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Cerebral Circulatory Support During Low Flow Cerebral Perfusion: A Retrospective Review in a Pediatric Hospital

Background: The development of continuous regional cerebral circulation (RCP) during periods of whole body circulatory arrest, allow for selective blood flow to the cerebral circulation during neonatal aortic arch reconstruction. The Somanetics noninvasive INVOS Cerebral Oximeter (Somanetics, Inc. Troy, MI), detects the variation between the total light signal emitted by the device and the light absorbed by extra cranial tissue through a distal electrode over the forehead. Conclusions about the average oxygenation can be derived from the spectral absorption at two wavelengths (730 and 810 nm). These measurements reflect the changes in regional hemoglobin oxygen saturation (rSO₂ index) in cerebral circulation. The assessment and guidance of cerebral perfusion and oxygenation with arch reconstruction using the Near-infrared Spectroscopy (NIRS) during continuous regional cerebral perfusion is starting to emerge.

Methods: A retrospective chart review and data analysis was performed on patients who underwent regional cerebral perfusion for aortic arch reconstruction. The NIRS data was used to identify specific anatomic, hemodynamic, and perfusion variables that contributed to an improvement or a decline in peripheral oxygenation during regional cerebral perfusion.

Results: The study subject's average weight was (3.15 ± 0.53) kg and height (50.23 ± 2.5) cm. The average bypass time was 157.9 minutes with an average cross clamp time of 35.6 minutes. The RCP times were 47.63 ± 14.6 minutes and the circulatory arrest times were 6 minutes or less. Perfusion flow rates during RCP were initiated at (0.10 ± 0.03) L/kg/min. and increased to a maximum of (0.195 ± 0.06) L/kg/min. The mean perfusion pressure was (28.63 ± 12.83) mmHg and the mean hematocrit was (28.38 ± 3.89) percent. The subjects were cooled to a nasopharyngeal mean temperature of (18.25 ± 0.34) °C during RCP. The left and right NIRS values maintained a strong correlation during CPB. The right thigh NIRS values indicated little or no correlation with the left or right NIRS values during RCP.

Conclusions: We theorize that continuous regional perfusion is a source of significant peripheral somatic blood flow through collateral circulation during deep hypothermic circulatory arrest. Regional Cerebral perfusion, as indicated by the right thigh NIRS values, provided little or no somatic flow via collaterals.

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A Simple Anticoagulation Sensitivity Test for Heparin Resistance During Cardiopulmonary Bypass

Purpose: Anti-coagulation for the open-heart surgery patient undergoing cardiopulmonary bypass (CPB) is achieved with the use of heparin. To measure the effect of heparin, the activated clotting time (ACT) test is performed. The commonly acceptable target time of anticoagulation adequacy is 480 seconds or greater. Some patients however, exhibit resistance to standard dosing of heparin and do not reach target anticoagulation time (480 seconds). Antithrombin III deficiency has been previously cited as the cause of heparin resistance. Early detection of heparin resistance may avoid both the delayed start of CPB and inadequate anticoagulation, if emergency bypass is required.

Methods: We developed an anticoagulation sensitivity test (AST) was by adding 12 units of porcine mucosa heparin to standard celite ACT tube (International Technidyne). Prior to anticoagulation, four milliliters of blood were drawn from the patient arterial line. As per manufacturer instruction, two milliliters of blood were added to each tube (ACT-baseline and ACT-AST). In the ACT-AST tube however, 12 units of porcine mucosa heparin were also added. Later in the procedure, three minutes after anticoagulation with 4 mg heparin/kilogram body weight, a second sample (ACT-CPB) was taken to determine anticoagulation adequacy. The ACT times of each sample were recorded for three hundred procedures occurring during the year 2004 and retrospectively reviewed.

Results: Heparin resistance occurred in approximately twenty percent of the patients ($n = 61$). In fifty-four patients, heparin resistance was predicted by the ACT-AST. This was determined by the presence of an ACT-AST time and an ACT-CPB which were both lower than 480 seconds. The false-negative rate was 5%.

Conclusions: Heparin resistance occurs in patients undergoing CPB. We describe a simple and reliable test to avoid the delays of assessing anticoagulation for CPB (90% reliability). Depending on program guidelines, patients can be given additional heparin or Antithrombin III derivatives to aid in anticoagulation. An additional ACT must be performed and reach target times prior to CPB initiation. Testing of patient's blood prior to the time of incision for sensitivity to heparin is a way to avoid a delay that can be critical in the care of the patient. Commercial tests are available, but efficacy data is limited and they lead to added inventory expense. This method of titrating a diluted Heparin additive, mixed with patient's blood in a familiar ACT test, has proven to be an inexpensive and reliable test to predict patient's sensitivity to heparin.

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Clinical Evaluation of the Capiox RX 15 Hollow Fiber Oxygenator

With the current trend in open heart surgery toward smaller prime and lower surface area circuits, greater demand is being placed on the perfusionist to select an oxygenator that will perform safely and efficiently under a wide range of patient and blood flow ranges and yet still able to maintain a small prime volume. A newly developed pediatric and small adult oxygenator with the X Coating™, Terumo's biocompatible, hydrophilic polymer surface coating that reduces platelet adhesion and protein denaturation has recently been introduced to the market. The Terumo Capiox RX 15 oxygenator has a blood flow range of 0.5–4 or 5 l/min, dependent upon the reservoir being used and a low static priming volume of 135 mL. The present study tests this oxygenator for gas transfer, blood path resistance, and blood handling characteristics in a standardized setting during clinical application and compares this data to our current standard of the Sorin Lilliput II oxygenator and the Cobe Optamin Oxygenator over this range of patients. The device was evaluated for pressure drop through the oxygenator as well as pre and post pO₂ and CO₂ exchange capability, and by calculating shunt fraction and diffusing capacity during the cooling and rewarming periods of bypass. Blood trauma was evaluated for by increase in lactate dehydrogenase (LDH) levels and visual inspection of free hemoglobin in the effluent of the hemofiltration device as well as postoperatively in urin hemoglobin sedimentation. Heat exchange coefficients were also calculated during the cooling and warming period and compared to our current standard oxygenators. The Capiox RX 15 offers good gas exchange capabilities across a wide range of blood flows and patient size, a low pressure drop, and low blood flow trauma during normal cardiopulmonary bypass parameters.

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Factors Which Influence the Effectiveness of Autologous Priming

Purpose: The purpose of this study was to determine which factors impact the ability to perform autologous priming (AP) of the extracorporeal circuit. Second, the effects of AP on transfusion requirements were evaluated.

Methods: After IRB approval, a retrospective review of all adult cardiopulmonary bypass (CPB) patients between January 1, 2005 and October 30, 2005 ($n = 174$) was conducted from prospective internal database. Patients were assigned to five groups based on standard distribution of AP: AP_A: 0 mL, AP_B: 0–499 mL, AP_C: 500–700 mL, AP_D: 701–1000 mL, and AP_E: >1000 mL.

Results: Of the 55 recorded variables, 21 did not significantly impact the AP, including pre CPB hematocrit and volume balance. AP was more effective with mitral valve surgery and low autotransfusion requirements. When more AP was taken, less non-prime volume was given during CPB (AP_A = 1463 ± 1340, AP_B = 945 ± 550 mL, AP_C = 623 ± 537 mL, AP_D = 609 ± 477 mL, AP_E = 556 ± 550, $p < 0.05$), and fewer patients received red blood cell transfusions (AP_A = 40.5%, AP_B = 29.2%, AP_C = 26.9%, AP_D = 20.8%, AP_E = 19.1%, $p < 0.05$) to maintain similar CPB Hct's (AP_A = 25 ± 4%, AP_B = 25 ± 4%, AP_C = 25 ± 4%, AP_D = 26 ± 4, AP_E = 26 ± 3, $p = NS$).

Conclusions: More volume is given during CPB when less AP it taken, even when prime volumes are excluded. When AP is used effectively, fewer patients require transfusion to maintain the desired hematocrit.

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In-vitro Evaluation of the Air Separation Ability of Four Cardiovascular Manufacturer Extracorporeal Circuit Designs

Purpose: Neurologic injury is a common complication of cardiac surgery. There is evidence that cerebral microemboli during cardiopulmonary bypass are the principal cause of cognitive deficits after coronary artery bypass grafting. Recent studies have demonstrated the majority of cerebral emboli occur during "perfusionist interventions" (i.e., drawing blood samples and administering drugs via the sampling manifold) and these microemboli consists mostly of air. Furthermore, an increase in perfusionist interventions is associated with increased postoperative cognitive impairment. Fresenius Medical Care Extracorporeal Alliance (FMCEA) and The Ohio State University (OSU) have collaborated to conduct an exhaustive study of the GME separating ability of various extracorporeal circuits (ECC). We investigated whether there are differences in the air separation ability of four manufacturer's ECCs most commonly used by FMCEA clinicians at their facilities across the United States.

Method: An in vitro circuit was designed to produce gaseous microemboli (GME) to simulate relevant clinical scenarios to test complete ECC circuits. A uniform distribution of GME was introduced into the tested ECCs under controlled flow, temperature, line pressure and simulated blood conditions so that the air-separating ability was measured over a range of GME from 0–150 microns. Continuous venous air and boli of air were introduced into ECCs and output GME patterns by size, time

and count were measured, plotted and statistically compared. Complete ECCs with combinations of centrifugal and roller pumps, from Sorin Biomedica, Terumo Cardiovascular, Gish Biomedical and Medtronic were studied.

Results: Statistical analysis of device performance was used to rank the ECCs. 3-D graphic representations depicting elapsed time, GME size, and bubble count helped to visually rank the air-handling performance of the ECCs. **Conclusions.** There are substantial and significant air-handling differences between the ECCs from the four different manufacturers. The results from this work allows for additional and objective characterization of ECCs. This additional information provides an opportunity for clinicians to potentially minimize the risks of arterial air embolization and its associated deleterious neurologic effects while allowing clinicians to make better-informed consumer decisions.

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Clinical Pharmacology Reference Website for Perfusion Education Students

Purpose: Recent perfusion graduates typically have difficulty with the pharmacology sections of the American Board of Cardiovascular Perfusion exams. Clinical preceptors have noted that students lack the general knowledge of pharmacology required during their clinical rotations. The purpose of this project is to develop a pharmacology reference website for perfusion students to reinforce the particular body of knowledge and competencies associated with pharmacology for extracorporeal circulation.

