improved outcomes. Hemodynamic compromise in patients being grafted off pump is multifactorial, however it is frequently a result of right ventricular compression and reduction in right ventricular end diastolic volume and stroke volume. This can be avoided by gentle manipulation and using positioning devices and also by the manouvres described of herniating the heart in to the right chest Even though there has been a trend toward decreased neurologic events with the OPCAB brain injury can still occur. The elimination of the side biting clamp by the use of new devices that allow for isolation of the anastomotic site on the proximal aorta or the stapling devices hold hope for elimination of this detrimental aspect of coronary bypass There is also a trend toward a shorter length of stay in off pump patients. Improved outcomes such as shorter length of stay and fewer transfusions have also been shown in these high risk patients when revascularized off pump.

Even though there is a great body of data describing the results of OPCAB, there have been few randomized trials directly comparing OPCAB and on pump bypass. The most recent ones will be discussed.

THORACOSCOPIC PLACEMENT OF LEFT VENTRICULAR BIVENTRICULAR PACING LEADS

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Heart failure is the highest volume DRG. 78% of heart failure patients have at least 2 admissions per year and cardiomyopathy is the leading cause of cardiac readmissons. Heart failure patients take an average of 6 medications and 50% of them have 3 or more comorbidities. Study data show that from 1979 to 1992 hospital discharges incuding the diagnosis of heart failure have more than doubled. These patients have a very poor quality of life and even with treatment frequently die a very undignified miserable death.
Many patients with advanced systolic heart failure exhibit significant intra- or interventricular conduction delays (IVCD) that disturb the synchronous beating of the ventricles so that they pump less efficiently. This delayed ventricular activation and contraction is referred to as ventricular dysynchrony and is recognized by a wide QRS complex on ECG. Typically, the IVCD has a left bundle branch block (LBBB) morphology

Biventricular pacing provides a more synchronized ventricular pacing and has been shown to be an effective form of treatment for patients with cardiomyopathy and an IVCD. Frequently a combination pacer cardioverter defibrillator is necessary in these patients because of the high incidence of ventricular dysrythmias. The clinical consequences of ventricular dysynchrony are septal wall dyskinesis, increased pre-systolic mitral valve regurgitation, decreased left ventricular (LV) diastolic filling times and reduced LV dp/dt. Cardiac resynchronization allows for an improved contraction pattern and improved AV timing with a resultant clinical improvement.

The improved contraction pattern enhances interventricular synchrony, reduces paradoxical septal wall motion, improves LV regional wall motion, lowers end systolic volume and increases LV dp/dt. The improved AV timing reduces mitral regurgitation, increases diastolic filling time and improves dp/dt.

The leads for biventricular pacing are usually placed by the electrophysiologist with a right atrial lead, right ventricular lead, and a lead placed in the coronary sinus for LV pacing. Placement of the coronary sinus lead frequently is tedious and sometimes unsuccessful. The left ventricular lead can easily be placed directly on the lateral wall of the left ventricle thoracoscopically. When the patient has had a previous cardiotomy if necessary the left ventricular lead can also be placed through a minimal left lateral incision with thoracoscopic assistance. The pacing lead is exteriorized and then tunneled up to the infraclavicular region for attachment to the generator. The indication, technique and results of this approach will be presented.

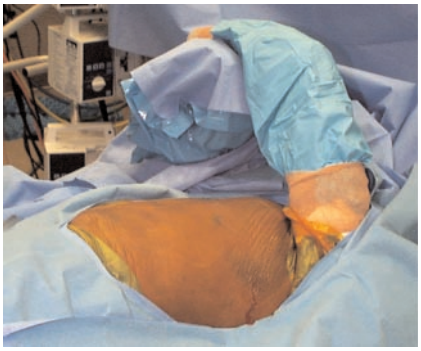

Figure 1. Patient positioning and draping to allow access for thoracoscopic placement of the lead and infraclavicular placement of the generator

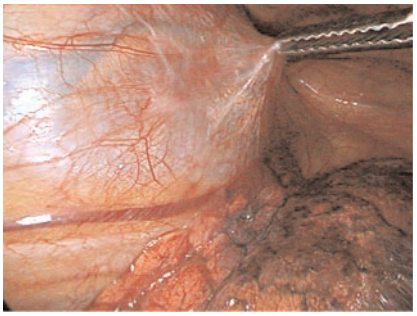

Figure 2. Pericardium unopened.

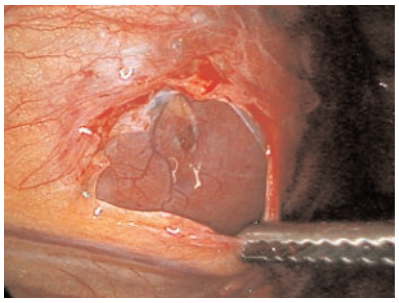

Figure 3. Lateral wall exposed.

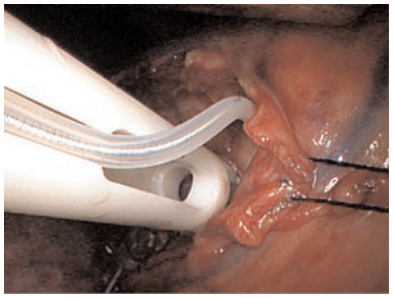

Figure 4. Attaching the lead.

IMPACT OF DIABETES ON INTENSIVE CARE UNIT OUTCOMES FOLLOWING CORONARY ARTERY BYPASS SURGERY WITH AND WITHOUT CARDIOPULMONARY BYPASS

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PURPOSE: Diabetes is a well-recognized risk factor for mortality, adverse clinical outcomes, and prolonged length of stay following coronary artery bypass grafting (CABG). Utilization of off-pump techniques (OPCAB) has been demonstrated to shorten mechanical ventilation time (MVT) and intensive care unit (ICU) length of stay in previous analyses when compared to conventional, on-pump (CCAB) procedures. It is therefore postulated that avoidance of cardiopulmonary bypass in CABG operations may mitigate the negative impact of diabetes on these outcomes.
METHODS: Preoperative risk factors and postoperative ICU outcomes were prospectively recorded and analyzed in a consecutive series of 1551 patients who underwent primary CABG over a 36-month period (1125 CCAB; 426 OPCAB). Patients in both groups were similar in preoperative clinical characteristics. Extubation parameters were maintained consistent across both groups. Prolonged intubation was defined as greater than 8 hours.

	OPCAB (n = 410)			CCAB (n = 1032)		
	Diabetics	Non-diabetics	p-Value	Diabetics	Non-diabetics	p-Value
Ventilation time (hours)	9.0 ± 7.9	9.9 ± 12.3	0.42	17.9 ± 9.5	12.4 ± 7.4	<0.001

RESULTS: Multivariate regression analysis demonstrated that advanced age, female gender, preoperative renal failure (RF), longer time on cardiopulmonary bypass (CPB), lower ejection fraction, and preoperative diabetes were significant independent predictors of longer MVT following CCAB. For OPCAB patients, only advanced age, preoperative RF, and non-elective surgery predicted prolonged MVT. Logistic regression analysis further identified diabetes, advanced age, female gender, and longer CPB time as independent predictors of prolonged intubation following CCAB, whereas only advanced age and female gender (and not diabetes) had the same impact in OPCAB patients. The presence of diabetes was also associated with significantly longer ICU length of stay in CCAB patients, an association which did not exist for OPCAB patients.
CONCLUSIONS: Preoperative diabetes is thus associated with significantly longer MVT following CCAB when compared to OPCAB patients. It thus appears that avoiding the use of cardiopulmonary bypass may limit the negative impact of diabetes on both MVT and ICU length of stay on patients undergoing CABG. This factor should be taken into account when planning operative strategy in order to improve outcomes, decrease resource utilization, and decrease overall costs associated with these operations.

ROBOTICALLY ASSISTED ENDOSCOPIC TRANSMYOCARDIAL LASER REVASCULARIZATION

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PURPOSE: Transmyocardial laser revascularization (TMR) has demonstrated symptom relief in patients presenting with refractory angina and inoperative coronary anatomy. TMR via thoracotomy has been approved for this subgroup of patients. The aim of the study was to assess feasibility and efficacy of robotically assisted endoscopic TMR using the ZEUS™ robotic surgical system (Computer Motion, Goleta, CA) and an excimer TMR system (Spectranetics, Colorado Springs, CO) in a porcine model.
METHODS: Five pigs, weighing 30–40 kg (mean weight 35.6 ± 4.2 kg), were used. Under general anesthesia and mechanical ventilation with an endotracheal tube, the animal was placed in a supine position. Three robotic arms for holding and operating an endoscope and two endoscopic instruments were fixed on the operating table. A 10 mm endoscope and two 5 mm endoscopic instrument ports were introduced into the left hemithorax. These three ports were set to make an isosceles triangle on the same side of the chest. A 1.4 mm flexible optic fiber TMR probe was also inserted directly into the left hemithorax between the two instrument ports. Endoscopic TMR was performed by a surgeon sitting on the console unit on the antero-lateral or lateral left ventricular wall using the ZEUS™ instruments holding and guiding the TMR probe through a monitor. The TMR probe was put on the ventricular wall, then laser energy delivery was started and the probe was pushed and advanced into the ventricular cavity. Euthanasia was administered at the end and the heart was explanted for histological examination.
RESULTS: Mean system setup time was 4.2 ± 0.6 minutes. Mean port placement time was 11 ± 1.7 minutes. Mean number of transmural TMR channels was 10 ± 3.6. Mean TMR procedure time was 5.0 ± 0.7 minutes. Bleeding from laser channels on the epicardium stopped spontaneously or with mechanical pressure for 30 to 60 seconds. All pigs tolerated the entire procedure without hemodynamic instability. Gross pathology and standard hematoxylin and eosin staining of the heart confirmed the creation of complete and patent transmural channels.
CONCLUSION: Endoscopic TMR using the ZEUS™ system is feasible in a pig model in creating transmural laser channels on the anterior and lateral left ventricle, and may provide significant advantage over the traditional approach in reducing perioperative morbidity and improving recovery.

PROPHYLACTIC ANTIBIOTIC PASTE REDUCES LEFT VENTRICULAR ASSIST DEVICE POCKET INFECTIONS

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BACKGROUND: Over 40% of patients with left ventricular assist devices (LVADs) develop device-related infections. These are attributed to local trauma, a percutaneous driveline that is susceptible to contamination, and a high incidence of reoperation in these patients. Oftentimes, the original focus on infection is the pocket in which the device sits.
METHODS: Since July 2001, antibiotic paste was administered to the preperitoneal pocket of 32 patients undergoing LVAD implantation. This population was compared with 43 historical controls who underwent LVAD implantation at the same institution between January 2000 and June 2001. The antibiotic paste was comprised of 1g vancomycin ($15), 1 g collagen hemostat ($100), and 1000 u/ml thrombin spray ($20). The total cost of a single application of paste was $135.
RESULTS: Demographically, the patients receiving the vancomycin paste were similar to the control group (Table 1). The rate of pocket infection was significantly lower in the treatment group [12.5% (4/32) vs. 44.2% (19/43), p = 0.005]. Outcome with regard to death or survival to transplant or explant was also comparable between the two groups.
CONCLUSION: Vancomycin paste is an inexpensive and effective method of prophylaxis against LVAD pocket infection.

	Paste	No-Paste	P Value
N	32	43	
Age (years)	49.2 ± 14.5	50.2 ± 12.3	0.734
Male/female	27/5	35/8	0.736
Death	15.5% (n = 5)	18.6% (n = 8)	0.493
Transplanted	78.2% (n = 25)	81.4% (n = 35)	0.726
Explanted	6.3% (n = 2)	0% (n = 0)	0.179
Pocket infection	12.5% (n = 4)	44.2% (n = 19)	0.005

PERFUSION FOR ROBOTIC AND MINIMALLY INVASIVE CARDIAC SURGERY

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Traditionally, cardiac surgery has been performed through a median sternotomy, which provides generous exposure of the operative field and allows ample access to cardiac structures for cannulation and institution of cardiopulmonary bypass. Recently, improvements in endoscopic equipment and techniques have resulted in an explosion of minimally invasive non-cardiac surgery. However, only after modifications in cardiopulmonary bypass, reductions in the size of incisions, and alternate incision site usage, were the possibilities of minimally invasive cardiac surgery (MICS) realized. Furthermore, advances in intracardiac visualization, instrumentation, and robotic telemanipulation have hastened a shift toward efficient and safe MICS.

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, as well as ventricular decompression. 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, this method should facilitate performance of operations in a closed chest environment using robotic assistance.

