ABSTRACTS
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DETOXIFICATION EFFICIENCY OF MOLECULAR ADSORBENT RECIRCULATING SYSTEM

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Introduction. A engineering model can be used to predict the time course and efficiency of bound toxin removal. Our objective was to identify real detoxification of single substances such as cytokines and bilirubin in the four points of the albumin circuit in a single treatment. The second step was to insert these parameters in a engineering model to identify removal capacity taking place in order to forsee the usefulness of further treatments.

Materials. One hundred seven AoCLF patients treated with MARS in waiting list for transplant, were enrolled in this study. Sample collections of IL-6 and bilirubin were performed before and at different times after the beginning of the treatment in blood circuit and in the 4 points of albumin circuit. Than the findings were inserted in an engineering model to evaluate detoxification efficiency . Results. Evaluation of IL-6 absorption capacity has shown that most efficiency obtained between the first and third hour of treatment with values between 0.94 and 0.83 for IL-6 and values between 0.90 and 0.85 for 71% of patients. In 29% of patients evaluated cytokines absorption capacity showed a mean values of 0.69 and bilirubin values of 0.67 after first hour of treatment. These values decreses and fell to below threshold, 0.40,after third hour.We stratified patients in two group: Responders(R)71% and No Responders (NR) 29%. In group R, we observed 42 recovery and 34 liver transplant, while in group NR included 5 liver transplant and 26 died. Conclusions. Detoxification curves referring to could be seen as predictive after first treatments when mathematical model has greater and more exhaustive data in order to confirm results.

SAFETY CONTROL DESIGN OF A VENTRICULAR ASSIST DEVICE CONSIDERING DETECTION OF HEART FAILURE

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Several studies show that a Ventricle Assist Device (VAD) can fail. These failures may occur because of low intelligence of the device. An intelligent control allows the device adaptability of the different situations. The proposal is to insert a supervisory control with a coordinate layer showed at figure 1. This layer able the system to detect failures and take decisions in order to maintain the system in a safe state. The IDPC and USP together created a design method for safety control. This method consists in systematic steps for design of a VAD Safety Control based on diagnosis and treatment of failures by formal concepts of modelling and validation. Using formal models obtained by Petri Net (PN), a computational simulation is implemented and mathematically validated is performed to ensure safety of the obtained model.

Implementing the proposed architecture and running simulations, it was noted that the control become more reactive, allowing the adaptation of control to the patient conditions. Considering the global control system instead of the local control, effective interaction between VAD and cardiovascular system were observed in the simulations. The control, degenerating and regenerating the system depending on the severity of the failure leading the system to a safe state. (Figure 1)
EFFECTS OF DFAT (DEDIFFERENTIATED FAT) CELLS IN CASES OF ARTIFICIAL DERMIS GRAFTS – RAT EXPERIMENTAL STUDY
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Purpose of Study: ASCs (adipose derived stem cells) have been demonstrated to stimulate angiogenesis. Our group has established an adipocytes progenitor cell line from mature adipocytes and named these cells DFAT (dedifferentiated fat) cells. The DFAT cells have been showed to have multilineage differentiation potential similar to that of ASCs. The purpose of this study was to investigate the effects of the DFAT in cases of artificial dermis grafts in rat models.

Methods Used: The DFAT cells were obtained by dedifferentiation of mature adipocytes from SD rats. Full-thickness wounds treated on the back of SD rats were treated with artificial dermis (Pelican®, Gunze Co., Japan). Prior to the artificial dermis grafting, following four groups were established: control group (AD alone), DFAT group (treated with DFAT cells), bFGF group (treated with bFGF (Kaken Co., LTD., Japan)), combination group (treated with DFAT cells and bFGF). In 7 days, the specimens were subjected to the histologic examination.

Summary of Results: In the control group, visible stained capillary formation was not observed in the dermis layer. In the DFAT group, vascular invasion into the artificial dermis was observed and the dermis like-tissues were thickened due to increase of extra cellular matrix generation compared with the control group. In the combination group, the capillary invasion into the dermis layers were much more accelerated than in the DFAT group, which was enhanced in a dose-dependent of bFGF. The present study revealed that the DFAT cells accelerate the generation of dermis like tissues and the effect was enhanced with the bFGF in the cases of the artificial dermis grafts.

HEMOGLOBIN (HB) PHARMACOLOGICALLY CROSS-LINKED WITH ATP, ADENOSINE AND REDUCED GLUTATHIONE (GSH) DESIGNED TO TREAT ANEMIA AND ISCHEMIC DISEASES
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Effective Hb-based blood substitutes may offer a solution to transfusion medicine problems such as blood shortages, transmission of bloodborne pathogens and the red blood cell storage lesion. We have developed HemoTech, a blood substitute that utilizes the concept of "pharmacologic cross-linking." It consists of bovine Hb cross-linked intramolecularly with ATP and intermolecularly with adenosine, and conjugated with GSH. In this composition, ATP prevents Hb dimerization, and adenosine permits formation of polymers and counteracts the vasoconstrictive and pro-inflammatory properties of Hb via stimulation of adenosine receptors. ATP also serves as a regulator of blood vessel tone through activation of P2Y receptors. GSH introduces electronegative charge onto the Hb surface that blocks Hb’s transglomerular and transendothelial passage and shields heme from nitric oxide and reactive oxygen species. HemoTech and its manufacturing technology have been extensively tested including viral and prion clearance validation studies and various non-clinical pharmacology, toxicology, genotoxicity and efficacy tests. The clinical proof-of-concept was carried out in sickle cell anemia patients. The performed preclinical and clinical studies indicate that HemoTech works as a physiologic oxygen carrier and has efficacy in treating acute blood loss anemia by providing a temporary oxygen bridge and stimulating erythropoiesis, sickle cell disease by correcting vaso-occlusive/inflammatory episodes and hematocrit, and ischemic vascular diseases particularly thrombotic and restenotic events.

A NOVEL METHOD FOR CLEARANCE OF PRIONS AND VIRUSES FROM HEMOGLOBIN (HB)-BASED BLOOD SUBSTITUTES
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To be an effective blood substitute, Hb solutions of human or bovine origin must have a satisfactory oxygen carrying capacity and be non-toxic, non-immunogenic, non-pyrogenic, and pathogen-free. This includes being free of prions of human- and bovine-origin that cause Creutzfeldt-Jakob Disease (CJD) and Bovine Spongiform Encephalopathy (BSE), respectively; and viruses. The manufacturing process for these products must be validated to clear these pathogens by at least two major and independent (orthogonal) clearance steps. One step must be inactivation and the other step must be removal. We have developed a robust integrated orthogonal prion/viral clearance method that comprises; (1) selective hollow fiber nanofiltration, (2) anion membrane chromatography, (3) hydrophobic solvent treatment, and (4) heat inactivation. The clearance validation tests were conducted by BioReliance/ Invitrogen Laboratories (Rockville, MD) using bovine Hb spiked with prions, and enveloped (Bovine Viral Diarrhea Virus – BVDV, Leukemia Virus C-Type Retrovirus - X-MulV, Bovine Rhinotracheitis Virus – IBR) and non-enveloped viruses (Encephalomyocarditis Virus – EMCV, Bovine Parvo Virus – BPV). The tests confirmed that this technology is extremely effective in elimination of prions and viruses. While the clearance of viruses was on average, 1 - 3 log10 reduction value (LRV) above the FDA limits, the prion elimination was more than 10 LRV’s, exceeding FDA requirements by 5 LRV’s. This technology is fully operational, consistent with any batch size, and can be used in the manufacturing of free Hb-based blood substitutes and other therapeutics derived from human or bovine sources.

NITRITE-ENHANCED ATP SYNTHESIS AND RELEASE FROM RED BLOOD CELLS (RBC) IS ATTENUATED BY EXTRACELLULAR HEMOGLOBIN (HB) IN HYPOXIA AND NORMOXIA
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Although it has been established that Hb has nitrite reductase activity that generates systemic nitric oxide (NO) (Am J Physiol 2008;295(2):H743-54) and nitrite enhances the release of ATP from RBCs (Am J Physiol 2009;297:H1448-503), which induces vasodilation by stimulating the P2Y-purinergic receptor on the endothelium that is linked to the production of NO; there is still controversy regarding the mechanism by which extracellular Hb causes vasodilation. Since the oxygen affinity of Hb can modify the erythrocytic ATP release and Hb is highly reactive with nitrite and NO, this study was undertaken to investigate the impact of extracellular Hb on nitrite-induced ATP synthesis and release from RBCs. Fresh human RBCs suspended in isotonic PBS buffer (10% Hct, pH 7.4), were exposed to purified bovine Hb (1.3 g%) and sodium nitrite (500 µM), under hypoxic and normoxic conditions. After 1 hour of incubation at 37 deg C, RBCs were evaluated for intracellular ATP and supernatants were screened for ATP, nitrite and ferric Hb. Results confirmed that nitrite stimulates ATP synthesis and releases from Hb, more in hypoxia than normoxic conditions. Extracellular Hb diminished the effect of nitrite in both oxygen environments. A rapid consumption of extracellular nitrite was associated with formation of ferric Hb. It appears that extracellular Hb suppresses the nitrite-induced ATP synthesis and release from RBCs, which may contribute to Hb-mediated vasodilatation.
PARTICLE IMAGE VELOCIMETRY VISUALIZATION AND ANALYSIS OF FLOW AT THE TIP OF HEMODIALYSIS NEEDLES
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Objective: During hemodialysis, extracorporeal blood circulation passes through extremely narrow needles at a rate of approximately 200 ml/min. The resulting jet flow or turbulence, particularly at the tip of the venous needle, can damage the hemodialysis shunt vessel and presents a risk of vascular stenosis or related blood coagulation. The present study applied particle image velocimetry (PIV) to visualize flow around the tip of several commercially available needles and conducted flow analysis.

Methods: 4 types of 17-G needle were investigated. Needles were inserted into a simulated blood vessel formed by a polyvinyl chloride tube and water was circulated at a flow rate of 700 ml/min within the tube. Needles were connected to the venous outlet of the hemodialysis circuit, while the arterial outlet was inserted into a bucket filled with water seeded with tracer particles. The flow rate of water removing from the needle was set at 200 ml/min. The simulated blood vessel was illuminated from below with laser sheet light and flow around the tip of the needle was observed laterally to the simulated blood vessel using a high-speed camera. Flow analysis was conducted on recorded images using specialized analysis software.

Results and Discussion: Returning water drained rapidly into the tube from the needle tip. This suggests rapid impact of blood with the intravascular wall over long periods of time, potentially resulting in intimal thickening or coagulation due to retention of blood. Furthermore, during blood return, flow out of needle side holes was barely observed, indicating that side holes are largely ineffective for preventing the formation of jet flow at the needle tip.

EARLY DETECTION OF BLOOD COAGULATION DURING HEMODIALYSIS USING NON-INVASIVE MONITORING OF BLOOD FLOW SOUNDS
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Objective: During Hemodialysis, coagulation is diagnosed visually, via palpation or based on changes in pressure such as venous, dialyseate and transmembrane pressures. However, pressure values may vary due to causes other than coagulation. Furthermore, visual observation and palpation involve judgment based on the experience of medical staff and sense of touch, resulting in a risk of qualitative judgments in which findings differ depending on the staff member. The present study investigated a simple, non-invasive method for early detection of blood coagulation, focusing on changes in blood flow sounds generated by coagulation. Methods: A water-primed blood circuit and dialyzer were prepared in a basic experiment. Acceleration sensors were externally attached to each of the center positions of pillow, venous air trap chamber and dialyzer which are common sites of coagulation in the blood circuit. Water was then circulated at a flow rate of 200 ml/min using a hemodialysis roller pump and blood flow sounds at each sensor were sampled and subjected to time-frequency analysis. Next, an artificial foreign object was injected into the venous air trap chamber to simulate coagulation and blood flow sounds were again sampled and analyzed. Results and Discussion: Characteristic frequency components were obtained from blood flow sounds at each sampling site. Furthermore, injection of a foreign object resulted in different frequency components compared to those sampled prior to injection. The present findings suggest that non-invasive sampling and analysis of blood flow sounds may enable early detection of blood coagulation during hemodialysis.

DEVELOPMENT OF THE CELL TRANSPORT DEVICE IN AUTOLOGOUS CULTURE PROCESS
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Purpose: Autologous cultures are widely conducted in for regenerative medicine. Cells are obtained from a patient at a medical institution, and are cultured at a cell processing center. In case these establishments are in different locations, the transport process is necessary for this medical treatment. So, we aimed to develop the cell transport device. Methods: The biphasic system that consists of perfluorocarbon (PFC) and medium containing fetal bovine serum was used as a retention mechanism of anchorage dependent cells. During cell transport, the cells are floating on an interfacing surface. The survival rate and growth potential of three cell lines were evaluated at each temperature (8, 25 and 37 °C) in the biphasic system. A battery and a microcomputer were used to control temperature of the biphasic system. Results: In this biphasic retention system at 37 °C for 72 h, Murine fibroblast (3T3) and Rat aortic smooth muscle (A-10) cells had equivalent survival rate to initial value. In contrast, Mouse vascular endothelial (RCB1994) cells had a low survival rate. RCB1994 cells retained at 37 °C had a high specific growth rate at early phase in the growth culture. The cellular aggregations were observed at 37 °C, and were unformed at 8 °C. The developed temperature control system could maintain 37 °C in retention container for 72 h with a battery. The retention container equipped with mesh structure was designed and fabricated to harvest cells aseptically.

Conclusion: The autonomous cell transport device was developed with the biphasic system consisted of PFC and medium, and high survival rate and growth potential of cells could be maintained at 37 °C for 72 h in the biphasic retention system.

PROPOSAL OF A METHOD FOR NONINVASIVE, ONGOING MONITORING OF THROMBUS FORMATION INSIDE PCPS CIRCUITS
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Objective: We attempted to visualize the flow of blood when connector branches (Y- and T-shaped branches), where blood is considered more likely to pool, were closed off in one direction with forceps, with the aim of designing a device for noninvasive, ongoing monitoring for the occurrence of thrombosis in PCPS circuits. To quantitatively compare degrees of blood pooling, we quantified various parameters that indicate blood flow characteristics.

Methods: To visualize blood flow using particle image velocimetry (PIV), we mixed microparticles in the water that would enable visualization. We added a recirculation line to the PCPS circuit, and stopped the flow of blood using forceps to close off the line. We then irradiated the area from a point downward from the bifurcation tube (where the connector was connected) with a laser light sheet. We then used dedicated flow analysis software to calculate various parameter values indicating blood flow characteristics, such as flow velocity, vorticity and Reynolds stress. We attempted to quantitatively compare the degrees to which blood pooled, based on differences between the bifurcation tubes.

Results and Discussion: Looking at the results of visualization of blood flow using PIV, we were able to confirm vortex flow at the part of the circuit closed off with forceps. Moreover, when we compared various parameters indicating blood flow characteristics, such as vorticity, we were able to quantitatively confirm differences in the degree of blood pooling based on differences in the shape of the bifurcation tube and the site at which the circuit was closed off using forceps.
ASAIO BIOENGINEERING ABSTRACTS

FLUID PARAMETERS AFFECTING CHANGES IN SHUNT MURMURS ARISING FROM DIFFERENCES IN DEGREE OF STENOSIS
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Objective: Changes in the form or degree of intravascular stenosis can affect the state of intravascular blood flow. These changes can result in abnormal vortex and turbulent blood flows, which are believed to affect shunt murmurs parameters indicating the state of the hemodialysis shunt vessel, such as frequency components and duration. The present study empirically verified changes in blood flow and shunt murmurs that arose from different degrees of stenosis and investigated related fluid parameters in order to quantitatively evaluate these changes.

Methods: Water was circulated through an angiostenosis model, which comprised a polyvinyl chloride simulated blood vessel with a clamp to provide artificial stenosis. Shunt murmurs pre- and post-stenosis were measured using acceleration sensors and flow was visualized using particle image velocimetry (PIV). Water seeded with tracer particles was circulated through the model at a flow rate of 700 ml/min. Acceleration sensors were attached at 2, 5, and 7 cm, respectively, from the clamp and shunt murmur measurement, and time-frequency analyses were conducted using a Bio Sound Analyzer. Circulating water seeded with tracer particles, the model was illuminated from below with laser sheet light, and flow in the vicinity of the stenosis was observed using a laterally placed high speed camera.

Results and Discussion: Changes were observed in the frequency components and duration of shunt murmurs depending on the degree of stenosis. Furthermore, the results of PIV visualization suggested that evaluating fluid parameters such as vortex and turbulent flow energy enables quantitative evaluation of the effects of flow on shunt murmurs.

AN AUTOMATED PERFUSION SYSTEM FOR USE IN EXTRACORPOREAL SUPPORT ASSISTED DONATION AFTER CARDIAC DEATH (EDCD)
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Extracorporeal support assisted donation after cardiac death (EDCD) has been limited by circuit complexity, qualified staff, safety related to circuit pressures, and logistics of cardiac death donation. With these limitations in mind, we developed the Automated Perfusion System (APS) for use in ECD. The APS has several advantages over standard ECS systems: 1) A collapsible pump chamber with starting ability; 2) Automated sweep flow; 3) Compact circuit and self-priming tube; 4) Easy assembly (pre-assembled pumphead and tube kits); 5) Portability (mount to cart or bedside); 6) User-friendly interface. The APS is capable of blood flows >4 L/min. We used the APS in a porcine model of uncontrolled EDCD (uEDCD) to evaluate resuscitation of kidneys for transplant.