Methods: A list of drug categories was compiled based on suggestions from perfusion education clinical preceptors. The OSU Circulation Technology (CT) Class of 2006 authored several drug pages based on a master list. Each drug page contains the chemical name, generic name, site of action, mechanism of action, indications, contraindications, dosages, how it is supplied, patient chart abbreviations, methods of elimination, and perfusion citations for the use of the drug. We used Microsoft Word® and FrontPage® to design the web layout.

Results: The website features most major categories of drugs that perfusionists encounter, with links to specific drug pages created by the CT Class of 2006. The website is found at www.circtech.org/. The pharmacology site employs the power of the Internet to associate educational sites and evidence posted at .com or .org sites.

Conclusions: The authors hypothesize that perfusion student use of the pages will increase the comprehension and understanding of the care of a cardiac patient supported with ECC. We believe this webpage will aid in the improvement of graduates' scores in the pharmacology sections of the American Board exams. The site also provides a quick reference for perfusion students while at distant clinical rotations.

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Gaseous Microemboli Separation, Management and Elimination by the Arterial Line Filter

Background: It is well documented that cardiopulmonary bypass (CPB) is associated with perioperative cognitive dysfunction. Although most probably multifactorial, one of the chief concerns regarding this cognitive decline is gaseous microembolism (GME). Current studies indicate a great degree of performance variability among arterial line filters (ALF) ability to separate GME. The aim of our study was to quantitatively rank and compare 9 currently available ALFs as determined by their air separating performance, thus establishing an objective performance profile of the devices.

Methods: Following FDA guidance documents for ALF submissions, an in vitro test circuit was constructed. The test circuit apparatus was maintained under controlled flow, temperature, line pressure and simulated blood conditions. ALFs were challenged by both a continuous GME distribution and a 50 cc room air bolus. Air-separating ability was measured over a range of GME from 0–120 microns. Each of the 9 filters was subjected to 3 trials and GME management was assessed by Embolus Detection and Classification (EDAC) system.

Results: Statistical analysis of device performance was used to rank the ALFs. Each ALF was ranked on their ability to separate air in both a continuous GME and bolus challenge. Graphical representations depict elapsed time, GME size, and bubble count.

Conclusion: The ALF is the last line of defense in the extracorporeal circuit. There is significant variation among device performance. The work represented here allows clinicians to make better-informed and objective consumer decisions about ALFs. The goal is to minimize arterial air embolization and its associated detrimental sequelae.

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Predicting Baseline Cerebral Tissue Hemoglobin Oxygen Saturation (SrO₂) in Pediatric Congenital Cardiac Surgery Patients

Objectives: Pediatric cardiac surgery with cardiopulmonary bypass (CPB) has been acknowledged to potentially cause brain damage during periods of decreased prolonged cerebral SrO₂ levels. If the cerebral oxygen level monitoring is to be useful, it will be useful to predict the expected baseline SrO₂ for a specific pediatric patient. We hypothesized that there is a predictive relationship between the baseline SrO₂ and a specific patient's age, weight, gender, Aristotle Score, first arterial blood pO₂ (PaO₂), and/or the type of cardiac defect.

Methods: After obtaining IRB approval, the recorded SrO₂ values from the Invos® Cerebral Oximeter (Somanetics, Troy, MI) for 392 pediatric cardiac surgery patients were analyzed. The SrO₂ sensor was positioned and recorded while the child was being prepared for surgery before anesthesia. The first ten minutes of SrO₂ readings for each patient were averaged and entered into a database as the baseline SrO₂ value along with the parameters listed above. SrO₂ relationships were studied employing analysis of variance and multiple logarithmic regression using SPSS® (SPSS, Inc., Chicago, IL).

Results: Age of patients ranged from 0.1–6310 days. Weight varied from 1.9–125 kg. 276 patients were not hypoxic (PaO₂ < 60 mmHg) compared to the 113 that were. There were significant differences in baseline SrO₂ associated with age, body weight and the type of defect, but not with gender or Aristotle Score. Baseline SrO₂ correlated significantly ($p < 0.01$) and most highly with the age, weight, PaO₂ and the presence of hypoxia. The best-fit predictive equation ($r = 0.471$, $p < 0.001$) for SrO₂ included the variables age in days and the presence of hypoxia. The mean SrO₂ was 64% and the standard error for prediction was $\pm 12\%$.

Conclusions: A moderately accurate equation to predict baseline SrO₂ for children prior to anesthesia and cardiac surgery may be stated from our experience with 392 patients. Baseline SrO₂ correlates significantly with age, weight, PaO₂ and type of the patient's cardiac defect.

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Use of the DMAIC Performance Improvement Model in Cardiac Surgery

Purpose: Use of the DMAIC (Define, measure, analyze, improve and control) performance improvement model has dramatically improved all aspects of the business environment. By reducing errors this tool improves quality and reduces costs. DMAIC methods were applied in the healthcare setting of a cardiac surgical unit to improve operating room turn-around time (TAT) and reduce blood product waste (BPW).

Methods: DMAIC methodology was applied to two metrics in the cardiac surgery unit. Problems initially addressed were to TAT and BPW. TAT was the time from when a patient leaves the operating room until the next patient can be started. BPW was the amount of blood products wasted due to expiration. This was primarily due to blood products being ordered too early or that blood products were sent to the intensive care unit and left unused. For both of these metrics, processes were analyzed with respect to involved personnel, equipment, time and ordering practices. Benchmark data were obtained and used for comparison to current practice.

Results: By critically reviewing procedural steps involved in each metric and devising improvement strategies, we reduced both TAT and BPW. TAT was lowered to less than 40 minutes and BPW was less than 10% over a 12 month period.

Conclusions: Applying DMAIC in the healthcare setting of a cardiac surgical unit improved operating room TAT and reduced BPW. Critical analysis of each procedural step is necessary and involves multi-disciplinary input. Process flow charts help identify critical steps which influence outcomes. The multidisciplinary group must analyze collected data and devise process improvements. These process changes need to be continually monitored to assure that improvement is sustained. Feedback is provided to staff in the form of dashboards, which list current metrics over a time period.

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Effects of Aprotinin on Patients With Protein C System Deficiency Undergoing Cardiopulmonary Bypass

Purpose: Aprotinin is increasingly being used in high doses as a therapeutic agent in cardiac surgery where benefits including reduced post operative blood loss have been reported. Earlier reports had linked aprotinin to incidents of thrombosis following cardiopulmonary bypass (CPB) procedures. It was later learned that these thrombotic were caused by insufficient anticoagulation. Anecdotal accounts however still exist in regard to aprotinin-related thrombosis. Because aprotinin has been

shown to inhibit activated protein C, it is important to clarify whether the use of aprotinin in patients with protein C system deficiency, with an incidence of 0.5%, could accentuate the defect and precipitate thrombosis during CPB. The protein C system is a major physiologic anticoagulant system, which has been shown to be activated during cardiopulmonary bypass. In the activated form, Protein C is a major inhibitor of blood coagulation which inactivates factor V and factor VIII. Studies have shown that the activation of protein C may play an important role in the maintenance of the integrity of the cardiovascular system during cardiac surgery.

Methods: A literature review was performed to determine whether any information was available to determine the effects of aprotinin in the presence of a protein C deficiency. We reviewed, the physiologic aspects of protein C system, laboratory evidence of the interaction between aprotinin and protein C system, the effects of aprotinin on the protein C system during CPB as well as the results of utilization of aprotinin in patients with protein C system deficiency during cardiac surgery.

Results: Available literature suggests that thrombosis may occur in patients with protein C deficiency when aprotinin is used for CPB procedures due to defect accentuation.

Conclusions: Protein C deficiency may be the cause of unexplained thrombosis when aprotinin is used during CPB procedures. Patients suspected of protein C deficiency should be tested and this deficit corrected if aprotinin is used. Otherwise aprotinin therapy should be avoided in this patient population.

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Comparison of Computerized Perfusion Electronic Records to Hand-Written Records During Cardiopulmonary Bypass in Children

Purpose: The development of electronic perfusion records (EPR) during cardiopulmonary bypass (CPB) by the perfusionist is slowly gaining acceptance, but lags far behind the use of manual record keeping (MPR) to the EPR is to improve organization, completeness, and accuracy. The purpose of this study was three-fold: A) to compare the accuracy of manual record keeping and EPR in the pediatric perfusion setting, B) to evaluate the integrity and accuracy of perfusionist hand-written charts, and C) to evaluate and describe the time management of the perfusionist during pediatric cardiac surgery.

Methods: A) Twenty-one cases were studied. The EPR, MPR, and the anesthesiologist manual chart were the three records studied. Arterial blood pressure (ABP) values recorded on each chart during seven specific events were compared. A multivariate analysis was performed between three charts to calculate the error in the ABP. B) We selected 10 cases and found the average difference between lines charted on the MPRs. In addition, we calculated the standard deviation of the mean ABP for the pump-run of the EPR and handchart to assess the EPR's sensitivity. C) Ten cases were studied. Task management and time expenditure by the perfusionist was divided into four main timed categories with each category containing a subset of predetermined tasks. The tasks performed by the perfusionist were directly observed, placed into one of the four main categories during a time span from heparin infusion to the end of modified ultrafiltration (MUF) procedure. The time elapsed during each of the tasks was recorded.

Results: A) There was a significant large CPB event effect and a small between records effect. There was a significant but small interaction effect between record type and events. B) The actual difference between charting lines was an average of 5.45 minutes which was significantly greater than 5 minute standard ($p = 0.022$). There was no significant difference between the EPR ABP average and the hand-charted average. C) The majority of perfusionist activity time was spent scanning or idle (820 seconds) which was significantly ($p = 0.037$) more than time spent performing ECC related tasks (562 seconds). Less time was spent performing electronic charting during all periods of CPB than the other three perfusionists activities ($p < 0.005$). There was significantly more scan/idle activity during the "cooling to warming" time period than the other time periods studied ($p < 0.001$).