In traditional 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. Despite new cannula designs, gravity-assisted drainage is inadequate and augmented venous return is used to provide total cardiopulmonary support. Most commonly, this is performed with kinetic or vacuum assistance. Usually, cannulation methods are governed by the incision selected. When selecting an upper or lower hemi-sternotomy, direct arch cannulation is possible. We rely on the Seldinger technique to place a Biomedicus type of 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 a standard cross-clamp can be used for minimally invasive valve surgery. Specialized flexible-handle clamps have been developed to increase exposure and prevent inadvertent dislodgment. 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 monitored and antegrade cardioplegia is given via a central catheter lumen. Continuous TEE monitoring is important to detect balloon migration.

Myocardial preservation in MICS has been similar to sternotomy-based operations. Many surgeons prefer to use antegrade cardioplegia. 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 arresting cardioplegia is given via the occluded aortic root. For supplemental cardioplegia, doses are administered either into the coronary ostia for aortic surgery or 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. Near the end of the operation, we infuse carbon dioxide (1-2 liters/minute) into both the left atrium and ventricle and then ventilate both lungs to draw the gas deep into the pulmonary veins. 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 should be applied to remove residual cardiac air. TEE monitoring should assure adequate air removal before weaning the patient from cardiopulmonary bypass.

Minimally invasive and robotic cardiac surgery allow the surgeon to perform operations that traditionally called for a median sternotomy through much smaller incisions. Modifications in cardiopulmonary perfusion have become necessary as the surgeon is now removed from the operative field. MICS requires TEE expertise and a team approach with the anesthesiologist and the perfusionist playing a similar critical role as the surgeon. Perfusion management requires the perfusionist to monitor more parameters as surges in systemic or cardioplegia flow can dislodge the endovascular balloon clamp, causing disruptions of operations. Preliminary data suggest that these minimally invasive operations can be done in a safe manner with appropriate modifications of the cardiopulmonary bypass circuit (5). Further study is needed to analyze the outcomes, long-term efficacy, recovery times and cost-effectiveness of minimally invasive and robotic cardiac surgery.

REFERENCES

1. Stevens JH, Burdon TA, Peters WS, Siegel LC, Pompili MF, Vierra MA, St Goar FG, Ribakove GH, Mitchell RS, Reitz BA. Port-access coronary artery bypass grafting: a proposed surgical method. J Thorac Cardiovasc Surg 1996;111:567-73.
2. Chitwood WR Jr. Minimally invasive cardiac valve surgery. In: Franco KL, Verrier ED, editors. Advanced therapy in cardiac surgery. 1999.
3. Chitwood WR Jr, Nifong LW. Minimally invasive videoscopic mitral valve surgery: the current role of surgical robotics. J Card Surg 2000;15:61-75.
4. Webb WR, Harrison LH Jr, Helmcke FR, Camino-Lopez A, Munfakh NA, Heck HA Jr, Moulder PV. Carbon dioxide field flooding minimizes residual intracardiac air after open heart operations. Ann Thorac Surg 1997; 64:1489-91.
5. Ceriana P, Pagnin A, Locatelli A, Maurelli M, Minzioni G, Spreafico P, Degani A, Viganò M. Monitoring aspects during port-access cardiac surgery. J Cardiovasc Surg 2000;41:579-83.

POLITICS OF MERGING SPECIALTIES

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One of the primary questions posed by those in resident training has to do with their future ownership of practices. The technological changes that have occurred over the past 15 years, especially around revascularization of the heart, have taken cardiovascular practitioners on a collision course. Although circumstances are different from locale to locale, those practicing interventional cardiology have had significant changes in their practices because of technologies available to them. Their dominance of the treatment of coronary artery disease with these technologies has led them to feel that they should own cardiac surgery practices along with their own. In truth, both sectors (i.e., cardiologists and cardiovascular surgeons) should be working together, sharing clinical and financial outcomes. This opportunity to change will define actual cases where cardiology practices have in fact been cardiac surgical practices. What will be a potential landmark decision is currently being litigated in the mid-Atlantic region. We will discuss politics of merging specialties. Please plan to arrive at the session with questions.

SIZE IS AT THE HEART OF THE MATTER: UPDATE ON ADVANCED CIRCULATORY SUPPORT TECHNOLOGY

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INTRODUCTION: For over forty years cardiopulmonary bypass (CPB) has provided definitive or palliative surgical treatment options never before available for patients with severe cardiac pathology (25–33). 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. Recently, percutaneous revascularization procedures and "off pump" revascularization have shed new light on complications related to CPB (17, 21–22).

The perfusion and cardiothoracic communities have identified and engaged clinical issues associated with CPB including hemodilution, inflammatory response, platelet activation, anticoagulation, blood loss, organ dysfunction and neurological complications. Each of these issues may elicit various clinical changes with a myriad of clinical outcomes. To date, no single aspect of surgical technique or technology appears to have had a profound effect on patient outcomes. However, the key may lie in a multifactoral approach to handling the dilemmas posed by cardiothoracic procedures (18). One such approach to cardiac procedures may be improving CPB to include, biocompatible surfaces, improved clinical practices, addressing blood material interaction, and optimized circuit performance. Clinical practices include handling of shed or suctioned blood, management of coagulation, blood gases, temperature, cannulation, drug therapies, cardioplegia, pressure and surgical techniques. Blood-material interaction addresses the concern of CPB circuit components such as biomaterial surface areas, surface activity, debris, and biochemical reactions. Circuit performance embodies designs which optimize sterility, sheer stress, air emboli protection, areas of blood

flow stasis, gas exchange, pump type, continuous or pulsatile flow, as well as open versus closed systems (7–10, 15, 19, 23–24).

Inflammatory response is a major contributor to post operative patient morbidity. Contact of foreign surface activates white blood cells, platelets, and the coagulation, fibrinolytic and complement cascades resulting in systemic inflammatory response syndrome (SIRS). SIRS is a syndrome comprised of numerous pathological conditions including capillary leak and neurological dysfunction (1–6, 11–14, 16, 20–21).

Although various surface modifications have been utilized, traditional CPB has undergone few changes in the last 20 years. However, CardioVention Inc., (Santa Clara, CA), recently has developed an integrated CPB system, the CORx System, which addresses the issues of venous air handling, foreign surface area, and hemodilution.

The CardioVention CORx disposable system minimizes hemodilution by reducing the standard adult CPB prime volume from over 1500 ml to less than 500 ml. Platelet activation and inflammatory response to foreign surface area exposure is mitigated by reducing CPB system surface area from over 12 m^2 in conventional CPB circuitry to 1.4 m^2. The risk of air embolization with associated neurocognitive dysfunction (34–41) is reduced with an AirVac™ System, which is a sensor regulated venous air handling system.

Early results from a data registry that includes data from 186 "mini-system" supported patients and 55 "traditional CPB" patients indicate clearly significant improvements in levels of: post-dilutional hematocrit drop (–19.5% vs. –41.5%, $p < 0.001$); end-of-support hematocrit drop from baseline (–18,9% vs. –43.5%, $p < 0.001$); and allogenic blood units transfused (0.15 vs. 0.44, $p = 0.03$). The extent to which significant reductions in the dilution of both formed elements (allogenic donor exposures) and plasma proteins (colloid osmotic pressure) contributed to a significant reduction in post-operative mechanical ventilator time (289 min. vs. 455 min., $p = 0.008$) remains to be determined. The case mix is 58% beating heart vs. 35% stopped heart, and 6% of those cases include valves and other procedures. In Europe, 69% (n = 209) of the CORx cases were stopped heart vs the USA, 84% (n = 345) beating heart. Total revascularizations in CORx vs control (4.2 vs 4.5) anastomosis. CORx beating heart vs op cab procedures average (4.24 vs 1.7) anastomosis.

The opportunity to explore cardiopulmonary bypass in a miniaturized fashion continues to challenge the perfusion armamentarium. The combination of air removal, pumping and oxygenating functions in the CORx system allows for a reduced priming volume and thereby a reduced hemodilutional effect with resulting higher Hgb values and optimized blood oxygen carrying capacity. Preservation and maintenance of hemoglobin level is essential for oxygen transport and delivery to tissue beds, especially in the challenged physiology of the cardiac surgical patient (41). Additionally, smaller cardiopulmonary bypass surface area may reduce blood surface contact activation and subsequently lower systemic inflammatory response (1–6). This reduction in systemic inflammatory response may be also be recognized by elimination of blood air interface. This system is noted for the elimnination of exposure to antifoam A and silicone agents, which may itself significantly reduce the inflammatory response. The CORx system is also attractive in its ability to provide reduced or zero blood/air interface thereby reducing blood element trauma and the activation of blood components.

REFERENCES

1. Utley, JR. The history of the concept of inflammatory responses to cardiopulmonary bypass. Perfusion 1996;11:190-5.
2. Hall RI, Smith MS, Rocker G. The systemic inflammatory response to cardiopulmonary bypass: pathophysiological, therapeutic, and pharmacological considerations. Anesth Analog 1997;85:766-82.
3. Wan S, LeClerc J, Vincent J. Inflammatory response to cardiopulmonary bypass, mechanisms involved and possible therapeutic strategies. Chest 1997;112(3):676-92.
4. Asimakopoulos G. Systemic inflammation and cardiac surgery: an update. Perfusion 2001;16:353-60.
5. Royston D. Systemic inflammatory responses to surgery with cardiopulmonary bypass. Perfusion 1996;11:177-89.
6. Edmunds LH. Inflammatory response to cardiopulmonary bypass. Ann Thorac Surg 1998;66:S12-6.
7. Baufreton C, Intrator L, Jansen PG, et al. Inflammatory response to cardiopulmonary bypass using roller or centrifugal pumps. Ann Thorac Surg 1999;67(4):972-7.
8. Morgan IS, Codispoti M, Sanger K, Mankad PS. Superiority of centrifugal pump over roller pump in paediatric cardiac surgery prospective randomized trial. Eur J Cardiothorac Surg 1998;13(5):526-32.
9. Brooker RF, Brown WR, Moody DM, et al. Cardiotomy suction: a major source of brain lipid emboli during cardiopulmonary bypass. Ann Thorac Surg 1998;65(6):1651-5.
10. Hsu LC. Biocompatibility in cardiopulmonary bypass. J Cardiothorac Vasc Anesth 1997;11(3):376-82.
11. Miller BE, Levy JH. The inflammatory response to cardiopulmonary bypass.. J Cardiothoracn Vasc Anesth 1997;11(3):355-66.
12. Royston D. The inflammatory response and extracorporeal circulation. J Cardiothorac Vasc Anesth 1997;11(3):341-54.
13. Taylor KM. SIRS—the systemic inflammatory response syndrome after cardiac operations. Ann Thorac Surg 1996;61(6):1714-20.
14. The systemic inflammatory response to cardiopulmonary bypass. Proceeding of the Hammersmith Perfusion Workshop 1995. Perfusion 1996; 11(3):175-290.
15. Janvier G, Baquey C, Roth C, Benillan N, Belisle S, Hardy JF. Extracorporeal circulation, hemocompatibility, and biomaterial. Ann Thorac Surg 1996;62(6):1926-34.
16. Hill GE. The inflammatory response to cardiopulmonary bypass. Int Anesthesiol Clin 1996;34(2):95-108.
17. Brasil LA, Gomes WJ, Salomao R, Buffolo E. Inflammatory response after myocardial revascularization with or without cardiopulmonary bypass. Ann Thorac Surg 1998;66:56-9.
18. Daniel S. Review on the multifactorial aspects of bioincompatibility in CPB. Perfusion 1996;11:246-55.
19. Courtney JM, Matata BM, Yin HQ, et al. The influence of biomaterials on inflammatory response to cardiopulmonary bypass. Perfusion 1996;11:220-8.
20. Gott JP, Cooper WA, Schmidt FE, et al, Modifying risk for extracorporeal circulation: trial of four anti-inflammatory strategies. Ann Thorac Surg 1998;66(3):747-53.
21. Asimakopoulos G. Mechanisms of the systemic inflammatory response. Perfusion 1999;14:269-77.
22. Czerny M, Baumer H, Kilo J, et al. Inflammatory response and myocardial injury following coronary artery bypass grafting with or without cardiopulmonary pass. Eur J Cardiothorac Surg 2000;17(6):737-42.
23. Heparin-coated cardiopulmonary bypass circuits: current status. Perfusion 2201;16(5):417-28.
24. Gourlay T. Biomaterial development for cardiopulmonary bypass. Perfusion 2201;16(5):381-90.
25. Lewis FJ, Taufic M. Closure of atrial septal defects with the aid of hypothermia; experimental accomplishments and the report of one successful case. Surgery 1953;33:52-9.
26. Bigelow WG, Callaghan JC, Hopps JA. General hypothermia for experimental intracardiac surgery. Ann Surg 1950;132:531-9.
27. Swan H, Zeavin I, Blount SG Jr, et al. Surgery by direct vision in the open heart during hypothermia. JAMA 1953;153:1081-5.
28. Gibbon JH Jr. Application of a mechanical heart and lung apparatus to cardiac surgery. Minn Med 1954;37:171-85.
29. Kirklin JW. Open heart surgery at the Mayo Clinic—the 25th Anniversary. Mayo Clin Proc 1980;50:339-41.
30. Lillehei CW. A personalized history of extracorporeal circulation. ASAIO J 1982;28:5-16.
31. Cooley DA. Recollection of early development and later trends in cardiac surgery. J Thorac Cardiovasc Surg 1989;98:817-22.
32. Melrose DM. A mechanical heart-lung for use in man. Br Med J 1953;2:57-66.
33. Kurusz M, Butler BD, Katz J, Conti VR. Air embolism during cardiopulmonary bypass. Perfusion 1995;10:361-91.
34. Reed CC, Kurusz M, Lawrence AE Jr. Air embolism. Safety and techniques in perfusion. Stafford, TX: Quali-Med, 1988:239-46.
35. Kumar AS, Jayalakshmi TS, Kale SC, et al. Management of massive air embolism during open heart surgery. Int J Cardiol 1985;9:413-6.
36. Brenner WI. A battle plan in the event of massive air embolism during open heart surgery. J Extra-Corp Technol 1985:17:133-7.
37. Rozanski J, Szufladowicz M. Successful treatment of massive air embolism. J Card Surg 1994;9:430-2.
38. Schabel RK, Berryessa RG, Justison GA, et al. Ten common perfusion problems; prevention and treatment protocols. J Extra-Corp Technol 1987: 19:392-8.
39. Menkin M, Schwartzman RJ. Cerebral air embolism; report of five cases and review of the literature. Arch Neurol 1977;34:168-70.
40. Peirce EC II. Specific therapy for arterial air embolism (Editorial). Ann Thorac Surg 1980;29:300-3.