Methods: Non-anticoagulated pigs (30Kg) were subjected to prolonged cardiac arrest (60min). ECD, using the APS for 4hr with thrombolitics, or rapid recovery (RR) of the kidneys, was performed. Kidneys were transplanted into healthy nephrectomized recipients. Adequate function was defined as serum creatinine (Cr) < 5.0 in the first 72 hrs.

Results: 12 kidneys were transplanted from the APS group. Two grafts (16.7%) failed due to ECS run instability. All kidneys from the RR group failed within 48 hrs.

Conclusion: The APS is a novel device that addresses multiple shortcomings of EDCD and successfully resuscitates EDCD kidneys. The collapsible pump chamber prevents cavitation, excessive circuit pressures, and automatically adjusts flow to venous return. The automated sweep flow eliminates need for manual adjustments and prevents hypocapnia. The compact design minimizes heat loss and reduces priming volume.

IN-SITU THERMOGELLING POLYPEPTIDE FOR 3D CELL CULTURE

Purpose of Study: Polypeptides exhibit unique secondary structures such as random coils, beta-sheets, and alpha-helix. For example, the poly(ethylene glycol)-poly(alanine-co-phenyl alanine) (PEG-PAF) with the mixed composition of D-alanine and L-alanine exhibited random coil secondary structure, whereas the PEG-PAF with the enantiomeric alanine (100/0 and 0/100) exhibited alpha-helical secondary structure. Based on the control of the structural parameter of polypeptide such as sequence, stereochemistry, molecular weight, we have developed a series of thermogelling polypeptide-based block copolymers. Aqueous solutions of thermogelling polymers undergo a sol-to-gel transition as the temperature increases. In this study, we carried out feasibility studies of the polymers as three dimensional (3D) cell culture matrices.

Methods: The 3D matrices were generated by injecting cell suspension into preheated site at 37 °C, through temperature-sensitive sol-to-gel transition. Cell culture medium was optimized for the each cell types. For example, for the adipose-tissue derived stem cell (ASC), low glucose Dulbecco’s modified eagle medium (DMEM) containing 10% fetal bovine serum and 1 % penicillin/streptomycin were used.
Summary: Chondrocytes encapsulated in the in situ formed gel preserved their spherical phenotypes and showed significantly different biomarker expression depending on the nanostructure of the polypeptide. Three dimensional culture of ASCs in the polypeptide thermogel exhibited not only chondrogenesis but also cross-differentiation into neurogenesis.

INCREASING LOCAL OXYGEN TENSION USING NANOMAGNETS BASED TARGETED DRUG DELIVERY SYSTEM IN A WHOLE ANIMAL MODEL
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Radiation therapy is often ineffective in treating cancer due to low oxygen tension in the tumor. We investigated a strategy to increase oxygen tension in a localized area of tissue using a nanomagnets based drug delivery platform. Using the hamster window chamber model, we measured the in vivo oxygen distribution to quantify the changes in the tissue oxygen induced by our drug coated nanomagnets, with and without a magnetic field applied to the studied region. Without nanomagnets (n = 7), we determined normal (baseline) oxygen distribution. Experimental group (n = 10) received 5 mg/kg of nanomagnets coated with L35, a hemoglobin (Hb) allosteric effectors. L35 lowers Hb oxygen affinity and cooperativity, thus facilitating the release of oxygen from the Hb to the tissue. After administration of the nanomagnets, a magnetic field was applied either during the first or second hour post treatment. Oxygen distribution increased from 27.7 ± 4.4 mmHg to 30.9 ± 4.4 mmHg (P<0.05) after treatment and application of the magnetic field, whereas without the magnetic field the oxygen distribution decreased to 25.3 ± 5.0 mmHg (P<0.05). Application of the magnetic field limited the L35 effects to the tissue of interest. In the absence of the magnetic field, the effects of L35 were systemic, increasing oxygen release to tissue located prior to the window chamber and limiting oxygen supply. Increased local oxygen levels by nanomagnets may lead to better treatment of hypoxic tumors. Bring oxygen to a specific area can increase free radical formation and increase anti-tumor therapy efficacy. Acknowledgements: Supported by grants R01-HL52684, R01-HL62354, R01-HL078840.
CLINICAL VALIDATION OF RAPID HEMODYNAMIC DATA ANALYSIS
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Introduction: Hemodynamic data requires precise analysis for perioperative studies. Decisions using rapid calculations in real time can lead to errors. We developed a spreadsheet-based rapid analysis (SRA) using commercial software and describe the validation of SRA against post hoc manual processing (PMP).

Methods: Flow velocity by ultrasonic aortic flow probe and arterial pressure were recorded during a biventricular pacing protocol in pediatric heart transplant patients intraoperatively (n=9) and/or in the intensive care unit (n=16) over 30 second intervals. Cardiac output (CO) and mean arterial pressure (MAP) were assessed by averaging data in single respiratory cycles by pre-programmed custom macros. The chosen respiratory cycle was copied and pasted into a spreadsheet. 36 CO measurements and 96 MAP measurements were averaged to produce 18 and 48 final values, respectively. These values were available instantaneously. Calculations were compared to PMP by a blinded observer, with ectopy stringently eliminated and corrections to zero point performed. These 36 measurements of CO and 96 measurements of MAP were evaluated by our statistician. Inter-examiner reliability coefficient, testing the reliability of SRA versus PMP, was 0.9970 for CO and 0.9975 for MAP.

Conclusions: SRA, using low-cost commercial software, allows rapid calculations in the operating room or at the bedside. Accuracy of SRA is confirmed by PMP, when original data quality is adequate. SRA is a feasible alternative to post hoc confirmatory analysis when rapid intraoperative calculations are necessary.

EXTERNAL FIXATOR PIN COATINGS USED TO REDUCE THE INCIDENCE OF INFECTION
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Introduction: External fixators are commonly used in orthopedics in both the acute and elective setting. External fixators involve the insertion of pins into bone and the construction of an external frame for stability. The incidence of infection is up to 70%. An infection occurs when planktonic bacteria adhere to external fixator pins, subsequently producing biofilm, which makes treatment difficult and may require pin removal. The vital step in the development of infection is the initial bacterial adhesion to the pin. The aim of this review is to assess pin coatings which may prevent this initial bacterial adhesion.

Discussion: External fixator pin coatings must reduce bacterial adherence, whilst showing no cytotoxicity or effect on osteointegration. Current biomaterials in development to reduce bacterial adherence are titanium-copper alloys, nitric oxide coatings, chitosan coatings and nanosilver coatings. The majority of work shows promising results, but most has been performed in-vitro. Hydroxyapatite coated pins have demonstrated reduced pin site loosening due to improved osteointegration, but only one of five human randomised controlled trials have shown a reduction in the incidence of pin site infection. Antibiotic coated pins have been shown to reduce pin site infection in several animal studies, with gentamicin the most studied. The best method of integrating antibiotics onto pins is unclear with hydroxyapatite and poly-DL-lactide coatings the currently favoured techniques.

Conclusion: Infection in external fixator pin sites is a considerable problem, and the use of novel techniques may reduce initial bacterial adherence and therefore reduce pin site infections, and improve patient outcomes.

EFFECTS OF AUTOLOGOUS STEM CELL TRANSPLANTATION ON CELL PROLIFERATION AND APOPTOSIS IN CHRONIC NON-ISCHEMIC HEART FAILURE

Objectives: Bone marrow cells (BMCs) have been shown to improve function in ischemic heart disease, but its effect in non-ischemic cardiomyopathy is still unknown. We evaluate the hypothesis that epimyocardial application of BMCs in doxorubicin (DOX)-induced cardiomyopathy induces cell proliferation and decrease apoptosis.

Methods: Heart failure was induced in rabbits by injection of DOX and they were divided into four groups: transplant group (BMC, n=15), medium group (medium, n=9), control group (control, n=9) and diseased group (DOX, n=7). Cells were isolated by bone marrow aspiration and labeled. Cell proliferation (Ki67) and apoptosis (TUNEL-assay) were analyzed by immunohistochemical studies four weeks later.

Results: Cell proliferation by Ki67 immunostaining was noted in cell-treated hearts. The proliferation was almost the same like the proliferation in the control group. Also the cell proliferation in the medium group was higher it was less than in the transplanted group. In the untreated group proliferation was much less compared to the other groups. Also the cardiomyocytes proliferation was higher in the BMC group, but not significantly. There were no differences in right ventricle and septum. Apoptosis was minimal reduced in cell-treated group, but not significantly compared to the untreated group. Only in the control group there was sig-nificantly less necrosis and less cell death. There were no differences in apoptosis between the other groups.

Conclusion: Autologous BMC transplantation induces cell proliferation and reduces cell apoptosis. This regulation could be one possible mechanism in myocardial regeneration.
CFD DERIVED PARAMETERS AND MODELS FOR IN-VITRO BLOOD DAMAGE ASSESSMENT

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Purpose: Computational Fluid Dynamics (CFD) derived parameters, such as shear stress and exposure time, and models have been utilized to evaluate the mechanically induced blood damage potentials for Ventricular Assist Devices (VAD). This work aimed to compare different CFD based methods to in-vitro results for the HVAD® Pump and Levacor® VAD®.

Methods: The grid independent steady-state CFD flow solutions were obtained. The flow weighted residence times were calculated for different shear stress intervals and plotted on the shear stress-exposure time chart provided by Hellums to be evaluated against the RBC lysis and platelet activation curves. Additionally, the shear stress thresholds were used to evaluate the hemolysis and thrombus formation potentials. Furthermore, the power-law based Eulerian method was utilized as a hemolysis model. The in-vitro hemolysis and platelet activation experiments were performed with human blood in a VAD-driven loop.

Results: The Hellums chart analysis showed that profiles of both pumps stayed below RBC lysis and platelet activation curves. The shear stress thresholds indicated that the isolated volumes of the shear stresses above the threshold values were aligned with the in-vitro results. Eulerian hemolysis predictions were found to be in qualitative agreement with the in-vitro measurements.

Conclusions: The Hellums chart analysis indicated the overall effect for range of shear stress and exposure times. Furthermore, the threshold approach and Eulerian damage model were found to be helpful for the prediction of VAD-induced blood damage.* Caution: Investigational device, limited by United States law to investigational use.

BEARING DESIGN FOR A TEMPORARY WEARABLE LOW-FLOW ROTARY BLOOD PUMP SYSTEM

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Purpose: The Arteriovenous Fistula Eligibility (AFE) System™ uses a rotary blood pump to dilate peripheral veins, enabling the creation of reliable vascular access sites for hemodialysis. Design requirements include wide operating range, low blood damage, modest cost, and 6 week mission life. A durable bearing is essential. Methods: A centri-fugal pump design with pivot bearings was chosen. Bearing materials, geometry, and loading were optimized. Alumina toughened zirconia (ATZ) ceramic was selected for its wear resistance. Rotor-housing gaps were set to 125 µm (top) and 350 µm (bottom) to minimize hemolysis. Top bearing forces were reduced magnetically using a motor backplate. Two identical pumps were prototyped in poly-carbonate and run with staircase speed profiles on blood analog flow loops. Overall bearing stack height (BSH) was monitored over 6 weeks, followed by bearing wear analysis. Results: Measured loss of BSH was 60 µm and comparison of pre- and post-test bearings showed total axial wear 15 µm. (Figure 1)

Conclusions: The bearings demonstrated excellent durability throughout the 6 week test. The apparent abrupt early loss of BSH was most likely due to housing shape change from water absorption and thermal effects. The shift from one BSH plateau to another at 4000-5000 RPM coincided with load shifting from the bottom to the top pivot bearing. Further pump life tests are planned.
IMPLANTABLE CENTRIFUGAL BLOOD PUMP: PRELIMINARY ACUTE "IN VIVO" EXPERIMENTS
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A new model of Implantable Centrifugal Blood Pump (ICBP) has been developed to be used as Left Ventricular Assistance Device (LVAD) and is composed basically of a conical impeller, ceramic pivot bearings and Brushless Direct Current (BLDC) motor. In vitro tests showed satisfactory results of hemolysis and hydrodynamic performance on previous works. ICBP titanium prototypes were assembled in order to perform acute in vivo tests in swine models with weight between 45 kg and 75 kg. This work aims to evaluate the ICBP operation and prototypes performance in subsequent hours of surgery. The surgical act consisted of right lateral thoracotomy, carrying out the connections between the ICBP and left ventricle and the aorta anastomosis. During Left Ventricular Assistance, ICBP rotational speed was fixed in 1800 RPM with 4L/min of blood flow and a mean arterial pressure of 50 mmHg. Plasma Free Hemoglobin (PFH) measurement was performed through the “Harboe Method”. The values of activating clotting time (ACT) and PFH were considered normal. ICBP prototype overall performance presented satisfactory results.

DEVELOPMENT OF A NOVEL AUTOLOGOUS VALVE WITH A STENT (BIOVALVE STENT) FOR TRANSCATHETER IMPLANTATION
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Purpose: A novel autologous aortic valve (Biovalve) was developed, using simple, safe and economical in-body tissue engineering. This technique enabled us to make all kinds of valve prostheses, including standard type, full root type and stent type. In this study, we investigated a potential of the stent type (Biovalve Stent) for transcatheter aortic valve implantation (TAVI) in a goat model.

Methods: Biovalve Stents were prepared by about 2-month embedding of the molds assembled using plastic rods and a metallic stent, in the subcutaneous spaces of goats. After extracting the molds and removing the part of plastic rods only, it was confirmed that Biovalve Stents with trileaflets, similar to those of the native aortic valves, were made of completely autologous connective tissues. Nine Biovalve Stents (8 were self expandable type and 1 was balloon expandable type) were implanted in the in situ aorta with TAVI apical approach.

Results: The Biovalve Stents were successfully implanted into the aorta. Histological examination of the Biovalves 2 months after TAVI showed the autologous cells covered the laminar surface of the Biovalve leaflets and also got into the body made of the connective tissues.

Conclusion: The Biovalve Stent satisfied the higher requirements of systemic circulation in goats for 2 months with the potential for TAVI. (Figure 1)

IN VITRO INVESTIGATION COMPARING DIFFERENT IMPELLER ANGLES OF A NEW MODEL OF CENTRIFUGAL BLOOD PUMP TO BE USED AS TEMPORARY VENTRICLE ASSIST DEVICE (TVAD)
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A new model of centrifugal blood pump for temporary ventricle assist device (TVAD) has been developed and evaluated. Device design is based on centrifugal pumping principle associated to the usage of ceramic bearing, resulting in a pump with reduced priming (35 ± 3 ml) and application up to 30 days. Rapid prototyping technology has been used for pump production with three different impellers and each pump with four different outlet port angles. In vitro experiments were performed with those prototypes, using a mock loop system composed by Tygon® tubes, oxygenator, digital flow meter, pressure monitor, electronic driver and adjustable clamp for flow control, filled with water glycerin (1/3 solution) simulating blood viscosity and density. Flow versus pressure curves were obtained for rotational speed of 1000, 1500, 2000 an 2500 rpm. Results showed that the rotor with lines impeller demonstrated better hydrodynamic performance, independently of the outlet port angles. However, an intermediate model rotor will be tested to determine the best rotor design and outlet port angles will be determined by ergonomics docking console drive. Additional hemolysis tests are being prepared.
**DEVELOPMENT OF A HYBRID MEMBRANE OXYGENATOR USING FIBROUS SCAFFOLDS AND CELLS**

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**Purpose:** Most of artificial organs used in clinical consists mainly of artificial materials, therefore there are problems such as thrombus formation, and bio-compatibility at the surface of blood contact. In case of an artificial lung, plasma leakage and thesaurus formation are still remain in the long term circulation. The causes of these problems in the artificial lungs are thought of as direct contact of blood with artificial materials. In order to eliminate these problems, we have developed a hybrid artificial lung constructed of membrane filled with two types of cells. In adaptation, we measured the gas exchange performance of the hybrid cell sheet. **Methods:** Fibrous scaffolds were fabricated with the segmented polyurethane by using the electrospinning method. Hybrid cell sheet was prepared with fibroblasts and vascular endothelial cells cultured on scaffold. Perfluorocarbon (PFC) and blood filled at under and upper side of the cell sheet in a small housing. The housing of the oxygenator was formed with a stereo lithography. To evaluate the gas exchange performance, we have conducted in-vitro experiments using bovine.

**VIDEO EXAMINATION OF FLUID THROUGH A ROTATING PROPELLER**


An intra-ventricular pump was designed and built following the requirements set forth by Dr. Dongfang Wang of the University of Kentucky. The pump was 10 cm in diameter could pump 5.5 lpm and produced a pressure of 135 mmHg at 8000 rpm. Direct observation of the actual propeller could not be done and the use of a locked rotor computer fluid study is misleading. The video study used large scaled models (28 times larger) to study the overall flow pattern through the propeller, the flow around the tips of the blade, the bow wave in front of each blade and the effect of the hub. The flow pattern formation was visualized using smoke streams. The video results found major flow direction changes caused by the hub as well as secondary flow patterns. The straight blade tip drag forces and centrifugal forces caused large eddy flows on the front of the blades. These findings lead to the redesign of the blade and hub shape. The redesigned blade shape allows the fluid to enter from the front of the propeller and the periphery without the eddy formation. Cavitation studies were done by placing this updated blade design on a boat propeller and powering a boat in the Columbia River. With the limited studies it was found that the cavitation was eliminated. It was also found that the driving force of the propeller at half the standard operating RPM was greater than at the standard operating range (3500 rpm).