Conclusion: A) There was a difference between ABPs recorded by the three different methods. It appears that there is a "meaning effect" in the anesthesia record values and there was no difference in ABP values recorded manually by perfusionists and the values collected by EPR. B) It appears that there was no difference in the fidelity of charted ABPs between the EPRs and MPRs. C) For the task distribution, removing the manual charting activity from perfusionists' duties would yield on the average, about 20% more of the total time to devote to other activities

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Hemoconcentration vs. Cell Washing: A Meta-Analysis of the Results of Infusing Processed Residual Pump Blood

Purpose: The objective of this meta-analysis is to compare the results of the available evidence-based literature comparing the two most popular cell salvage methods to process residual pump blood after cardiopulmonary bypass.

Method: A meta-analysis of 11 randomized pump blood processing studies (378 patients) was performed. Analysis outcome parameters were measured one hour after the infusion of the processed residual blood. The parameters compared were hematocrit, platelet count, total protein concentration, colloidal osmotic pressure, fibrinogen and free plasma hemoglobin

concentration. Effect Sizes for each parameter from each study were calculated using Cohen's *d*. 95% confidence intervals were calculated for each study. The meta-analysis group parameter 95% confidence interval was constructed.

Results:

Post-Infusion Parameter	RC Studies	Patients Per Group	HC Group Mean	HC – CW Mean Diff	MA 95% CI Min	MA 95% CI Max	Sig @ <i>p</i> = 0.05
Hematocrit	8	106	28.8	-1.1	-2.2	-0.1	Yes
Platelet count	5	74	194	43	24	62	Yes
Total protein concentration	3	42	5.4	0.7	0.5	1.00	Yes
Colloidal osmotic pressure	3	48	14.4	2.2	1.4	3.1	Yes
Fibrinogen concentration	3	55	245	25	-5	55	No
Plasma free hemoglobin concentration	3	48	35	4	-4	11	No

RC = randomized controlled; HC = hemoconcentration; CW = cell washing; MA = meta-analysis; CI = confidence interval; Sig = statistical significance.

Conclusion: Cell washing is superior to hemoconcentration in regard to hematocrit after infusion. Hemoconcentration is superior to cell washing in regard to platelet count, total protein concentration and colloidal osmotic pressure. There is no difference in fibrinogen concentration or plasma free hemoglobin concentration between the pump blood processing methods. Currently there is an inadequate number of randomized controlled studies comparing the two popular methods to process residual pump blood. The statistics suggest that increasing the number of studies and patients will decrease the range of the confidence intervals, possibly revealing significant differences. Additionally, more post-infusion parameters such as allogeneic blood usage, renal function measures, residual heparin concentration and viscoelastic coagulation measures should be studied.

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A Modified ECMO Circuit Utilizing the Myocardial Protection System®

Purpose: Hemodilution, especially in pediatric patients, continues to be a major concern with extracorporeal circulation systems. Various methods to reduce prime volumes are continually being explored. By utilizing the MPS® (Quest Medical, Inc, Allen, TX) and replacing both the standard roller pump, boot, and heat exchanger from the traditional ECMO circuit, the goals are to substantially reduce the prime volume with this new, modified system. The MPS® is able to continuously monitor line pressures while simultaneously providing arterial-venous flow and blood temperature regulation.

Methods: The MPS® tubing set was adapted to accommodate a traditional re-circulating ECMO circuit. The MPS® was compared and contrasted to traditional ECMO circuit using an in-vitro simulator while monitoring the three main variables for an ECMO circuit; patient mean systemic arterial pressure, pre-membrane pressure and pump flow. By building a parameter comparison matrix between the MPS® and traditional ECMO systems we were able to compile a list of recommended changes that would enable the MPS® system to function independently as an ECMO system.

Results: Through the comparison matrix we became aware of necessary modifications to the MPS® before it could safely be used as an ECMO system. The main recommended modifications include: three separate, simultaneous pressure displays, the ability to display and servo-regulate the inlet pressure, and elimination of the crystalloid source so that both pistons can operate at a 1:1 ratio from a single inlet source.

Conclusions: The most common complications associated with ECMO mechanical failures as published by the 2004 ELSO survey are 1) air in circuit, 2) pump malfunction and 3) raceway rupture. The MPS® is able to identify and/or manage air in the venous side of the circuit. Once the manufacturer modifications are incorporated into the MPS making it a specific ECMO pump, it will be a viable ECMO.

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Autologous Priming Technique to Reduce Blood Transfusion in Pediatric Cardiopulmonary Bypass

Abstract: Excessive hemodilution during cardiopulmonary bypass is associated with decreased oxygen carrying capacity, edema and organ dysfunction. The use of blood products is often necessary to prime the extracorporeal circuit for pediatric

cardiac surgical patients. However, the use of blood products carries serious risks both in the acute and long-term aspects of patient care. Autologous priming of the extracorporeal circuit used in conjunction with ultrafiltration, pharmacologic manipulation and cell salvage may decrease the need for blood transfusion in the pediatric cardiac surgical population. We have developed a technique that enables us to perform transfusionless complex congenital heart repair targeting patients as small as 5 kg.

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Ergonomic Perfusion Checklist: Basic Human Factor Design for the Heart Lung Machine

Purpose: Ergonomic considerations have not widely been applied to the heart lung machine and perfusion workstation. Henceforth, the purpose of this study was to determine if current workstation designs follow basic ergonomic principles. These principles were put in an easy checklist for perfusionists to use, all for the purpose of making a safer, more efficient design that will decrease musculoskeletal disorders.

Methods: Two hospitals were chosen, one where perfusionist's stand and another where they sit during cases. Detailed measurements of the heart-lung machine and location of all monitors and accessories were recorded in centimeters. A computer assisted design (CAD) program was used to illustrate the maximum reach and visual field for 50th percentile females and males for both hospital designs. A checklist was made of the most important ergonomic considerations.

Results: Standing hospital had nothing but the blender within the perfusionist's maximum reach and the placement of the reservoir resulted in excess neck flexion of over 52°. In addition, the standing hospital's heart rate, ECG, and pressure monitor was placed 180° behind and 187 cm above the perfusionist resulting in a decrease in perfusionist use. Excess glare and cold temperature were also observed. The sitting hospital had all pump controls and temperature readings linked to an adjustable touch screen monitor allowing most actions to be within the maximum reach. However, the hemodynamics monitor was not in viewing range and the chair used had a minimum height that was higher than the average male and female's minimum height. This would result in the perfusionist needing to either lean their torso forward or place their feet on the wheels.

Conclusions: There are many ergonomic problems with the perfusion workstation, especially with older hospital designs. By using this ergonomic checklist, perfusionists can recognize ergonomic issues more readily and can correct them to increase reaction time, reduce scan time, increase monitor usage, and decrease musculoskeletal impact from extreme reaches of the neck, torso and arms.

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A Website for Evidence-Based Practice for Perfusion. What Is It and How Do We Do It?

Objectives: Perfusionists have traditionally made clinical decisions based on theory and individual experiences. Yet we know that clinical decisions based on experience do not always result in optimal medical results. Perfusionists must base their clinical decisions on the integration of the highest research evidence available as well as clinical expertise and patient priorities. Educational tools need to be developed for perfusionists and students to use to integrate EBM into clinical practice and the writing of procedure guidelines.

Methods: Through The Ohio State University School of Allied Medical Professions' "The Model Project", a website for perfusionists is posted and may be used as an educational model for tackling the issues encountered when applying the rules of evidence-based medicine in the clinical setting.

Results: The Perfusion section of the Model Project will define the elements of evidencebased practice in the context of clinical perfusion services and patient care. The user will define and understand the different levels of evidence, including the strengths and limitations. The website identifies databases that will lead perfusionists to different levels of evidence. The educational module identifies the steps to evidence-based practice and creating guidelines for perfusion protocols for perfusion services.

Outcome: Future perfusion students, current perfusion students, and clinical perfusionists may use the website to understand how to evaluate the current body of available perfusion literature and be able to apply the rules of EBM to their clinical practice.

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Bacteriostatic and Bactericidal Properties of Platelet Rich Plasma in an *in vitro* Pseudomonas Model

Purpose: Nosocomial infections following cardiac surgery continue to be a significant problem, in both incidence (1.44–9.9%) and severity, despite the use of perioperative prophylactic antibiotics. Patients who survive sternal wound infections incur,

within the first year postoperatively, more than \$20K more in costs than patients who do not. Infected patients who die incur approximately \$60K in additional costs beyond those of the surviving infected patients. *Pseudomonas*' prevalence across patient populations and growing resistance to customary antibiotics makes it an ideal model to investigate alternate ways of killing bacteria that does not involve the risk of overmedicating and increasing bacterial resistance.

Methods: Following IRB approval, 50 mL whole venous blood was collected from ten 40–60 year-old healthy volunteers and concentrated into PRP employing the Angel® (Cobe Cardiovascular, Arvada, CO). PRP volumes were normalized to 10 mL using PPP. A disc diffusion assay was preformed to determine the ability of PRP to stop bacteria growth and kill existing bacteria as compared to control (no treatment). Assays were preformed in triplicate from each donor. Using the Plateletworks® (Helena Laboratories Corporation, Allen Park, MI) device, platelet count and white blood cell count was measured in whole blood and in PRP.

Results: In all trials the PRP treated discs proved bactericidal as compared to controls (12.9 ± 5.4 mm inhibition vs 0 ± 0 mm, $p < 0.001$). The platelet and white blood cells counts were concentrated from 230 ± 47 K/mm³– 3089 ± 1018 K/mm³ and from 5.1 ± 1.3 K/mm³– 9.8 ± 2.1 K/mm³ ($p < 0.001$), respectively. A viability assay showed 93% of the PRP cellular blood elements were alive at the end of incubation.

Conclusions: The ability of PRP to stop bacterial growth and kill existing bacteria in vitro, combined with its proven wound healing properties, make it an ideal topical application to help reduce the incidence of sternal wound infections.

