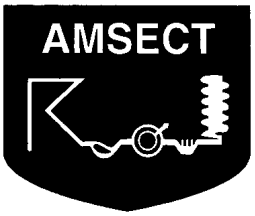


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# Abstracts

## THE EFFECT OF LEUCODEPLETION ON THE EXPRESSION OF LEUCOCYTE ADHESION MOLECULES CD11b, CD18 AND CD62L, DURING IN-VITRO EXTRACORPOREAL CIRCULATION OF HUMAN BLOOD

To examine the effect of leucodepletion on the expression of leucocyte surface adhesion molecules (and markers of leucocyte activation) CD18, CD11b, and CD62L in fresh whole human blood.

200mls of blood were taken from ten patients undergoing CABG five minutes after the initiation of CPB from the arterial outlet of the oxygenator. The blood was circulated for 60 min within a simulated extra-corporeal circuit. A specially designed leucocyte-depleting filter was attached on the extra-corporeal circuit during the circulation of the blood taken from five patients. No filter was used during the circulation of the blood taken from the remaining five patients, which were used as controls. At 10 min intervals, 500 μl blood samples were withdrawn from the circuit and analysed for the expression of CD18, CD11b, and L-selectin with flow cytometry.

In the control samples there was a relative increase in the expression of CD18, CD11b, and CD62L above baseline after 60 min ($p = 0.7$). In the leucodepleted samples, a highly significant decrease in the expression of CD11b ($p < 0.0001$) and CD62L ($p < 0.0001$) and a less merked reduction in the expression of CD18 ($p = 0.08$) were seen. Furthermore, the expression of each of the CD11b ($p < 0.0001$), CD18 ($p = 0.0001$), and CD62L ($p < 0.0001$) activation markers were significantly less in the leucodepleted samples compared to control samples.

Leucocyte-depleting filters signifiantly reduce the expression of CD18, CD11b, and CD62L during in-vitro extra-corporeal circulation of fresh human blood.

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## QUANTIFYING PLATELET GEL COAGULATION USING SONOCLOT™ AND THROMBELASTOGRAM™

There is little *in vitro* research discussing platelet gel composition and the resulting strength and degradation characteristics using point-of-care technologies. There must be a quantifiable way of determining the structural integrity of the resulting formed platelet gel thrombus. Currently in the area of perioperative blood management clinicians employ two devices designed to predictably monitor structural integrity of thrombi in whole blood. The Thrombelastogram™ (TEG™) and Sonoclot™ measure the elasticity of the clot as it forms and subsequently degrades naturally. The objective of this study is to determine the application of TEG™ and Sonoclot™ technologies as point-of-care devices for technicians employing platelet gel therapy.

Collected bovine blood was anticoagulated with CPD and processed using a previously published plasma sequestration protocol. The resulting platelet rich plasma was stored in a sequestration bag in a water bath to maintain the blood temperature at 37°C. Sequestered bovine platelet rich plasma was made into platelet gel using three different thrombin concentrations. Five Sonoclot™ and TEG™ analyses were attempted at each of the three-thrombin concentrations for a total of thirty trials. A Chi-Squared test was performed on the validity of the device tracings.

It was discovered that six of the Sonoclot™ tests and fifteen of the TEG™ tests yielded valid results. Nine of the Sonoclot™ signatures were deemed invalid. The value of the Chi-squared test was calculated to be 12.86, determining a p-value of less than 0.001.

Despite the vast use and growing popularity of platelet gels, a method in which to quantify platelet gel characteristics has yet to be reported. Technology to quantify platelet gel strength must first be standardized. Based on the data collected in this study, the TEG™ is a valid means for analyzing platelet gel clot, whereas the Sonoclot™ provided unreliable analysis results.

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## CARDIOPULMONARY BYPASS IN PATIENTS WITH PRE-EXISTING COAGULOPATHY

Patients with preexisting coagulopathies undergoing surgical interventions are at increased risk for bleeding complications. This is especially true for cardiac surgical procedures with cardiopulmonary bypass (CPB) due to the necessity for heparinization and the utilization of the extracorporeal circuits that have destructive effects on most of the blood components. In this review, cases of cardiac surgeries in patients with certain preexisting coagulopathies are summarized, which would shed a light on future managements of such patients undergoing cardiac procedures with CPB. Preexisting coagulopathies include: antithrombin III deficiency, heparin induced thrombocytopenia, cancer, factor XII deficiency, hemophillia, idiopathic thrombocytopenic purpura, protein S deficiency, and drug induced platelet inhibition. In summary, preexisting coagulopathy in patients undergoing open-heart surgeries, if not recognized and appropriately managed, can cause serious complications. Management of patients undergoing cardiac procedures should include a routine coagulation work-up and a thorough past medical history examination. If any of the foregoing is abnormal, further evaluation is warranted. Proper diagnosis and management of the preexisting coagulopathy disorders is of crucial importance to the surgical outcome and long-term morbidity.