41. Cooper JR, Giesecke NM. Hemodilution and priming solutions. In: Gravlee GP, Davis RF, Kurusz M, Utley JR eds. Cardiopulmonary bypass, principles and practice, second edition. Philadelphia: Lippincott Williams & Wilkins, 2000:186-96.
42. Butler BD, Kurusz M. Embolic events. In: Gravlee GP, Davis RF, Kurusz M, Utley JR eds. Cardiopulmonary bypass, principles and practice, second edition. Philadelphia: Lippincott Williams & Wilkins, 2000:320-41.

ADVANCED THORASCOSOPIC PROCEDURES ARE FACILITATED BY COMPUTER-AIDED ROBOTIC TECHNOLOGY

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PURPOSE: Computer (robotic) enhancement has been used to facilitate simple thoracoscopic procedures such as internal mammary artery (IMA) mobilization. This report describes the use of robotic technology in advanced thoracoscopic procedures.
METHODS: Nine patients underwent advanced thoracoscopic procedures utilizing the Da Vinci robotic surgical system (Intuitive Surgical, Mountain View, CA) at our institution.
RESULTS: Patients 1 through 5 underwent endoscopic phrenic nerve mobilization with insertion of bilateral phrenic nerve pacemakers. The indications were quadriplegia (n = 2), central hypoventilation syndrome (n = 1), and intractable hiccups (n = 2). Three 1-cm incisions were made to access each hemithorax. Patient 6 underwent robotically assisted thoracoscopic left lower lobectomy for a lung mass. Patients 7 and 8 underwent robotically assisted resection of posterior mediastinal masses. Patient 9 underwent robotically assisted left ventricular lead placement for biventricular pacing for heart failure.
CONCLUSIONS: Robotic technology can be used to perform advanced intrathoracic maneuvers thoracoscopically. The increased visualization and instrument dexterity afforded by this technology may facilitate the development of minimally invasive thoracic approaches that were previously not feasible.

DOES ROBOTIC TECHNOLOGY MAKE MINIMALLY INVASIVE CARDIAC SURGERY TOO EXPENSIVE? A HOSPITAL COST ANALYSIS OF ROBOTIC AND CONVENTIONAL TECHNIQUES

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OBJECTIVE: While potential benefits of robotically assisted cardiac surgery include decreased morbidity and improved recovery, some have suggested a prohibitively high cost. This study was undertaken to compare the actual hospital costs of open and robotically assisted cardiac procedures.
METHODS: Clinical and financial data were obtained from our hospital database for patients undergoing atrial septal defect (ASD) or mitral valve repair (MVr). Procedures were performed by sternotomy or minithoracotomy (OPEN, n = 68), or with robotic assistance (ROBO, n = 30) using the Da Vinci system (Intuitive Surgical, Mountain View, CA). Total cost was comprised of direct (patient-specific) and indirect (facility-specific) costs and was further subdivided into operative and postoperative costs.
RESULTS: Intraoperative cost was higher for robotic ASD (p = 0.064) and robotic MVr (p = 0.025) as compared to open. However, for both ASD and MVr, there was no significant difference in total cost of robotic versus open procedures (table).

	Direct Cost	Indirect Cost	Total Cost	Operative Cost	Postoperative Cost
ASD OPEN	13958 ± 7409	14667 ± 8517	28625 ± 15694	12444 ± 5747	12367 ± 8571
ASD ROBO	13829 ± 4939	13571 ± 5361	27400 ± 10221	16264 ± 5780	11358 ± 6430
p	.954	.665	.794	0.064	0.707
MVr OPEN	18595 ± 10885	18758 ± 11387	37351 ± 22066	16611 ± 5540	13019 ± 6818
MVr ROBO	17284 ± 5313	17516 ± 7223	34800 ± 12313	20549 ± 4079	11539 ± 10619
p	.663	.704	.681	0.025	0.594

CONCLUSIONS: Beyond the initial capital investment associated with robotic technology, robotic surgery does not increase total hospital cost. While intraoperative costs are higher for robotic procedures, these are offset by a less costly postoperative course. This may be secondary to a trend toward decreased ICU and hospital stay for robotic patients. Thus, it is possible that the benefits of minimally invasive surgery may justify investment in this technology.

ATRIAL FIBRILLATION ABLATIVE SURGERY: NEW ENERGY SOURCES

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Surgical treatment of cardiac arrhythmias has a long history in the discipline of cardiac surgery. Wolf-Parkinson White (WPW) syndrome was one of the first arrhythmias treated using surgical principles. Dr. Will Sealy performed the first WPW operation at Duke University, and this opened the door for surgical therapy of arrhythmias. Emergence of less invasive catheter based therapies soon replaced surgery as the treatment of choice for WPW syndrome. Dr. James Cox rekindled the surgical interest with his pioneering work in the field of atrial fibrillation. He studied the mechanism behind this re-entrant tachyarrhythmia and soon developed the Cox-Maze operation. Based on Dr. Cox's pioneering work and good results, surgeons from around the world are once again focusing on arrhythmia surgery.

Contemporaneously, cardiologists introduced catheter based therapy for arrhythmias and soon attempted atrial fibrillation ablation, however, these procedures often require eight hours in the electrophysiology lab. Many patients with atrial fibrillation have concomitant mitral valve disease with a dilated left atrium. Thus, surgeons began adding ablative procedures to valve operations. This has lead to the introduction of both different energy sources and delivery systems.

The energy source used most frequently early on has been radiofrequency (RF). Radiofrequency continues to be a reliable source however; dry RF requires high-energy output (up to 150 watts) to obtain a high temperature of 80° Celsius. Recently, irrigated RF has been introduced which allows lesion creation with a lower temperature and energy output. The use of electrical current has also been used in both monopolar and bipolar configurations. Current bipolar devices provide impedance feedback indicating when a transmural lesion has been generated. Microwave (MW) catheters use a type of irradiation to generate the lesion. Attention to direct tissue contact is not as imperative using MW and lesion spread is not as varied as with some other energy sources. Cryoablation has been part of the Cox-Maze procedure for many years and recent delivery systems allow lesion creation using a malleable catheter-like tip. Cryoablation does not cause cell necrosis and therefore the underlying collagen matrix is not disrupted providing support surrounding the lesion. Other energy sources being developed and investigated include laser and ultrasound. There is limited experience with these energy sources, however, as the search for the perfect energy source continues, expect to read reports of their use.

For many reasons, this is an exciting era in cardiac surgery. In terms of atrial fibrillation ablative surgery, we now have many choices. One may make choices based on the energy source, the delivery system, or both.

BUILDING A ROBOTICS PROGRAM

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Approximately 100 robotic surgical systems have been sold in the United States since we received our first system in November 1999 and our second system in June 2000. This equates to just over one system every two weeks in the United States alone. Even though financial constraints have altered many institutional programs at centers around the globe, hospitals, academic centers, and individual practices continue to purchase systems. This is expanding the demand for technology development, training, and support.

During the decision process of starting a robotics program, there are several fundamental issues to be considered. Firstly, one must decide on areas of interests. In developing our program, we decided to pursue a multidisciplinary approach by including not only cardiac surgery, but also general surgery, urology, vascular surgery, and gynecology. This decision is usually based on financial support for the purchase of the system. Along with this process, develop a business plan to help guide thoughts, as well as, direct facility leaders. As program builders, we should always "bring something to the table" when negotiating for new programs.

A robotic users group should be established to provide input from all potential users, as well as, facility administrators who are responsible for providing financial support. One must also consider the need for clinical trial support especially if embarking on procedures that are not FDA approved. A research-oriented person must oversee the IRB process and accurate database management. This facilitates publishing in peer-reviewed journals, which brings highlight and exposure to the supporting institution.

Support from practice partners, colleagues and a facility administrator is vital. There is no doubt that many robotic cases require more support and operating room time in the early phases of the learning curve. This does decrease over time; however, it should be considered when developing a comprehensive program.

Lastly, enlist the assistance of legal counsel when reviewing all letters of intent, purchase agreements, service contracts, and payment schedules. Most important, always keep your immediate "boss" informed during the process so that he or she is not surprised by potential problems.

TOTALLY ENDOSCOPIC BIVENTRICULAR PACING SYSTEMS USING daVINCI ROBOTICS

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PURPOSE: Restoration of ventricular synchrony using biventricular pacing is associated with improvements in left ventricular ejection fraction, NYHA functional class and quality of life. Transvenous placement of the left ventricular pacing lead into the coronary sinus may be limited due to thrombosis of vascular access vessels or anatomic variants of the coronary sinus. This study reports our initial experience with totally endoscopic epicardial lead placement using daVinci robotics.
METHODS: Under general anesthesia, with a double lumen endotracheal tube and using CO2 insufflation to 8–10 mmHg, the chest was explored using the daVinci robot. A 10mm working port was also placed.
RESULTS: Nine leads were placed in eight patients. There were five men and 3 women; ages 66–81 (mean 75 years). These include patients having placement of epicardial lead only (n = 3), epicardial lead and generator (n = 4), or epicardial lead, transvenous leads, and generator (n = 1). Adhesions were identified in 4/8 patients including the three patients with previous heart surgery. Six patients had totally endoscopic procedures while 2 patients required creation of mini thoracotomy for lysis of adhesions. Operative times decreased with experience and varied by procedure with recent lead only placement in less than 90 minutes. Bipolar and unipolar leads were used. Initial left ventricular pacing thresholds ranged from 0.8 to 3 volts. Length of hospital stay was average of 3.5 days (range 2–6). Endoscopic patients required less analgesia and half (3/6) required no narcotics analgesia after their procedure. One patient had a complication of right atrial lead displacement which required repositioning. There were no deaths.
CONCLUSIONS: daVinci robotics enable safe, accurate and reliable epicardial pacing lead placement without thoracotomy.

NEUROCOGNTIVE DATA FROM THE COOP CABG TRIAL

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BACKGROUND: Proponents have argued that off-pump coronary artery bypass grafting (CABG) may result in fewer neurocognitive changes than traditional on-pump surgery. The purpose of this study was to compare preoperative neurocognitive function with that at 30 days following either on- or off-pump CABG to determine whether cardiopulmonary bypass was associated with neurocognitive impairment.
METHODS: This prospective, randomized trial enrolled 56 consecutive patients who were assigned to undergo on- (n = 27) or off-pump (n = 29) CABG. All but one off-pump patient underwent a baseline neurocognitive examination comprised of 13 neurological tests assessing seven areas: mental status, language, verbal memory, visual memory, visual construction, attention, and executive skills. An identical battery of tests was repeated at 30 days following surgery. The scores were standardized according to age-specific criteria. Diffusion weighted MRI scans were also obtained in 13 patients
RESULTS: In none of the seven areas was there a significant change in neurocognitive performance in either the on- or off-pump groups. Additionally, the changes from baseline to 30-days did not differ between groups for any cognitive area. The randomized groups were also compared with respect to the proportion of patients experiencing a decline of at least one standardized unit for each cognitive area using Fisher's exact test. No statistically significant differences between the groups were noted. A trend towards MRI defects was noted in the on-pump group.
CONCLUSION: At 30 days following surgery, neurocognitive performance was unchanged compared to baseline in both on- and off-pump patient groups. Cardiopulmonary bypass was not associated with increased risk to any of seven major areas of neurocognitive ability, although subtle anatomic defects may be present.