**Conclusion:** Physical models should be used to confirm computer simulations.

**IN VITRO SHEAR RATE MEASUREMENTS ON THE SURFACE OF A ROTATING DISC FOR VARYING NON-NEWTONIAN BLOOD ANALOGS**


Polyurethane is commonly used in medical devices for its ability to provide structural support and high biocompatibility. Smooth polyurethane is used to reduce platelet adhesion, decreasing thrombogenic effects. To aid in vitro platelet adhesion studies on rotating discs, shear rates at the surface of a smooth polyurethane-coated disc were calculated from tangential velocities, measured using laser Doppler velocimetry (LDV). Analog fluids were created to model the viscoelastic properties of platelet rich plasma (PRP) and 20% and 40% hemocrit blood. LDV measurements were taken 100 µm below the surface of a 20 mm diameter disc rotating steadily at 283 RPM. The Newtonian PRP analog was used to verify a theoretical shear rate calculation, while the non-Newtonian fluids were needed to provide shear rate data for the platelet adhesion studies conducted using whole blood. The PRP shear rates ranged from 252.76-680.38 s⁻¹ from r=3 mm to 7 mm and agreed well with the theoretical values. Within the same range, the 20% and 40% hemocrit blood fluids ranged from 286.08-626.52 s⁻¹ and 207.12-611.61 s⁻¹, respectively. Pulsatile velocity data were also collected at 10, 86, and 150 beats/min using a cardiac waveform. These results provide a shear rate profile for platelet adhesion studies.

**COMPUTATIONAL MODELING OF IVC FILTER DEPLOYMENT AND BLOOD FLOW IN COMPLIANT, PATIENT-SPECIFIC VEIN GEOMETRIES**

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Pulmonary embolism (PE) is a potentially life-threatening condition in which an embolus obstructs pulmonary blood flow, usually as a result of deep vein thrombosis (DVT) or trauma. Anticoagulant therapy is often used to prevent PE in patients who are at risk. When anticoagulants are contraindicated, an inferior vena cava (IVC) filter may be implanted to capture emboli. PE still occurs in some cases, suggesting either failure in emboli capture or filter-induced thrombosis. This study seeks to better understand the hemodynamic effects of IVC filter implantation via a novel computational pipeline. Three IVC geometries were investigated: two patient-specific, and one idealized. Finite element analysis was used to simulate filter deployment in each vein geometry. For the patient-specific cases, the vein was modeled as an anisotropic hyperelastic material. An inverse analysis was performed to obtain the approximate in vivo stress state of each vein. Blood flow was then simulated via computational fluid dynamics (CFD) using the deformed vein and filter geometries. The CFD results were validated using a physical model of the idealized geometry and particle image velocimetry. The simulations yielded maximum vein displacements of approximately 10% of the IVC diameter. Possible sites of thrombogenesis were revealed downstream of the filter head while the filter legs produced only slight disturbances in the flow. Wall shear stress was also quantified and assessed for thrombogenicity. In future work, this methodology could be automated for clinical application as a tool or virtual surgery or as a patient-specific guide for IVC filter selection and placement.
BIO-INSPRIED, ANTI-COAGULANT SURFACES: ROLE OF FLOW RATE AND NO CONCENTRATION
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Mechanisms for reducing coagulation at artificial surfaces show modest reductions in short-term coagulation but are insufficient for demanding, long-term applications. Therefore, we propose the combined use of surface nitric oxide (NO) with anti-fouling coatings to synergistically reduce coagulation in a manner similar to endothelial cells. Polypropylene (PP) membranes were either left uncoated or coated with commercial poly-2-methoxyethylacrylate (PMEA) (X-coating, Terumo Cardiovascular). They were then placed in a flow cell, allowing standardized platelet rich plasma (PRP) to flow over one side at either 300 mL/min (Re=7.1) or 60 mL/min (Re=1.4) while different NO gas concentrations (0, 100, 500, and 1000 ppm) flowed on the opposite surface at a gas/PRP flow ratio of 2 (n=6 ea). The PRP was recirculated for 8 hr and platelet adhesion was quantified using a lactate dehydrogenase assay. All results are presented as the percent of the control (PP with zero NO) adhesion (see graphs). In general, both NO and PMEA individually reduced adhesion. When used together, the reduction in adhesion was additive. NO was also more effective at the lower PRP flow rate. The use of these combined strategies is thus warranted. Future studies will examine this strategy with ultra-low fouling zwitterionic coatings as well as in vivo studies to determine the minimum necessary NO concentrations. (Figure 1)

LVAD PATIENT DIFFERENCES IN PLASMA PLATELET GPIB FRAGMENT PREDICT BLEEDING RISK
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Purpose: Gastrointestinal bleeding (GIB) occurs in 30% of continuous flow ventricular assist device (CFVAD) patients. Given that nearly all CFVAD recipients demonstrate a loss of large von Willebrand Factor (vWF) multimers, we examined other factors contributing to the risk of GIB events.

Methods: Blood samples were obtained on all inpatient days and outpatient clinic visits from 52 patients receiving Thoratec HeartMate II (41), WorldHeart Levacor (6), or Syncardia temporary Total Artificial Heart (TAH; 3). Assays were performed to quantify plasma levels of glyocalcin (the platelet GPIb [vWF receptor] ectodomain fragment), platelet microparticle coagulation activity, thrombin antithrombin, Coagulation Factor XII, thromboxane B2. Statistical analyses were performed using Stastica (Statsoft) to examine assay levels prior to, during, and after confirmed bleeding, thromboembolic (TE), and infectious events.

Results: Plasma glyocalcin was observed to be elevated compared to pre-operative values in all HeartMate II, TAH, and 3 of the Levacor recipients. A glyocalcin value above 4 mg/mL (normal range 0-2 mg/mL) was 92% predictive of a bleeding event. A failure of the glyocalcin level to decrease below 2.5 mg/mL or an increase following a bleeding event was 97% predictive of a subsequent bleeding event. There was not a consistent signal which could be determined to predict TE or infectious events with greater than 50% accuracy.

Conclusion: Glyocalcin may be a biomarker to indicate patients at risk for GIB and particularly re-occurring GIB events. The mechanism causing platelet GPIb fragment shedding requires further investigation to elucidate the mechanisms contributing to GIB bleeding risk.

ANALYSIS OF HIGH SHEAR INDUCED THROMBUS FORMATION PROCESS ON PIPE ORIFICE FLOW BY LASER SHEET VISUALIZATION METHOD
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To avoid the thrombus in rotary blood pumps and heart valves, it is necessary to understand the fundamental physical mechanism for thrombus formation on high shear flows. So in this paper, the thrombus formation on various pipe orifice flows with several kinds of geometries was visualized by laser sheet (Figure 1) and thrombus formation rate on the wall. (Figure 1) And the effect of flow rates on the thrombus ratio in the same configuration was also investigated. Then the mechanism between shear flows and thrombus was analyzed to compare this with the results of CFD-based prediction data.
IN VIVO EVALUATION OF THE SKIN CONDITIONS AROUND THE PERCUTANEOUS SITE OF VAD SYSTEM
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Percutaneous site infection is serious problems for the patients implanted VAD. However, it is still unclear about a relationship between the onset of bacterial infection and physiological changes of the skin conditions around the percutaneous site. In this study, under a chronic goat study we evaluated the bacterial and the physiological conditions such as temperature, moisture, blood circulation and pH, of skin surface around the percutaneous site. We used three test tubes modified a percutaneous cannula of the extracorporeal pneumatic VAD system. The tubes were made of polyvinyl chloride tubes (20mm outer side diameters) covered with SPU porous material (thickness 2.0mm, length 100mm, porous size 0.2 mm), these tubes were surgically placed from skin to subcutaneous tissue. After implantation, we did not take any interventions such as sterilization at all. Until three months after implantation, the wound healing and adhesion between skin and test tubes were maintained in good condition. However, on fourth month the percutaneous site infections were observed in all tubes. Both of skin temperature and skin moisture were maintained normal ranges (32°, 21%). However, these values increased (35°, 28°) before development of inflammation, and bacterial flora on the skin was substituted a normal flora for a pyogenic flora, streptococcus sp. On the other hand, pH of skin surface consistently indicated higher values (pH 6.0-6.3) than normal area (pH 4.5-6.0), and skin blood circulation consistently decreased. This study demonstrated that evaluation of skin condition in the percutaneous site was very important for the detection of the onset of percutaneous site infection.

TRANSUTANEOUS ENERGY TRANSFER SYSTEM USING A MAGNETICALLY COUPLED MOTOR-GENERATOR SET
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High energy, implanted devices such as a Ventricular Assist System traditionally utilize a percutaneous driveline for power transfer and this is prone to infection. Coil-coil TETS technology has been the primary alternative, but has problems with heating & coil alignment. A novel TETS technology, consisting of a system of a magnetically coupled motor and generator that eliminates the risk of driveline infection with wireless power transfer, is explored. The external motor (rated 50 Watt) transfers power through a neodymium magnetic clutch, to a commercially available brushless motor used as a three phase generator in our system. The three phase signal is rectified to DC and a buck converter drops the voltage to 12V and increases current output, resulting in 30W useful power. The system was designed to transfer much more power than the typical VAD consumes (4-10W) so as to allow the eventual use of implantable batteries and intermittent charging via this wireless technology. The motor and magnetic clutch system was independently characterized using a dynamometer to determine efficiency vs. torque over a range of different speeds, breaking torque vs. axial separation distance, and axial force vs. axial separation distance. The maximum efficiency for motor and magnetic clutch system was determined to be at 59% at 0.0266 Nm of torque (10,000 RPM). The breaking of the magnetic link at a certain torque was tested against separation distance of the couplings and shown to be independent of rotational speed. The axial force due to separation distance characterized the attractive force of the coupling which is useful in determining the compressive force applied to the skin.

TRANSIT-TIME FLOWMETER ON A CHIP

Transonic has been refining transit-time ultrasound flow meter technology for 30 years. TSIC8 is our next generation flowmeter on a chip that brings Transonic flowmetry to a larger range of applications. The specifications for this IC are:
- Operational performance (zero offset, temperature stability, noise) equal to our discrete-component flowmeters;
- Accepting our full range of flow probes: 0.5mm–36mm;
- Self-Calibration feature;
- Low implementation complexity allowing OEM customers to put chips on board rather than purchasing complete factory calibrated flow boards;
- Low Power to enable chronic implants/telemetry

The TSIC8 chip consolidates our conventional analog flowmeter circuitry into one chip, allowing for lower power, smaller footprint and simple embedding in OEM devices. TSIC8 can operate any Transonic two- or four-transducer sensor. With ancillary electronics, the TSIC8 chip offers:
1) Differential (upstream/downstream) transit-time samples: the basic transit-time flow measurement
2) Common-mode transit-time signal: the basis for ultrasound indicator dilution measurement (cardiac output, blood volumes)
3) An ultrasound amplitude signal: to provide continuous signal quality and flow sensor integrity monitoring

TSIC8 can be configured to operate sensors from 0.6-14.4MHz with a differential drive voltage of 0.3-4V. When operated with a 14.4MHz sensor, TSIC8 can have a maximum sampling rate of 56KHz. It can operate with ultrasound received signal as low as 10mV and can measure transit times down to pico-seconds. Flow noise and zero offset meet our discrete component flowmeter specifications.

TSIC8 operates with +/-2.5V power supply and 0-2.5V digital control, consuming less than 50mW. It will be available in a 64 pin TQFP or QFN package.

FLUID RESUSCITATION: COMPARISON BETWEEN TYPICAL NORMOXIC FLUID RESUSCITATION AND HYPOXIC FLUID RESUSCITATION
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Despite improvements during fluid resuscitation, there is a need in improving the outcome. Plasma expanders (PES), can maintain blood volume. They stabilize hydrostatic capillary pressure and perfusion; enhance oxygen delivery by maintaining blood volume and sustaining adequate blood flow. Using 100% O2 as coadjuvant, can help improve the physiological response to fluid resuscitation.

The hemorrhagic shock resuscitation protocol in awake Syrian hamsters includes hemorrhage of 50% of the blood volume followed by 1 hr of hypovolemic shock, and resuscitation with HES, with 50% of the shed volume. The coadjuvant is administered by inhalation during resuscitation. MAP and HR are monitored during the experiment. Arterial blood is used to determine hematocrit, blood gases and pH. Intravital microscopy is used to measure microcirculatory parameters (FCD, vessel diameter, RBC velocity). HR, pH, pCO2, BE, arteriolar diameter, are restored during 100% O2 inhalation. MAP, arteriolar flow, FCD, venular diameter and venular flow are improved with the administration of 100% O2 as coadjuvant. O2 increases perfusion and tissue oxygenation compared to control group. It restores BE and pCO2 levels to normal baselines, indicating that lactate clearance is adequately performed, augmenting the rate clearance, which is correlated to the positive outcome of HS. 100% O2 inhaled supplementation prevents cardiovascular collapse, and allowed animals to maintain superior systemic and microvascular hemodynamic conditions. This was evidenced in the maintenance of heart rate, microvascular function, FCD and lactate clearance.
FLUID RESUSCITATION: COMPARISON BETWEEN TYPICAL NORMOXIA RESUSCITATION AND NITRIC OXIDE AS COADJUVANT DURING RESUSCITATION
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This study investigated the systemic and microvascular hemodynamic changes related to increased nitric oxide (NO) availability following fluid resuscitation with a Plasma Expander (PE), made available by inhalation of 90 ppm of NO in a 20% O2 gas mixture. PE5 maintained blood volume. They stabilize hydrostatic capillary pressure and perfusion; enhance oxygen delivery by maintaining blood volume and sustaining adequate blood flow. The hemorrhagic shock resuscitation protocol in awake Syrian hamsters includes hemorrhage of 50% of the blood volume followed by 1 hr of hypovolemic shock, and resuscitation with HES, with 50% of the shed volume. The coadjuvant is administered by inhalation during resuscitation. MAP and HR are monitored during the experiment. Arterial blood is used to determine hematocrit, blood gases and pH. Intravital microscopy is used to measure microcirculatory parameters (FCD, vessel diameter, RBC velocity). HR, pH, arterial diameter, venular diameter and venular flow are restored during NO inhalation. MAP, pCO2, BE, arterial flow, FCD are improved with the administration of NO as coadjuvant. NO promotes vasodilatation and increases perfusion compared to control group, altering organ function by regulating regional blood flow and organ perfusion. It also helps in lactate clearance, augmenting the rate clearance, which is correlated to the positive outcome of HS. NO inhaled supplementation prevented cardiovascular collapse, and allowed animals to maintain superior systemic and microvascular hemodynamic conditions. This was evidenced in the maintenance of heart rate, microvascular function and FCD.

THROMBOSIS AT ECMO CONNECTOR JUNCTIONS IS RELATED TO LOW SHEAR RATES
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Thrombus formation in the ECMO circuit results in a shortened circuit lifespan, increased infection risk, circuit failure, and systemic embolization. ECMO circuits from pediatric patients were obtained from CHOA/Egleston (n=9). The distribution of clots on tubing, connectors, or at junctions was recorded. Clots were analyzed for fibrin and platelets. The shear rates were quantified using a computational fluid analysis.

All circuits had clot formation. The tubing accounts for 90.9% of the surface area exposed to blood; whereas, the connectors surface area is only 9.1% of the circuit, excluding the oxygenator and blood filter. We found that the clots were found at the connectors (40/42, 95%, p<0.05). The clots appeared to initiate at the connector junctions exposed to both connector and tubing material. Histological analysis showed clots as fibrin-rich with few platelets. The CFD analysis of the junction revealed pockets both upstream and downstream of the ends where shear rates were very small (< 150/s, Re 60) with a recirculation region downstream. The clot location occurred at regions of low shear less than 150/s, but not at higher shear regions (>300/s) of tubing or connectors (p<0.05). Thus, 95% of the thrombosis in ECMO circuits formed at the low shear connector junctions. Fibrin-rich blood coagulation requires a triad of blood abnormalities, unusual surface, and stagnant hemodynamics. While blood abnormalities and artificial surfaces are always present, the third factor of stagnant or very low shear rates is caused by the geometry of connectors and creates the focal thrombosis. We are presently developing ways to eliminate these stagnant zones to reduce the amount of thrombosis in ECMO loops.

PREPARATION AND CHARACTERIZATION OF BONE ADHESIVES FOR TRAUMA SURGERY
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An adhesive capable of binding small bone fragments in comminuted periarticular fractures is an attractive alternative for orthopedic surgeons. This experimental study was directed to formulate and evaluate 6 different bone adhesives: Three based on chitosan and calcium carbonate (CaC03), with high, low and null content of hydroxyapatite (HA). The other three are based on alginate and CaC03 with high, low and null content of hydroxyapatite (HA). Physicochemical characterization was conducted by rheological test, mass loss analysis, apparent density, SEM and EDS tests. For the mechanical characterization three standard protocols were proposed using cancellous bone from bovine proximal humerus; the first and second protocols are tensile tests with a controlled fracture at 90º (TT90) and 45º (TT45) relative to the load direction; the third protocol is a 3 point flexural test (3PFT). An ANOVA test (p<0.05) and Tukey’s posthoc were performed to compare all properties of each bone adhesive with those of Kryptonite®, a commercial bone cement with adhesive properties that has shown promising in vivo results and has FDA approval. Preliminary results of the physicochemical evaluation estimated density of all formulations is approximately 1.23 g/ml. Grid structures were observed, using electronic microscopy, for all adhesives. And for the mechanical evaluation TT90 have shown that bond strength of the adhesives based on chitosan is not significantly different to that of Kryptonite®. In conclusion the developed biodegradable bone cements based on chitosan present appropriate physicochemical properties and mechanical strength similar to that of commercial bone cement.