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## HEMICOLECTOMY WITH CONCOMINANT HEATED INTRAPERITONEAL CHEMOTHERAPY: A CASE REPORT

The use of heated intraperitoneal chemotherapy is an emerging new adjunct in the treatment of adenocarcinoma of the colon. Documentation regarding perfusion circuitry and techniques associated with this therapy remain largely undescribed, however. After consultation with the surgical service team, a custom designed circuit was constructed for this procedure.

Institutional approval and informed consent were obtained for surgical debulking and heated intraperitoneal chemotherapy for a 58-year-old female. Following surgical resection, a right hemicolectomy was performed and pathological specimens obtained. A modified custom circuit utilizing a roller pump was first primed with 3 liters of Dianeal® PD-2 and recirculated until a temperature of 41°C was obtained. The circuit was then connected to the patient for infusion of perfusate via Blake drains placed in the deep pelvis. Two additional drains were placed in the subdiaphragmatic space for return. Perfusate containing 30 mg Mitomycin was circulated at 1 L/min for 60 min at 41°C. An additional 10 mg Mitomycin was then administered through the circuit for an additional hour under similar conditions. Upon completion, a washout procedure was performed with 2 additional liters of Dianeal® PD-2. The patient tolerated the procedure well and was discharged postop day 7.

We describe a successful utilization of a perfusion administered heated intraperitoneal chemotherapy regimen as an integral part of successful treatment of adenocarcinoma of the colon.

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## THROMBELASTOGRAPH™ ANALYSIS OF PLATELET GEL CLOT FORMATION MADE FROM DIFFERENT CONCENTRATIONS OF THROMBIN

Autologous blood therapies, such as allogenic platelet fibrin gels, are successful in decreasing the risks of disease transmission and blood typing errors. In this way, platelet gel can help provide control of intraoperative and postoperative bleeding. In an earlier study, the TEG™ was demonstrated to yield consistent valid clot tracings for platelet concentration gel formation at three different thrombin concentrations. The hypothesis evaluated herein is that there is no difference between TEG™ parameters when analyzing platelet gels formed with calcium chloride, platelet rich plasma and three different concentrations of thrombin.

Bovine blood from a single donor was sequestered into platelet rich plasma (PRP) and was made into platelet gel using calcium and three different concentrations of thrombin (667, 1000, 2000 U/ml). The platelet gels were analyzed with the TEG™ analyzer and the results were recorded. A one-way ANOVA test was performed to TEG™ maximum amplitude (MA), time to MA (TMA), coagulation index (CI), or alpha angle (Angle).

The one way ANOVA test was performed between thrombin concentrations for MA ($P = 0.19$), TMA ($P = 0.443$), CI ($P = 0.257$) and Angle ($P = 0.323$). Altering thrombin concentration did not affect the MA, TMA, CI, or Angle as measured by the TEG™ analyzer. These trials were conducted with a statistical power of 0.023.

As the thrombin concentration was varied, no significant statistical difference for the TEG™ parameters was discovered employing this method. Increasing the number of trials at each thrombin level may lead to measured significant differences in the observed trends in the TEG™ parameters.

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## ASSESSING THE ACCURACY OF POINT-OF-CARE-TESTING ANALYZERS FOR HEMOGLOBIN AND HEMATOCRIT MEASUREMENTS UNDER VARIOUS HEMODILUTIONS

The rapid expansion of point-of care-testing (POCT) as a reliable substitute for conventional laboratory analyzers in an acute setting has been well received. However, recent concerns regarding the accuracy of hemoglobin/hematocrit (Hct)/ Hgb) measurements during cardiopulmonary bypass (CPB) has been raised. These results may lead to improper utilization of blood products. The aim of this study was to evaluate four POCT analyzers with respect to Hct/Hbg values during simulated CPB conditions. Bovine whole blood was collected and tested at three levels of hemodilution. The measured values were compared to a conventional laboratory analyzer, the Coulter Counter, which served as the "Gold Standard". The results were analyzed for significance using a paired-T test. While two of the analyzers correlated closely with the conventional laboratory standard, one analyzer revealed a statistically significant difference that may influence the quality of patient care. As reported by others, the results suggested that conductivity measurements of hematocrit and hemoglobin under simulated cardiopulmonary bypass settings are influenced by many factors, that if uncorrected can yield inaccurate clinical values. Further in vivo experiments should be conducted on a larger scale with human subjects to determine the true impact on patient care and cost containment of POCT analyzers.

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## AUTOLOGOUS PLATELET GEL APPLICATIONS DURING CARDIOVASCULAR SURGERY EFFECT ON WOUND HEALING

The purpose of this study was to examine whether the application autologous platelet gel (APG) was beneficial to patients undergoing cardiovascular surgery. Benefits have been shown in clinical studies with the APG applications in cosmetic surgery by enhancing the healing in soft tissue. Clinical studies have also shown benefits in oral and maxillofacial surgery by presenting evidence that growth factor additions to bone grafts produced a quantifiably enhanced result in comparison with grafts performed without its use. Although APG has been approved for postoperative healing, there were no studies published in the literature describing the effects of APG adapted in the cardiovascular surgical setting.