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Clinical Evaluation and Biocompatibility of Hyaluronan Based Heparin Bonded Extracorporeal Circuits With Reduced Versus Full Systemic Anticoagulation in Reoperation for Coronary Revascularization

Purpose: In contrast to widespread popularity of novel heparin coated extracorporeal circuits, uncertainty exists whether reduced anticoagulation is feasible and whether documented positive outcome is due to heparin dosage or coating itself. This prospective randomized study compares novel hyaluronan based heparin bonded circuits vs. uncoated controls under challenging clinical setting including biomaterial evaluation

Methods: During the period from March until December 2005, 60 patients undergoing reoperation for coronary artery bypass grafting were allocated into two equal groups ($n = 30$): Group 1 was treated with hyaluronan-based heparin-bonded circuits (GBS™, GISH Biomedical Inc., USA) and group 2 with uncoated control circuits (D-708 Avant®, Dideco, Italy). In the study group, half of the patients ($N = 15$) received low systemic heparin (125 IU/kg, ACT > 250 seconds) or full dose like control group. Blood samples were collected after induction of anesthesia (T1) and heparin administration before cardiopulmonary bypass (CPB) (T2), 15 minutes after initiation of CPB (T3), before cessation of CPB (T4), 15 minutes after reversal with protamine (T5), and the first postoperative day at 8:00 a.m. (T6). Complete blood count, leukocytes and fibrinogen levels were evaluated. Serum albumin fractions, C3a and IL-2 levels were documented. Hematologic outcome was evaluated by thromboelastography, free plasma hemoglobin and thrombin-antithrombin III complex (TAT). CD11b/CD18 expressions were determined by flow cytometry. Blood cell adhesion on fibers was analyzed on optical microscopy and scanning electron microscopy. Desorbed protein amount on circuits was evaluated by spectrophotometer. Fibers were placed in tissue culture and attached cells were counted. Perioperative follow-up was thoroughly monitored.

Results: Blood sampling times of only statistically significant measurements vs. control ($p < 0.05$) were indicated for IL-2, CD11b/CD18 and TAT-max.

	IL-2 (pg/mL)		Postop Bleeding (mL)		CD11b/CD18 (% change)		TAT-max (ng/mL)		Postop Atrial Fib (N)	
	LOW	FULL	LOW	FULL	LOW	FULL	LOW	FULL	LOW	FULL
Group 1 (Hyaluronan)	T3:27 ± 4 T4:21 ± 4	T4:33 ± 4	405 ± 50	412 ± 50	T3:21 ± 4 T4:5 ± 1 T5:12 ± 2	T4:14 ± 2 T5:19 ± 2	T5:164 ± 35	T5:180 ± 40	1	0
Group 2 (Control)		T3:84 ± 6 T4:55 ± 6	684 ± 50		T3:41 ± 4 T4:36 ± 3 T5:29 ± 3		T5:139 ± 30		6	

Conclusions: Reduced systemic heparinization combined with hyaluronan based heparin bonded circuits is biochemically and clinically safe resulting in low thrombin formation. Both strategies with heparin coating provided better perioperative clinical outcome and biocompatibility vs. uncoated controls.

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First Clinical Use of a 3rd Generation Ventricular Assist Device: The Ventrasist LVAS

Purpose: Ventricular assist devices (VAD) are used for treating the failing heart in a number of clinical scenarios, these include postcardiotomy support, Bridge to Recovery (BTR), Bridge to Transplant (BTTx) and latterly as an alternative to transplantation the so called destination therapy (DestTx). First generation VADs were pulsatile devices such as the Novacor and the Thoratec. Second generation devices were axial flow pumps such as the Jarvik 2000 and the Heartmate II. A third generation of VADs has been developed these are centrifugal pumps that are bearingless and designed for long term support. One such third generation device is the Ventrasist LVAS. This device was developed in collaboration with our unit and we have followed its progress from the design board through animal studies and now to human implants. The device small enough to be used in the pediatric population, has successfully been deployed in children. The design and function of the Ventrasist will be discussed along with the details of the pilot trial and our current clinical experience.

Methods: After Institutional Review Board approval was obtained the Ventrasist LVAS was implanted in patients as DestTx or as BTTx. Patients included in this trial were ineligible for Transplantation due to their age (>65 yo), or required Mechanical Circulatory Support to make it to transplantation.

Results: Nine patients were enrolled in the pilot trial (DestTx $n = 5$. BTTx $n = 4$) Two of the destination therapy patients remain on the device today and three of the BTTx group were successfully bridged.

Conclusion: The ventrasist LVAS is the first of the third generation VADs to be implanted clinically. It is a novel and simple to use device that has wide clinical applications for both the Adult and pediatric population.

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Clinical Trials Results of a Synthetic CABG

Purpose: Every year about 100,000 Americans die because of inadequate supply of autologous vessels for a bypass operation. These are the so-called "no-option" patients. For the past 40 years many researchers have attempted to develop a synthetic coronary bypass graft with disappointing results. The purpose of this ongoing study is to prospectively evaluate the safety and efficacy of a novel polyurethane-based microporous, compliant graft leading to eventual regulatory clearance for clinical use.

Methods: After receiving Ethical Committee approvals, "no option" patients were enrolled at the Instituto da Cardiologia, Porto Alegre Brazil, in a Phase I trial to test the safety and efficacy of the synthetic graft. All patients had enough autologous vessels to complete at least one coronary bypass, but had autologous insufficient vessels to complete all necessary revascularizations. All patients were followed angiographically for six (6) months, and clinically for an additional six (6) months. For a total follow-up of one (1) year. Clinical end points were MACE, graft patency, angina and safety.

Results: To date three "no-option" patients were implanted in Brazil. All patients received one CardioPass bypass in the right coronary artery, which showed pre-operative stenoses between 55 and 72%. All patients were diabetics, had severe angina, and had undergone previous bypass surgery. Patients were implanted using purse string sutures, and received no ambulatory anticoagulation. As of this writing, all patients are alive, angina-free and enjoying a high quality of life.

Conclusions: Based on these encouraging preliminary results, we are applying for a Phase II pivotal clinical trial in Brazil. The trial will consist of a total of three patients involving three separate institutions, each headed by a Principal Investigator. Our objective is to obtain regulatory clearance in Brazil, followed by unrestricted availability to all hospitals.

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Independent Risk Factors for the Development of Infectious Endocarditis Requiring Valvular Replacement Surgery

Purpose: The purpose of this study was to examine variables associated with the development of IE in a cohort of patients undergoing valvular replacement surgery and to subsequently identify independent variables that increase the probability of IE requiring valve replacement surgery.

Methods: Institutional Review Board approval was obtained prior to data collection. A retrospective review was conducted of all patients undergoing valve replacement surgery from 01/05/2000 until 08/31/2005. The data was obtained from the Society of Thoracic Surgery (STS) national surgical database. Patient data sets included: patient age, smoking history, hemodialysis status, history of previous valve surgery, the presence or absence of diabetes mellitus, morbid obesity, hypertension, hypercholesterolemia, and endocarditis. A total of 960 patients were identified and 676 (70.4%) were included in the study analysis. 284 patients (29.6%) were excluded secondary to incomplete data sets. Statistical analysis was performed to identify the probability of coming to surgery for valve replacement secondary to IE and to determine independent risk factors for developing IE (Chi-squared test, step-wise logistic regression analysis, SPSS v.12 for Windows).

Results: Of the 676 patients evaluated in this study 9.76% ($n = 66$) were diagnosed with having infective endocarditis which necessitated surgical intervention. Following logistic regression analysis; age (Odds Ratio = .957) dialysis (Odds Ratio = 2.488), and previous valvular surgery (Odds Ratio = 2.959) were found to be independent predictors for development of infective endocarditis.

Conclusions: A recent study investigating the clinical characteristics and outcomes in IE patients with end-stage renal disease found the mortality rate to be as high as 73% in this subset of patients. Our study model determined previous valve operation as the most significant predictor for infective endocarditis. Other independent predictors for endocarditis identified were dialysis and age.

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Case Series: Hematological Changes in the “Golden Hours” After CPB With an Off-line Technique of Modified Ultrafiltration of Residual Circuit Blood Utilizing the Hemobag®

Purpose: The Hemobag® (HB; Global Blood Resources LLC, Somers, CT) technique allows the open-heart team to safely concentrate the residual cardiopulmonary bypass (CPB) circuit contents and return a high volume of concentrated clotting factors and blood cells back to the patient. The HB technique appears to have many of the benefits of modified ultrafiltration (MUF) after CPB in regard to rapidly concentrating the patient’s autologous blood and plasma without the surgical time delay associated with the traditional MUF techniques.

Method: Hematocrit, platelet count, fibrinogen concentration, PT, PTT and INR were compared in ten random HB adult cardiac surgical patients at two times after CPB: 1) post acute normovolemic hemodilution (ANH) infusion and protamine administration, and 2) after admission to ICU, approximately one hour after CPB and HB content infusion. Minimal cell processing was also used in these patients to conserve blood.

Results: Except for PTT, all parameters changed significantly from the post-protamine and ANH infusion, to approximately one hour after HB blood infusion and arrival in the ICU. These patients had a significantly higher average hematocrit, platelet count and fibrinogen concentration. Significant reductions in PT and INR were also observed after HB content infusion however, there was only a strong trend in decreased average PTT. These patients did not receive any allogeneic blood products during their hospital admission.

Conclusions: Use of the Hemobag® technique for salvaging blood is associated with significant increases in the patient’s protein and cellular concentrations and lowered coagulation times in the important, first few golden hours following CPB. The changes associated with the Hemobag® off-line MUF technique may provide the same physiologic benefits in adults that are well known and reported with traditional MUF procedures. This technique offers our perfusionists a new role in further optimizing hemostasis hours after the termination of CPB.

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Perfusion Training Versus Private Pilot Training: Unveiling the Myth of Comparison

Perfusionists are well acquainted with the comparisons sometimes made between those skills required to operate the perfusion console, and those skills required for cockpit management during flight. For example, perfusion students are taught that a ‘visual scan’ of console operation status indicators, and a ‘visual scan’ of relevant circulatory dynamics, taken together, will allow the perfusionist to be appraised of the adequacy of perfusion. Likewise, as to students of flight, a ‘visual scan’ of flight instruments is used to determine relative airframe attitude and altitude, as well as to discover navigational status. In this sense, the ‘visual scan’ is common to both perfusion care and flight training programs.

Nonetheless, there does exist divergence as to learning and teaching methods between perfusion education and private pilot training. Obvious, and most striking, is the fact that the management of perfusion care involves little or no risk of personal injury to the console operator. As is readily apparent, exactly the opposite exists for the PIC (pilot in command) of an aircraft. While this distinction is not determinative of the many differences between perfusion care education and private pilot training, it is nonetheless a driving force in terms of the depth and breadth of training in both fields.