NAPKIN TO PATENT: CLUES FOR SUCCESS

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We will review how a young investigator takes an innovative concept and reduces the idea to a practical application that can help patients. Of course, the first painful lesson is that for every 20 great ideas, only 1 will succeed, but therein remains the challenge.

First, protect your intellectual property by dating all your drawings and notes, involving a non-inventor as a witness, mailing a copy of your idea to yourself periodically (and saving without opening), and file for patents early, even if only provisional. Remember to use non-disclosure forms and above all, know your prior art.

Second, you should evaluate the intellectual property options. As you write your patent, you can divide your claims, which are the heart of the patent, into 5 categories. Apparatus (strongest), means and functional apparatus (broadest), methods and use or method of treatment (difficult to defend) and composition of matter. Evaluate a patent attorney by the clients they represent, venture capitalists with whom they have worked, and the number of patents they have sold.

Third, design a comprehensive business plan including a background, concept, objective, management team, marketing plan, competition, patent position, regulatory obstacles, and of course the financial plan. The executive summary is critical to catch the interest of investors, so spend the time needed to make this "advertisement" worthy of your idea.

Fourth, you will need money. Venture capitalist or corporate partners will want answers to the following questions:

1. Are you solving a big problem (>100,000 products, or enough to start a company)
2. Is idea technically feasible
3. How much lead time do you have
4. How fast can you get to market
5. How strong is development and management team
   a. i.e. You want "Mr Right", not "Mr Right Now"
6. Can you reach your customer effectively (if >5000, need strategic partner)
7. What rate of return will first investment make.
   a. >50% INR (10X money in 5 years)
   b. Must have IPO potential of acquisition value >$100M

At the end of the deal, founders will often own 20–30%, VC will take 40–60% and management will own 15–20%

Royalties will be negotiated based on a variety of subtle nuances of the patent, but as rules of thumb, 5% is reasonable if the patent is already issued. However, do not expect more than 3% if the physician approaches the company directly or 1.5% if the idea is added to an existing technology.

In summary, your major value to a company or private investors (in ascending order) is your creation of the napkin drawings or concepts, initiation of IP protection, an accurate market survey, successful prototypes, animals trials, and of course clinical experience. A pencil and paper are cheap so be ready to make the investment of time and energy needed if you really want a success. If you decide not, don't complain later that you had thought of the idea first.

UPDATE ON VADS

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Numerous advances in the surgical treatment of heart failure have led to innovations in our management of the heart shape (ACORN, D'Or procedures, STITCH Trial), potentially viable cardiac muscle, and high risk valve surgery. The foundation of many of these aggressive reparative approaches is

the availability of cardiac replacement therapy. Cardiac assist devices have become an important adjunct to the management of the end-stage heart failure patient and are the standard of care for most potential heart transplant patients with life-threatening heart failure refractory to medical therapy. Significant advances in both the technology and clinical experience have taken place over the past decade. Currently, there are a wide array of devices both available and in development that range from simple, percutaneous, left-sided support devices to total artificial hearts. Not only is proper patient selection critical to success but also proper device selection will greatly impact on a patient's outcome. In addition, the growing long-term success with device support has led to the possibility of permanent support. This discussion will briefly describe the main device types while providing an algorithm for selecting the proper device for the proper patient.

TYPES OF PUMPS. Extracorporeal. *Abiomed BVS 5000*. The Abiomed BVS 5000 (Abiomed Cardiovascular Inc.; Danvers, MA) is a short-term uni or biventricular support system comprised of external pumps driven by a computer controlled drive console. First approved by the FDA in 1992 for postcardiotomy support, the indications for use have grown to include acute myocardial infarction, myocarditis, right ventricular support in conjunction with a long-term left ventricular support device, bridge to recovery and bridge to transplant. As a result, the device has become one of the most commonly used means of short-term mechanical cardiac support and remains the only device approved by the FDA for all patients with potentially reversible heart failure.

Advantages that have made the BVS system popular are the ease of insertion and simplicity in operation obviating the need for a full-time perfusionist. The system functions reliably for several days with average support duration between 5 and 9 days, an attribute that has been particularly helpful in community hospitals needing to transfer patients to a transplant center for further treatment. The system has proven effectiveness in both acute myocarditis and postcardiotomy cardiogenic shock. In addition, the cost may be closer to centrifugal pumps than previously expected, especially when centers consider the savings created by avoiding full time trained staff to support the device. For these reasons, the BVS system has become our standard for bridging patients to longer-term devices in our Spoke and Hub network. This network consists of Spoke hospitals that do not have long-term VAD or transplant capabilities but can support patients on short-term devices such as the BVS 5000.

When appropriate patients are identified, rapid screening and support is instituted at the Spoke hospital. The Hub hospital is notified and expeditious transfer is arranged so long-term support can be instituted if necessary.

Disadvantages of this device include the requirement for continuous anticoagulation, limited mobility compared to implantable devices, and the requirement to remain in an ICU. Flow rates are also limited compared to other devices and maximum flow rate of 6 L/min may not be enough for septic or large patients. Although patients have been supported as long as 90 days, the device is best suited for short-term use (<10 days). For these reasons we do not use the device if we feel the support period will be greater than 7 days.

Thoratec paracorporeal VAD. The Thoratec ventricular assist device (Thoratec Laboratories Corp.; Pleasanton, CA) consists of an externalized pneumatic pusher plate pump positioned subcostally connected to a drive console. The drive is capable of uni or biventricular support with flows up to 7 L/min although maximum flows of 5 to 5.5 L/min are more commonly found due to the relatively long inflow cannula. The cannulae are tunneled exiting from the upper abdominal wall connected to the extracorporeal pump. The device was first used clinically in 1982 for postcardiotomy support and in 1984 as a bridge to transplantation. and has received FDA approval as both a bridge-to-recovery and a bridge-to-transplant.

The main advantage of the Thoratec system is the ability to provide long-term biventricular support, an attribute that has become increasingly important with prolonged waiting periods for transplant. The paracorporeal position has benefits as well, including identification of clot and device exchange without invasive surgery. Survival to transplant has ranged up to 74% with support durations over 200 days. The device can be placed into patients below 20 kg although it is not recommended for neonates.

The major limitations of the Thoratec system are the limited mobility and rehabilitation potential due to a large drive console and the need for chronic anticoagulation. New, portable drive units will allow portability that should overcome the limitations of the original system. In case of high output requirements, other devices may be desired due to flow limitations. The Novacor or HeartMate may be used in this case in conjunction with the Thoratec providing right-sided support. Another alternative may be a total artificial heart.

Even with limited portability and the need for chronic anticoagulation, the Thoratec VAD system provides a valuable adjunct to the cardiac assist device armamentarium due to the ability to provide long-term, biventricular support.

Intracorporeal. *Thoratec HeartMate*. The HeartMate (Thoratec Laboratories Corp.; Pleasanton, CA) LVAD is an implantable, long-term, univentricular cardiac assist device distributed by Thoratec Laboratories Corp. Based on work started in the mid-1960's, the first clinical implantation of the HeartMate took place in 1986. The HeartMate was the first mechanical circulatory support device to be approved by the FDA for bridging to transplant. Both a pneumatically driven (implantable pneumatic, IP) and an electrically powered (vented electric, VE) version exist. Most hospitals now have converted to the portable electric version allowing discharge to home on support. Both systems function with a pusher-plate mechanism delivering up to 10 L/min of flow. The driveline containing the electric cable and an air vent exits the skin to attach to the external drive console. Both inflow and outflow porcine valves are attached to the pump. The inflow cannula is attached to the LV apex and the outflow is via the ascending aorta. The blood-contacting portion of the pump incorporates titanium microspheres and the flexible diaphragm is covered with textured polyurethane. This promotes the formation of a pseudointimal layer. This unique surface may be responsible for the low thromboembolic risk associated with the HeartMate despite the lack of anticoagulation. The HeartMate's very low thromboembolic rate (<5%) without anticoagulation has become its main advantage. In addition, patients can be discharged home while awaiting transplant where they can resume almost all their normal activities and rehabilitate.

Patients must have a BSA of at least 1.5 m^2 to accommodate the abdominally placed pump. Proper screening of potential recipients is critical. Early complications are related to technique. The major causes of perioperative mortality are hemorrhage and right heart failure (RHF). These have been reduced with the introduction of aprotinin (Bayer; Tarrytown, NY) and nitric oxide. Flows of less than 3.0 L/min (cardiac index < 2.0) may predispose to clot formation inside the pump. If right-sided support were necessary, a different device would need to be placed. Device failure, requiring replacement, has been reported to occur in about 12% of patients.

The REMATCH study was undertaken using this device as an alternative, rather than bridge to transplantation. One hundred twenty nine nontransplant candidates in NYHA class IV heart failure were randomly assigned to receive a HeartMate or optimal medical therapy. There was a 48% reduction in the risk of death from any cause in the LVAD group compared to the medical therapy group. One and two-year survival was 52% vs. 25% and 23% vs. 8% for the LVAD and medical therapy group, respectively. These data supporting mechanical therapy over medical therapy may have profound effects on the treatment of end stage heart failure in nontransplant candidates in the future and have already resulted in FDA approval for destination therapy.

World Heart Novacor N1000PC. The Novacor N1000PC (Baxter Healthcare Corporation; Berkeley, CA) is a wearable left ventricular assist system with implantable pump and externalized vent tube, controller and batteries. Its dual pusher-plate design provides symmetrical movement minimizing mechanical torque. The first successful bridge to transplant implantation took place in 1984 and it received FDA approval for bridge-to-transplant in 1998. Inflow comes from the LV apex and outflow is through the ascending aorta with flows up to 10 L/min. Patients can ambulate with little impairment after implantation. Many patients have been successfully discharged from the hospital to await transplant. It also has an excellent mechanical reliability rate with few device failures.

Device specific exclusion criteria include blood dyscrasias, presence of a prosthetic aortic valve and a recipient body surface area of less than 1.5m^2. As with most devices, preoperative multi-system organ failure is predictive of poor outcome as well. Similarly, bleeding and RHF are the most significant perioperative complications. Anticoagulation must be maintained with coumadin (INR 2–3) and with aspirin. Despite anticoagulation, the embolic stroke rate associated with the Novacor device has been high (26%). However, recent inflow cannula/conduit modifications have dropped the embolic stroke rate to 12%. Newer conduits using polytetrafluoroethylene may lower the embolic stroke rate further. The device is undergoing clinical trials and is being reviewed by the FDA for destination therapy.

Total Artificial Hearts. The CardioWest TAH (CardioWest Technologies, Inc.; Tucson, AZ) is a pneumatic, biventricular, orthotopically implanted total artificial heart with an externalized driveline to its console. It consists of two spherical polyurethane chambers with polyurethane diaphragms. Inflow and outflow conduits are constructed of Dacron™ and contain Medtronic-

Hall™ (Medtronic, Inc.; Minneapolis, MN) valves. The pump began as the Jarvik-7 TAH used in the early 1980's. Despite early obstacles, a new investigational device exemption study started in 1993. The trial showed support durations of 12 to 186 days with a 93% survival to transplant. European experience with the CardioWest TAH has been slightly worse although encouraging with 70% surviving to transplant. In those studies, the average support duration was 34 to 36 days with the longest being 186 days. The most common cause of death was multiorgan failure while common morbidities were renal dysfunction (38%) and infection (37%).

The TAH benefits from having the ability to provide excellent, early support avoiding irreversible end organ damage in rapidly decompensating critically ill patients. Unlike the other biventricular devices, it obviates the presence of the native heart. This is particularly useful in situations where leaving the native heart in place would be detrimental or impossible (infection or cardiac tumors).

Adequate intrathoracic space is required to accommodate the TAH. Fitting criteria include BSA >1.7m^2, cardiothoracic ratio 0.5, LV diastolic dimension >66mm, AP distance >10cm and combined ventricular volume >1500ml. Careful intraoperative fitting is critical. In addition to size requirements, strict anticoagulation with coumadin, aspirin, Persantine and Trental is needed. Rehabilitation is limited as well due to the current large console. A portable console for the CardioWest TAH is in development however.