SILICON NANOPORE MEMBRANES (SNM) PREVENT CYTOKINE INFILTRATION UNDER CONVECTIVE TRANSPORT
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Purpose: Type 1 diabetes results from autoimmune destruction of insulin-producing cells. Our silicon nanopore membranes (SNM) exhibit monodisperse pore size distribution with 1% variation, which enables superior selectivity relative to conventional polymeric membranes. This key experiment investigated the feasibility of using SNM as an immune barrier to prevent islets from cytokine attack under convective transport.

Methods: A closed loop fluid circuit with SNM assembled in a flow cell device was used to recapitulate local blood circulation. Devices consisted of 400 mouse islets loaded between SNM membranes with a pressure difference of 51.7 – 77.6 mmHg. A combination of TNF-α (1000U/mL), IL-1 β (50U/mL), and IFN-γ (1000U/mL) was used to induce islet apoptosis in both flow cell and control static conditions. After 6-hour culture, islets from each group were stained with fluorescein diacetate(FDA) and propidium iodide(Pi). Viability among different groups was compared using a confocal microscope. Results: Islet viability from device with cytokines was comparable to control static culture without cytokines as well as device without cytokines. The control static culture with cytokines showed significant more cell death than the flow cell device with cytokines after 6 hours.

Conclusion: This result demonstrated the feasibility of using SNM to protect islets from pro-inflammatory attack. SNM could potentially reduce the immunosuppressants required by current therapies and lead to possibilities of using xenogeneic sources to overcome donor shortage for future Type 1 diabetes treatment.
INTEGRATING BIOMECHANICS, HEMODYNAMICS AND MECHANOBIOLOGY TO PREDICT ARTERIAL ADAPTATION INDUCED BY CONTINUOUS-FLOW LEFT VENTRICULAR ASSIST DEVICES

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Although the acute interaction of a continuous-flow left ventricular assist device (LVAD) with the ventricle and arterial system leads to complex regional pressures and flows, experimental challenges arise from interactions among chronic local adaptation, local biomechanics, and network hemodynamics. To develop a tool to predict chronic vascular adaptation following LVAD implantation, we modified a classical model of the systemic arterial circulation. Each artery was assumed to adapt to circumferential wall stress and endothelial shear stress. Consistent with reported values, simultaneous adaptation of all arteries resulted in normal values of radii, wall thicknesses, wall stiffnesses, pulsatile pressures, and pulsatile flows. Decreasing the pulsatility of the input flow to model the combined action of the ventricle and the LVAD led to an acute decrease in regional pulse pressures. Arterial adaptation subsequently increased arterial stiffness and partially restored chronic pulsatile pressures. These findings suggest that there is loss of arterial compliance (and thus increased cardiac afterload), which may negatively impact cardiac recovery or transplantation. The current work also reveals a new homeostatic principle: vascular adaptation to circumferential wall stress maintains pulsatility. By integrating biomechanics and mechanotransduction in a network, our novel approach allows us to explore not only the biological basis of different outcomes of specific patient populations such as infants, young adults, and the elderly but also potential pharmacological interventions.

A FLUID DYNAMIC STUDY OF THE HEARTMATE II CONTINUOUS FLOW VENTRICULAR ASSIST DEVICE UNDER PHYSIOLOGICAL PULSATILE CONDITIONS

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Heart disease is currently the leading cause of death in the United States. Ventricular assist devices (VADs) can be used clinically as a rehabilitative measure in cases of heart disease when transplant hearts are unavailable. Patients with an implanted continuous axial flow VAD, such as the Heartmate II (HMII), often experience spontaneous bleeding due to the uncurling and cleaving of the von Willebrand factor, a glycoprotein in the clotting cascade. Previous studies have been performed using laser Doppler velocimetry (LDV) to collect velocity data and determine areas of high Reynolds stress and turbulence intensity within the outlet cannula of the HMII under steady flow conditions. Maximum normal and shear stresses were calculated to be 6429 and 2875 dyne/cm², respectively. Using the same conditions, a pulsatile pump was added to the flow loop to mimic a diseased left ventricle. The pump was operated at 78 bpm with a stroke volume of 49 ml and systolic/diastolic pressures of 56/6 mmHg. Three component velocity data was collected at the same cross sections as previously done for comparison of stresses throughout the cardiac cycle to those calculated from purely steady flow. The flows were very similar with some differences in the magnitudes of the stresses and turbulence intensities.

FLUID DYNAMIC STUDY OF A COMPLIANT MODEL FOR AN INFERIOR VENA CAVA FILTER

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Deep vein thrombosis afflicts a reported 48 in 100,000 persons, resulting in severe medical consequences for many as the thrombus may dislodge to form a pulmonary embolism. Inferior vena cava (IVC) filters were developed to prevent such emboli from reaching the lungs. The goal of this study was to measure the flow about a G2 Express IVC filter to avoid further thrombosis. A model of the IVC was constructed to match its compliant nature, and retain physiologic accuracy that is not extensively accounted for. Particle image velocimetry (PIV) mapped the flow profile with high spatial resolution for the unfiltered, filtered, and clot-containing IVC. The mock circulatory loop features an open chamber to reduce optical distortion. Clinically observed flow rates for resting and exercise conditions were matched for the iliac (0.6 lpm, 2 lpm, respectively) and renal (0.75 lpm) veins. The outlet pressure of the IVC was maintained at 11 mmHg. PIV post-processing algorithms were adapted to fit the compliant model, eliminate noise, and calculate wall shear rate. The flow impact following implantation of the filter and clot was quantified. Undesirable flow features including regions of recirculation, stagnation, and low/high wall shear rate were identified.

DEVELOPMENT OF A HEART VALVE BIOREACTOR TO CONDUCT IN VITRO FLUID DYNAMIC STUDIES

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About 290,000 heart valve replacement surgeries are performed every year as the demand for artificial heart valves increases 10-12% annually. Despite advancements in mechanical and bioprosthetic artificial valves, irregular fluid dynamics cause complications such as thrombosis, hemolysis, calcification, and stenosis. The need for a better alternative has led to the development of a tissue-engineered aortic heart valve. Before this valve can be a viable option, its fluid dynamic properties need to be tested and compared to current artificial valves. A mock circulatory flow loop and nontoxic blood analog fluid were developed for in vitro testing of the aortic valve at 50 bpm with a flow rate of 2.5 lpm and 75 bpm with a flow rate of 5 lpm. In this study, the flow patterns of a native porcine aortic valve were measured by particle image velocimetry (PIV). Velocity maps in the aortic sinuses and downstream of the aortic valve were analyzed for areas of turbulent jets and vortices. The porcine valve flow patterns will be used as a comparison to the flow associated with a tissue-engineered valve to assess viability.
THE EFFECTS OF HEMATOCRIT AND ROTATION TIME ON PLATELET ADHESION TO A POLYURETHANE UREA SURFACE

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Platelet adhesion to the polyurethane urea (PUU) blood sac in the Penn State 50 cc ventricular assist device is a primary event in thrombosis. Prior to adhesion, platelets must first be convected to the material surface. Red blood cells have been shown to increase platelet transport by platelet margination and to enhance platelet diffusivity as a function of shear rate. The aim of this study is to determine the effects of hematocrit (Hct) and rotation time on platelet adhesion to PUU. A rotating disk system is used to deliver a steady waveform to the PUU surface. The disk is rotated in either 20% Hct or 40% Hct whole bovine blood for 0.5, 1, or 2 hours. Adhered platelets are immunofluorescently labeled with a primary CAPP2A mouse anti-bovine antibody and a secondary Alexa-Fluor 488 donkey anti-mouse IgG, and the PUU material is imaged at specific locations using confocal microscopy. The shear rate at each imaging location is experimentally determined using laser doppler velocimetry. A platelet adhesion coefficient is calculated from the average platelet count, mass flux, and rotation time. For both 20% Hct and 40% Hct, platelet adhesion is found to exponentially decay with increasing shear rate.

IN VITRO AND COMPUTATIONAL STUDIES OF THROMBUS GROWTH AND ASSOCIATED WALL SHEAR STRESS DEVELOPMENT IN A BACKWARD-FACING STEP GEOMETRY

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Thrombosis remains an obstacle in current cardiovascular devices. Regions of separated flow have shown to be strong contributors to thrombosis. A backward-facing step (BFS) geometry was selected for its ability to produce well-defined flow separation. Bovine blood was circulated through a BFS model for time periods ranging from 10 to 90 minutes at a constant flow rate. When the predetermined time was reached, magnetic resonance imaging (MRI) was used to capture the 3D topography of the formed thrombi, and the thrombi showed linear growth until approximately 45 minutes, when the size reached asymptotic values for volume of 0.1-0.14 cm³ and exposed surface area of 1.5-2 cm². Significant standard deviation values were seen in the thrombus sizes when a flow time was used more than once; however, the variability relative to the mean, determined by calculating the relative standard error, decreased with increasing flow time. The geometries captured using MRI were converted to meshes for use in computational fluid dynamics (CFD) simulations using OpenFOAM. Steady simulations were used to assess the wall shear stress (WSS) patterns on the exposed thrombus surfaces, and the velocity patterns that developed nearby. Areas of low WSS were correlated with recirculation regions near the thrombus surface, while areas of high WSS (a maximum value of 24.3 dynes/cm²) were correlated with regions with little or no flow separation. These results will aid in the development and validation of computational thrombus growth models.

HYDRODYNAMIC CHANGES INDUCED BY TRANSFUSION OF STORED BLOOD

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Human red blood cells (RBCs) can be stored for up to 42 days under controlled conditions. Numerous changes occur in the RBCs during storage, altering their biological function. This study links stored cells mechanical changes with hemodynamic functional alterations induced by transfusion of these cells. Hemodiluted rats were exchange transfused (50% of their blood volume) with rat stored RBCs (14 days at 4°C in CDPA-1) and compared to fresh cells. Storage modified static and dynamic red cell mechanics. Systemic hemodynamics were similar between fresh and stored cells; although, microvascular hemodynamics were drastically affected by stored cells. Microvascular blood flows were reduced after transfusion of stored cells compared to fresh cells. Stored cells reduced oxygen delivery due to limited blood flow and increased RBCs oxygen affinity. The presence of stored cells in circulation affected cell-to-cell and cell-to-wall interaction, disrupted erythrocyte cell free layer (CFL) thickness and wall shear stress (WSS) homeostasis. Stored cells mechanical alterations affected hemodynamic homeostasis in small arteries, including diameter, RBC velocity, blood flow, and oxygen delivery; in addition to the mechanical interaction of flowing red cells with the vasculature. In conclusion the reduced cell deformability induced by the RBC “storage lesions” caused changes in microvascular hemodynamics, endothelial cell mechanotransduction, and red cell dynamics when introduced into the circulation. Therefore, the mechanical properties blood banked cells may determine transfusion ability to achieve its intended goal. Supported by grants R01-HL52684, R01-HL62354, R01-HL078840.

CHARACTERIZATION OF BLOOD CLOT FORMATION IN A BACKWARDS-FACING STEP MODEL

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The continued development of cardiovascular assist devices is constantly thwarted by the effects of thrombosis. Many of these devices produce regions of stagnant flow or low wall shear stress, making these areas especially prone to clotting. To better understand the process of coagulation in artificial devices, a histological analysis of thrombi formed in a backward-facing step model is performed. An in vitro flow loop containing the backward step model is constructed and whole bovine blood is used to produce a thrombus. Flow loop operation is at 0.79 and 1.5 L/min in order to mimic two physiological flow rates that occur within arteries. Once a thrombus is formed, it is harvested from the model, paraffin embedded, and analyzed histologically through staining with hematoxylin and eosin (H&E). H&E allows for the visualization of both red and white blood cells and fibrin structures. Cross sections of the clot were viewed beginning in regions near the step and extending approximately 3 mm downstream. Several studies were performed, each showing a dense packing of cellular components with a fairly uniform distribution in areas of the clot that are closest to the step. Further downstream of the step, a much looser packing of components and large sections of fibrin in areas that were exposed to blood flow were observed, suggesting that blood clot “aging” plays an important role in cellular entrapment. Obtaining a better idea of the cellular makeup of a formed thrombus and how it forms over time in an artificial device will assist in the understanding of how to minimize thrombosis in the future development of cardiac devices.
DEVELOPMENT OF A MAGNETIC BEAD MICRORHEOMETRY SYSTEM TO STUDY THROMBUS RHEOLOGY

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The primary objective of this study was to develop a magnetic bead microrheometry system to measure spatially heterogeneous thrombus rheology. Previous studies in thrombus rheology studied entire thrombi as one homogenous, but have not accounted for the heterogeneous composition of thrombi. The spatial variation in magnetic force in the proposed area of thrombus formation was calibrated by measuring the displacement of 45 μm fluorescent paramagnetic beads embedded in polyacrylamide hydrogels of homogenous tunable elasticity. Nm-scale displacements of beads were measured using bead tracking software that cross-correlated bead position between recorded frames. Polyacrylamide hydrogels with an elasticity of 0.2 kPa and 1.61 kPa were used to calibrate the working area of the system and gather displacement data for beads in that area. These values were chosen to represent the upper and lower bounds of previous thrombus rheology studies. This force distribution in the gel due to magnetic force on the bead was assessed using finite element analysis performed using COMSOL Multiphysics software. Force was then derived by integrating the total force of the gel on the bead after a prescribed displacement. The force calculations were interpolated to map force as a function of position within the working area in order to test samples of spatially non-uniform elasticity. By studying thrombus rheology using magnetic bead microrheometry, localized measurements of elasticity can be used to correlate with local cellular and fibrin composition, as well as correlate between regions exposed to flow as compared to interior regions.

POWERING IMPLANTABLE VENTRICULAR ASSIST DEVICES: IN VIVO EXPERIMENTATION OF A NEW PERCUTANEOUS OSSEOINTEGRATED CONNECTOR

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Abdominal drivelines powering implantable ventricular assist devices (VAD) are associated with a high risk of infection. This remains a constant threat to the long-term success of all modern VAD systems. Percutaneous osseointegrated implants have been used successfully since the 1970s as prosthetics support (maxillofacial surgery) demonstrating that a safe permanent percutaneous passage is possible on the calvaria. However, such implants do not transfer electricity. This study assesses a new type of percutaneous connector designed for powering VAD, leveraging materials and methods that have been proven successful with percutaneous osseointegrated implants. The endosseous percutaneous connector was designed to be implanted in the calvaria. Implantation was a single-stage process so that the connector and the VAD can be implanted during the same intervention. The safety of the percutaneous passage was studied in ten non-electrically functional connectors through an in vivo study (ewes) in a three months follow-up period. (m=88.2, SD=8.2). Stability and osseointegration were also studied. No cutaneous and bone infection was observed. Connectors were stable and osseointegrated. One case of skin necrosis was reported but it did not compromise the stability of the connector (n=1;p=0.1). One animal developed enteritis (non-related to the device) which was ultimately fatal (n=1;p=0.1). The connector shows promising results. Osseointegration of the implant is a key point to provide an excellent long-term anchorage and limit infection risks. The connector seems to be a safe solution to supply electrical power for implantable mechanical circulatory support.

IN VITRO EVALUATION OF AN EXTERNAL COMPRESSION DEVICE FOR FONTAN MECHANICAL ASSISTANCE

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While Fontan palliation in the form of the total cavopulmonary connection has improved the management of congenital single ventricle physiology, outcomes for patients with this disease are still suboptimal. Ventricular assist devices can normalize failed Fontan hemodynamics. To minimize blood contacting surfaces, we evaluated an external compression device (C-Pulse Heart Assist System, Sunshine Heart Inc.) as a Fontan assist device. A mock circulation was developed to mimic pediatric hypertensive Fontan hemodynamics. The Sunshine C-Pulse, coupled with polymeric valves and an elastic tube, was used to provide external mechanical assistance. The effect of the number and placement of valves, distal or proximal, on inferior vena cava pressure (IVCP) was studied. The effect of device inflation volume and compression rate on maintaining low IVCP was investigated. With one valve, the device was unable to lower IVCP below 15.5 mmHg from a hypertensive IVCP of 18 mmHg. With two valves, the C-Pulse was able to maintain IVCP as low as 8.5 mm Hg while providing pulsatile pressure with a pulse pressure of 16 mm Hg. The device increased venous return to the atrial reservoir up to 180 mL/min above baseline. Clinically, “off pump” placement of an external compression device could allow for bridge to recovery or transplantation in the setting of low IVCP for pediatric Fontan patients. (Figure 1)
ASSOCIATION BETWEEN LEFT VENTRICULAR ASSIST DEVICE (LVAD) DRIVE-LINE EXIT SITE HEALING AND POST-IMPLANT HEMATOCRIT LEVELS

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Introduction: Slow driveline exit site (DLES) healing in LVAD patients increases the risk of acquiring an infection. Normal hematocrit levels post-surgery are critical for effective wound healing. In this study, the association between DLES incorporation and patient hematocrit was examined.