This manuscript is intended to describe the two educational processes in detail, including the role of oversight organizations, and how applicable regulation and law determine the content, width, and breadth of both training programs. Furthermore, the applicability of crew resource management techniques and well-established decision making processes as to both disciplines is described in detail. Finally, this manuscript will describe the feasibility of applying some of the flight-related safety and quality measures to the field of perfusion care practice, with the anticipated benefit of providing even safer and more effective perfusion care, including during the educational process.

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Heat Production by a Centrifugal Pump: Product of Resistance or Flow?

Purpose: The purpose of this study is to investigate whether the resistance the pump works against or the flow rate produced has a larger impact on the heat production with the utilization of a centrifugal pump.

Method: Three resistors were tested creating a high, medium, and low resistance to blood flow. These resistors were used to simulate potential afterloads within the patient. A simple circuit was created and primed with normal saline. Temperature was measured within the box. All components of the circuit were insulated, except for the pump head. In one part of the experiment the resistors were changed out, but the revolutions per minute remained constant. In the second part of the experiment, the resistor stayed constant, and the revolutions per minute were varied.

Results: Revolutions per minute produced more heat than resistance alone. The highest revolutions per minute produced 0.2303°C/min transferred to solution, compared to 0.208°C/min for the highest resistance at 4000 RPMs. The lowest RPMs produced the least amount of heat (0.0288°C/min). When resistance was varied, and the centrifugal pump was run at 4000 RPMs, approximately the same amount of heat was produced ($0.1838 \pm 0.0180^\circ\text{C}/\text{min}$) for all the resistances.

Conclusion: Revolutions per minute had a larger impact on heat production than resistance. When the pump is run at higher revolutions per minute, heat is produced. This heat is directly transferred to the solution it is in contact with. Thus, patients requiring higher flows are at an increased risk of heat transfer to the blood. Monitoring blood temperatures is more critical in these patients to avoid unnecessarily heating the blood, especially at mild hypothermic temperatures.

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An Interactive Computer Model of Respiratory Support Using Pumpless, Arterial-Venous Extracorporeal Bypass

Purpose: An interactive computer simulation of pumpless arterio-venous extracorporeal CO₂ removal (AV-ECCO₂R) has been developed based on the gas exchange and blood flow characteristics of the Medtronic *Minimax-Plus* membrane gas exchanger. Since AV-ECCO₂R is meant to supplement or in some cases supplant mechanical ventilation, the model includes a mechanical ventilator exchanging gases with the native lung.

Method: The patient's height, weight, sex and age are entered into the model as variables from which rates of O₂ consumption, CO₂ production, cardiac output and dead space volume are calculated from published nomograms. Additional operator inputs include membrane lung gas flow, oxygen fraction to both the membrane lung and mechanical ventilator, tidal volume and ventilator frequency. The patient's blood pressure can be factored up or down to show the resultant effect on extracorporeal blood flow and gas exchange. Pulmonary shunt can also be manipulated to illustrate how respiratory distress affects blood gases. The outputs of this model are the rate of CO₂ removal by the membrane lung, P_aCO₂, P_aO₂ and pH_a.

Results: The model was used to predict the physiological impact of varying the blood flow through the A-V bypass. The mechanical ventilator was turned down as the bypass flow increased while maintaining the PaCO₂ at 45 mmHg. Under these conditions, with the patients \dot{V}_{CO_2} at 180 mL/min, maximum A-V ECCO₂R allowed for a reduction in mechanical ventilation to 44% of control from 345 mL/min to 152 mL/min.

Conclusions: This interactive computer model has proved useful as a training tool for demonstrating how AV-ECCO₂R and positive-pressure artificial ventilation interact in supporting a patient's gas exchange requirements. In addition, since it is possible to change certain parameters to emulate the performance of different membrane lungs, this model can serve as a useful resource for simulations of AV-ECCO₂R.

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Growth Factor Levels in Platelet Concentrates From Normal Subjects

Purpose: Platelets are critical in wound healing due to their role in two important processes: clot formation and the release of growth factors. Platelet rich plasma (PRP), a concentrated platelet suspension, has been used in many surgical specialties as a wound healing treatment; however, few controlled clinical studies have been conducted to prove the efficacy of the PRP. It has been suggested that one major barrier is the lack of data assessing the quality of the PRP product, its potency, and a standard protocol for the creation and dissemination of the PRP. Therefore, we analyzed the concentration of growth factors, concentration of platelets and platelet function in PRP prepared from healthy adults.

Method: Venous whole blood was collected in ACD from twenty 40–60 year old healthy, non-pregnant volunteers who abstained from aspirin intake 72 hours prior to blood collection. Whole blood was assayed for platelet count, platelet function, white blood cell (WBC) count, hemoglobin, and hematocrit (Plateletworks® Helena Laboratories, Beaumont, TX). Approximately 10 mL of PRP was separated from whole blood using the Secquire™ Cell Separator (PPAI Medical, Fort Meyers, FL). The PRP was assayed for platelet count, platelet function, white blood cell (WBC) count, hemoglobin, and hematocrit using the

Plateletworks® and was stored at -70°C for subsequent analysis of platelet derived growth factor (PDGF), transforming growth factor-beta1 (TGF- β 1), insulin like growth factor (IGF), and vascular endothelial growth factor (VEGF) using commercial enzyme-linked immunosorbent assays (ELISA) kits (R&D Inc., Minneapolis, MN).

Results:

Factor	Venous Blood (<i>n</i> = 20)	PRP (<i>n</i> = 20)	<i>p</i> value
Platelet count (K/mm ³)	226 ± 49	662 ± 193	<0.001
% Platelet Function (%)	68 ± 15	31 ± 19	<0.001
# Functional Plts (K/mm ³)	156 ± 55	186 ± 120	NS
Hematocrit (%)	38.6 ± 4.6	26.1 ± 5.4	<0.001
WBC (K/mm ³)	5.9 ± 1.4	12.3 ± 7.7	0.001
IGF-1 (ng/mL)	95 ± 19.5	105 ± 32.7	NS
VEGF (pg/mL)	166 ± 75	436 ± 255	<0.001
PDGF (ng/mL)	93 ± 20.4	252 ± 111.1	<0.001
TGF- β 1 (pg/mL)	7.3 ± 8.6	15.8 ± 12	0.015

Values are mean ± one standard deviation.

Conclusions: This study demonstrated that PRP does provide certain growth factors in higher concentrations than baseline but there was no correlation between platelet counts and growth factor concentrations in either the PRP or venous blood. In addition, the % functional platelets was lower in the PRP resulting in no difference in the concentration of functional platelets between the PRP and venous blood. Further work is warranted to ascertain what predicts growth factor concentrations in PRP.

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Evaluating the Efficacy of Intra-Aortic Balloon Pump Timing Using the Auto Mode of Operation With the Datascope CS100

Background: The intra-aortic balloon pump (IABP) was first introduced by Mouloupoulos et al. in 1962 and was described clinically by Kantowitz et al. in 1968. The subsequent development of the IABP has resulted in its widespread application, resulting in over 70,000 applications per year making it the most common cardiac assist device after pharmacology. The correct timing of the inflation and deflation of this device is critical to it being clinically advantageous to the patient. The purpose of this research was primarily to examine the Datascope CS100 automated timing of inflation and deflation and secondarily to create an awareness of the dangers of solely relying on technology for patient treatment decisions in lieu of clinical evaluative skills.

Methods: Timing data was collected from 165 IABP patients from January 1, 2003 to March 31, 2005 using the Datascope series System 97, System 98, and CS100 IABP consoles. Timing criteria used in the evaluation of IABP application included properly defined inflation at the dicrotic notch of arterial pressure waveform and proper deflation resulting in a pre-systolic decrease of arterial pressure by 5–10 mmHg. These parameters were evaluated by examining a printed strip from the IABP console once timing was established.

Results: Before implementation of the CS100, 78.6% of inflations and 53.6% of deflations were correct when using the three criteria listed above. After implementation of the CS100, 83.3% of inflations were correct (an increase of 4.7%) and 44.4% of deflations were correct (a decrease of 9.2%).

Conclusion: Though some improvement in consistency of IABP inflation quality was observed, a net decrease in the quality of IABP deflations was observed. Total reliance on the Auto operation mode of the CS100 is not warranted and imposing clinical judgment in therapeutic application is necessary to avoid dangerous timing errors. An awareness of the dangers of solely relying on technology for patient treatment decisions vs. the use of technology combined with clinical evaluative skills for assessing therapeutic intervention to improve patient care is discussed.

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Improving outcomes in ventricular assist device patients transferred From spoke hospitals and converted to an ambulatory device at hub hospitals

Purpose: In this retrospective study, the implant courses and outcomes of Ventricular Assist Device (VAD) patients transferred from spokes and converted non-surgically to ambulatory devices at hubs are evaluated. Factors affecting the crucial decisions to transfer and to convert devices have not previously been characterized.

Methods: Data from 50 patients at 27 US hub institutions were voluntarily submitted to the ABIOMED VAD data registry between December 2003 and December 2005. The patients were transferred from spokes on the BVS5000 Blood Pump and converted to the AB5000 Ventricle (both ABIOMED, Inc) at hubs. Comparisons of implant indications, course and end-organ function at time of conversion were made between surviving and expired patients.

Results: Patients with known outcomes ($n = 45$) who were transferred and converted had a post-explant 30-day survival rate of 38%. Of the surviving patients 59% were weaned, 35% transplanted, and 6% received a destination device. Average implant to transfer time was 1.5 vs 2.0 days for survived and expired patients respectively whereas, support time from transfer to conversion was 4.75 vs 4 days respectively. At the time of device conversion, a total bilirubin threshold level of 3.5 mg/dl was predictive of survival ($n = 26$, $p = 0.01$, odds ratio = 3.3, 95% confidence interval: 1.34–8.30). Patients who survived were supported longer than those who expired (35 vs 21.1 days, maximum: 81 days, $p = 0.026$). At least 18 patients recovered sufficiently on the AB5000 to tolerate extubation and 11 patients were able to ambulate.