New TAHs are in development that will allow for full implantability and hospital discharge. The AbioCor TAH (Abiomed Cardiovascular Inc.; Danvers, MA) consists of an internal thoracic pump, internal rechargeable battery, internal electronics and an external battery pack. External power is delivered via a transcutaneous energy transmission (TET) coil located on the chest wall. The pump consists of two ventricles with their corresponding mechanical valves. Its stroke volume is between 60 and 65cc with an output of between 4 and 10 L/minute. A centrifugal pump moves hydraulic fluid between each ventricle providing alternate left and right ventricular pulsatile flow. There is an atrial balance chamber that adjusts for left and right atrial pressures. As with previous TAHs, fitting is critical. The Abiofit system has been developed using three dimensional computed tomography reconstruction to size patients before implantation. Anticoagulation is maintained with coumadin and Plavix. The first human implantation took place on July 2, 2001 at Jewish Hospital in Louisville, Kentucky. The implantation, part of the initial AbioCor trial, represents the first implantation of a totally implantable TAH. Endpoints include 60-day mortality and quality of life measurements with an anticipated size of 15–30 patients and centered over two years. To date, five patients have been implanted totaling nearly a year of support without device malfunction.

Axial Flow Pumps. Axial flow pumps represent one of the newest generations of assist devices. They can provide full cardiac support in a much smaller pump with fewer moving parts and less blood contacting surface than pusher-plate devices. In addition to their small size, their design is notable for nonpulsatile flow. Several studies have demonstrated metabolic and neurohumoral changes in organ perfusion compared to pulsatile flow. However, both clinical and long-term animal studies have failed to show significant differences in morbidity and mortality with axial flow pumps. The most promising devices are the Heartmate II, DeBakey VAD, and Jarvik 2000. These devices weigh between 53 and 176 g and can generate flows in excess of 10 L/min.

The Jarvik 2000 axial flow pump, HeartMate II and the DeBakey axial flow pump all have similar features as mentioned above. Their small size allows implantation into smaller patients than most pulsatile pumps. This also makes placement and explantation easier. With less moving parts there are fewer points of friction therefore increasing their expected durability. Although there is controversy over long-term nonpulsatile flow, most patients maintain some native cardiac function and therefore continue to have pulsatile blood flow. Therefore, full support with these devices may be not only unnecessary but even detrimental due to the unknown effects of long-term human nonpulsatile flow and the potential to suck down the ventricle if the pump flow is set too high.

Unfortunately, if there is a device failure there are few options or backup mechanisms in place other than replacement. Additionally, since they lack valves, if device malfunction does occur the patient can develop the equivalent of wide-open aortic insufficiency. The DeBakey pump has already been successfully implanted in a small number of patients in Europe. In addition, the Heartmate II and the Jarvik 2000 have been successfully implanted in humans.

DEVICE SELECTION: There are currently five FDA approved assist devices, in addition to the intra-aortic balloon pump, for these indications. In addition to the FDA devices, there are several other VADs in development and clinical use.

Device selection is invariably influenced by both availability and physician experience. Although much has been published on individual devices, few studies have compared assist devices at a single institution. Currently there are two major indications for cardiac assist device support: bridge-to-recovery and bridge-to-transplant. Destination therapy, although probable, currently remains investigational.

Important clinical issues when choosing a device include the expected duration of support, need for biventricular support, cost, device related risks, and patient characteristics. Blood type and potential time on the transplant wait list will also affect the choice of long-term device. Institutional standard of care, ranging from community practice to tertiary heart failure/transplant centers, also influence device selection.

Patients who may require mechanical circulatory support can be divided into three main categories listed below. These different clinical scenarios and patient needs dictate the best type of device to use.

1. Profound Shock—those in acute, profound shock e.g. postcardiotomy cardiac arrest, potentially with end organ failure and right heart failure
2. Decompensating congestive heart failure (CHF)—more chronically ill patients who are transplant candidates
3. Non-transplant candidates—patients not at a transplant center and who have potentially recoverable myocardium

These scenerios will be discussed during the meeting. Patients in profound shock with end organ dysfunction and right heart failure need early, excellent support to avoid permanent end organ damage and increase their chances of survival. The preferred devices in such a scenario are the Abiomed BVS 5000, Thoratec device and the TAH (if available). These devices provide full biventricular support reestablishing near normal hemodynamics and allowing myocardial recovery. Early implementation of biventricular support is critical in patients with severe biventricular failure. While on ventricular support, the potential for myocardial recovery and neurological status can be determined. If a prolonged support period is expected, a longer-term device should be implanted such as the Thoratec or TAH. Despite their severe cardiac failure, these patients can be successfully salvaged with survival rates approaching that of the general cardiac transplantation population.

Patients who suffer from more chronic CHF and who are transplant candidates may decompensate before receiving their transplant. In these patients the potential for long-term support must be considered. Hospital discharge and rehabilitation become important factors in choosing a device for this patient population. Longer-term support, with end organ recovery and better rehabilitation, is associated with better long-term survival. Therefore, the recommended devices are the implantable HeartMate and the Novacor LVAD. Treatment of RHF, if present, is mandatory. The use of inhaled nitric oxide has dramatically improved the management of RHF. If necessary, an RVAD must be placed to avoid irreversible end organ damage and death.

Non-transplant candidates may be patients at non-transplant centers or with recoverable cardiac function. Patients at non-transplant centers, who may benefit from a longer-term device and transplant workup, can be safely transferred once stabilized. Many patients transferred on assist devices are successfully weaned without requiring a long-term implantable LVAD. Preferred devices for use in this setting are the Abiomed BVS 5000 due to relative ease of implantation. Long-term care decisions should be made within 3 days. If longer-term support is necessary, an implantable device can be implanted later.

CONCLUSION: With the growing success of mechanical circulatory support, the number of ventricular assist devices coming to market is rapidly increasing. Selecting the correct device requires consideration of both clinical and institutional issues. It is important to have more than one type of device in one's armamentarium in addition to strong communication with outside referring institutions. As both device related challenges are met and patient selection criteria become more refined, the survival and quality of life of patients suffering from cardiac failure will continue to improve.

WORLD ECONOMIC FORUM: AN INSIDER'S VIEW

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The annual World Economic Forum meeting brings together this planet's most influential decision-makers to discuss the building of wealth. Over the past several years as demonstrators have petitioned outside the guarded entrances to the meeting halls, many participants had the epiphany that

countries cannot sustain creation of wealth without also building health. But what are the action steps for this simultaneously noble and self-serving goal?

"The Possible American" study, released by the World Economic Forum's Global Leaders of Tomorrow, reveals that the U.S. leads the world in many of the diseases of modern life and fails to reach its full health potential. Are we really that ill? Obesity is present in over a third of Americans and has become a more important predictor of chronic ailments and worker quality of life than any other public scourge. The illnesses caused by obesity also lead to the most number of lost workdays of any single ailment and increase pharmaceutical and hospital expenditure to palliate untreatable degenerative ailments. For example, diabetes resulting from obesity has risen by a third since 1990 and the treatment costs $100 billion a year.

Emotional ailments have also increased disproportionately in this country. In Mexico, the rates of anxiety and depression are 3–4 times *lower* than the US. Yet the longer migrants from Mexico live in the US, the closer their levels of anxiety and depression reach those of the majority population. This list of disappointing health failures is long and ponderous.

And the solution is not simply throwing more money at the problem. When measured across the country, expenditures on health and achievement of wellness are not correlated. Individual states are ranked for healthy days/year, medical care expenditures and overall health score in the appendix. The "Possible American" report argues that Health is an economic resource that should be nurtured. Healthy people not only make fewer demands upon the health and social care systems, they are also more productive. In fact, 75% of illness costs to business is lost productivity rather than direct expenditures for health care costs.

So what should we do? First, we need a new understanding of "wellness" based on wider influences on health, including how long the commute to work takes and how often a sick child prevents the parents from functioning fully at work. This definition has to be customized to individual communities since we all have different pain points. The challenge will be to ensure that the opportunity to reach one's potential becomes the birthright of all. This battle has already been engaged by some. After Philadelphia was voted the "fattest city" in America, the city government announced initiatives to help its citizens lose 76 tons in 2001. The effort included appointing a city health "czar", launching school education programs, adding bike lanes and racks, sponsoring monthly walk-to-work days, and increasing access to gyms and sporting-good stores. Philadelphia decided to invest in economic and social prosperity and garnered corporate support from Subway and Time Warner Cable, among others. As a result, the "Fun, Fit, and Free 2000" initiative spurred additional private public partnerships and led Philadelphia to rise 4 spots from the bottom on the obesity charts.

Second, just as holistic medicine has led to empowerment of patients with improved results in health care, we need a more holistic approach to government. The current system encourages a fragmented approach to disease management. Effective health policies require feedback and interaction between the various agencies and levels of government and business. Leaders in charge of health, education, and transportation should have overlapping responsibilities (and budgets) so they are forced to speak with each other. For example we spend most of our health dollars on the elderly and provide inadequate support for the pre-teen age group. We make our society's growth more sustainable by investing wisely in high quality day care and elementary school education, as well as broad parental leave policies. The private sector should lead this effort, as the dividends will accrue preferentially to business over time. At the same time, government sponsored education programs could dramatically impact on future health expenditures, especially if we can successfully address the rapidly increasing childhood obesity epidemic.

Third, Americans are included in policy decisions almost as an afterthought. Yet having autonomy and a sense of control in one's life is important for health, so involving people in the decision making process to create a more responsive political system will in itself improve health. Health care governance has to be locally driven and cannot simply be legislated at the federal level. As health economist Jeff Lemieux from the Progressive Policy Institute reminds us, "Health policy making in Washington is usually about financing and control of health care. It is rarely about health itself." In particular, private public partnerships must be created that are based on collaboration rather than advocacy. Instead of lobbying for government action, business should lead initiatives to improve health and solicit government to partner in the effort. As WEF members George Soros and Aryeh Neier from the Open Society Foundation remark, "With its focus on the social, environmental, and behavioral causes of illness, the "Possible American" effectively demonstrates the way that public and individual responsibility go hand in hand in building a healthy society." Americans cannot abdicate our responsibility to our own wellness.

ABOUT THE REPORT: *Since a country's virtues are often also its vices, the blueprint for building and sustaining healthy societies will vary widely across the globe. This document is one of several created with the Scottish Council Foundation, Columbia University and the World Economic Forum's Global Leaders for Tomorrow that outline specific arguments for a more holistic approach to the private and public sector's approach to health.*

YOGA WORKSHOP

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Yoga has been one of the most commonly used modalities for patients and physicians in the Columbia-Presbyterian Heart Institute. This modality appeals to many healthcare providers and their patients because it is physically demanding yet mandates that the mind be clear and focused on the task of staying calm and breathing deeply. In fact, many of us still take deep breaths prior to difficult or dangerous stitches in the OR.

Many cultures use Yoga for routine medicinal purposes. The Thai believe that the Yoga poses came from animals that naturally seek these positions. Huston Smith, the religious scholar, has argued that these exercises, including Tai Chi, are physical extensions of the spiritual goals of Zen Buddhism. One school believes in reducing the amount of Chi consumed, while the other emphasizes that increasing one's Chi with these frictionless maneuvers can sometimes demand tremendous physical strength.

The class will teach stretching exercises using Yoga maneuvers. This foundation could help you keep limber daily and might interest you in more daring classes. Many find Yoga a transition to meditation, but easier for the Western mind, which has difficulty emptying itself.

NITINOL U-CLIPS IN ROBOTIC ASSISTED MITRAL VALVE REPAIR: A SHEEP MODEL

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PURPOSE: Robotic mitral valve repair using annuloplasty bands has been performed in over fifty patients at our institution. This procedure has been shown to reduce blood transfusions, shorten hospital stay, and hasten return to normal activities. However, the robotic assisted repair also increases cardiopulmonary bypass time and arrested heart time. With an increased risk of stroke, arrhythmia, and other significant morbidities due to longer bypass time, a more efficient suture technique was evaluated to reduce robotic time.

MATERIALS AND METHODS: Suffolk sheep (6 controls and 6 experimental) were used for the trial. The control group had Cosgrove-Edwards annuloplasty bands (Edwards Lifesciences, Irvine, CA, USA) placed using conventional 2-0 Ticron (U.S. Surgical, Norwalk, CT, USA) sutures in a mattress fashion to secure the band along the annulus. The experimental group had Nitinol U-clips (Coalescent Surgical Inc., Sunnyvale, CA, USA) placed in the same mattress fashion to secure the band. Post-operative ECHO was used to assess mitral function and the animal was kept alive for six months before necropsy. Pathologic analysis was performed to assess annuloplasty ingrowth.

RESULTS: Total clip placement time was significantly decreased at 2.6 minutes versus total suture placement time at 4.9 minutes ($p < 0.001$). The main difference in time occurred between clip deployment at 0.75 minutes versus 2.78 minutes for suture tying ($p < 0.000003$). Pathologic review showed no difference in growth patterns at six months while echocardiographic imaging showed zero to minimal mitral valve regurgitation during the same time course.