Methods: The Artificial Heart Program (AHP) database was queried for HeartMate II (HMII) or HeartWare (HW) patients who had consistent DLES assessments. To monitor healing, the AHP developed a DLES score ranging from 1 to 4 (1, fully incorporated; 4, open wound). These were then compared to patient hematocrit (HCT) values post-implant. Results: 65 patients were included (mean age 58 ± 15, 86% male, 56 HMII, 9 HW). Average time to incorporation was 72 ± 60 days. At each time interval, the change in both DLES score and HCT were calculated. From 3 weeks to 1 month post implant, patients had the highest increase in HCT. From 2 months to 3 months, our population had the greatest increase in DLES wound healing. (Figure 1)

Conclusion: Over time, patient HCT increases and DLES score decreases. HCT values increased most in early patient recovery, whereas DLES healing increased greater in the later recovery period. This observation highlights the known importance of HCT for wound healing post-surgery. A larger patient population is needed to confirm a correlation.

2D VELOCITY MAPPING WITH ECHO-PARTICLE IMAGE VELOCIMETRY

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Background: Doppler ultrasound is widely used in clinical practice. An inherent limitation is that Doppler methods only measure the velocity component parallel to the ultrasound beam. Echo-Particle Image Velocimetry (PIV) is an ultrasound technique in which regions of two sequential B-mode images are cross-correlated to calculate 2-D velocity vectors for a fluid containing scatterers. Measurement of blood velocity requires high spatial and temporal resolution, the ability to measure velocities 1 m/s and software to average multiple pulse cycles. Methods: Pulsatile flow was established in a flow phantom consisting of a latex tube (diameter: 5 mm), reservoir, flow meter (steady flow) and pump. The working fluid was water with contrast microbubbles. An Ultrasonix RPS500, with linear transducer providing a longitudinal cross section, was used to acquire radiofrequency (RF) data at 14 MHz (sampled 40 MHz). The RF data was post-processed using a PIV code. This calculates the local correlation between successive frames, then sums the correlation results for identical phases of 50 cardiac cycles. The technique was also applied to measuring velocities in the rabbit abdominal aorta. The rabbit was anaesthetised, the abdomen opened and contrast agent injected as a bolus. The transducer was placed in contact with the aorta to record the RF data, which were processed offline. Results and Conclusions: Flow rates in the phantom were in good agreement with measurements from the transit time flow meter. 2D velocity vector maps showing the change in blood velocity throughout the cardiac cycle were obtained for the rabbit aorta. EchoPIV has a number of potential applications for assessing functionality of artificial organs in vivo.

FABRICATION PARAMETERS ALTERING MICROSTRUCTURE OF SMALL INTESTINAL SUBMUCOSA VASCULAR GRAFTS DRASTICALLY MODULATE PATENCY, ENDOTHELIALIZATION AND REMODELING IN VIVO

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Small intestinal submucosa (SIS) is an extracellular matrix scaffold that has been evaluated for remodeling vascular tissue. Our previous studies proved that fabrication parameters alter SIS microstructure. Here we explored if four types of SIS vascular grafts with microstructural differences differ in patency, endothelialization and remodeling outcomes in an in vivo model. We fabricated four different types of scaffolds using a 2^4 factorial experimental design: 1) preservation (P) or removal (R) of a dense collagen luminal layer; 2) hydrated (H) or dehydrated (D) state. Grafts (4.5mm ID) were implanted in the left and right carotid arteries of 8 Yorkshire swine (25 kg, n=4) for 7 days. Patency was evaluated macroscopically and histologically (H&E, MT). Thrombi coverage area, cellular infiltration, multinucleated giant cells and vascularity were quantified with H&E and MT. Immunohistochemistry assays are ongoing for endothelialization (CD34) and classification of the immune response in the remodeling or scarring pathway by phenotypes of macrophages: M0 (undifferentiated, CD68), M1 (scarring, CCR7) and M2 (remodeling, CD206). Quantification will comprise endothelial cell area coverage, M2: M0 and M2: M1 ratios. Macroscopically, we observed a 100% patency for RD and PD grafts, 75% for RH and 50% for PH. RD grafts had a soft tissue-like texture, while PD grafts were highly stiff. Two RH and two PH grafts had a narrowing of the lumen. H grafts had a strong fibrotic response outside the graft. We observe so far that there were drastic modulations of the host response to microstructurally different SIS grafts.

COMPARATIVE BIOCOMPATIBILITY ASSESSMENT OF COATINGS APPLIED ON HOLLOW FIBER MEMBRANES OF BLOOD OXYGENATORS

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Purpose: Bio compatible surface modification to blood contacting membranes of oxygenators is essential to mitigate material induced blood-trauma, to minimize systemic anticoagulation and to maintain their prolonged clinical durability. This study was performed to compare in-vitro blood-biocompatibility of newly developed heparin-based coatings with established commercially available coatings on hollow fiber membranes (HFM). Methods: Eight coated HFM samples with one uncoated HFM samples were evaluated. The coatings included two in-house coatings based on heparin and quaternary ammonium salts and six commercial coatings on HFM (CHS, Bioline, Safeline, CBAS, Phisio, and X-Coating). Each HFM sample was incubated in 3 mL of heparin-anticoagulated (5 IU/mL) human whole blood and rocked for 3 hrs at 37°C. Blood-chemistry, spectrophotometry and electron microscopy analyses were performed to determine protein adsorption, platelet adhesion and thrombotic depositions on the surfaces. Results: Uncoated and Safeline coated surfaces are vulnerable to thrombus, followed by Phisio and X-Coating. The in-house heparin based bioactive-coating surfaces exhibited similar enhanced non-thrombogenic performance in comparison with the three commercial bioactive surfaces (Bioline, CBAS and CHS). Conclusion: The results suggest that the bioactive coatings offer improved blood-compatibility and new in-house hydrophilized heparin-based bioactive coating is in par with accepted commercial coatings.
USE OF PERFLUOROCARBON BASED OXYGEN CARRIER IMPROVES LACTATE CLEARANCE IN RESUSCITATION FROM EXPERIMENTAL HEMORRHAGE COMPARED TO ISOTONIC SALINE IN A SWINE MODEL

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The use of perfluorocarbon based oxygen carriers (PFCOCs) has been proposed as an alternative to blood transfusions in cases of major blood losses. In developing countries the most common cause of severe hemorrhage is violent trauma. Although there are protocols for handling and treatment of trauma patients, often these standards are not followed due to logistic and/or economical restrictions.

We compared the outcome of fluid resuscitation from a severe hemorrhage using a PFCOC or the most used solution in Colombia’s emergency rooms (isotonic saline SSN). We used a 3 step protocol: bleeding, shock and resuscitation. Yorkshire swine were treated with SSN (group 1, n=4) or PFCOC (group 2, n=4). We monitored the hemodynamic response: arterial pressure (AP), pulmonary artery pressure (PAP), venous pressure (CVP) and gas transport. We also studied metabolic response: arteriovenous PO2, pH, base excess and lactate. These variables were measured at baseline, after hemorrhage, after shock and 15, 30 and 60 minutes after resuscitation.

All the animals completed the protocol. We found no difference in the hemodynamic response for both groups. The main result of our experiments was that lactate clearance rate was improved when the solution used was PFCOC (0.0339 +/- 0.18 mmol/L/min) compared to SSN 0.9% (0.0069 +/- 0.0099 mmol/L/min). Better lactate clearance has been related to survival rate in critically ill patients and with days in the ICU.

CHARACTERIZING LEFT VENTRICULAR ASSIST DEVICE PARAMETERS FOR EARLY THROMBUS DETECTION

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Purpose: Thrombus formation in patients with a Left Ventricular Assist Device (LVAD) occurs infrequently, but can be catastrophic. Thrombus detection through laboratory and clinical parameters are sometimes too late and the use of LVAD parameters (pump speed, flow, pulsatility index, and power) to assist in diagnosis is untested. The aim of this study was to determine any relationships between LVAD parameters and thrombus formation.

Methods: The Artificial Heart Program database was queried for patients who received an LVAD exchange due to thrombus formation between 2011 and 2012. LVAD parameters were collected for each patient and stratified into two phases: 1) from implant discharge to exchange readmission, 2) from exchange readmission to the exchange. The phases were analyzed using a two-sided Student’s T-test. (p-value < 0.05 was significant).

Results: Four patients (average age 61 ± 8 years, 100% male) received an LVAD exchange due to a confirmed thrombus formation around the stator of a HeartMate II. The change in LVAD parameters are below. (Table 1)

All patients had at least one significant parameter change with the change in pulsatility index being significant for all patients.

Conclusion: These data suggest that closely monitoring LVAD parameters could help detect thrombus formation. A larger experience is needed to validate common relationships that would complement current laboratory and clinical parameters for early LVAD thrombus detection.

STUDY OF THE INTERACTION OF A PERFLUOROCARBON BASED OXYGEN CARRIER WITH COLLOID PLASMA EXPANDERS AND BLOOD

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Perfluorocarbon (PFC) based oxygen carriers have been widely studied and characterized, but knowledge about emulsion interaction with blood and colloid based plasma expanders (PEs) is limited. We analyzed the effects of the interaction between PFC emulsion, blood and clinically used colloid PEs. The selected PEs were: Human serum albumin and Hydroxyethyl starch. A mixture of 80% v/v PFC emulsion and 20% v/v PEs was used to dilute blood to 30% Hct. In vitro rheological behavior of mixtures was analyzed and in vivo analysis of blood flow in microvessels using intravital microscopy in a clinical relevant scenario was performed. The results show that interaction between emulsion and PEs with blood induces aggregation between PFC droplets and red blood cells (RBCs), as evidenced by changes in rheology and by visual microscopic inspection. PFC droplets tend to form aggregates in presence of PEs’ electrolytes; the degree of aggregation depends on electrolyte concentration and shear rate.

In the microcirculation, PFC droplets and RBC aggregates induced blunted blood flow velocity profiles compared to non-aggregating mixtures, indicating a more viscous suspension at low shear rates near the center of the vessel as observed in the rheological measurements in vitro. In microcirculation regions with low shear rate (e.g. small arterioles, postcapillary venules, and pulmonary circulation) the aggregates could cause capillary occlusion, pulmonary emboli and focal ischemia.

Further studies will be oriented to develop an emulsion that exerts oncotropic pressure, avoiding the emulsion-PEs mixing procedure and its secondary effects.

DUAL IMPELLER PROJECT OF IMPLANTABLE CENTRIFUGAL BLOOD PUMP AFTER SEVEN YEARS

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The implantable Centrifugal Blood Pump with Dual Impeller has original features for a long term Ventricular Assistance Device (VAD). The project started in 2006 at Baylor College of Medicine as part of an international and multicenter study involving Brazil and United States of America. This work presents a review of the last seven years of the project. Methodology was based in following steps: three-dimensional modeling with Computer Aided Design (CAD); Computational Fluid Dynamics (CFD) simulations; Rapid Prototyping (RP) in different materials; wear evaluation in ceramic pivot bearings system; in vitro testing with a cardiovascular simulator; electromechanical actuator assessment in dynamometer; human blood experiments for measurement of Normalized Index of Hemolysis (NIH); anatomical tests in calves and human cadavers; and in vivo animal tests with pigs (undergoing). Only three animals received the VAD during “In Vivo” animal experimentation but preliminary results are promising. Several previous steps in development chain confirmed earlier the recent implants results, like CFD and in vitro tests. The fact was considered a satisfactory example of how a project should be conducted in order to minimize costs with unnecessary experimentation and optimize time to achieve a simple and robust design, mechanically reliable, safety in terms of hemolysis and hydraulically efficient. This review highlights our good and bad experiences and its role in ICBP development.
BIO-INSPIRED, ANTI-COAGULANT SURFACES: ROLE OF SURFACE COATING TYPE
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Blood-contacting surfaces promote coagulation and clot-induced complications. Their surface properties differ from a healthy blood vessel endothelium, which utilizes a low fouling surface, anti-platelet nitric oxide (NO) release, and other mechanisms to prevent clot formation. In this study, platelet adhesion was quantified on surfaces with either zwitterionic polycarboxybetaine (PCB) or poly(methoxyethylacrylate) (PMEA) surface coatings. Gas permeable polypropylene (PP) was grafted with PCB using a “graft-to” approach and PMEA via a standard commercial process (Terumo X-coating). To determine platelet adhesion, the membranes were placed in a flow chamber and standardized platelet rich plasma (PRP, 1 x 108 platelets/mL) was recirculated at 0.3L/min on one side of the membrane (n=4-5). PRP was re-circulated for 8hrs and surface platelet adhesion was quantified using a lactate dehydrogenase assay. All results are presented as a percentage of platelet adhesion on uncoated PP. Platelet adhesion on PP modified with PMEA and PCB were 82.6 ± 9.3% and 52.7 ± 5.6%, of control, respectively. Thus PCB was shown to be more effective than PMEA at reducing fouling. Future studies will optimize the PCB surfaces to increase blood flow, examine the surfaces with NO flux to further reduce platelet binding, and test these coatings in vivo.

ON THE MECHANISMS OF THROMBOSIS IN ASSISTED BLOOD CIRCULATION: TRAFFICKING OF RED BLOOD CELLS AND PLATELETS IN MICROFLUIDIC SYSTEMS
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Platelet deposition on artificial surfaces is strongly influenced by the advection of platelets towards the wall – in which red blood cells (RBCs) play an important role. The objective of this study is to investigate the trafficking of RBCs and platelets in three representative micro-channels that mimic irregularities commonly found in artificial organs: (A) a sudden expansion having a backward step and sharp constriction, (B) a straight channel with an obstruction, and (C) a serpentine channel with multiple bends (See Figure). A suspension of platelets, RBCs and transparent, hemoglobin-depleted RBC ghosts are visualized using a high-speed camera and inverted microscope. Image analysis is performed to characterize the pathways of representative RBCs and platelets as well as their steady-state distribution (concentration fields). The studies revealed regions of elevated platelet concentration, believed to be caused by their interaction (collisions) with RBCs, as a function of flow rate and hematocrit. On-going studies will provide insight into the interaction force field between RBCs and platelets that in turn can be translated to a multi-phase rheological model. The ultimate objective is to improve the mathematical prediction of thrombus deposition in gaps, steps and bends in blood-wetted devices. (Figure 1)

POLYETHER ETHER KETONE (PEEK) ASSESSMENT FOR VAD APPLICATION: COMPARISON WITH COMMERCIALLY PURE Ti AND HEMOCOMPATIBILITY TESTS
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Background: Last decade, Ventricular Assist Devices (VADs) contributed for the decrease in death rate in patients waiting for a heart transplantation. Polyether ether Ketone (PEEK), have been used for trauma, orthopedic and spinal implants, showing encouraging results. This work shows an assessment of PEEK for VADs application. Main objective is to analyze the potential of PEEK for VADs application.

Methods: PEEK mechanical properties and results from hemocompatibility tests were compared with data from commercially pure titanium (CPTi). Hemocompatibility tests consisted of laboratory and biochemical analysis from blood samples that had direct contact with testing materials and also positive and negative controls.

Results: In characterization tests, PEEK presented lower values in hardness, tenacity and impact tests in comparison to CPTi, however, these values do not disqualify PEEK, considering that the mechanical stresses in a VAD are not elevated. PEEK presents better characteristics than CPTi in density and has the feature of molding production. Hemocompatibility tests previous results, do not indicated major differences between materials, even though; further toxicity and corrosion resistance tests should be performed.

Conclusion: The data obtained so far indicates no issues about long term blood contact biocompatibility of PEEK, appointing potential for its use in VADs.

Keywords: PEEK, Ventricular Assist Devices, Hemocompatibility.
FIRST APPROXIMATION TO THE DEVELOPMENT OF 3D-MATRIXES FROM SIS MEMBRANES
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Small intestinal submucosa (SIS) is an acellular collagen matrix used for tissue regeneration, with clinical limitations due to its laminar geometry. Our group has been working on SIS sponge grafts, obtaining complex geometries without losing regenerative capacity. Using pulverization, gelification, cross-linking and liofilization procedures on porcine SIS membranes, 3D-matrixes have been obtained. Pulverization was achieved by mechanical abrasion of compacted dry SIS under controlled temperature. The powder was solubilized in acetic acid and pepsin. Two solutions were studied: 0.5% w/v (S0.5) and 1% w/v (S1) of SIS powder. Gelification was achieved by cross-linking the solution with glutaraldehyde (GA). After liofilization, the samples were observed under Scanning Electron Microscope (SEM).
SEM allowed identifying the structure of the sponges (Fig. 1), constituted by pores 75 µm to 200 µm in diameter, and micro-pores 1 µm to 8 µm in diameter. S0.5 sponges hold their structure after 72 h in de-ionized water. Both have pores large enough to hold cells, but characterization of mechanical (compressive and flexural tests, and pore distribution), chemical (composition and cross-linking degree) and biological (collagen viability) properties is currently undergoing to assess medical viability. Due to cytotoxicity associated to GA, other cross-linking agents, such as EDC, will be considered. (Figure 1)

INFLOW CANNULA ENHANCEMENTS AND BIOCOMPATIBILITY RESULTS FOR THE PEDIAFLOW® PEDIATRIC VAD
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Preliminary ovine biocompatibility results of the frozen-design PediaFlow® pediatric VAD (PF4) were promising with mean free hemoglobin below 8.0 mg/dL despite suboptimal pump performance due to inflow cannula kinking. (A, B). With a fixed depth and shallow bend, achieving adequate drainage required extensive manipulation of the heart leading to excessive strain and eventual kinking of the inflow cannula at the connector. Addressing these limitations, the second generation utilized a stainless steel coiling instead of Nitinol, a larger bend radius, and a reinforced connection junction. This inflow cannula was kink resistant (C) and enabled the PF4 to achieve a flow rate >2.0 L/min for the study duration while maintaining superb biocompatibility.
Acknowledging the varying anatomical configurations of pediatric patients and the challenges faced during implantation, a 3rd iteration has been designed for the final series of pre-clinical studies (D). A new U-type parabolic tip lowers the likelihood of a full occlusion during potential suction events while minimizing the pressure losses caused by fenestrated-type cannulae. The metal reinforced tip assists insertion while serving as a radiopaque marker during imaging. A detachable sewing ring will ease placement while enabling variable insertion depths using a tool-less spring clamp mechanism to optimize ventricle offloading. (Figure 1)

Figure 1: PediaFlow® inflow cannulae. A, B explanted 1st Gen, C explanted 2nd Gen, and D) prototype U-type, variable-depth, 3rd Gen.
DEVELOPMENT OF A PASSIVE-CONTRACTING HEART PLATFORM FOR DEVICE TESTING, RESEARCH AND TRAINING

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Purpose: integration of biological samples into in vitro mock loops is fundamental to better simulate real device’s operating conditions. We developed and tested a novel cost-effective in vitro platform, able to house a passive heart and simulate its contraction through the dynamic pressurization of the ventricular walls. The system was designed to test assist devices, prosthetic valves and to simulate transcatheter procedures under physiologic hemodynamic conditions and simultaneous endoscopic visualization.