Conclusions: Patients transferred on the BVS5000 benefited from easy, safe conversion to the AB5000 which provided them with longer term support and enabled activities such as ambulation. The decisions to transfer patients and convert support devices should be based on clinical indicators to optimize outcomes. Liver function post-implant at the spoke and prior to conversion may be a good indicator of patient survivability.

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Whole Blood Thrombin: Development of Process for Intra-Operative Production of Human Thrombin

Purpose: Currently, thrombin based clotting agents used for topical hemostasis with absorbable sponges, fibrin sealants and platelet gels are primarily derived from bovine or pooled human plasma sources. Autologous thrombin has important safety advantages in that it does not carry the same safety concern as pooled plasma derived products for their potential to transmit an infectious disease. In addition, autologous thrombin avoids exposure to bovine derived proteins that carry the risk of immunogenicity associated complications such as allergic reactions and post-operative hemorrhage due to development of cross-reactive anti-bovine antibodies that inhibit the human coagulation cascade. The goal of our research was to develop a new rapid and reliable technique to generate autologous human thrombin in the intra-operative setting from whole blood as the starting source material. By using whole blood instead of plasma as the starting material, it is possible to avoid the delay in thrombin availability to the surgical team due to the conduct of a plasma separation step. The purpose of this study was to evaluate the performance characteristics of thrombin product generated using the new whole blood method.

Methods: The process device consists of a tubular reaction chamber containing activating glass microsphere beads. To prepare active thrombin, 4 ml of thrombin reagent (a mixture of calcium chloride and ethanol) is added to 12 ml of anti-coagulated blood in a reaction chamber. The contents were mixed by inversion several times and incubated for 15 minutes with the reaction chamber laying on its side and the beads inside the chamber were evenly dispersed. At end of 15 minute incubation period, the blood/beads were mixed by agitation followed by centrifugation step for 12 minutes at 2100 × g. At the end of the centrifugation step, the thrombin activated serum was harvested from the reaction chamber.

Results: The average activity of the thrombin produced at room temperature by this device was 76 ± 40.9 IU/ml ($n = 66$). The total processing time was less than 30 minutes. The system was compatible with ACD anticoagulant (8%–12%). The average volume of thrombin harvested from each aliquot of blood was 5.3 ± 0.5 ml. Stability, defined as the time above 30 IU/ml, was determined to be temperature dependent. Clot times with platelets concentrates at 1:3 and 1:10 ratio were less than 10 and 30 seconds, respectively. **Conclusions:** A process for the preparation of thrombin from whole blood under conditions compatible with the resources of an operating room has been developed. The device is simple to use, requires 30 minutes and can consistently produce thrombin solutions that achieves rapid clotting of platelet concentrates, plasma and fibrinogen concentrates even when mixed at ratios of 1:10.

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Successful Management of a Left Ventricular Device Failure in an Outpatient Setting

Background: Chronic, progressive, end-stage heart failure results in substantial health care costs and immeasurable suffering for both individuals in particular and society in general. Ventricular Assist Devices (VAD) have an increasing role in supporting patients with severe circulatory compromise. These devices provide support and make it possible for patients to be discharged to their homes and possibly are even returning to work whether awaiting transplantation or on Hemodynamic Restoration Therapy (HdRT). System failures and device malfunctions however, do occur and are the most common cause of death for patients on VAD support. We present a device failure involving a HeartMate XVE Bridge to Transplant (BTT) that occurred while the patient was at his home, over 100 miles from our center.

Case Report: A 54 year old male had a Heartmate XVE implant four days following redo coronary artery bypass surgery

(REDO CAB) for treatment of post-operative low output failure. After the patient and his wife underwent training and demonstrated competency in device management, the patient was discharged to his home on post-operative day (POD) 43. Training was also provided to the local emergency medical technicians and local hospital prior to the patient's return to the community. After 447 support-days, 2 "red heart" alarms occurred. After initiating hand pumping of the device, the patient's companion contacted our center and the local rescue was activated. The patient was transported by life flight to our center where he was placed on a pneumatic console and subsequently transferred to a regional transplant center. The patient then went on to being successfully transplanted.

Summary: It's imperative to have a definitive strategy and clear support plan to address system malfunctions and device failures. Considering the growing number of VAD patients discharged home, these occurrences will become more common outside of the hospital setting. Education of clinicians, patients and their companions as well as local rescue teams and community hospitals is essential.

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Cardiac Surgery Instrument Panel

Background: Cardiac surgery patients commonly receive care within separate units in the hospital that are highly interdependent however geographically and organizationally distinct. Cohesive quality improvement efforts are difficult to initiate due to challenges posed by this relationship.

Methods: An instrument panel was developed to provide information about the current overall performance of the system in multiple domains including: mortality, complications, resource utilization, and customer satisfaction. Interviews with clinical staff in surgery, in the cardiothoracic intensive care unit (CTICU), and the Cardiac Surgery step down unit nurses to determine key measures. The instrument panel was constructed and posted in clinical areas. The instrument panel was updated quarterly.

Results: Trends in outcomes were visible to clinical staff across the cardiac surgery system. Inferences were made related to quality improvement initiatives. An over all improvement in the incidence of sternal wound infections and transfusion rates was observed. A correlation between atrial fibrillation rate and atrial fibrillation prophylaxis protocol was observed.

Summary: An instrument panel provides information related to the overall performance of the system to all of the members of the team. This information unifies disciplines around key measures, focuses the team and provides direction related to improvement opportunities.

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Automatically Negative Pressure and Volume Control in Use of Minimized ECC Systems With an Easy to Use Setup

Minimized extracorporeal systems (MES) drain venous blood directly into the arterial pump omitting venous reservoirs. Potential benefits of these systems are improved patient stability, reduced inflammation, decreased need for vasoconstrictive agents and less hemodilution.

Two major causes impairing the effectiveness of MES were identified in our investigations.

1. The creation of highly negative pressure in case of volume shortage (bleeding) and luxation of the heart.
2. Continues venous air aspiration

Another aspect in use of minimized ECC system is the patient's safety. In case of unexpected complexity, the need to change the system without risk for the patient is the challenge for the Perfusionist.

Our new designed system consist a kinetic negative pressure and volume compensation, with freely selectable rate from -25 mmHg to -100 mmHg and the possibility to switch back and forward between the minimized ECC system and open reservoir ECC setup strategy, without circulatory stops in case of unexpected complexity or continues venous air aspiration. The system was tested in a laboratory and additional in an animal lab model. No negative pressure higher the setup limited pressure was observed. The switch back and forward between the two strategies was to do without problems also the automatic volume control works fine.

The system improves the safety and effectiveness of minimized ECC setup and can be used with all different kind of MES.

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Novo-Seven® Use in a Non-Cardiac Pediatric Ecmo Patient With Uncontrolled Bleeding

A six-week old 4.5 Kg male patient was admitted to the pulmonary service with a positive culture for respiratory syncytial virus (RSV). Within hours, he was transferred to the PICU for respiratory failure. The patient was intubated and mechanically ventilated for 35 hours, eventually requiring high frequency oscillatory ventilation (HFOV) due to progressive hypoxemia. On PICU day 2, he developed a left sided pneumothorax. The patient's condition continued to deteriorate leading to the use of VA ECMO on day 3. Once on ECMO the patient was very stable on HFOV settings of Hz-15 Amplitude-38 cmH₂O Mean Airway Pressure-17 cmH₂O FiO₂-0.21 and an ECMO pump flow of 111 mL/Kg/min. On day 3 of ECMO, the patient's left pneumothorax reaccumulated. A 16 Fr Argyle catheter was placed to reduce the pneumothorax with no significant bleeding noted from the site or chest tube. On ECMO days 3–6 blood output from the chest tube was 10–30 cc/h. On ECMO day 6, the bleeding increased to greater than 40–90 mL/h. The patient's coagulation values at the time of the bleeding increase were; PT 12 seconds, PTT 92 seconds, platelets 142,000 mm³, and fibrinogen 303 mg/dl. Amicar was started at 30 mg/Kg/h after an initial loading dose of 100 mg/Kg. Amicar was continued over the next five days while the patient concurrently received platelets 1300 mL, PRBC 4267 mL, and FFP 3147cc.

On day 9 of ECMO, the decision was made to administer recombinant factor VIIa via the ECMO circuit. Prior to the delivery of rVIIa a quantitative factor VII level was measured which indicated a greater than normal factor VII level = 149% (reference range 20–70%). Because of the variability in dosing regimens, we choose to give this patient a total of 90 mcg/Kg of Novo-Seven® (Novo Nordisk, Princeton, NJ) The dose was divided into two 45 mcg/Kg aliquots and administered to the ECMO circuit two hours after the Amicar was stopped. Within twenty minutes of initial aliquot, the output from both chest tubes had dropped to zero. The second aliquot was administered to the circuit one hour after the completion of the first. The chest tube output remained zero and chest radiograph ruled out hemothoraces over the next four days.

On ECMO day 13, the patient began bleeding from this left chest tube at a rate of 1–10 cc/h. This continued until ECMO day 15 when the bleeding increased to 20–40 mL/h where it remained until ECMO day 16 when the patient was again treated with recombinant factor VIIa. Again, this resulted in chest tube output returning to zero where it remained throughout the rest of this ECMO run. The ECMO circuit remained clot free throughout and following the rVIIa administrations. The patient was weaned off ECMO on hospital day 28 and discharged home on hospital day 66.

Novo-seven® in the presence of severe bleeding during ECMO appeared to be a safe alternative for this patient. The presence of greater than normal quantitative factor VII level should not exclude similar patients from treatment with recombinant factor VII.