CONCLUSIONS: With more cardiac procedures progressing to minimally invasive technique, better technology to improve existing and emerging techniques must be found. Nitinol U-clips help to reduce arrested heart time and therefore improve outcomes in turn by decreasing morbidity. Further validating their use, pathologic and echocardiographic analysis showed no difference postrepair between suture and U-clip placement. Nitinol U-clip use is intuitive, easily learned, and effective in securing the annuloplasty band to the mitral annulus.

SELECTIVE INTRINSIC COAGULATION CASCADE INHIBITION FOR CARDIOPULMONARY BYPASS

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Heparin-based cardiopulmonary bypass has been the mainstay of clinical cardiac surgical practice since the origin of the specialty. Its predominant action is the indirect blockage of thrombin generation by the potentiation of the activity of anti-thrombin 3. Protamine reversal allows the eventual achievement of surgical hemostasis.

Thrombin generation, however, occurs as the penultimate component of the final common pathway of the coagulation cascade, and its inhibition is associated with unavoidable hemorrhagic morbidity. We have demonstrated in rodent, canine and primate models that selective inhibition of the intrinsic coagulation cascade can be achieved by blocking Factor IX with a decoy activated-inhibited competitive molecule (IX ai). In canine, primate, and compassionate-use patient settings, we have shown that Factor IXai administration allows maintenance of a patent cardiopulmonary bypass circuit with preservation of extrinsic-limb pathway function, i.e. wound related hemostasis is preserved during and after the conduct of cardiopulmonary bypasss. No reversal of the agent is required.

Commercialization of Factor IXai has been impeded by the high cost of production of this high molecular weight, large complex protein. Advances in medicinal chemistry have allowed the development of a low-molecular weight, highly selective Factor IX antagonist. The safety profile of this orally bioavailable agent compares highly favorably to both heparin and warfarin. Clinical trials of this agent are anticipated to begin in the coming year, and may offer cardiac surgeons an important new tool in coagulation management.

LEFT VENTRICULAR ASSIST DEVICES: EVOLUTION FROM BRIDGE TO TRANSPLANT TO LONG-TERM DESTINATION THERAPY

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We have implanted left ventricular assist devices (LVADs) in 227 patients as bridges to cardiac transplantation over an 11-year period at a single institution. 158 patients (69.6%) survived to cardiac transplantation after implant durations of 4 to 397 days. Increasing experience allowed evolution from primarily in-patient intensive care unit management to prolonged periods of out-of-hospital support. Similar experience at collaborating institutions raised the question of the potential usefulness of wearable LVADs as a long-term destination therapy for end-stage heart disease patients ineligible for cardiac transplantation.

From 1996 to 1998, we randomized 21 patients to receive either LVAD (n = 10) therapy or state-of-the-art optimal medical management (OMM, n = 11) at 7 centers. One-year survival in LVAD patients was 40% compared to 20% in the control group (p = NS) while no device patients survived beyond 21 months. This preliminary experience generated modifications of the device employed (Thoratec VE Heartmate), and refinements of patient management protocols. We therefore initiated a 20-center randomized trial (N = 129) of LVAD versus OMM management with the primary hypothesis that LVAD therapy would reduce all-cause mortality by 33% over a 2-year observation period.

Kaplan-Meier survival analysis showed a 48% reduction in all cause mortality in the LVAD group (RR = 0.52 (0.34-0.78; p = 0.001). The probabilities of one and two-year survival were 52.1% vs. 24.7% (p = 0.002) and 22.9% vs. 8.1% (p = 0.09) in LVAD and OMM patients, respectively. The frequency of serious adverse events was 2.35 (1.86-2.95) times greater in the LVAD group with a predominance of infection, bleeding, and device malfunction. Quality of life, as measured by the SF-36, the Beck depression inventory and NYHA functional classification, was significantly improved in the LVAD group at one year. Cost data will be presented.

This experience illustrates the rapid evolution of LVAD therapy as a highly effective bridge to transplantation and a clearly effective, complicated, and improving approach to long-term definitive management of end stage heart failure.

This abstract reflects a body of investigation of more than 10 years duration of exploratory clinical observation culminating in a rigorous randomized trial of left ventricular assist device therapy. We have reported the bridging experience in previous publications and presentations, yet the complete single center experience reported here has not been presented. The preliminary randomized trial conducted from 1996 to 1998 was presented in 1999 at the American Heart Association Scientific Sessions, but these results have not been published.

The larger randomized trial was presented in November, 2001 at the American Heart Association Scientific Sessions and published simultaneously as an early web-edition release in the *New England Journal of Medicine*. Cost data, which we plan to present, have neither been presented nor published, yet will not be completely acquired for analysis until approximately March 2002. We are confident we will have meaningful cost and cost-effectiveness data to present at the time of the ASA meeting.

3F THERAPEUTICS, INC. AORTIC BIOPROSTHESIS CLINICAL EXPERIENCE AT THE JAGIELLONIAN UNIVERSITY, KRAKOW, POLAND

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PURPOSE: The purpose of this abstract is to present clinical and hemodynamic data for the 3F Therapeutics, Inc. Aortic Bioprosthesis in association with clinical use of the device at the Department of Cardiovascular Surgery and Transplantology, Jagiellonian University, Krakow, Poland.
MATERIALS: The 3F Therapeutics, Inc. Aortic Bioprosthesis is manufactured from three equal sections of equine pericardial tissue. The basal or inflow aspect of the bioprosthesis is fitted with a woven polyester sewing cuff for annular fixation. The outflow aspect contains three integral commissural attachment tabs that are reinforced with a similar material. The overall design of the device results in a tubular structure.
PATIENT POPULATION: A total of 29 patients with a mean age of 51.9 years underwent AVR with the 3F Aortic Bioprosthesis™ from January to September 2002. The predominant aortic valve lesion was stenosis in 23 pts. A total of 6 patients presented with AV insufficiency, 25 with rheumatic (post inflammatory) AV disease, 3 with senile/degenerative disorders and one with congenital valve disease. Postoperatively, patients were followed from one to six months, with echocardiography being performed preoperatively, postoperatively at discharge and at 3-6 months for all patients.
METHODS: Surgical access was facilitated by conventional sternotomy. Cold, crystalloid cardioplegia with antegrade delivery was used in all cases, and no concomitant procedures were performed. Aortic cross-clamp time ranged from 51 to 91 minutes, with a mean of 68.7 minutes. Overall bypass time ranged from 75 to 150 minutes, with a mean of 104.2 minutes. Attachment of the inflow aspect of the bioprosthesis to the native annulus was facilitated with continuous, running sutures. The three, integral commissural tabs of the outflow aspect were attached with individual sutures and reinforced with pledgets on the external surface of the aorta. A total of 2 patients received a 23 mm valve, 5–25 mm, 6–27 mm and 16–29 mm in diameter.
RESULTS: There were no intra-operative complications, structural deterioration or aortic insufficiency leading to reoperation. At the six month follow-up interval, the rate for freedom from perivalvular leak, endocarditis and thromboembotic events for all patients was 100%. Postoperative echocardiography indicated excellent overall hemodynamic performance, with a peak systolic gradient (mean) of 14.7. Mean gradient (mean) was 9.1 at discharge. Two patient deaths observed during the study were not device related. To date, there have been no complications in the surviving patients and no reoperation attributable to valve hemodynamics or bleeding.
CONCLUSIONS: The 3F Aortic Bioprosthesis™ in a small group of patients (29 pts.) and with short term follow-up has demonstrated very good hemodynamic performance and no valve related complications as of the six month follow-up interval. The 3F Aortic Bioprosthesis™ is thin and easy to handle. There are no mechanical components, which make the 3F Aortic Bioprosthesis an excellent alternative to homografts. Early results are encouraging, but further follow-up is needed to determine the long-term durability.

A TOTALLY ENDOSCOPIC TECHNIQUE FOR OFF-PUMP EPICARDIAL ABLATION OF ATRIAL FIBRILLATION ON BEATING-HEART

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INTRODUCTION: We report in this abstract the feasibility of a totally endoscopic technique to treat paroxysmal or chronic atrial fibrillation (AF). A surgical microwave ablation procedure was performed on a 74-year-old

female patient with paroxysmal AF. The patient was symptomatic with episodes of AF approximately every week resulting in dizziness and syncope. Past treatments included multiple drugs including amiodarone and dofetilide, which were unsuccessful. Because the pulmonary veins (PV) are likely the ectopic foci for paroxysmal AF (Haissaguerre et al, 1998), the procedure was performed to isolate them from the left atrium (LA).

METHODS: Three ports were created into the right pleural space (5 mm x2, 10 mm) and four into the left (5 mm x3, 10 mm). After opening the pericardial sac on the right side, the superior and inferior vena cavae were dissected free, as was the inter-atrial groove. A 14 French red rubber catheter was inserted beneath the SVC into the transverse sinus toward the LA appendage. A second catheter was inserted underneath the IVC into the oblique sinus. The distal end of both catheters were retrieved through a left pericardiotomy, tied together and used as a guide for the flexible, unidirectional Flex 10 microwave ablation device (AFx Inc., Fremont, CA). The Flex 10 was passed completely around the four PVs. The location and orientation of Flex 10 was confirmed posterior to the LA appendage by direct inspection. The ablation procedure was performed by sequentially heating adjacent 2-cm ablation sections at 65 watts and 90 sec per lesion until the pulmonary veins were isolated. A total of 8 sections were activated, for an overall ablation time of 12 minutes. The LA appendage was then removed using an EndoGIA stapler (Ethicon, Cornelia, GA, USA). Hemostasis was immediate.

RESULTS: The patient was in normal sinus rhythm after the procedure and was discharged home on postoperative day 2 in sinus rhythm.

CONCLUSION: Totally endoscopic off-pump epicardial AF microwave ablation procedures are safe and technically feasible. This report demonstrates the first step toward performing a completely endoscopic ablation pattern similar to the original maze for patient with chronic AF with the FLEX 10 device.

INDICATIONS AND OUTCOMES OF THE ROSS PROCEDURE

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OBJECTIVES: 1. To review the indications and surgical techniques of the Ross procedure. 2. Review the outcomes, including morbidity and mortality, functional status, and long-term survival following the Ross procedure at the University of Southern California.

OVERVIEW: In the past decade, the pulmonary autograft has emerged as a viable choice for young individuals with aortic root pathology not amenable to repair. This is due in large part to the durability of the pulmonary autograft in the aortic position. Freedom from thrombosis and long-term anticoagulation also provide support for its application. The present indications for the Ross procedure continue to broaden. Patient age is certainly a factor, with the upper limit varying between centers. Patients with active endocarditis may be considered candidates for the procedure. Athletes also are an appropriate subset based on the lack of need for anticoagulation. Contraindications to the Ross procedure include multivessel coronary artery disease as well as multi-valve pathology in which a second valve replacement is required. Severely depressed left ventricular function is also a contradiction.

We reviewed our institutional experience to assess midterm results with the Ross procedure. In a 7-year period, 111 patients with a median age of 15.7 years underwent the Ross procedure. 95 patients had isolated aortic valve disease and 16 pediatric patients had a more complex left ventricular outflow tract obstruction. There were 3 early (2.7%) and 3 late deaths over a median follow-up of 3.6 years (range 6 months to 7.6 years). Actuarial survival at 5 years was 94 ± 2%. In pediatric patients, the pulmonary autograft annulus enlarged from 14.7 ± 6.2 mm to 22 ± 6.3 mm. This growth followed the expected increase in pulmonary valve diameter based on body surface area. Eight reoperations were necessary for autograft insufficiency at a median interval of 14 months (range 2 days to 31 months).

The Ross procedure can be performed with good results in appropriately selected individuals. Growth of the autograft has been appropriate in pediatric patients, but close long-term follow-up is needed as the potential for autograft insufficiency does exist.

REFERENCES

1. Pessotto R, Wells WJ, Baker CJ, Lund C, and Starnes VA. Midterm results of the Ross procedure. Ann Thorac Surg 2001;72(5 Suppl):S336-9
2. Oury JH. Clinical aspsects of the Ross procedure: indications and contraindications. Semin Thorac Cardiovasc Surg 1996;8(4):328-35.
3. Gonzalez-Lavin L, Metras D, Ross DN. Anatomic and physiologic bases for the Ross procedure. J Heart Valve Dis 1996; 5(4):401-3.
4. Oswalt JD. Acceptance and versatility of the Ross procedure. Curr Opin Cardiol 1999;14(2):90-4.

THE FUTURE IS NOW, ROBOTICALLY ASSISTED HEART SURGERY

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A novel technological achievement, computerized telemicromanipulation, or surgical robotics, is expanding minimally invasive surgical capabilities and creating excitement among both surgeons and patients. Robotically assisted surgery is currently under intense investigation and its prospects are potentially limitless.