Methods: the ventricles of a swine heart were housed in a fluid-filled chamber, connected to a piston pump whose cyclic displacement induced ventricular contraction. The atrioventricular corona was held and sealed with a rapid-prototyped vacuum seal, so as to exclude the atria from any external pressurization. The heart apex was fixed to avoid bending and displacement under pressure. The aortic root was connected to a mock circulation mimicking the human systemic impedance. The left atrium was connected to a dynamic preload. Endoscopic access was provided through the aorta, while the connection to LVADs was possible through the heart apex.

Results: the platform was able to reliably reproduce physiologic cardiac hemodynamics, in terms of both pressure and flows (BP 120/80 mmHg, CO 4 lpm at 80 bpm). High speed video recordings showed the great potential of the system of observing valve dynamics in pulsatile conditions.

Conclusion: the system represents a very promising tool for an accurate hemodynamic, kinematic and morphologic analysis of the interactions between cardiovascular devices and the heart. Also, visualization studies including transcatheter procedures are possible.

REAL TIME CHARACTERIZATION OF FLOW INDUCED PLATELET DEPOSITION ONTO CLINICALLY-RELEVANT OPaque SURFACES

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Purpose: Many ventricular assist devices (VADs) utilize a highly polished titanium alloy, TiAl6V4, as a blood contacting surface. However, few studies have examined platelet deposition onto alternative opaque surfaces in real time. Using hemoglobin depleted red blood cells (RBC ghosts) and long working distance optics to visualize platelet deposition, we sought to perform such an evaluation.

Methods: Fluorescently labeled platelets were mixed with human RBC ghosts and perfused across 6 opaque materials (TiAl6V4, silicon carbide (SiC), alumina (Al2O3), 2-methacryloyloxyethyl phosphorylcholine polymer (MPC) coated TiAl6V4, yttria partially stabilized zirconia (YZTP), zirconia toughened alumina (ZTA)) for 5 minutes at a wall shear rate of 400s⁻¹. Fluorescent microscopy was used to visualize platelet deposition.

Results: The images acquired were evaluated for platelet surface coverage using a customized Matlab (Mathworks) program and statistically analyzed by a repeated measure ANOVA. Al2O3, MPC, YZTP, and ZTA were found to be significantly less thrombogenic than TiAl6V4 (P <0.01). Platelet images were validated by electron microscopy.

Conclusion: The videos of TiAl6V4 show the formation of thrombi covering approximately 5% of the surface area after one minute blood perfusion. These thrombi grew in the direction of flow over time, resulting in a maximum surface coverage of 15%. Al2O3, MPC, YZTP, and ZTA had significantly less platelet deposition than TiAl6V4, with a maximum surface coverage of less than 5%. This study indicates that Al2O3, MPC, YZTP, and ZTA are promising alternatives to TiAl6V4 and may improve the thrombo-resistance of blood-wetted devices, such as VADs.

AORTIC VALVE OPENING DYNAMICS IN CF-LVAD SUPPORT

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Purpose: Patients under prolonged c-LVAD support exhibit aortic valve fusion at higher levels of support. In cases where maintenance of aortic valve function is required, e.g., patients who may be bridged to recovery, the level of pump speed should be chosen such that fusion does not occur. In this study we aim to test in what pump speed range the valve leaflets exhibit partial separation during opening, in an in-vitro study on a porcine heart.

Method: A porcine heart was mounted in a fluid-filled chamber capable of compressing and relaxing the ventricular part of the heart. The atra of the heart were not subjected to external loads. The left part of the heart was connected to a mock circulatory system resembling the systemic impedance. A Micromed LVAD was connected to the apex of the heart, and ejected into the aorta. The external chamber volume was varied rhythmically at 80 BPM, to drive the motion of the heart chambers. The mock circuit was tuned such that BP was 90/45 mmHg@3L/min CO. Using a high-speed video camera with an endoscope, the motion of the aortic valve was recorded at pump speeds varying from 7,500-12,500 RPM in 500RPM steps. Simultaneously, BP and CO were recorded.

Results: Under the preset circumstances, the aortic valve remained permanently closed at 12,000RPM and above. At 11,500RPM, the valve opened, but the leaflets remained in contact near the aortic root. At 11,000RPM and lower, the valve leaflets separated completely at peak systole.

Discussion and Conclusion: Even though the use of a transparent fluid instead of blood may slightly influence the results, partial separation of the valve leaflets only occurs in a very narrow pump speed range (500RPM).
CAVAL COLLAPSE MODELING FOR CARDIOPULMONARY Bypass
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Caval collapse over the caval axis was studied for wall-less (Smartcanula®) and control (Biomedicus®) venous cannulas. Flow is measured sequentially for right atrial + hepatic + renal + iliac draining using centrifugal pump and an experimental bench set-up (afterload 60 mmHg). At 1500 rpm and atrial position (2000; 2500 rpm), Q values are 3.4 versus 0.77* l/min: p< 0.05* (6.03 versus 0.43*; 8.01 versus 0.58*) and pressure values are -15.18 versus -46.01* mmHg (-31.62 versus -119.94*; -74.53 versus -228.13*) for wall-less and Biomedicus cannula respectively. At hepatic position, Q values are 3.34 versus 2.3* l/min (6.67 versus 0.42*; 9.26 versus 0.18*) and pressure values are -10.32 l/min versus -23.35* (-20.25 versus -119.09*; -42.83 versus -239.38*). At renal position, Q values are 3.43 versus 2.48* l/min (6.56 versus 0.41*; 8.64 versus 0.22*) and pressure values are -9.64 versus -20.87 mmHg (-20.98 versus -127.68*; -63.41 versus -239). At iliac position, Q values are 3.43 versus 1.62*/min (6.01 versus 0.55*; 9.25 versus 0.58*) and pressure values are -9.36 versus -30.6* mmHg (-33.57 versus -120.27*; -44.18 versus -228*). Our experimental evaluation demonstrated that the wall-less cannula outperforms the commercially available control cannula with superior flow despite less negative pressure.

CENTRIMAG VENTRICULAR ASSIST SYSTEM: CLINICAL OUTCOMES IN ACUTE DECOMPENSATED HEART FAILURE PATIENTS AS BRIDGE TO DECISION
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Introduction: The Centrimag ventricular assist system (CVAS) is increasingly being used as a bridge to decision in patients with acute decompensated heart failure. We present our experience with this device system for both uni and biventricular support.
Methodology: Retrospective data collection was done to identify patients implanted with CVAS over 3 years. Clinical data was collected regarding the indications, demographics and outcomes (30-day mortality, transplant or long-term device implantation) for these patients.
Results: Thirty patients underwent implantation of CVAS over 3 years. Clinical data was collected regarding the indications, demographics and outcomes (30-day mortality, transplant or long-term device implantation) for these patients. Most patients were African Americans (41%) and males (66%). The mean age of this cohort was 51±14 years. Indications for LVAS included chronic heart failure (n=16, 53%), complications of acute myocardial infarction (n=5), post-cardiomyotomy (n=3, 17%), post transplant (n=3, 10%) and others as myocarditis/peripartum cardiomyopathy (n=3, 10%). The median days on CVAS were 27 days (1-113 days). 30-day survival was 70% in our cohort. Two patients underwent orthotopic heart transplant post-CVAS placement, 20 patients underwent implantation of long-term permanent ventricular assist devices (continuous flow device n=14, paracorporeal n=6).
Conclusion: The CVAS system is an efficient and reliable temporary device as a bridge to decision/recovery in acute decompensated heart failure patients.

CHEST COMPRESSIONS IN THE HEARTMATE II POPULATION
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Purpose: Outcomes of 7 patients with HeartMate II left ventricular assist devices (LVAD) who received chest compressions were examined to determine both cannula integrity and outcomes.
Methods and Materials: We retrospectively reviewed all HeartMate II patients at our center receiving chest compressions between April 2009 and July 2012 for cardiovascular/neurologic outcomes and potential cannula dislodgement.
Results: Seven of 190 patients implanted received chest compressions (Gender M: F 6:1, ages 50-80 years, duration of chest compressions <1 minute to 2.5 hours, duration on pump 50-1324 days). There were no patients who received surgery at our institution who were lost to follow-up. Three of 7 patients had return of neurologic function. Two additional patients had return of peripheral circulation and heart function without return of neurologic function. One patient had documented flow on the device without return of native heart function. Stable pump parameters (Flow 3.7-6.6 and Hgb levels) were documented in 5 of 6 patients. Autopsy was performed on 3 patients including the one patient where pump parameters were not documented. Direct observation during autopsy showed no inflow and outflow grafts disruptions. Using autopsy and adequate flow through device as proxy for intact inflow/outflow cannulas, none of the seven patients receiving chest compressions had cannula dislodgements.
Conclusions: In this small sample retrospective study, chest compressions in patients with LVADS appear to be safe and potentially beneficial.

WE CAME, WE CANNULATED, WE DECIDED: ECMO TO IMPLANTABLE MECHANICAL CIRCULATORY SUPPORT
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Placement of LVAD/TAH as a bridge to recovery or transplantation is a widely accepted treatment modality. Preexisting organ dysfunction adversely affects patient survival after placement of an implantable mechanical device. We present our experience at two institutions using ECMO in patients with cardiogenic shock to stabilize organ function prior to implantation. From July 2008 to October 2012, 17 patients in cardiogenic shock with preexisting organ dysfunction were supported on ECMO before LVAD (15/17, 88%) or TAH (2/17, 12%) placement. Patients were managed by similar ECMO algorithms from both institutions and all underwent weaning trials prior to conversion to LVAD or TAH. Pre-ECMO and pre-LVAD/TAH end-organ functions were compared. Survival after placement of LVAD/TAH were analyzed between the subgroups. AST decreased from 166+/–239U/L at ECMO implantation to 61+/–7U/L at LVAD/TAH implantation. ALT decreased from 97+/-132U/L to 56 +/–45U/L. Serum creatinine decreased from 1.8+/–0.5mg/dl to 1.3+/–0.7mg/dl. The interval between ECMO initiation and LVAD/TAH placement was 10+/–6 days (range 3–26 days). Overall survival to discharge after LVAD/TAH was 77% (13/17). The survival to discharge among those who transitioned off ECMO within 14 days was 92% (12/13), which was significantly better than those who were on ECMO longer than 14 days, 25% (1/4), p<0.05 by student t test. ECMO can immediately stabilize circulation and provide organ perfusion in patients with cardiogenic shock. After improvement of organ function, LVAD or TAH implantation can be performed successfully in this patient collective; with patients supported for less than 14 days having the highest survival.

ASAIO CARDIAC ABSTRACTS
EXTRACORPORAL MEMBRANE OXYGENATION (ECMO) WEANING IN INTENSIVE CARE UNIT USING THE MINIATURIZED HEMODYNAMIC TRANSSESOPHAGEAL ECHOCARDIOGRAM (HTEE)
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Introduction: Ventricular function assessment is important to determine if the patient is able to wean from ECMO. The weaning process may take hours and conventional TEE may not always available. We have been utilizing miniaturized hTEE for ECMO weaning in our ICU.

Methods: From October 2011 to June 2012, 21 patients underwent venoarterial ECMO. Left and right ventricular function and volume status was assessed by continuous HTEE. Weaning protocol included decrease of ECMO flow, volume replacement, and inotropes. If hemodynamics were stable, ECMO flow was placed on minimum and hTEE was continued at least 1 hour. If the biventricular recovery is noted, ECMO was removed the following day. If the isolated left ventricular failure documented by the hTEE while ECMO wean, left ventricular assist device was placed.

Results: Of the 21 patients, 7(33%) had non-recoverable left and right ventricular function and care was withdrawn; 6 (29%) had left and right ventricular recovery and underwent optimal medical therapy or revascularization for underlying coronary artery disease; and 8 (38%) had right ventricular recovery without improvement of the left ventricular function. These 8 (100%) patients underwent LVAD placement; none subsequently developed profound right ventricular failure. The positive predictive value for ventricular recovery by hTEE was 100% using the standardized ECMO weaning protocol (95% confidence interval 73 – 100%).

Conclusions: The hTEE-guided ECMO weaning protocol accurately predicted the ability to successfully wean ECMO to decision.

CHRONIC NON-PULSATILE BLOOD FLOW IN THE HUMAN BODY
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Introduction: On March 2011 was performed the first implantation continuous-flow Total Artificial Heart (CFTAH) in Texas Heart Institution. Craig Lewis suffered from amyloidosis with advanced heart failure. His two native heart chambers were removed and two continuous ventricular assist devices (VAD) Heartmate II were implanted as CFTAH. That was at the first time when CFTAH produced pure non-pulsatile flow in the human pulmonary and the human systemic circulatory systems with an intention doing long-term mechanical circulatory support. Czech Jakub Halik had his heart replaced with two HeartMate II last April 2012 after an aggressive cancerous tumor was found. Both patients died due to kidney a liver failure. Before the first human implantation in Texas, various prototypes of the CFTAH were implanted in more than 40 calves.

Methods: The aim of my contribution is to analyze this „off label” implantation from the ethical-legal view. The main differences between pulsatile and non-pulsatile blood flow will be explained. Hybrid blood flow will be characterized. Description of the quality of microcirculation and its dependency on the kind of macrocirculation will be provided. The common principles of the evidence-based medicine and the state of the art will be mentioned. I will emphasize the evidence based medicine for tissue perfusion and the state of the art for pulsatile flow vs. non-pulsatile flow.

Conclusion: On the basis of the state of the art it is difficult to confirm long-term benefits of non-pulsatile blood flow in the mammalian circulatory system. More prospective studies solving this problem are needed. More interdisciplinary discussion about this should be done before clinical implantations CFTAHs in humans.

RADIAL ACCESS FOR PERCUTANEOUS CORONARY INTERVENTIONS (PCI) LEADS TO A REDUCED COLLAGEN-INDUCED PLATELET AGGREGABILITY COMPARED TO FEMORAL ACCESS
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Modern PCI techniques including radial artery catheterization have been associated with decreased rates of myocardial infarction and death compared to femoral artery approach. It was established that radial artery access was linked to inferior post procedural levels of C-reactive protein in stable coronary artery disease compared to femoral access. To date, however, the differences in platelet reactivity in these two PCI approaches have not been established. The objective of this study was to assess platelet responses in patients undergoing radial vs. femoral access in elective PCI. The study group consisted of 8 women and 9 men with coronary artery disease (CAD) and a median age of 60.5 years. Eight patients were subjected for PCI via radial and 9 via femoral access. Platelet aggregation in response to collagen was assessed immediately before (A), during (B) and 6 hr (C) after PCI by aggregometry (PICA, Model 600, Chrono-Log Corp., Havertown, PA). Results indicate that PCI performed via femoral access immediately increased platelet aggregability, which continue to be high 6 hrs after the procedure (A 71.1%, B 87.8%, C 88.0%). Radial access did not affect platelet aggregation during the procedure (A 70.1%, B 70.2%), however, caused its increase 6 hrs after (C 82.1%). It appears that the radial artery catheterization is less thrombogenic than femoral in terms of platelet aggregation.
SEVERITY OF END ORGAN DYSFUNCTION AS A PREDICTOR OF SURVIVAL AFTER IMPLANTATION OF LEFT VENTRICULAR ASSIST DEVICES (LVAD) FOR BRIDGE TO TRANSPLANTATION (BTT)

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**Purpose:** The optimal timing of implantation of LVAD for BTT in patients with advanced heart failure is controversial. We hypothesize that severity of end-organ dysfunction as determined by the sequential organ failure assessment (SOFA) score, prior to implantation, is a determinant of outcomes after LVAD implantation.

**Methods:** We determined the pre-implant SOFA scores and outcomes of 55 consecutive patients who received HeartMate II or Heartware LVAD as BTT at our institution since January 2007. SOFA score was calculated based on pre-implant hemodynamics, oxygenation, platelet count, creatinine, bilirubin and neurological status. Kaplan-Meier analysis was used to compare survival across SOFA score subgroups.