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Utilizing Aprotinin and Recombinant Factor VIIa During Extracorporeal Membrane Oxygenation for Treatment of Diffuse Alveolar Hemorrhage as a Result of Wegener's Granulomatosis

The following case report describes the use of Aprotinin and Recombinant Factor VIIa for alveolar hemorrhage while on Extracorporeal Membrane Oxygenation (ECMO) during the treatment of Wegener's Granulomatosis. Wegener's granulomatosis is a systemic disease characterized by vasculitis and granulomatous lesions that can affect multiple organs throughout the body by limiting blood flow and causing tissue necrosis. A 14-year-old female presented after 5 weeks of treatment for otitis media. The patient continued to deteriorate, leading to respiratory failure that subsequently necessitated the institution of high frequency ventilation and Nitrous Oxide, and ultimately the initiation of Extracorporeal Membrane Oxygenation (ECMO) support. Not until the initiation of ECMO was the diagnosis of Wegener's Granulomatosis made. Subsequently, the patient developed diffuse alveolar hemorrhage (DAH) unresponsive to all other forms of medical management. Aprotinin and Factor VII were initiated in an effort to control the coagulopathy while on ECMO. Here in we describe the anatomical, pathophysiological and mechanical issues and challenges presented as a result of using this pharmacologic regime during ECMO.

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A Novel Calculation to Estimate Blood Volume and Hematocrit During Bypass

Purpose: Patient blood volume impacts most facets of perfusion care, including volume management, transfusion practices, and pharmacological interventions. Unfortunately, there is a wide variability in individual blood volumes, and experimental measurement is not practical in the clinical environment. The purpose of this study was to evaluate a mathematical algorithm for estimating individual blood volume.

Methods: After IRB approval, volumetric and transfusion data was prospectively collected for 165 patients and applied to a series of calculations. The resultant blood volume estimate (BVE) was used to predict the first and last bypass hematocrit. The estimated hematocrits using the BVE and $65 \text{ ml} \cdot \text{kg}^{-1}$ were compared to measured hematocrits using the Pearson moment correlation coefficient.

Results: There was a wide range of BVE ($35, 64 \pm 22, 129 \text{ ml} \cdot \text{kg}^{-1}$). Using the BVE, the estimated hematocrit was similar to the measured first (24.7 ± 6.4 vs $24.5 \pm 6.2\%$, $r = 0.9884$, $p > 0.05$) and last (24.5 ± 5.9 vs $25.1 \pm 5.7\%$, $r = 0.9001$, $p > 0.05$) bypass hematocrit. Using $65 \text{ ml} \cdot \text{kg}^{-1}$ resulted in larger difference between estimated and measured hematocrit for the first (25.6 ± 4.5 vs $24.5 \pm 4.5\%$, $r = 0.7110$, $p > 0.05$) and last (23.8 ± 3.6 vs $25.1 \pm 4.7\%$, $r = 0.5990$, $p = 0.001$) bypass hematocrit.

Conclusion: Using the BVE formula to estimate blood volume more accurately estimated hematocrit than using $65 \text{ ml} \cdot \text{kg}^{-1}$.
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Procedural Characteristics of Uncontrolled Hemorrhage in Cardiac Surgery

Purpose: Patients with uncontrolled hemorrhage require massive transfusion therapy and consume a large fraction of blood bank resources. Institutional guidelines have been established for treatment, but early identification and prevention in susceptible patients remains challenging.

Methods: Uncontrolled hemorrhage was defined as meeting institutional guidelines for recombinant FVIIa administration. Patients who received rFVIIa were compared to patients who did not require the therapy but were operated on during the same time period. After IRB approval, demographic, operative, and transfusion data were analyzed from a prospective database.

Results: Patients receiving rFVIIa were more likely to undergo multiple procedures (2.6 ± 0.8 vs 1.8 ± 0.8 , $p < 0.001$); aortic surgery (59% vs 11% , $p < 0.005$); have a higher Cleveland Clinic Clinical Severity Score (7.8 ± 2.7 vs 5.5 ± 4.0 , $p < 0.005$); require longer bypass (265 ± 92 vs 159 ± 63 , $p < 0.001$), cross clamp (182 ± 68 vs 112 ± 56 , $p < 0.001$), and circulatory arrest (15 ± 24 vs 2 ± 7 , $p < 0.05$) times; and require more autotransfusion (2580 ± 1847 vs 690 ± 380 , $p < 0.05$).

Conclusion: Uncontrolled hemorrhage is associated with more complex surgery requiring longer bypass times.
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Job Analysis and Student Assessment Tool for Perfusion Education Clinical Preceptors

Introduction: The clinical perfusion education system centers on the cardiac surgery operating room and the perfusionist who serves as a clinical instructor for the perfusion student. One method to improve the quality of perfusion education would be to create a valid method for perfusion students to give feedback to clinical teachers.

Method: The preceptor job analysis consisted of a literature review and interviews with preceptors to list their critical tasks, critical incidents, cognitive and behavioral competencies. Behaviorally anchored rating traits associated with the clinical educators' tasks were identified. From a list of several clinical preceptor traits, students voted for the top five statements to validate the instrument items. Each of the five instructor traits is associated with several BARS to facilitate rater training to use the instrument. The perfusion instructor rating instrument with a 0-4, "very weak" to "very strong" Likert rating scale was then used by perfusion students to evaluate the performance of clinical instructors on each trait. A "good preceptor average" (GPA) is then calculated. Visual indications of teacher success are created.

Results: The five preceptor rating traits for student evaluation of clinical instructors (SECI) are: "The clinical instructor: 1) encourages self-learning, 2) encourages clinical reasoning, 3) meets student's learning needs, 4) gives continuous feedback and 5) represents a good role model." GPA scores from 158 student-preceptor relationships for 14 students rotating at 18 affiliate institutions with 91 clinical instructors were evaluated. The mean overall GPA was 3.5 ± 0.7 and was skewed to the left, ranging from 1.0-4.0 with a median = 3.8. Only seven of the SECI relationships earned an overall GPA less than 2.0.

Conclusions: Analyzing the role of the clinical instructor and performing SECI are methods to improve the quality of a perfusion education program. The instrument has content validity based on the job analysis and student confirmative survey results.

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An Innovative Design to Prevent Reversal of Roller Blood Pump Rotation in the Event of Electromechanical Failure: An Easy Solution to a Devastating Problem

Purpose: Despite the advanced technologies of battery back-up for heart-lung consoles and the availability of system-wide generators, electromechanical failure is still occurring. Several heart-lung machine manufacturers provide unsafe hand cranking devices to use in the case of an emergency while utilizing a roller blood pump. A new design has been engineered to eliminate safety and quality issues for the perfusionist and the patient when the need for hand cranking presents itself.

Methods and Materials: A ratchet-style hand cranking device was fabricated by means of a steel plate with adjustable pins. The adjustable pins allow for use with different models of the Cobe®, Stockert®, and Jostra® heart-lung consoles, which contain roller pumps with 180 degree roller heads. Additional modifications such as battery-powered drill accommodations and fluorescent markers are also used in the design.

Results: A uni-directional modified hand cranking device for Cobe®, Stockert®, and Jostra® heart-lung machines that eliminates safety hazards and enhances quality of patient care. The hand crank was trialed in an in-vitro test circuit.

Conclusions: This innovative design is an improvement in safety compared to the current hand crank provided by Cobe®, Stockert®, and Jostra®. With this modified hand cranking device, accidental reverse rotation of the roller pump head cannot occur. Fluorescent markers will improve visualization of the pump head in low light situations. The ergonomic design improves efficiency by reducing fatigue. Most importantly, a "safe" safety device will replace the current design provided by these manufacturers, thus improving our quality of care as health care providers.

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Electrostatic Potential Generated During Extracorporeal Pump Prime Circulation Prior to Cardiopulmonary Bypass Initiation

Background: The development of electrostatic potentials generated during cardiopulmonary bypass procedures utilizing polyvinylchloride (PVC) tubing in conjunction with roller pumps is well established. The resulting damage from the electrostatic discharge (ESD) has been widely reported to affect gas transfer devices, but details of potential damage to electronic components commonly used during extracorporeal circulation has not been similarly documented. The purpose of this investigation was to measure the ESD potential generated from a primed, circulating, adult cardiopulmonary bypass (CPB) pump prior to the initiation of CPB.

Methods: A typical adult CPB pump prime, which included albumin, sodium bicarbonate, heparin, and plasmalyte-A® was circulated at flows ranging from 500 ml/min to 6 L/min, for one minute. Pump circuitry consisted of uncoated PVC tubing (3/8" x 1/2"). An electrostatic discharge potential was then determined utilizing a digital multimeter (Fluke 8062 A).

Results:

Flow (LPM) (× 1 minute)	Continuous Voltage Generated (DC volts)	ESD Potential Generated (DC Volts)
0.0 (no flow)	0.0	0.0
1.0	6.5	175
2.0	10.5	194
3.0	12.0	305
4.0	12.5	412
5.0	14.0	523
6.0	15.0	600**

**Exceeded range of measurability.

Conclusions: The ESD potential spike generated from an adult CPB circuit elicits a charge in excess of 600 DC volts (6 L/min, 1 minute). Damage to sensitive electronic components is likely for charges in excess of 10 V. Sensitive electrical components in the CPB circuit may be damaged by ESD potential spikes of this magnitude. Preventative measures, such as circuit charge dissipation, may reduce the potential for such damage.

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Off-Pump Left Ventricular Assist Device Supported Myocardial Revascularization During Post-Infarct Cardiogenic Shock

Abstract: Since involvement in the pre-market approval study by the senior author in 1989, we have used the BVS5000 Blood Pump (ABIOMED, Inc.) to provide circulatory assistance for patients during postcardiotomy cardiogenic shock. Because mortality in postcardiotomy shock patients increases exponentially with addition of high-dose inotropic medications and Intra-Aortic Balloon Pump (IABP), we believe early intervention with ventricular assist device (VAD) support prior to the onset of systemic organ failure is essential to improving outcomes. Standardization of best practice protocols for hemostasis, anticoagulation, and intraoperative implant techniques have resulted in fewer bleeding complications, improved weaning, and

improved survival. Additional opportunity exists for patients suffering from post acute myocardial infarction (AMI) shock that would not otherwise be candidates for immediate conventional revascularization. We describe a post AMI shock patient supported with the AB5000 Ventricle (ABIOMED, Inc.). This patient initially received CPR from his wife followed by external counter shocks from EMS personnel, but he rapidly reverted to ventricular fibrillation until amiodarone was administered upon arrival to the Emergency Department. Cardiac catheterization showed high-grade lesions and an ejection fraction of 10%. There was a brief but unsuccessful balloon angioplasty attempt. IABP was placed and provided some diastolic augmentation. The patient then had what ultimately was an eight unit upper gastro-intestinal bleed. He continued to demonstrate hemodynamic compromise despite maximum inotropes; however, the gastro-intestinal bleed seemed to preclude prolonged systemic anticoagulation. The patient was thus placed on left-sided AB5000 Ventricle support and revascularized. He was supported for a further seven days, eventually recovering unassisted cardiac function and was discharged from the hospital. This is the first report of a patient undergoing supported bypass (VADCAB) with this device and it will also discuss technical and procedural considerations with respect to our VAD experience at a non-transplant center.