The principal investigator in this quasi-experimental pilot study randomly assigned 32 subjects, 16 males and 16 females to either the control group or the experimental group. Postoperative pain, postoperative wound infections, swelling, discoloration, and postoperative blood loss were measured in the morning of postop day 1 and 3 in the ICU and 30 days postop during the doctor's office visit. Baseline and final product platelet counts and platelet aggregation tests were also measured on each autologous blood specimen.

Our pilot study showed increased healing on the chest wounds and sapheneous vein retrieval sites on the subjects with the APG application. Postoperative wound infections sites were decreased, and postoperative pain was decreased as measured by the monitoring criteria for defining a surgical site infection (SSI). Swelling and discoloration were markedly reduced on the sapheneous vein retrieval sites.

This pilot study did provide evidence that the application of APG during cardiovascular surgery was beneficial to the subjects. Although the sample size was small, this pilot study will encourage future research as a viable intervention for clients undergoing cardiovascular surgery.

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## THE USE OF HYDROXY-ETHYL STARCH SEDIMENTATION FOR AUTOLOGOUS BUFFY COAT PREPARATION

The use of hydroxy-ethyl starch (HES) has been used in the umbilical cord blood banking industry for the separation of blood components. The focus of this study is to examine if the use of HES is feasible to separate the buffy coat for use in platelet gels.

Sixteen cubic centimeter (cc) of blood were collected from each of seven canines into anticoagulant citrate dextrose (ACD) at a ratio of 8:1. A 3 cc sample of the shed whole blood was used to obtain initial cell counts and a base line Thrombelastogram™ (TEG™). Three cc of 6% Hespan™ were added to a 15 cc ACD-whole blood and allowed to separate by gravity for 60 minutes. Cell counts and TEG™ analyses were performed on the resulting layers: red blood cells (RBC) layer, buffy coat (BC), and plasma layer. Results:

**Table 1.** Sedimentation of RBCs with hespan: separation results by layer

| Parameter | Whole Blood | RBC Layer | Buffy Coat (BC) | Plasma Layer | ANOVA p Value |
|---|---|---|---|---|---|
| Hematocrit | 30 | 49 | 17 | 6 | <0.001 |
| WBC Count | 6.7 | 2.4 | 8.1 | 8.2 | 0.004 |
| Platelet Count | 121.4 | 7.0 | 173.1 | 236.1 | <0.001 |
| TEG Coag Index | 1.7 | −1.3 | 1.0 | 1.8 | 0.005 |

Mean values for seven observations of whole blood and sedimentation layers, p values are the result of one-way analysis of variance (ANOVA). TEG™ Coag Index is the Thrombelastograph™ Coagulation Index.

The results of this study suggest that HES-assisted gravity sedimentation of whole blood significantly reduces the red blood cells in the BC and plasma layer while significantly increasing the platelet count in the BC and plasma layer. The TEG™ results suggest that the BC and plasma layer are functional and HES does not affect clotting of the resulting BC and plasma layer.

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## SYNTHESIS OXYGENATOR

The use of arterial line filters has long become a standard of practice in the field of cardiac surgery. Sorin Biomedica has designed an adult hollow fiber oxygenator that not only incorporates their Mimesys® biomimicry coating technology, but also has incorporated a 40-micron arterial filter as an integral component of this redesigned membrane oxygenator. The Synthesis® oxygenator has been in clinical use in Europe since the spring of 2002, and was released in North America in the fall of 2003.

We did a prospective, randomized clinical evaluation of 54 Synthesis oxygenators and compared them to 54 uncoated Monolyth oxygenators with external arterial line filtration (Affinity®). Parameters examined included patient demographics, blood gases, plasma free hemoglobin, platelet loss, resistance, pressure differentials, and priming volume.

When compared to the Monolyth group, there was no significant difference found in the Synthesis group with regards to patient demographics, O2/CO2 transfer and acid base balance. However, we concluded there were improvements in platelet protection, hemodynamic resistance, and reductions in priming volumes when using the PC coated Synthesis oxygenators for cardiopulmonary bypass. Therefore, the Synthesis oxygenator was considered safe and easy to use, with potential benefits to patient care.

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## FRACTRIONAL DIFFERENCE FORMULA: AN AID IN DEFINING OXYGEN TRANSFER PERFORMANCE

All membrane oxygenators are tested according to the Association for the Advancement of Medical Instrumentation (AAMI) referencing maximum blood flow and oxygen transfer under specific conditions (120 gms/L ± 10, an $SvO_2$ of 65% ±5 and an $FiO_2$ of 1).

Oxygen transfer across the membrane depends on the incoming conditions of hemoglobin, blood flow, and venous saturation and all three parameters are related to the patient oxygen consumption ($O_2C$). The resulting arterial pO2 is used as the standard to judge oxygenator performance and depends not only on the incoming conditions but also the fraction of inspired oxygen ($FiO_2$). Therefore, a formula was developed in which the inlet conditions were compared to the resulting $pO_2$ (mmHg) taking into consideration the $FiO_2$. The formula known as the "Fractional Difference" can easily be used to compare the oxygen capability of each individual oxygenator.