**Results:** The mean pre-implant SOFA score was 4.00±3.05. The overall 30-day mortality was 5.5% with no significant difference among SOFA score subgroups. Pre-implant SOFA score was significantly lower in survivors at 12 months (2.74±1.71 vs 6.80±4.51; p=0.03). One year survival for SOFA scores 0-2, 3-5, 6-9 was 94%, 72%, 33% respectively. (Figure 1)

**Conclusions:** These results show that pre-implant SOFA score is a powerful predictor of survival after LVAD therapy. Long-term outcomes of heart transplantation may be significantly improved by early LVAD implantation, before development of end-organ dysfunction.

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EFFECTS OF BLOOD PRODUCT TRANSFUSION IN PATIENTS WITH LEFT VENTRICULAR ASSIST DEVICES

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**Background:** Transfusion of blood products perioperatively during cardiac surgery has shown to be associated with adverse clinical outcomes. The aim of this study was to evaluate differences in clinical outcomes in left ventricular assist devices (LVAD) patients based on transfused blood products.

**Methods:** Retrospective analysis was done on 171 patients with continuous flow LVADs over 4 years. Data was collected on the number of blood products transfused: packed red cells, platelets, cryoprecipitate, fresh frozen plasma (FFP) intraoperative and 2 days perioperatively. Patients were dichotomized based on postoperative hospitalization: 30 days (Group 1) and >30 days (Group 2).

**Results:** There were 78.4% males, 89% destination therapy. Group 2 had significantly greater units of total transfused blood products (37.74 ± 16.84 vs. 31.47 ± 16.79 Units, p=0.01). There was no difference in packed red cells (p=0.09). Significantly greater units were transfused of the following: platelets (0.02), FFP (0.04) and cryoprecipitate (0.01). Group 2 had significantly lower preoperative hemoglobin without significant elevation of INR. Multivariate regression (age, hemoglobin, total blood product, ALT) showed that total units of blood products was an independent predictor of the length of stay (LOS) (OR=1.10, CI=1.004-1.10, p=0.02). Amongst the blood products, cryoprecipitate was independently related to LOS (OR=1.10, CI=1.01-1.19, p=0.01). There was no difference in long term mortality between groups (p=0.71 by log rank).

**Conclusions:** Increased perioperative blood product transfusion (mainly cryoprecipitate) in CF-LVAD patients is associated with increased LOS. It however does not impact readmissions or mortality.
A NEW AXIAL FLOW PUMP INSTALL THE BASE OF ASCENDING AORTA: INITIAL REPORT OF DEVELOPMENT OF THE VALVO PUMPS

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Introduction: We have already developed the axial flow pump “Valvo Pump”. However the axial flow pump is too long to implant at the aortic valve position. In this study, we develop a new miniature axial flow pump “Valvo Pump II” that can install the base of the ascending aorta.

Methods: The new axial flow pump consists of a stator, an impeller in which four neodymium magnets are incorporated, and the impeller is directly driven by the stator. Rotation of the impeller is suspended by a passive magnet bearing and by a hydrodynamic bearing. Sizes of the new axial flow pump is a diameter of 34 mm and a length of 50 mm, and the new axial flow pump is able to install at the base of the ascending aorta posterior to the Valsalva sinus.

Results: Performance of the axial flow pump was evaluated by in vitro experiments. The new axial flow pump has a pump outflow of 3.8 L/min. against a pump differential pressure of 100 mmHg at a rotational speed of 12000 rpm. The CFD analysis shows that the axial flow pump theoretically has a pump outflow of 5 L/min under the same condition.

Conclusion: Further studies including in vitro hemolysis tests and animal studies are required, the new axial flow pump “Valvo Pump II” might be promising to be a new VAD.

IS CLOSTRIUM DIFFICILE INFECTION A RISK FACTOR FOR PATIENTS REQUIRING LEFT VENTRICULAR ASSIST DEVICE?


Background: Clostridium difficile associated diarrhea (CD) is a common infection after cardiac surgery resulting in gastrointestinal complications and death. On the other side patients requiring left ventricular assist device (LVAD) have an increased mortality rate per se.

Methods: Between 12/1999 and 06/2012 a total number of 3899 patients (59.0% male, age 67±19 years) were tested for CD because of diarrhea after cardiac surgery. 1652 of these were CD positive (42.4%), 59 (1.51%) pts. of the total group received LVAD; these 59 pts. formed the study group. Cox-regression, Kaplan-Meier-Curves were generated.

Results: 15 (25.4%) pts. were CD positive tested compared to 44 (74.9%) which were CD negative. Preoperative parameters as gender, age, COPD, diabetes mellitus were not significant different in CD positive vs. CD negative. Postoperatively CD positive pts have a trend to longer ventilation time (864.7±1013.0 vs. 455.1±543.0; p=0.051). All other postoperative parameters as dialysis, gastrointestinal complications, tracheotomy, ITP stay was not significant different. Overall 30-day mortality was 10.2% with no difference between CD positive and CD negative (6.7% vs. 11.4%; p=0.724). For long-term survival log Rank-test showed no differences in former CD positive or negative pts. (p=0.517)

Conclusions: CD associated diarrhea is a common problem in the early postoperative phase after LVAD implantation. However, no typical perioperative risk factors influencing CD positive diarrhea could be found in our cohort. CD positive diarrhea does not influence early and late mortality in this selected patient group.

A MINIATURE AXIAL FLOW PUMP WITH SUSPENDED ROTOR

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Object: To suspend the impeller of axial flow pumps by hydrodynamic, magnetically levitating field. Methods: The axial flow pump is composed of a cylindrical pump house, an impeller with magnetic rotor and a diffuser. The axial displacement of the impeller is restricted by the magnetic field formed by the rotor and the electromagnetic stator. A tiny gap is formed between the blade tip of the impeller and pump house since the diameter of impeller is slightly less than the inner-diameter of the cylindrical pump house. Hydrodynamic force will produced inside this gap on rotating of the impeller, limiting its radial movement. Thus the impeller will be fully suspended by hydrodynamic—magnetic force. An outlet diffuser is arranged behind the impeller to enhance the pump efficiency, with its blades projected directly from the wall of the pump house, eliminating the center hub which is usually for holding the blades, making a hollow space in the diffuser center. This design allows blood flow through the centric passage to wash out the “dead area” behind the impeller, in favor of enhancement of antithrombotic performance.

Results: Currently the prototype is 23mm in diameter and 65mm in length, yielding a flow rate of 5L/min at 100 mmHg pressure with a rotating speed of 14000rpm. The normalized hemolysis index (NIH) is 0.12g/100L. Conclusion: Our newly developed axial flow pump with hydrodynamic, magnetically levitated impeller is feasible for left ventricular assistance, just for in vivo animal test in future studies.

DISCHARGING HOME AN 8 YEARS OLD CHILD ON INTRA-CORPOREAL LVAD AS BRIDGE TO DECISION

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Introduction. Discharging adult LVAD on support home has become routine treatment. Pediatric VADs were mainly used as an inpatient treatment so far because of the relatively complexity and size of the equipments.

Case report. We report the case of an eight years old child (BSA 0.97m2) suffering from inotropist dependent biventricular heart failure due to chemotherapy-induced acute toxic cardiomyopathy after treatment of a bone sarcoma. The child was provided with an intra-corporeal left ventricular assist device (LVAD; HVAD Heartware) as a bridge to candidacy. Apart from prolonged medical supportive right ventricular recovery postoperative course was uneventful. Ventilation time was 7 days, ICU stay 28 days. The child was discharged home after three and a half month in hospital after extensive training of the child, parents, family doctor, the whole school class including teaching staff and emergency services. In a multipart concept first institutional guidelines were created for emergency situations and provided for everyone. Then training was offered at our institution including lectures (how the systems functions, different alarms) followed by hands-on training with a special simulation tool. A workshop for the emergency service was organized. Finally training was done at the home village of the child including her whole class mates.

If long-term ventricular assist device is necessary as BTV in children with a body surface area above 0.6m2 an intra-corporeal VAD implantation should used. It offers considerably more mobility to the patients and contributes to improved quality of life.
EFFECT OF VALVE HOUSING OSCILLATION ON HINGE POINT STAGNATION IN ARTIFICIAL HEART VALVES

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OBJECTIVE: We examined a novel strategy to reduce the thrombogenicity of mechanical heart valves. Despite extensive research into valve materials and flow dynamics, mechanical valves remain susceptible to thrombus formation and require life-long anticoagulation. Areas of flow stagnation near the valve hinge point are thought to be prone to thrombus formation. We propose a novel technique to enhance blood mixing, and thereby reduce stagnation through perturbing the valve housing to disrupt the blood surface boundary layer. We conducted bench-top feasibility studies to test the concept that micro-mixing vortices can be induced with low frequency vibrations in a valve model as a means to modify hinge flow-stagnation zones.

Methods: A 2x scale model of a bileaflet mechanical heart valve was immersed in a glycerol:water solution test chamber, to which phenol red dye was added at the hinge point. The valve was then vibrated with an electromechanical oscillator, and dye washout patterns were imaged using a video microscope. The images were then processed and analyzed.

Results: Oscillation of the valve housing model reduced hinge area flow-stagnation and that optimal mixing was obtained with a duty cycle of 400 milliseconds of oscillation and a voltage dependent oscillator drive signal augmentation effect was seen until a plateau was reached.

Conclusions: Low frequency vibration improves mixing and reduces flow-stagnation near the valve hinge areas. The proposed technique is readily translatable to the clinical setting. The imposed vibrations can be imparted to the valve housing entirely outside of the blood path and easily adapted to existing approved heart valves.

REDUCTION OF MICROVASCULAR OBSTRUCTION BY PARA-AORTIC COUNTERPULSATION ON ACUTE ISCHEMIA/REPERFUSION IN PIGS

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To achieve complete myocardial reperfusion after epicardial coronary flow restoration is critical for infarct healing after revascularization. Paradoxically, this reperfusion after ischemia is accompanied by the "no-reflow" phenomenon due to ultrastructural alteration of the reperfused microvascular bed. An acute myocardial infarction was produced by a complete ligation of the left anterior descending (LAD) coronary arteries for 1 hour in 10 pigs. Reperfusion was performed immediately after flow restoration for 2 hours using 3 scenarios: control group (n=3, no assist device), intraaortic balloon counterpulsation group (n=3, IABP), and paraoartoc counterpulsation group (n=4, PABP). The objective of the present research is to assess if no-reflow area can be reduced by counterpulsation support. Both Evans Blue and Thioflavin S staining methods were used to differentiate tissues with or without microvascular obstruction (MO) phenomenon. Postmortem triphenyltetrazolium chloride (TTC) staining was used to indicate infarcted myocardium. The results show that both TTC and MO areas were comparable for the control and IABP groups. However, a 4-5 fold reduction of TTC and MO areas was achieved by the PABP group. This initial finding conjectures that counterpulsation support is useful for reducing ischemia reperfusion injury. However, a meticulous enforcement of counterpulsation support matters in the tissue level microvascular perfusion assist.

IN-VITRO EVALUATION OF VASCULAR AUTOREGULATION ON TRANSIENT POSTERIOR CEREBRAL ISCHEMIA CAUSED BY SUBCLAVIAN COUNTERPULSATILE CONTRACTION UNLOADING

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1Department of Aeronautics and Astronautics, National Cheng Kung University; 2Heart Science and Medical Devices Research Center, National Cheng Kung University.

Partial-support counterpulsatile blood pumps arose recently as a potential early interventional modality for treating heart failure. Implanted devices via subclavian artery was shown to be surgically attractive owing to its advantage of simplicity and safety. However, it was found that severe transient ischemia may occur in right posterior cerebral perfusion under subclavian counterpulsatile contraction unloading. The aim of the present research is to investigate if brain autoregulation can autonomously alleviate counterpulsatile device-induced cerebral ischemia. To achieve vessel autoregulation simulation, an existing tilting-base mock loop was modified by adding adjustable resistors regulated by a proportional-integral (PI) controller implemented with Ziegler-Nichols algorithm. By varying the PI gain constants the cerebral autoregulation was realized in terms of different transient responses quantified by autoregulation indices. The results show that cerebral autoregulation, typically requiring 5-10 seconds response time, cannot effectively compensate unloading ischemia caused by counterpulsation characterized by shorter time scale. The design of subclavian counterpulsation, hence, should delay the deflation timing of pumping control into heart systole and weaken contraction unloading with longer pump filling period, implying compromised contraction unloading therapy that is provided by subclavian counterpulsation.

THE MVAD® PUMP: MOTOR STATOR CORE LOSS CHARACTERIZATION

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Purpose: Investigation of the MVAD® pump motor stator core loss behavior was conducted. A core loss fixture and a method to characterize the magnetic behavior of the MVAD pump stator over a range of frequencies were developed. Methods: The MVAD® pump motor design features a three phase brushless DC stator with ferromagnetic laminations and copper wire windings arranged in a six slot configuration. The stator's magnetic behavior is important since its core magnetic losses impact pump system efficiency. A system to measure the core loss of MVAD stators was developed using a custom core loss fixture consisting of 16 copper wire turns wound in a closed loop geometry bundle; the stator under test was then placed within this bundle. The signal path of the setup consisted of a signal generator, a power amplifier, and a power analyzer. Power analyzer parameters of current, voltage, and power were collected for several runs with a sinusoidal frequency sweep of 1 Hz to 10 kHz; data was collected for the fixture with and without stators. Results: The magnetic losses inherent to the fixture were characterized independently as a baseline with a flat frequency response. The core loss measurements of individual stators yielded a characteristic theoretical bandpass frequency response morphology with a peak core loss found at 2 kHz. In conclusion, this method could be used to describe the transfer function of the stator's core magnetic behavior. It also has the potential to be used for future motor evaluation and for investigation of core loss performance variability between different stators during manufacturing operations. CAUTION: Investigational device. Limited by United States law to investigational use.
A NOVEL PEDIATRIC BIVENTRICULAR ASSIST DEVICE: TEST BENCH RESULTS
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Introduction: Most pediatric ventricular assist devices (VADs) currently used in children are extracorporeal pulsatile or centrifugal pumps. Research today focuses on miniaturizing existing adult continuous flow pumps. These VADs require long-term anticoagulation therapy and extensive surgery, and two devices need to be implanted for biventricular support. We created an external biventricular assist device for children made of Nitinol and evaluated its performance on a test bench. This device supports the heart with a compressing movement mimicking the cardiac muscle’s contractions.

Methods: Coiled Nitinol wires were attached vertically between two discs, placed at the apex and base of a pediatric heart model. Energy was provided by a laboratory power supply. Ejection fraction, heart rate, cardiac output and generated systolic pressure were measured on a test bench allowing variation in preload and afterload settings. Results: The heart model had an end-diastolic volume of 26 ml. Our test bench settings were a preload range of 0 – 15 mmHg and an afterload range of 0 – 160 mmHg. To reach the device’s maximal contraction, a power supply of 35 volts and 3.5 amperes during 1.5 seconds was necessary. With a diastole lasting 1.5 seconds to obtain complete relaxation, we achieved a heat rate of 20 beats per second. The ejection fraction range went from 34.4 % to 1.2 % as the afterload increased, along with a cardiac output from 180 ml/min to 6 ml/min. The device generated a maximal systolic pressure of 30 mmHg. Conclusions: External biventricular assistance in child’s size heart is technically feasible. Further testing remains necessary to assess this VAD’s in-vivo performance range and its reliability.

DEVELOPMENT OF THE TYPEII AXIAL FLOW PUMP FOR LEFT VENTRICULAR ASSISTANCE
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Object: To evaluate the performance and effects of our recently meilerioted typell axial flow pump. Methods: Typell axial flow pump is 23mm in diameter and 65mm in length. Six pigs, weight 55-60kg, were anesthetized intravenously. The left chest was entered through fifth costal space. Then, typell axial flow pump was connected between LV apex and descending thoracic aorta. Aortic pressure and left ventricular pressure were recorded simultaneously. Results: Typell axial flow pump can be totally implanted into the thorax without difficulty. At baseline the left ventricular systolic pressure (LVSP) measured 137±23mmHg. The LVSP was instantly decreased with the increase of pump rotational speed. Typically, the LVSP was lowered to 32±14 mmHg at the pump speed of 12000rpm while the aortic systolic pressure maintained at 122±28 mmHg. The animals survived up to 25 days without thrombus problem and, there was no deterioration regarding visceral organ function. The plasma free hemoglobin was variable from 30mg-500mg/L during the period. Conclusion: Typell axial flow pump has a good anatomic fit, and is promise for clinical use in future.

HEMODYNAMICALLY OPTIMIZED OUTFLOW CANNULA FOR CARDIOPULMONARY BYPASS
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Purpose: Stroke and cerebral hypoperfusion are inevitable complications of cardiopulmonary bypass (CPB). In part this is caused by altered flow conditions in the aortic arch and the sandblast effect of the cannula jet. In the past years, we have developed a validated computational model to analyze aortic flow conditions during CPB. This model was now applied to develop a novel CPB outflow cannula which reduces neurologic complications.

Methods: The Multi-Module-Cannula (MMC) is based on a generic elbow cannula that was iteratively improved. It features an inner wall within the cannula body to smoothly guide the blood, and an expanding diffuser element with an additional side hole and elliptical shape for easier insertion. The MMC was virtually placed into a model of the human aortic arch. Performance and qualitative hemolytic potential were analyzed using computational fluid dynamics. The model was validated by particle image velocimetry and in-vitro blood tests. All values were compared to a standard commercial elbow cannula.