At the University of Southern California we are currently actively interested in expanding the realm of robotically assisted heart and thoracic procedures. We participated and helped complete the da Vinci mitral repair trial and are active in the ASD and TECAB trials. Other procedures that are amenable are thoracic tumors, left ventricular lead placement and atrial fibrillation ablative procedures. We have performed more than twenty mitral valve repair procedures for myxomatous mitral valve pathology. Repair of this lesion utilizing neo-choradae without leaflet resection is effective, reproducible and amenable to robotic mitral valve repair. Myxomatous posterior leaflet mitral valve prolapse repair was accomplished by the placement of polytetra-fluoro ethelene sutures between the free-edge of the posterior leaflet and papillary muscle and by placement of an annuloplasty ring. No leaflet tissue was resected. This simple repair technique is effective, durable, limits bypass time, and allows conservation of valvular tissue

We envision that robotically assisted surgery may decrease the hospital stay, intensive care stay, and shorten the time before a patient can return to work. This would reduce hospital costs, perioperative complications, and patients may return to normal activity sooner with less pain. Robotically assisted cardiothoracic procedures may allow patients to undergo increasingly complex procedures without the pain and morbidity associated with standard open surgical techniques. The benefits of such an approach are obvious especially since advancing age and multiple co-morbidities are prevalent in our current healthcare patient population.

THE FDA AND CARDIOVASCULAR DEVICES

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The goal of the FDA Cardiovascular Devices Division is to ensure that medical devices approved for marketing are safe and effective. The process of device approval will be discussed, including;

1. What types of products the FDA approves.
2. How the FDA regulates manufacturers, not practitioners.
3. Why device labeling is important.
4. The process for device approval from idea to final approval.
5. The difference between the Pre Market Approval process and the 510K process and the history of device approval.
6. The need for good clinical trial design including the choice of endpoints and the statistical analysis of data.
7. Randomized trials, controlled trials, and Objective Performance Criteria.
8. Who works for the FDA.
9. How the FDA solicits outside advice.
10. The problems with conflict of interest among advocates for devices.
11. Hints for working most productively with the FDA.
12. How the FDA works with CMS and NIH.

The use of the mechanical valves over the past ten years has decreased significantly. In our Institution the use of mechanical valves for aortic valve replacement has gone from 50% 10 years ago to 15% while the use of biological prosthesis has increased accordingly from 45% to 85%. In mitral position the use of the mechanical valve has dropped from 55% to 18%, the use of biological prosthesis has slightly increased from 15% to 22% and obviously mitral valve repair have significantly increased from 25% to over 60% of all mitral valve surgery. This trend seems to be common to many other institutions around the country. I will present data that will help to answer the question if this trend if justified or not. I will refer to the only 2 randomized trials that have been done on mechanical and biological prosthesis and I will also refer to the present American College of Cardiology and American Heart Association prosthetic heart selection guidelines. I will also mention our personal experience.

The factors that influence valve section are the thromboembolic rate, the risk of bleeding, the incidence of re-operation and the survival, and finally the guidelines of the American Heart Association. There are two randomized trials that have been performed and the results of which have been published in the past ten years. One is the VA trial, the results of which were published in 2000 and the other one is the Edinburgh trial which was published in the New England Journal of Medicine in 1991. If we look at the thrombenbolic rate, the VA trial shows that there was no difference between the mechanical and the tissue valve both in aortic and mitral valve position. For the aortic valve, the freedom from thromboembolism was 75% at 15 years and 80% for mitral valve. In the Edinburgh trial it was 80% for aortic valve and 70% for mitral valve. The Edinburgh trial showed exactly the same results with the only difference that in the aortic position in the tissue valve seems to have a higher thrombenbolic rate. In our institution at 15 years there was no difference in thromboembolic rate between mechanical and the biological prosthesis, the freedom being 75% for the aortic valve and exactly the same for the mitral valve. So there was no difference in overall embolism rating between tissue and mechanical valve. An analysis of the risk factors thromboembolism after aortic valve replacement showed that the embolism was strongly rated to age, presence of coronary artery disease and diabetes. Patients with coronary artery disease have a higher thromboembolic rate, indicating that the thromboembolism in these patients may not only be related to the aortic valve but in fact to other sources. In the VA trail the freedom from hemorrhage was better for the biological prosthesis in aortic position, being 80% at 15 years versus 60% at 15 years The Edinburgh trial showed that the freedom from hemorrhage was better for biological prosthesis in aortic position while there was no difference in mitral position. Our Cedars-Sinai experience showed that in aortic position the freedom from hemorrhage was 92% for biological prosthesis in aortic positions versus 85% for mechanical prosthesis and this was statistically significant while there was no difference for mitral valve prosthesis.

In summary, in aortic position the bleeding rates are higher in mechanical valves, in mitral valve position there is no significant difference. The other factor that influences the choice of valve selection is the re-operation rate. And we all know that the biological prostheses have an intrinsic re-operation rate. In our institution, in 15 years the freedom from re-operation for aortic valve was 67% and for mitral valve was 52% for biological prosthesis, the mechanical prosthesis had an excellent freedom for re-operation; in aortic position was 99%. Mitral position was 93%. There is an intrinsic risk of dying from re-operation. A recent report by Blackstone and Pluth shows that the overall mortally for the re-operation on over 2200 patients was 10% and this re-operation risk increased significantly with the patient's age, going from 11% between age 60-70 to 17% over age 70. So, if we match the life expectancy of the patient with the valve survival we know by statistics that median survival for a patient aged 65 is 18 years and for mitral valve is 15 years. Now if 18 years is the median survival in patients age 65 and 15 years is the median survival in patients age 69, this will suggest that the cutoff for mitral valve should be 70 and for the aortic valve should be 65. These randomized trials of the VA study and the Edinburgh study showed that the survival is really the same between tissue and mechanical prosthesis and that the only difference is increased bleeding episodes in patients who have a mechanical aortic valve, but in mitral position the difference is not significant at all.

In conclusion, our personal experience based on this data and our significant trend over biological prosthesis may not be completely justified and maybe a more balanced approach should be used especially if we consider the significant risk of re-operation.

ATRIAL FIBRILLATION SURGERY USING LINEAR LASER TECHNOLOGY

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BACKGROUND: Currently there are multiple energy sources used to create atrial lesions in the treatment of atrial fibrillation. Here we present a new and innovative method of surgically isolating the pulmonary veins utilizing laser technology. The Optimaze Surgical Ablation System has been shown to be a rapid, safe and effective method of creating atrial lesions in animal models. This device is now in early clinical trials, and our experience thus far is described below.

METHODS: The Optimaze Surgical Ablation System was used to create lesions around the base of the pulmonary veins and left atrial appendage (LAA). In addition, two connecting lesions were created from the pulmonary veins to the base of the LAA and another to the annulus of the mitral valve. Laser energy was delivered via a 5 cm probe at 5 Watts/cm for 36 seconds.

RESULTS: At our center 6 of 6 patients are in sinus rhythm after 3 months. There were no complications directly associated with the Optimaze Surgical Ablation System.

CONCLUSION: Using laser energy to create linear atrial lesions appears to be effective and safe in the early clinical experience. The device is easy to use and creates lesions in only 36 seconds. Based on these early findings further use of the device appears warranted.

OFF-PUMP EPICARDIAL ATRIAL FIBRILLATION SURGERY UTILIZING A NOVEL BIPOLAR RADIOFREQUENCY SYSTEM

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BACKGROUND: The current standard for surgical treatment of atrial fibrillation involves endocardial ablation with cardiopulmonary bypass and atriotomy. This study was undertaken to evaluate a novel radiofrequency (RF)-enabled clamp system designed to create transmural lesions on the beating heart epicardially using bipolar RF.

METHODS: A set of differently shaped clamps modified to deliver bipolar RF energy were used to create a series of lesions in a beating heart canine model. The pulmonary veins and atrial appendages of six dogs were electrically isolated using bipolar RF energy. The right and left atrial appendages served as controls for the right and left pulmonary veins, respectively. Temperature controlled RF energy was delivered to maintain a tissue temperature of 80°C for 15 seconds. Electrical isolation was assessed acutely and after 4 weeks by a bipolar pacing protocol.

RESULTS: A total of 24 circumferential lesions were created. By pacing analysis, 100% of these lesions were electrically isolated acutely and 95% four weeks later. At four weeks, 92% of lesions were transmural by histologic analysis, and 96% demonstrated endocardial continuity.

CONCLUSION: Bipolar radiofrequency ablation utilizing a novel bipolar RF clamp device results in electrical isolation and histologic transmurality in an off-pump epicardial model.

CELLULAR APPROACHES TO PREVENTING HEART FAILURE

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Cell transplantation has recently come of age and offers the promise to restore cardiac function despite extensive myocardial damage.[1] Professor Menasche in Paris recently completed the evaluation of ten patients in a Phase I trial of skeletal myoblast transplantation after an extensive myocardial infarction.[2] The results are very encouraging. All of the patients showed symptomatic improvement with evidence of increased perfusion and return of function to the infarct region. However, myoblast transplantation was performed as an adjunct to coronary bypass grafting, and therefore the effects of cell transplantation cannot be differentiated from the effects of coronary bypass grafting. Four of the ten patients developed postoperative arrhythmias necessitating aggressive antiarrhythmic therapy. Muscle cell transplantation has been beneficial in a large number of preclinical animal studies.[3–7] Bone marrow derived mesenchymal stem cells offer another alternative to restore cardiac function after a myocardial infarction.[8–10] These adult stem cells can develop into cardiomyocytes and can participate in the formation of new blood vessels and the supporting cells required for cardiac regeneration. Clinical trials of mesenchymal stem cells are being performed. A direct comparison between muscle cells and adult stem cells will be required to determine the optimal cell source for cardiac restoration.

Cell transplantation has also been effective in preventing thinning and dilatation in animal models of a dilated cardiomyopathy.[11–12] Cells transplanted into the anterior left ventricular myocardium engrafted, induced

angiogenesis and directed the remodeling of the extracellular matrix. In addition to the local effects of the engrafted cells, matrix remodeling of the remote myocardium was also noted. The profound effect of cell transplantation on remodeling suggests that this treatment may be beneficial for patients who have a dilated cardiomyopathy. Cell transplantation may become an adjunct to surgical remodeling or left ventricular assist devices to prevent remodeling and ensure persistent improvement in cardiac function.

Gene therapy is under extensive evaluation to induce angiogenesis in patients with diffuse coronary disease who are not candidates for traditional methods of revascularization.[11–17] Cell therapy, either alone[18] or cells enhanced with angiogenic genes,[19] offers an attractive alternative for these patients.

Patients with congenital heart defects frequently require graft material for cardiac reconstruction. The graft materials currently available lack growth potential, are non-contractile and are thrombogenic. We have created a cell-seeded, biodegradable polymer scaffold and have evaluated its function in vitro and in vivo.[20–21] We were able to generate a tissue-engineered cardiac graft from autologous cells which survived in the right ventricular outflow tract of animals after the scaffolding dissolved. Bioengineered cardiac grafts have the potential to repair congenital heart defects and permit regeneration of the heart for these patients.

In conclusion, cell transplantation has come of age. The clinical trials currently being conducted are promising and offer the hope that the heart can be restored after an extensive myocardial infarction. In addition, cell transplantation has been employed successfully in models of dilated cardiomyopathy and to induce angiogenesis. Bioengineered cardiac grafts may restore cardiac function to infants with congenital heart defects. Cell transplantation may restore the heart by inducing cardiac regeneration.