The FDif refers to the difference in FiO2 and the pO2 expressed as a fraction ($FpO_2$=$pO_2$/(Pb-pH2O-pCO2)*100) (1). The $O_2C$ (y-axis) plotted against the FDif (x-axis), provides a guideline to the normal oxygen transfer of each membrane. In this paper the following oxygenators are evaluated for oxygen transfer, Micro Safe and Terumo Baby-RX, Dideco 901, and the Medtronic Mini-Max Plus.

Clincal evaluation of oxygenator performance has in the past been difficult due to the many variables and complicated formulas. The FDif may be used not only to evaluate oxygen efficiency but also to determine if the oxygenator is working within normal range.

Formulas: (1) FiO2-FpO2 Pb = Barometric pressure (taken as 760 mmHg)

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## ECMO AS A CIRCULATORY SUPPORT FOR LUNG TRANSPLANTATION

Since the first attempt to transplant a human lung in 1963 by Dr. and the first successful single lung transplantation (LTx) by Dr. J. Cooper, of Toronto, LTx has become an established treatment for patients with severe lung disease. Not all patients require circulatory support, however, it is indicated in patients with primary pulmonary hypertension and in children.

At the University Clinic of Vienna, Austria, extracorporeal membrane oxygenation (ECMO), was used instead of the traditional heart-lung machine so the technique of the ECMO system consists of a tip-to-tip heparin coated circuit, Affinity Membrane Oxygenator and a Centrifugal Biomedicus pump. Priming consists of a clear (colloidal) prime, filled by gravity. A partial bypass is used to allow the heart eject and pulsatile pulmonary artery pressure and an end-tidal carbon dioxide of 15 mmHg. If the patient becomes unstable, full flow is used. When the pulmonary artery is clamped the pulmonary pressure rises to such a high level that the cardiac hemodynamics are at risk. ECMO unloads the blood flow to the lungs and controls reperfusion of the new lung, minimizing the potential complication of reperfusion edema.

Reperfusion injury remains a significant problem in 10–20% of patients Therefore the technique of controlled reperfusion of the transplanted lung is very critical. Success of LTx has been greatly improved by the experience of team specialists, operative technique, and new medications. Patients suffering from lung disease can look forward to a future without having the feeling of suffocation.

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## COMPARISON OF METHODOLOGIES TO PREPARE AUTOLOGOUS PLATELET GEL

A platelet gel (PG) is produced by the addition of calcium chloride and thrombin to a platelet concentrate (PC). PG releases multiple growth factors that have the ability to initiate and stimulate one growth factor's function in the presence of others. This finding has given rise to the use of PG to modulate bone growth in orthopedic surgery and enhance healing in plastic and reconstructive surgery. The present study compared the commercial systems currently available for the preparation of PG in the hospital setting or in stand-alone surgical clinics.

All procedures were performed according to the manufacturers directions. The devices were evaluated with respect to ease of use, collection efficiency, platelet quality and growth factor release.

The SmartPReP requires only 5 processing steps compared to 12 to 24 required by other devices. The Smart PReP®2 and the MAGELLAN™ have the most reproducible and consistent PC evidenced by their low coefficient of variation of 6.5% and 9.0%, respectively. The mean platelet yield was 75.9% for the SmartPReP®2, 60.9% for the MAGELLAN™, 58% for the 3iPCCS®, 54% for the Sequestra, 42.6% for the Biomet, 31% for the CATS®, 31%for the Secquire, and 27% for the Interpore Cross®. The mean total amount of PDGF-AB and TGF-B1 obtained from the SmartPReP®2 PG is slightly greater than the 3iPCCS® but significantly greater than the other systems evaluated ($p < 0.05$).

The SmartPReP®2 and the MAGELLAN™ produced the most consistent PC. Only a system that can consistently produce a PC that is 4 to 5 times baseline should result in a protein load to enhance wound healing and bone regeneration based upon growth factor release data.

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## BEATING HEART VALVULAR AND COMBINED SURGERY: A NEW STRATEGY FOR MYOCARDIAL PROTECTION

Myocardial protection plays a major role in the management of patients with valvular and combined valvular and coronary artery disease. As the spectrum of cardiac patients is changing, we are being asked to perform surgery on patients with serious comorbodities (such as renal failure) and dilated cardiomyopathy. Over the years, new advances in cardiac surgery have evolved these procedures to include the use of normothermic systemic perfusion combined with simultaneous antegrade and retrograde perfusion of the heart during the period of aortic clamping for aortic valvular surgery, and perfused-beating heart on pump for mitral valve surgery. End-stage renal disease (ESRD) poses an important consideration for this type of beating heart surgery. In addition, this high-risk patient population seems to be best served by it. Complications of cardiopulmonary bypass, such as hemodilution, electrolyte imbalance, low cardiac output syndrome, and ischemic-reperfusion injury, have been well documented, and are especially deleterious in high-risk patients. We took a retrospective look at ten patients presenting with ESRD, who underwent perfused-beating heart surgeries due to valvular and coronary artery disease. The results showed no significant changes in the patients' preoperative and postoperative serum electrolyte level, cardiac output function was preserved, and demonstrated a favorable decrease in ICU length of stay. Much experience with this method, including a general patient population in addition to ESRD patients, indicates that this new technique in myocardial protection is safe, reliable, and is especially useful in patients who have serious comorbidites and/or have poor ventricular function undergoing valvular or combined valvular and coronary procedure.