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Roller Pump Fatigue in Coated vs. Non-Coated Tubing

Purpose: There are several factors that influence roller pump tubing fatigue during cardiopulmonary bypass such as spallation and tubing resiliency. Longer times spent on bypass are associated with a greater incidence of fatigue. The stress and fatigue are caused by the continuous compression of the pump rollers. We examined roller pump stress and spallation on coated and non-coated tubing.

Methods: Three manufacturers coated and uncoated tubing were run through a Cobe roller pump (Cobe Cardiovascular, Arvada, CO), and through a 0.5 micron pre-bypass filter for one, two, and six hours. The pre-bypass filter was used to collect any particulate matter that "broke away" from the inner surface of the roller pump tubing. At the end of the time, the tubing in the raceway, and the pre-bypass filter were observed using a scanning electron microscope (SEM).

Results: These pilot study results showed that there was a visible crease where the rollers of the pump were collapsing the tubing and that there were "craters" in the tubing. The pre-bypass filter collected particles, ranging from 20–50 microns, which were not observed in the control.

Conclusions: The longer amount of time tubing spends in the roller pump raceway being compressed by the rollers, the more particles break off the tubing, which may be collected in the pre-bypass filter. These particles could possibly make their way past a typical arterial line filter, make their way to the patient, and potentially cause serious neurological complications.

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Recirculating Gene Therapy: A New Role for the Perfusionist

Purpose: The incidence of heart failure is increasing in the population. Current methods for treating heart failure include heart transplantation, ventricular assist devices, and biventricular pacing. Transplantation is limited due to the availability of donor organs, the use of Ventricular assist devices as destination therapy and biventricular pacing is limited due to the costs involved. A new prospect for the treatment of heart failure is gene therapy. It was our aim to develop a method for delivering a perfusate containing a vector to the heart, capturing this perfusate and then recirculating it. Following the recirculation of the vector, the perfusate would be isolated and discarded, keeping systemic exposure to the vector to a minimum.

Methods: A circuit was designed using a pediatric oxygenator, roller pump, standard cardiology coronary artery catheter and a novel coronary sinus catheter. After Institutional Review Board approval, two groups of sheep were compared. Heart failure was induced in the sheep by pacing them at 180 bpm for 34 days. On day of surgery (DOS) The treatment group ($n = 9$) were investigated with and then treated with AdS16EPLN (PLN). The control group ($n = 5$) were investigated and treated with a marker vector AdLacZ. The animals were reinvestigated fourteen days after surgery.

Results: Improved contractility, improved ejection fraction and ventricular remodeling were seen in the treatment group. Left ventricular Contractility, ejection fraction and contractility continued to worsen in the control group. Leakage from the circuit into the systemic and pulmonary circulation was minimal.

Conclusion: The technique for recirculating gene therapy we have developed was shown to be a simple and effective method for delivering vectors to a target organ. The benefits of the technique include limited exposure of the pulmonary and systemic circulations to the vector and prolonged exposure of the target organ to the vector. With this system, isolated single organ perfusion for the delivery of gene therapy or stem cells is possible and is being investigated by our unit.

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Autologous Platelet Gel in Coronary Artery Bypass Grafting: An in vitro Analysis of Platelet Rich Plasma Using Multiple Cycles

Purpose: Autologous platelet gel (APG) has become an expanding field for Perfusionists. By mixing platelet rich plasma (PRP) with thrombin and calcium, platelet gel is prepared and used in many surgical settings. Platelet gel has been shown to improve healing and hemostasis in surgical patients. There are many devices used to produce PRP. This study evaluates the Medtronic Magellan™ Autologous Platelet Separator. The purpose of this study was to demonstrate that processing two cycles of the same syringe could reduce the amount of blood required to produce a specific volume of PRP.

Methods: Three sixty mL syringes of whole blood with anticoagulant were removed from fifteen elective coronary artery bypass patients. Each syringe produced nine mL of PRP and one mL was sent to the lab for analysis. The remaining whole blood in each syringe was processed a second time with a yield of five mL of PRP with one mL sent to the lab. With this data, the Magellan was assessed in three phases. The first phase focused on the consistency of the Magellan. Laboratory values of hematocrit, platelet count, white blood cell count, and fibrinogen were compared between each syringe processed by the device. The second phase dealt with the percentage of platelets in the PRP that the Megellan was able to capture. Finally, results of both cycles were combined and compared against baseline values.

Results: Most of the hematological factors evaluated between each syringe were consistent in both cycles. The Magellan was able to capture nearly 70% of all platelets in the PRP of the first cycle and 18.5% in the second cycle. By mathematically combining both cycles, platelet counts averaged 2.8 times baseline with a 3.3 times baseline increase when the volume of the two cycles was weighted. This weighted average was done to reflect a higher concentration of cycle 1 platelets than cycle 2 in each sample.

Conclusion: The study proved that processing each syringe of whole blood twice could reduce blood requirements while maintaining an effective platelet yield and volume. It also demonstrated that the Magellan does conform to benchmark testing done at Medtronic.

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Rapid, Bedside Quantification of Recirculation During Venovenous ECMO

Introduction: Since recirculation in dual lumen venovenous extracorporeal membrane oxygenation reduces oxygen delivery to the patient, quantification of recirculation may be helpful in optimizing patient care. The currently accepted technique for measuring recirculation uses blood saturations and is not clinically practical during VV-ECMO. A promising new technique, dilutional ultrasound may overcome these problems by providing less invasive and more rapid, bedside recirculation values. The purpose of this study is to do a comparison between these techniques.

Methods: One 16 kg swine was cannulated with a 15 french Origin dual lumen cannula and placed on venovenous ECMO. Two methods were used to measure recirculation. The first method, the "gold standard", calculated recirculation from blood oxygen saturations according to the following formula: $r = \frac{S^{preox} - SvO_2}{S^{postox} - SvO_2}$. The second method used the use of clamp-on sensors with a dilutional ultrasound technique. Simultaneously both techniques were performed in triplicate. Measurements were made at four pump flow rates; 200 ml/min, 400 ml/min, 600 ml/min, and 760 ml/min.

Results: Comparison of mean recirculation values were not statistically different between the two methods across all flow rates. The dilutional ultrasound technique produced quantification results in less than 1 minute compared to up to 10 minutes for the blood sampling technique.

Conclusion: The use of saline bolus dilution ultrasound to measure recirculation yielded results that were consistent with the validated blood oxygen saturation method. The dilutional ultrasound technique was faster and less invasive than the traditional blood sampling method.

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Effects of Antegrade Selective Cerebral Perfusion via Right Subclavian Artery on Cerebral Ultrastructure Free Radical and Excitatory Amino Acid in the Brain Tissue of Rabbits Induced by Deep Hypothermic Circulatory Arrest

Purpose: To observe the effects of antegrade selective cerebral perfusion (SCP) via right subclavian artery (RSCA) on cerebral ultrastructure, free radical and the contents of the excitatory amino acid (EAA) in the brain tissue of rabbits induced by deep hypothermic circulatory arrest (DHCA). Methods Sixteen rabbits weighting 2.3–2.8 kg were randomly allocated to 2 groups, each group consists of eight rabbits. One group served as control: received DHCA only. The other group animals served as experiment group: received DHCA and SCP via RSCA. Each group were placed on cardiopulmonary bypass (CPB) and cooled

to 18°C. The period of DHCA was 60 mins. While DHCA, The experiment group received SCP via RSCA. After 60 mins of DHCA, animals were rewarmed and weaned from CPB. All animals were executed at the end of experience and brain tissue was removed for ultrastructural examination and to measure the content of malondialdehyde (MDA), EAA and superoxide dismutase (SOD) activity in brain tissue.

Results: In experiment group, the activity of SOD and the content of Glu increased significantly, while the content of MDA and EAA in brain tissue decreased significantly as compared with that in control group ($p < 0.01$). Distinct cerebral untrastructural injuries were seen in the control group on transmission electron microscope. Overall quality level, the injury in control group was more severe than that in experiment group.

Conclusions: Oxygen free radical is an important factor in brain damage after DHCA. SCP could be a new approach to maintain blood supply to brain tissue during DHCA so that to minimize free radical reaction, inhibits the release of EAA during DHCA in rabbits and reduce the risk of brain injury.

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Protective Effects of Melatonin on Isolated Rat Myocardium After Ischemic-Reperfusion

Purpose: To investigate the protective effects of Melatonin(MLT) on myocardial injury ischemic-reperfusion in isolated Sprague-Dawley rat myocardium.

Methods: According to the preconditioning concentration of MLT,32 adult Sprague-Dawley rats (350~400 g) were randomly divided into 4 groups: groupI(Control group: n = 8), group I(10 μ M/L MLT: n = 8), group II(30 μ M/L MLT: n = 8) and groupIV(100 μ M/L MLT: n = 8). Hearts were subjected to 25 minutes of normothermic global ischemia followed by 60 minutes of reperfusion. The preischemia and postischemia myocardial function were assessed by the percentage recovery of left ventricular developed pressure (LVDP), $\pm dp/dt$ -max. The troponin I (cTnI) of coronary artery effluent was analyzed. The superoxide dismutase(SOD) and malondialdehyde(MDA) of myocardial cell were tested. The ultrastructure of myocardial cell was observed through transmission electron microscope.

Results: During 60 minutes reperfusion, LVDP, $\pm dp/dt$ max recovery had a significant improvement in preconditioning groups. $p < 0.05$. cTnI and MDA levels were the least in 100 μ M/L pretreatment group. $p < 0.05$ and pretreatment groups also had a higher level of tissue SOD. $p < 0.01$. The ultrastructure of myocardial cells were better preserved in pretreatment groups than that in control group.

Conclusion: These results indicate that Melatonin is an effective agent for reducing postischemic reperfusion injury.

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