REFERENCES

1. Weisel RD, Li R-K, Mickle DAG, Yau TM. Cell transplantation comes of age. J Thorac Cardiovasc Surg 2001;121:835-836.
2. Menasche P, Hagege AA, Scorsin M, Pouzet B, Desnos M, Duboc D. Myoblast transplantation for heart failure. Lancet 2001;357:279-280.
3. Li R-K, Jia Z-Q, Weisel RD, Mickle DAG, Zhang J, Mohabeer MK, Rao V, Ivanov J. Cardiomyocyte transplantation improves heart function. Ann Thorac Surg 1996;62:654-661.
4. Li R-K, Mickle DAG, Weisel RD, Mohabeer M, Zhang J, Rao V, Merante F, Jia Z-Q. Natural history of fetal rat cardiomyocytes transplanted into adult rat myocardial scar tissue. Circulation 1997;96(Suppl II):179-187.
5. Li R-K, Weisel RD, Mickle DAG, Jia Z-Q, Kim E-J, Sakai T, Tomita S, Schwartz L, Iwanochko M, Husain M, Cusimano RJ, Burns RJ, Yau TM. Autologous porcine heart cell transplantation improved heart function after a myocardial infarction. J Thorac Cardiovasc Surg 2000;119:62-68.
6. Li R-K, Jia Z-Q, Weisel RD, Merante F, Mickle DAG. Smooth muscle cell transplantation into myocardial scar tissue improves heart function. J Mol Cell Cardiol 1999;31:513-522.
7. Taylor DA, Atkins BZ, Hungspreugs P, Jones TR, Reedy MC, Hutcheson KA. Regenerating functional myocardium: improved performance after skeletal myoblast transplantation. Nat Med 1998;4:929-933.
8. Wang J-S, Shum-Tim D, Galipeau J, Chedrawy E, Eliopoulos N, Chiu RC. Marrow stromal cells for cellular cardiomyoplasty: feasibility and potential clinical advantages. Ann Thorac Surg 2000;120:999-1006.
9. Tomita S, Li R-K, Weisel RD, Mickle DAG, Kim E-J, Sakai T, Jia Z-Q. Autologous transplantation of bone marrow cells improves damaged heart function. Circulation 1999;100(Suppl II):247-256.
10. Tomita S, Li R-K, Weisel RD, Mickle DAG, Jia Z-Q. Bone marrow cells transplanted into a porcine infarct region induced angiogenesis and improved heart function. Circulation 2000;102(Suppl II):650.
11. Yoo K-J, Li R-K, Weisel RD, Mickle DAG, Li GM, Yau TM. Autologous smooth muscle cell transplantation improved heart function in cardiomyopathy. Ann Thorac Surg 2000;70:859-865.
12. Yoo K-J, Li R-K, Weisel RD, Mickle DAG, Jia Z-Q, Kim E-J, Tomita S, Yau TM. Heart cell transplantation improves heart function in dilated cardiomyopathic hamsters. Circulation 2000;102(Suppl III):204-209.
13. Laham RJ, Selke FW, Edelman ER, Pearlman JD, Ware JA, Brown DL, Gold JP, Simons M. Local perivascular delivery of basic fibroblast growth factor in patients undergoing coronary bypass surgery: results of a phase I randomized, double-blind, placebo-controlled trial. Circulation 1999;100:1865-1871.
14. Sellke FW, Laham RJ, Reul M, Post MJ, Ware AJ. Long-term effectfs of angiogenic therapy with bFGF protein. AATS 81st Annual Meeting, 2001.
15. Symes JF, Losordo DW, Vale PR, Lathi KG, Esakof DD, Mayskiy M, Isner JM. Gene therapy with vascular endothelial growth factor for inoperable coronary artery disease. Ann Thorac Surg 1999;68:830-836.
16. Rosengart TK, Lee LY, Patel SR, Sanborn TA, Parikh M, Bergman GW, Hachamovitch R, Szulc M, Kligfield PD, Okin PM, Hahn RT, Devereaux RB, Post MR, Hackett NR, Foster T, Grasso TM, Lesser ML, Isom OW, Crystal RG. Angiogenesis gene therapy: phase I assessment of direct intramyocardial administration of an adenovirus vector expressing VEGF121 cDNA to individuals with clinically significant severe coronary artery disease. Circulation 1999;100:468-474.
17. Kalka C, Tehrani H, Laudenberg B, Vale PR, Isner JM, Asahara T, Symes JF. VEGF gene transfer mobilizes endothelial progenitor cells in patients with inoperable coronary artery disease. Ann Thorac Surg 2000;70:824-834.
18. Kim E-J, Li R-K, Weisel RD, Mickle DAG, Jia Z-Q, Choi A, Tomita S, Sakai T, Yau TM. Angiogenesis by endothelial cell transplantation. J Thorac Cardiovasc Surg 2001;122:963-971.
19. Yau TM, Fung K, Weisel RD, Fujii T, Mickle DAG, Li R-K. Enhanced myocardial angiogenesis by gene transfer using transplanted cells. Circulation 2001;104(Suppl I):218-222.
20. Li R-K, Yau TM, Weisel RD, Mickle DAG, Sakai T, Choi A, Jia Z-Q. Construction of a bioengineered graft. J Thorac Cardiovasc Surg 2000;119:368-375.
21. Sakai T, Li R-K, Weisel RD, Mickle DAG, Kim ETJ, Jia Z-Q, Yau TM. The fate of a tissue-engineered cardiac graft in the right ventricular outflow tract of the rat. J Thorac Cardiovasc Surg 2001;121:932-942.

HOW TO OBTAIN GRANT FUNDING AS AN ACADEMIC SURGEON

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To obtain funding for academic pursuits requires preparation, preliminary data, assistance and support.

PREPARATION: Most cardiac surgical training programs in North America provide excellent training to perform most cardiac surgical procedures. A few programs excel at developing the academic skills necessary to compete in obtaining peer-reviewed funding. The surgeon is ideally suited to translational research. He can develop the skills required to compete with basic scientists and he maintains a close affiliation with clinical medicine. This relation is unique and offers an opportunity for academic development which is appreciated by both basic scientists and clinicians.

The field of study for the academic cardiac surgeon is extensive. He can participate in molecular biology, physiology, pharmacology, clinical epidemiology and health services. However, in each of these areas, he requires the active collaboration of basic scientists who devote their entire career to one aspect of this endeavour. The surgeon can develop the knowledge base required to compete and the ability to coordinate the activities of a large number of specialists. The skills required are usually developed during residency. At the University of Toronto, our residents usually spend three years in obtaining a PhD degree from the University and our training program is intended to develop academic cardiac surgeons.

PRELIMINARY DATA: After appointment to the staff, the academic cardiac surgeon initiates his training program. He must learn to combine academic pursuits with the rigors of clinical practice. It is during this formative stage that he will develop preliminary data required for his grant application. He must first forge alliances with basic scientists in either molecular or laboratory investigations or in clinical assessments. Developing preliminary data will establish the feasibility of these collaborations and the surgeon's ability to coordinate the team.

PERSISTENCE AND SUPPORT: The major attribute which will permit the successful career in academic surgery is persistence. Frequently, the surgeon will develop an excellent hypothesis, but will find significant barriers to completion of the research project. The surgeon must be resourceful and find alternative avenues of approach, consistently focusing on the clinical problem he hopes to solve. The essence of the academic cardiac surgeon is persistence.

In order to be successful, the academic cardiac surgeon must have the support of his group, his institution and his university, usually in that order. Although he requires financial support to initiate his preliminary studies, finances are seldom the major impediment to the development of an academic cardiac surgeon. Instead, the support he requires is the freedom to complete his investigations without sacrificing his ability to maintain his sta-

tus as a competent clinical cardiac surgeon. The major support he requires is a sufficient number of patients and dedicated operating time to maintain his clinical development in addition to the availability of personnel for his academic development. His dedicated time in the operating room is required rather than the availability of resources in the laboratory.

SUMMARY: In summary, successful grant applications require adequate preparation and preliminary data, but mostly the support of the cardiac surgical group, the institution and the university. However, most important for development is persistence.

THE APPLICATION OF EXPANDABLE MATERIALS IN THE DESIGN OF CARDIAC CANNULA.

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BACKGROUND: The availability of self-expandable materials offers the potential for new cardiac cannula designs. The flow characteristics of a funneled cannula tip and an expandable cannula body design were investigated.

MATERIALS AND METHODS: The distal tip of a 24 F straight aortic perfusion tip was replaced with a funneled tip of identical proximal inner diameter and length. The distal segment of a 16 F peripheral arterial cannula was replaced with a segment of self-expandable material. The pressure loss across each modified cannula was determined for a range of flows and compared to their counterpart controls. An internal jugular venous cannula modified with a distal segment of stent material was inserted into a canine to provide venous drainage during a bypass procedure.

RESULTS: Both the modified funneled tip cannula and the expandable body cannula exhibited a low resistance, comparable to standard cannula with larger insertional diameters. The modified internal jugular venous cannula maintained excellent venous return and appeared to stent open the superior vena cava.

CONCLUSIONS: The application of expandable materials in cardiac cannula construction broadens the design options for cardiac cannula. This may lead to an expansion in the role of percutaneus cannulation in traditional and minimally invasive cardiac surgery.

A SIMPLIFIED ENDOSCOPIC LENS CLEANING INSTRUMENT

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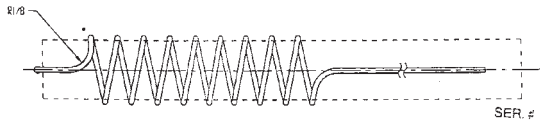
BACKGROUND: Fogging or the accumulation of tissue and body fluids on the endoscope lens interferes with maintaining a clear visual field during endoscopic surgery. Construction of a simplified device to channel cleaning fluid across the lens is attempted.

MATERIAL AND METHODS: A 18" length of stainless steel hypodermic needle tubing was bent to form a series of coils to surround the endoscope (Figure). The distal 2 mm of the tubing was bent at approximately a 90 degree angle and the proximal end was attached by small flexible tubing to a 30 cc syringe. Excess cleaning fluid on the lens was eliminated by drawing back on the syringe plunger.



RESULTS: The simplified design served to accurately align the device on the end of the endoscope and traverse a stream of cleaning solution across the lens surface. Accumulation of the washing fluid on the lens was overcome by back-pressure on the syringe.

CONCLUSIONS: The device was easily positioned and secured on the endoscope. It accurately directed cleaning fluid across the lens and allowed excess fluid to be drawn back from the lens. The simplicity of this design may eliminate sterilization issues since it could be manufactured as a disposable device for single patient use.

COUNCIL ON PRIVATE SECTOR INITIATIVES (CPSI) TO IMPROVE THE SECURITY, SAFETY, AND QUALITY OF HEALTH CARE

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The ability of the private sector to respond creatively to health security challenges confronting the nation has become even more apparent in the aftermath of the events of September 11. The Department of Health and Human Services is receiving a number requests from individuals and firms seeking our review of their ideas for improving the security, safety, and quality of our health care delivery system. The Department needs to foster this creativity by ensuring that we respond systematically and consistently to these requests and provide constructive feedback as appropriate. To facilitate this, Secretary Tommy Thompson established the Council on Private Sector Initiatives to Improve the Security, Safety, and Quality of Health Care (CPSI). This Council will ensure that our focus on public health preparedness is complemented by careful attention to the preparedness of our health care delivery system. This Council will also enhance our responsiveness to innovation by providing the private sector with a single point of contact at the Department.

The objectives of CPSI are as follows:

1. Provide the private sector with a single U.S. Department of Health and Human Services (HHS) point of contact for innovative ideas that cut across agencies and departments.
2. Coordinate requests from individuals and firms seeking HHS review of their ideas.
3. Ensure that HHS responds systematically and consistently to these requests.
4. Report to the Secretary on the Council's activities and actions resulting from them.

The Council consists of the Heads, or their designees, of the Center for Disease Control and Prevention, the Food and Drug Administration, the National Institutes of Health, and the Centers for Medicare and Medicaid Services, as well as the Assistant Secretary for Health, the Assistant Secretary for Planning and Evaluation, and the Director of the Office of Public Health Preparedness. To ensure appropriate coordination with other relevant Federal Departments, there is also representation from the Departments of Defense, Veterans Affairs, Energy, and the Office of Homeland Security.

The Council will refer those requests that fall within the jurisdiction of a single agency. It also will establish procedures to ensure the prompt review and follow-up of requests that involve multiple agencies or those in which agency responsibility is unclear.

We have established a Web site—www.cpsi.ahrq.gov—that gives companies and individuals instructions on how to submit a request as well as provide access to the contact persons within the Council who can provide further information.

EVALUATING TECHNOLOGIES: UNDERSTANDING COVERAGE, CODING, AND PAYMENT

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In order to effectively evaluate medical technologies, it is critical to understand coverage, coding and payment policies. The lifecycle of medical devices is particularly short; in order to maximize a product's utility, one needs to understand numerous processes of federal, state, and private payers of health care services. Coverage relates to a determination of the clinical effectiveness of a technology. This is typically based upon several, peer-reviewed and published studies that show statistical improvements in clinical outcomes. Coding relates to the assignment of identifiers to procedures, drugs and devices in order to submit claims to insurers. There are HCPCS, CPT, and ICD-9 codes—all within different deadlines and procedures. Coverage and coding are separate processes; coding does not imply coverage, although coverage results in codes. Payment relates to the valuation of these various codes. There are different payment policies—the most common for physicians' services is the one determined by Medicare, which is known as the Resource-Based Relative Value Scale. Most payment policies are prospective in nature.

In any evaluation, the following areas must be considered:

- Status of FDA activity (PMA vs. 510k)
- Choice of clinical data (e.g. appropriate outcome measures for payers)
- Point of service (inpatient vs. outpatient)
- Status of coding

Understanding these areas will allow one to make informed technology evaluations.