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## OPTIMIZING MANAGEMENT OF HIRUDIN ANTICOAGULATION

Accurate monitoring of anticoagulation, critical during cardiac surgery (CS), is especially critical for novel therapeutics, such as hirudins for which there are no known antidotes. The ACT, the standard for heparin monitoring, has been reported to be insufficiently sensitive to high levels of hirudins to be useful in CS. There is a need for a simple assay to monitor hirudins at the levels required for cardiac surgery that is accurate, sensitive, and easy to use.

During the REPLACE and REPLACE II clinical trials, the HEMOCHRON® Jr Signature ACT-LR and ACT+ (ITC) assays were employed to monitor Angiomax® (bivalirudin (BV), The Medicines Co.) in interventional cardiology procedures (PCI). During these trials, the ACT+ was observed to lose sensitivity at BV levels above 8-10μg/ml. A new assay, the ACTT, was developed to increase the linear sensitivity of the ACT+ to 15–20μg/ml BV to extend the clinical utility of the assay to CS levels.

Both *in vitro* dose response and *ex vivo* monitoring studies have been performed using the ACTT. *In vitro*, the ACT+ and ACTT clotting times diverge at 10μg/ml BV concentrations. The ACTT shows excellent linearity to BV ($r^2$=0.99) at concentrations to 30μg/ml. Reproducibility across donors was also superior with coefficients of variation across 13 donors less than 15% at clotting times >760 seconds.

The ACTT has been evaluated for monitoring BV during PCI in 36 patients. From *in vitro* data, an ACT+ of ~340 sec corresponds to a BV level of ~10μg/ml. The comparison of ACTT to ACT+ below 340 sec shows a slope near 1.0 and an average difference between the tests of 5%. At higher clotting times, corresponding to BV levels expected in CS where the ACT+ lacks sensitivity to BV, the slope of ACTT to ACT+ increases to near 3.0, with an average difference of 20%.These data suggest that the ACTT is sensitive to the high levels of BV required for CS.

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## RELATIVE EFFICIENCY OF VARIOUS CARDIOPULMONARY BYPASS COMPONENTS FOR AIR REMOVAL

Microemboli delivered to the patient during cardiac surgery via the cardiopulmonary bypass (CPB) circuit have deleterious effects on postoperative neurological function. Perfusionist interventions, referring to the injection of pharmacological agents and sampling from the manifold, have been identified as a source of cerebral emboli as measured by transcranial Doppler. The number of perfusionist interventions has also been associated with cognitive dysfunction postoperatively. The goal of this study was to determine the relative efficiency of various CPB components for air removal.

In a porcine model, air introduced into the venous line at a constant rate was monitored with a Hatteland bubble detector at four sites in the CPB circuit: venous line, post-reservoir, post-oxygenator, and post-arterial filter. Three different venous reservoirs were used: collapsible venous bag, vacuum-venous bag, and hard-shell reservoir.

The relative efficiency for the collapsible venous bag was 85%, vacuum-venous bag was 86%, and hard-shell reservoir was 97%. Oxygenator microemboli removal ranged from 24–48% and arterial filter removal was only 12%. When agitated saline was introduced into the venous line a 47% reduction was noted following circulation through a vacuum-venous bag. Microemboli introduced into the manifold were reduced by 84% when injected through an IV filter.

The venous reservoir is an important component for microemboli removal from the venous line. The use of an IV filter during drug administration into the manifold can decrease microemboli due to perfusionist interventions.

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## COMPETENCY EVALUATION FOR AUTOLOGOUS BLOOD RECOVEREY SYSTEM OPERATORS

Since the perfusion community has embraced autotransfusion, facilities are looking for ways to train and evaluate their employees. The guidelines set forth to assess, prove, track, and improve competencies are vague. The purpose of this paper is to describe a means of evaluating competencies of autologous blood recovery system operators.

A curriculum was developed that defined the skills necessary to perform autotransfusion in the operating room. The Adam's Model, also known as the AMOD scale, was used to measure these skills and rate the individuals on varying competencies from 0–6. Five auto transfusionists participated in a hands-on autologous blood recovery system simulator and rated. The data analysis was used to develop a training session aimed at increasing performance. The five auto transfusionists were then re-evaluated using the same simulator.

The AMOD results are graphically shown on histograms for comparison. The histograms show the varying skill levels of each individual before and after the training session.

The first competency evaluation was used as a needs assessment. The comparison of the histograms shows that a tailor made training session is effective in improving skills. Also, the AMOD scale combined with the hands-on autologous blood recovery system simulator is an extremely effective tool in evaluating and documenting employee competencies.

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## THE THROMBIN PROCESSING DEVICE – EVALUATION OF THROMBIN PRODUCED FROM THE PATIENT'S OWN PLASMA

Thrombin derived from bovine sources is commonly used to arrest bleeding during surgical procedures. However, complications such as postoperative hemorrhage can occur due to development of anti-bovine antibodies that inhibit human coagulation factor V. It would thus be advantageous to develop human sources of thrombin. This study evaluated human thrombin produced using a new thrombin processing device (TPD) containing ceramic beads.

Plasma (10 ml in citrate-based anticoagulant) was introduced into the TPD, mixed with 4 ml of an ethanol/$CaCl_2$ reagent, and incubated at 22°C for 60 min. Thrombin was harvested and activity was assayed by the modified Clauss method. The ability of TPD-produced thrombin to activate platelets was assessed by flow cytometry and compared with commercially available thrombin, $CaCl_2$, and Batroxobin stimulation

Activity of the TPD-produced thrombin was found to be 51.8 ± 12.4 IU/ml, n = 145. The ability of the TPD-produced thrombin to activate platelets was found to be equivalent to that of commercially available thrombin: CD62 expression: 83 ± 13% vs 88 ± 3%; Annexin-V binding: 10.3 ± 2% vs 11.4 ± 3%, respectively after 30 sec incubation. Using $CaCl_2$, no activation was seen after 2 min incubation and 61 ± 23% CD62 expression was seen after 10 min. Batroxobin did not activate platelets in this setting as no expression of CD62 after 30 min incubation.

The results indicate that TPD-produced thrombin from human plasma anticoagulated with citrate has consistent activity and the ability to activate platelets. This device will have an advantage in that it can be used to produce autologous thrombin for surgical patients.

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## EMBOL-X INTRA-AORTIC FILTRATION SYSTEM: CAPTURING PARTICULATE EMBOLI IN THE CARDIAC SURGICAL PATIENT

To evaluate the effectiveness of using an intra-aortic filtration system for prevention of particulate emboli transport and minimizing significant postoperative complications associated with particulate emboli.

Between October of 2000 and October 2001 a total of 146 patients were enrolled at ACMC as part of the multi-institutional randomized trial (1289 patients at 22 centers). Seventy-four patients (51%) received the Embol-X intra-aortic filter and 72 patients (49%) were enrolled in the control group. Patients were evaluated for neurologic deficit, myocardial infarction, renal insufficiency/failure, limb ischemia, and death at 12 h, 24 h, 72 h, 7 day, and 30-day postoperative intervals. All filters received histological examination for particulate matter.

Particulate matter was isolated in 70 (94.5%) of the filters successfully deployed. There was no statistically significant difference in the device related events between the filter and conventional cannulation groups (9/74 = 12.1% vs 7/72 = 9.7%). While not clinically evident, the primary event for both groups was ascending aortic intimal tears. There was one late death in each of the groups not related to the filter or cannula used.

The use of the Embol-X intra-aortic filter system has proven to be a safe and effective means to reduce the introduction of particulate emboli into the systemic circulation. Clearly the reduction of particulate matter by up to 95% justifies its utilization in cardiac surgery patients identified with an increased preoperative embolic risk.

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## THE UTILITY OF THE THROMBOELASTOGRAPH™ DURING ADMINISTRATION OF rFVIIA IN SEVERELY COAGULOPATHIC CARDIAC SURGICAL PATIENTS

Severely coagulopathic patients suffering from uncontrolled hemorrhage create significant challenges during cardiac surgery. Preoperative identification of patients at risk for excessive postoperative bleeding has proven to be elusive, and methods used for diagnosing coagulopathic conditions are often nonspecific and time consuming. The use of recombinant Factor VIIa (rFVIIa) has offered hope in treating severely hemorrhagic patients, but this intervention is extremely costly. Therefore, methods of identifying patients who may benefit from its use are desirable. We examined the use of the Thromboelastograph™ (TEG) to aid in the utilization of rFVIIa during cardiac surgery.

Between February and September 2003, rFVIIa was administered to 6 adult patients diagnosed with uncontrollable hemorrhage. Three patients had acute aortic dissections and 3 patients underwent combined valve and CABG surgery, with 1 patient receiving an intraoperative RVAD. Total CPB time was 195.0 ± 100.7 min (Mean±STDEV), aortic cross clamp time of 135.3 ± 77.6 min, and two patients had circulatory arrest periods of 37.0 ± 1.4 min. Four of the six patients required reexploration for bleeding following transfer to the intensive care unit. A mean dose of 3.5 ± 2.5 mg of rFVIIa was administered with 4 of 6 patients experiencing a positive outcome (immediate cessation of excessive bleeding). The TEG coagulation index (CI, normal –3 to +3) was –5.5 ± 3.4 prior to rFVIIa administration, which resolved to –0.1 ± 1.8 in the success group, but in the nonresponders (–6.1 ± 1.2). In conclusion, the use of rFVIIa resulted in resolution of severe hemorrhage in 66% of patients receiving this intervention as confirmed by TEG evaluation.

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## ESTABLISHMENT OF A QUALITY CONTROL PROGRAM FOR PLATELET GEL PREPARATION: A COMPARISON OF FOUR COMMERCIAL DEVICES

The production of autologous platelet gel (APG) has been shown to be an effective strategy in the promotion of wound healing in a variety of patients. However, the efficacy of this treatment is based upon clinical observation, which lacks objectivity. The present study describes the development of a quantitative quality improvement program for APG.

Between January and December 2003, 414 patients undergoing surgery had autologous blood removed for the production of APG with one of the following four devices: Harvest™ Generation I (GENI), Harvest™ Generation II, (GEN II), Fresenius Continuous Autotransfusion System™ (CATS), and Medtronic Magellan™ (MAG). Quality controls were performed on 193 patients, which included platelet count, fibrinogen, white blood cell count, and thromboelastography™ (TEG). A subset of 24 patients had additional volumetric determinations completed on samples taken from the whole blood-anticoagulant mixtures, and serve as the basis for this analysis. All data were corrected for volume differences between devices and is expressed as mean±SDEV. The GEN II had a significantly higher ($p < .01$) platelet yield (72 ± 25%, 4.5 times higher than baseline) when compared to GEN I (18 ± 4.5%, 2.1 times higher than baseline), the CATS (53 ± 15%, 2.4 times higher than baseline) and MAG (51 ± 34%, 3.0 times higher than baseline). All samples had significantly greater TEG coagulation indices when PRP were compared to PPP samples. In conclusion, there exists a significant difference in platelet yield amongst the tested commercially available systems.

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## ANTIBODY GENERATION RESULTING FROM REEXPOSURE TO BOVINE THROMBIN DURING SURGERY: REPORT OF TWO COMPLEX CASES

Antibodies to bovine thrombin have been identified in approximately 8% of patients undergoing cardiac surgery who have been previously exposed to bovine topical thrombin (BTT). The generation of these antibodies can result in both hemorrhagic and thromboembolic complications. We describe two catastrophic immunologic responses in two patients undergoing repeat surgery and re-exposure to BTT.

An 82-year-old female underwent an aortic root replacement and required reexploration for tamponade, receiving BTT during both procedures. Uncontrollable hemorrhage developed during the second procedure, which was diagnosed initially as DIC (TT – 19 sec, PT – 22.7, INR 2.71, aPTT – 53 sec) and later via factor analysis as having bovine thrombin antibodies (FII – 8 mg/dL, FV – 8 mg/dL, FVIII – 36 mg/dL, FIX 35 mg/dL, FX – 22 mg/dL). An 11-year-old male status post complete repair for hypoplastic left heart syndrome presented for spinal surgery for idiopathic scoliosis. During the operation the patient developed a severe coagulopathy, which resulted in cancellation of the surgery. Coagulation assessment revealed a factor deficiency of both FII (16 mg/dL) and FVII (49 mg/dL) with elevated PT – 19.9, INR 2.14, and aPTT – 42 sec. Thrombin time with human plasma was normal while the same test performed with bovine plasma was greater than 80 sec. Both patients required multiple transfusions of allogeneic blood products.

In conclusion, the use of BTT stimulates the immune system that may result in antibody formation, which may result in coagulopathic and/or hemorrhagic conditions.

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## IMPROVED OUTCOMES DURING CARDIAC SURGERY: A MULTIFACTORIAL ENHANCEMENT OF CARDIOPULMONARY BYPASS TECHNIQUES

Patients presenting for cardiac surgery with cardiopulmonary bypass (CPB) are more likely to have preexisting comorbidities, which has resulted in a steady increase in the risk associated with CPB. The resulting challenge has mandated the optimization of perfusion care. The purpose of this study was to retrospectively evaluate the impact of a number of aggregate, evidence based perfusion care changes on patient outcome.

After Institutional Review Board approval, two groups of patients were compared. The control group (n = 420) included all patients undergoing CPB in a 18 month period preceding a multifaceted change in perfusion techniques. The treatment group (n = 272) included all patients undergoing CPB after the changes. After matching the groups by procedure, multiple variables were analyzed, including demographic, preoperative, operative, and postoperative parameters.

The treatment group had a lower mortality rate than the control group (2.9% vs 9.3%, p = 0.001) despite being similar in predicted mortality (10.1 ± 7.6% vs 9.7 ± 8.1%, p = NS) and other preoperative and operative parameters. The lower mortality rate was concurrent with a lower incidence of reoperation for bleeding (8.8% vs 4.4%, p = 0.018), sternal infection (2.6% vs 0.7%, p = 0.062), permanent stroke (3.3% vs 1.1%, p = 0.050), and cardiac arrest (3.8% vs 1.1%, p = 0.025), and a trend of decreasing rates for other complications.

In conclusion, the patients treated after evidence based changes in CPB care were implemented had a decreased complication and mortality rate. Changes in perfusion practice can be implemented to improve the overall outcome of patients undergoing cardiac surgery.

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## APPLICATION OF PLATELET GEL IN CARDIAC SURGERY: EFFECTS ON STERNAL INFECTION

The use of plasmapheresis in cardiac surgery has failed to show an unequivocal benefit. However, the use of platelet gel may reduce sternal infection rates via poorly understood mechanisms related to a combination of white blood cell content and expedited wound healing. The purpose of the study was to retrospectively evaluate the incidence sternal wound infections in patients undergoing cardiac surgery.

Platelet gel patients (PG) (n = 134) received topical administration of a mixture of platelet rich plasma, 10% calcium chloride (5mL), and bovine thrombin (5,000 units)(platelet gel). The control group (CT, n = 297) did not receive platelet gel, but otherwise received similar sternal wound care.

After Institutional Review Board Approval, twenty factors reported in the literature to predispose individuals for sternal infection were recorded along with overall infection rate. No differences existed in any of the risk factors for sternal infection. The incidence of sternal infection was lower in the PG group than the CT group (1.5% vs 4.1%, p = 0.040), despite being similar in the incidence of leg (2.2% vs 2.4%, p = NS), urinary tract (1.5% vs 1.7%, p = NS), and systemic infection (3.0% vs 2.0%, p = NS).

In conclusion, the incidence of sternal infection in the group receiving topical platelet gel was lower than the control group, despite being at equivalent risk and experiencing similar rates of other infections.

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## DOES THE INTRA-AORTIC BALLOON PUMP AFFECT HEPATIC PERFUSION? A PROSPECTIVE STUDY

The intra-aortic balloon pump (IABP) augments left ventricular function and coronary perfusion by increasing arterial systolic pressure but decreasing afterload. The purpose of this study was to delineate whether or not these changes have a deleterious effect on hepatic and splanchnic perfusion in preoperative patients undergoing coronary revascularization.

Ten patients with normal liver function tests undergoing coronary revascularization, who required a pre-op IABP for low cardiac output or poor left ventricular function were included in the study. Liver blood flow was assessed by non-invasive measurement by dichromatic densitometry of the percentage disappearance rate (PDR) of indocyanine green (ICG). This dye is exclusively eliminated by the liver and does not undergo entero-hepatic circulation 0.25mg/kg of ICG were intravenously injected to the patients at two different stages; a) Before insertion of the IABPb). With the IABP *in situ* with 1:1 augmentation for 30 minutes.

The mean age of the patients was 72.9 ± 8.43 years with 6 males and 4 females. Insertion of the IABP was associated with a mean rise in arterial systolic pressure of 22.5% and a mean rise of 16.2% in arterial diastolic pressure as measured in the right brachial artery. Heart rate was unaffected. There was no significant difference in the PDR of ICG with or without the IABP augmentation (18.52 ± 3.13 vs 17.78 ± 3.26; paired *t*-test, p = 0.209).

The intra-aortic balloon pump does not significantly effect hepatic perfusion as shown by our methodology.

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## PARTIAL BOWLS USING THE HAEMONETICS CELL SAVER 5; DOES IT PRODUCE A QUALITY PRODUCT?

Controversy still exists on the validity of processing a partial bowl during the collection of shed blood lost through surgery. The purpose of this study was to assess the quality of red blood cells produced from a partial bowl of autologous suctioned blood using the *Haemonetics Cell Saver 5.* Suctioned blood was collected from 17 cardiac patients undergoing surgery. A partially filled cell saver bowl was washed with 1500 ml of NaCl. Reservoir and processed blood samples were examined for potassium (K+), leukocytes (WBC), hematocrit (HCT), platelets (plt) and plasma-free hemoglobin (PFH) and then compared to 22 previously studied full bowls. Results are summarized in the table below:

| | Full bowl | Partial Bowl | P value |
|---|---|---|---|
| % Plt removal | 86 ± 23 | 85 ± 6 | NS |
| % K+ removal | 91 ± 4 | 88 ± 4 | NS |
| % WBC removal | 35 ± 17 | 50 ± 13 | 0.006 |
| % PFH removal | 85 ± 6 | 85 ± 6 | NS |
| % RBC recovery | 94 ± 16 | 84 ± 17 | 0.02 |

In conclusion, the *Haemonetics Cell Saver 5* can produce a quality product from washing a partial bowl with a better washout of WBCs compared to a full bowl. However, there is a reduction in RBC recovery.

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## QUALITY OF RED BLOOD CELLS USING THE NEW ELECTA AUTOTRANSFUSION DEVICE

The purpose of this study was to evaluate the quality of washed, concentrated red blood cells (RBCs) produced by the new *Electa* autotransfusion device from *Cobe Cardiovascular (Dideco)*. Blood was collected intraoperatively in 16 cardiac surgery patients for whom routine cell salvage was being utilized and then washed using the *Electa*. 125ml bowls were used in the standard wash program. Reservoir and washed RBCs were analyzed for platelets (PLT), leukocytes (WBC), potassium (K+) and plasma free hemoglobin (PFH) removal, as well as hematocrit (HCT) and RBC recovery. Results

| | | Removal | | | |
|---|---|---|---|---|---|
| Post Hct | RBC Recovery | WBC | PLT | K+ | PFH |
| 58% ± 5% | 87% ± 10% | 54% ± 18% | 87% ± 6% | 91% ± 4% | 77% ± 17% |

are summarized in the following table and are expressed as Mean +/- SD.

Conclusion: The *Electa* produces a good quality washed RBC product that is comparable with most autotransfusion devices on the market.

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