Results: At 5 L/min CPB with MMC, the pressure drop is reduced from 68 to 61 mmHg and the max. Velocities are reduced from 3.7 to 3.3 m/s. Shear rates are reduced from 330 to 260 s/1. The qualitative dimensionless blood damage index is reduced from 0.37 to 0.03 by a factor of approx. 12, showing significantly reduced hemolytic potential of MMC. During standard CPB, cerebral blood flow is decreased from 15.3% of total flow down to 10.8%. Using MMC, it reaches almost physiological values with 14.3%. The MMC appears to be superior to a standard cannula and promises to reduce neurologic complications during CPB, which will be tested in animal trials as the next step. A patent is currently pending.

NUMERICAL STUDY OF PEDIATRIC LEFT VENTRICULAR ASSIST DEVICE WITH DIFFERENT IMPELLER DESIGNS
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Currently, pediatric circulatory supports are emerging as an alternative treatment and the need for this device support is increasing dramatically. In this study, we have developed and evaluated two impeller blade structures. Both of them had similar dimension except the gap-size at the inner-corner of blade: MUDP#1 (gap size = 0.66 mm) and MUDP#2 (gap size = 1.61 mm). Also they both were open backward straight blade with curved propeller face and second flow region on their center. The purpose of this study was to examine how the impellers with different gap-sizes at the inner-corner of blade affect the pressure-flow relationships and shear stress (τ). By using computational fluid dynamics, inflow-outflow different pressure was calculated at different speeds (3, 3.5, and 4krpm) and different flows (0 to 5 L/min). The simulation was repeated twice. From the simulation, the pressure-flow relationships of two designs demonstrated no explicit difference. Interestingly, the average-τ on impeller surface of MUDP#2 (58.0±8.47, 65.29±6.26 and 78.98±10.97 Pa) were higher than those of MUDP#1 (36.57±10.74, 40.11±10.89 and 45.50±13.98 Pa) at all speeds respectively. Similarly, the average-τ on housing surface of MUDP#2 (55.82±10.63, 69.85±7.41 and 77.47±7.44 Pa) were higher than those of MUDP#1 (42.93±18.44, 52.78±20.73 and 51.02±9.53 Pa). In addition, when comparing at each speed, the results showed that 5 out of 6 of the average-τ on housing surface were significantly higher than the average-τ on impeller surface (p<0.01). In conclusion, the gap-size at the inner-corner of blade affects flow pattern, including the magnitude of τ on both impeller surface and housing surface.
SHEAR STRESS ANALYSIS OF A CENTRIFUGAL BLOOD PUMP WITH DIFFERENT STRAIGHT IMPELLER BLADE PROFILES USING NUMERICAL STUDY

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Department of Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand.

The major concerns of using centrifugal blood pumps, a direct blood contact device, are hemolysis and thrombosis. Their main component is an impeller that rotates to propel the blood to attain normal condition. Importantly, impeller rotation can cause shear stress (τ) that affects blood composition and functions. Impeller blade profiles are one of these contributing factors. Thus, the objective of this study was to analyze the magnitude of τ from different blade profiles. There were three blade patterns used: forward-straight blade (FSB), 90-degree-angle straight blade (90SB) and backward-straight blade (8SB), all of which were straight blade with similar dimension except the angle of blades. By using computational fluid dynamics, inflow-outflow different pressure (DP) was calculated at different speeds (1, 1.4, and 2 krpm) and different flows (0 to 10 L/min). Results, the pressure-flow relationships of all three profiles demonstrated similar curves. At 5 L/min and 1.4 krpm, each design generated DP of 103, 105 and 106 mmHg, respectively. In all three profiles, the average-on impeller surfaces were not significantly different at all speeds (p-value > 0.05). However, the average-τ on the housing surface of 90SB (19.98±2.69, 33.21±1.90 and 55.89±2.54 Pa) were significantly higher (p-value < 0.01) than either FSB (15.94±2.32, 23.60±1.62 and 37.54±3.51 Pa) or 8SB (15.48±1.65, 23.21±2.41 and 35.76±1.58 Pa) at all speeds respectively. In conclusion, pressure-flow relationships and τ on impeller surface are not the only parameter that can be used to determine the quality of centrifugal blood pumps, but the τ on housing surfaces should also be considered.

TREATMENT OF LVAD INDUCED RVF FAILURE IN A HYPOXEMIC MODEL OF PULMONARY HYPERTENSION WITH ULTRAPURE NO

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GeNO, LLC, Cocoa, FL; 
Texas A&M University; 
Northeastern University.

Left ventricular assist devices (LVAD) are used as a bridge to transplant or destination therapy in end-stage heart failure, but is associated with impairment of right ventricular (RV) function, related to RV distension and underlying pulmonary hypertension. Increased RV afterload may lead to RV ischemia, decreased LV filling and pump failure. Inhaled nitric oxide (NO), a potent pulmonary vasodilator, may unload the RV and increase LV filling, LVAD flow and cardiac output (CO). A novel technology for generating inhaled NO based on the reduction of NO by ascorbic acid at inhalation was used to treat swine with combined hypoxia (FiO2 15%) induced pulmonary hypertension and LVAD induced RV failure. This form of NO (Nitrosyl-1000, GeNO, LLC) is ultrapure, devoid of contaminating toxic NOx. Swine (N=4, 40 kg) were cannulated in the ascending aorta and LV apex for Biomedicus (constant flow) LVAD insertion. The LVAD speed and flow which induced RV distension, LV collapse and loss of blood pressure were determined X4 in each swine through sequential increments, with or without inhaled NO (20 PPM). Increasing the LVAD speed linearly increased LVAD flow, but high speeds induce flow instability, LV collapse with RV distension and precipitous fall of LVAD flow and CO. Inhaled NO significantly increased the critical pump speed which evacuated the LV (3650 ± 488 vs 2719 ± 281 mmHg), maximal LVAD flow (2.4 ± 0.3 vs 1.8 ± 0.3 LPM), and maximum CO (3.3 ± 0.6 vs 2.2 ± 0.4 LPM). Inhaled NO resulted in a decrease of pulmonary vascular resistance and RV distension, and an increase in RV ejection. Alleviation of RV failure associated with LVAD use by NO promoted LV filling and LVAD performance.

INVESTIGATION OF HEMODYNAMICS IN THE ASSISTED ISOLATED PORCINE HEART

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Department of Cardiac Surgery, Medical University of Vienna, Vienna, Austria; 
Ludwig Boltzmann Cluster for Cardiovascular Research, Vienna, Austria.

Background: Currently the interaction between rotary blood pumps (RBP) and the heart is investigated in silico, in vitro and in animal models. Whereas in animal models isolated and defined changes of hemodynamic parameters are hardly achievable, in vitro/silico the heart-pump interaction cannot be modeled in its whole complexity. Aim of this work was to develop an isolated heart setup to provide a realistic heart-pump interface with the possibility to adjust hemodynamic parameters easily. Methods: A mock circuit mimicking the systemic circulation was developed. Eight porcine hearts were harvested using a protocol similar to heart transplantation. Then, the hearts were resuscitated using Langendorff perfusion with rewarmed oxygenated blood. A RBP was implanted and the setup was switched to the “working mode” with the left heart and the RBP working as in the physiologic situation. Both the unassisted and assisted hemodynamics were monitored. Results: In the unassisted condition, cardiac output was up to 9.5 L/min and DP/dtmax ranged from 521 to 3621 mmHg/s at a preload of 15 mmHg and afterload of 70 mmHg. With the RBP turned on, hemodynamics similar to heart failure patients was observed in each heart. Mean pump flow and flow pulsatility ranged from 0 to 11 L/min. Conditions with an open as well as a closed aortic valve and also suction events could be reproduced. Conclusions: An isolated heart setup including a RBP was developed which combines the advantages of in silico/vitro methods and animal experiments. Therefore, this tool provides further insight into the interaction between the heart and a RBP.
ROLE OF HEART TRANSPLANTATION IN THE ERA OF MECHANICAL CIRCULATORY SYSTEMS

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Aim: To reduce mortality on the waiting list, clinical outcome of a non randomized population having elective or emergency MCS vs. heart transplant was analyzed.

Methods: January 2007 to January 2013 refractory heart failure was diagnosed in 110 patients. There was no difference neither in terms of age, nor of sex and nor of indication. Patients were subdivided in 6 groups. In G1 and G2 were enrolled 39 and 20 NYHA IV transplanted patients. They had marginal (G1) or optimal donors (G2). In Group 3 and 4 we enrolled 26 and 13 NYHA III candidates. They received suboptimal (G3) or excellent donors (G4). In G 5 were enrolled 8 more NYHA IV “emergency” candidates. In G 6 were included 4 NYHA III candidates. All G5 and G6 patients had MCS Heart Mate II type implanted.

Result: See Table 1.

<table>
<thead>
<tr>
<th>RESULTS</th>
<th>G1</th>
<th>G2</th>
<th>G3</th>
<th>G4</th>
<th>G5</th>
<th>G6</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-day survival (%)</td>
<td>80±3</td>
<td>100</td>
<td>92±3</td>
<td>100</td>
<td>78±3</td>
<td>100</td>
</tr>
<tr>
<td>60 day survival (%)</td>
<td>80±3</td>
<td>100</td>
<td>92±3</td>
<td>100</td>
<td>80±3</td>
<td>90±3</td>
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<tr>
<td>freedom from right ventricular failure (%)</td>
<td>96±2</td>
<td>99±3</td>
<td>82±1</td>
<td>98±1</td>
<td>86±1</td>
<td>93±2</td>
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<tr>
<td>freedom from left ventricular failure (%)</td>
<td>92±2</td>
<td>94±2</td>
<td>89±2</td>
<td>93±2</td>
<td>86±2</td>
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<td>freedom from onset (%)</td>
<td>22±1</td>
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<td>29±1</td>
<td>37±1</td>
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<td>85±2</td>
<td>92±1</td>
<td>95±3</td>
<td>93±2</td>
</tr>
</tbody>
</table>

Conclusions: Results may show that all patients having MCS have a better post operative outcome. They do not suffer from long term side effects of the immunosuppression. Although further randomized studies are needed, in NYHA class III patients MCS implant should be actively considered.

LATE-ONSET RIGHT VENTRICULAR FAILURE EMERGES IN PATIENTS WITH SMALL LEFT VENTRICLE AFTER IMPLANTATION OF CONTINUOUS FLOW LEFT VENTRICULAR ASSIST DEVICE

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Purpose: Continuous flow (CF) left ventricular assist device (LVAD) has replaced pulsatile flow (PF) LVAD because of their advantage in better patients’ survival. However, late-onset right ventricular failure (RVF) after LVAD implantation has emerged as an increasing concern. We analyzed preoperative risk factors for late-onset RVF, and compared the results with those of PF LVAD.

Methods: We retrospectively analyzed hemodynamic and echocardiographic data from consecutive 20 patients who had received CF LVAD at 5 weeks after the surgery, and compared the results with those of 14 patients who had received extracorporeal PF LVAD. Results: Univariable analyses demonstrated that preoperative smaller LV diameter was the only preoperative independent risk factor for late-onset RVF, which was defined as persistent right ventricular systolic work index (RVSWI) >4.0 g/m2 at any rotation speed and after saline infusion test. A cutoff value for late-onset RVF was 67 mm of LV diastolic diameter (LVDD), which was determined by ROC analysis (AUC, 0.944). In contrast, there was no correlation between preoperative LVDD and postoperative RVSWI in PF LVAD group.

Conclusion: In the setting of small LV cavity, continuous sucking of septum may cause late-onset RVF.

THE PRIMARY CAREGIVER MODEL: A NOVEL APPROACH TO THE CARE OF PATIENTS ON EXTRACORPOREAL LIFE SUPPORT

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Extracorporeal Life Support (ECLS) is an infrequently used but important treatment for patients with severe cardiopulmonary failure. Staffing of trained personnel can limit use as need can be unpredictable. Traditional staffing models (TSM) require a trained ECLS specialist at bedside in addition to a RN. The primary caregiver model (PCGM) uses critical care RNs as primary caregiver and safely improves staffing and ECLS availability.

Methods: We performed a retrospective review of 317 adult patients at our institution on ECLS between January 2000 and December 2011. These were divided into two groups: PCGM, instituted in January 2010, and TSM. ECLS volume, transfer requests, circuit and patient complications, and survival were analyzed.

Results: 275 patients (86.8%) were managed using TSM and 42 (13.2%) using PCGM. Mean age with TSM was 43.4±10.9 yrs vs. 48.2±2.1 with PCGM (p=0.045). Mean time on ECLS was 141±49.3 hrs with TSM, vs. 228±55±5.8 hrs with PCGM (p=0.132). ECLS volume was highly variable. Transfer refusals due to staffing steadily increased from 2000 to a peak of 23 in 2009. There were 2 refusals in 2010 after PCGM was instituted, and none in 2011. 23 complications in 5 categories (hemorrhagic, mechanical, neurologic, pulmonary, renal) were compared between groups. None were statistically significant. There was no difference in survival to discharge (TSM 48.7%; PCGM 42.9%, p=0.478).

Conclusions: The PCGM is a safe method for staffing ECLS patients. While TSM may result in refusal of care due to inadequate staffing, PCGM expands ECLS capability with limited human resources and can handle large, rapid fluctuations in ECLS volume without compromising safety.
STROKE IS A MAJOR ADVERSE EVENT DURING CENTRIMAG SUPPORT
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The use of short-term VADs for acute heart failure is on the rise; we investigated the significance of stroke in our large experience with CentriMag (CM, Thoratec, Pleasanton, CA).

From 2007 to 2012 we retrospectively reviewed 107 patients, mean age 51 ± 17. P<0.05 was considered significant. Backwards stepwise multivariable logistic regression used p<0.10.

Device indications included failure of medical management (n=64), postcardiotomy shock (n=28), and graft failure post heart transplant (n=15) using configurations BiVAD (n=95) and LVAD (n=12). Stroke occurred in 20 (18.7%) of the patients, BiVAD (18.9%) and LVAD (16.7%). Median support duration was 14 days (range 1-145) with strokes occurring between days 1 to 34. (Figure 1)

Univariate predictors of stroke were preoperative acute myocardial infarction (AMI) (p<0.001), history of coronary artery disease (CAD) (p=0.004), history of hypertension (p=0.01), remote myocardial infarction (p=0.02), history of chronic kidney disease (p=0.06), and older age (p=0.09) and BMI (p=0.099). On multivariable analysis independent predictors of stroke included AMI (OR 3.7, CI 1.1-11.6, p=0.02) and CAD (OR 3.3, 0.80-13.4, p=0.09). LVAD inflow or outflow cannulation technique had no association.

Stroke was associated with decreased survival to discharge (35.0% vs 57.5%, p=0.07). Stroke is a major adverse event during support with CM and is associated with decreased survival.

THE ROLE OF MECHANICAL CIRCULATORY SUPPORT IN ACUTE MYOCARDIAL INFARCTION COMPLICATED BY CARDIOGENIC SHOCK: IMPLICATIONS OF IMPROVED IN-HOSPITAL MORTALITY
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Objectives: The mortality of patients with acute myocardial infarction (AMI) complicated by cardiogenic shock (CS) remains high. We sought to evaluate the effects of mechanical circulatory support (MCS) on in-hospital mortality in patients with AMI complicated by CS.

Methods: This is a retrospective review of adult patients who required MCS for AMI complicated by CS. Those patients who had undergone right heart catheterization (RHC) prior to MCS were included in the study. Baseline cardiac power output (CPO) was calculated as [mean arterial pressure (MAP; mmHg)]*[cardiac output (CO; L/min)]/451. The outcome of interest was in-hospital mortality.

Results: From 2007 – 2012, 49 patients were placed on short-term MCS for AMI complicated by CS at our institution. Among them, 27 patients underwent RHC within 24 hours prior to MCS. MAP was 59 ± 23 mmHg, mean CO was 2.7 ± 2.4 L/min and mean CPO was 0.44 ± 0.40 W. Overall in-hospital mortality was 41%. When the relationship between mortality and CPO was examined, the probability of mortality, especially at lower CPOs, appeared favorable.

Conclusions: MCS, particularly at low CPOs, was associated with better than historical survival of patients with AMI complicated by CS. These findings warrant rigorous clinical investigation of MCS in AMI complicated by CS. (Figure 1)
SAFETY AND FEASIBILITY OF THE COMBINED USE OF VENOARTERIAL EXTRACORPOREAL MEMBRANE OXYGENATION AND A PERCUTANEOUS LEFT VENTRICULAR ASSIST DEVICE WITH MICRO-AXIAL PUMP

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Purpose: Venoarterial extracorporeal membrane oxygenation (VAECMO) is gaining popularity as a treatment modality for refractory cardiogenic shock (RCS). LV distension may complicate the use of VAECMO. We review our experience with percutaneous micro-axial left ventricular assist device (pLVAD) use in combination with VAECMO for RCS.

Methods: This is a retrospective review of all patients who received combined support of VAECMO and pLVAD.

Results: Among 113 patients who received VAECMO for RCS, combined support was successful in 10 patients (age 60.3±16.8 years). Seven of the patients had RCS following acute myocardial infarction (AMI) while other etiologies included acute decompensated heart failure (1), postcardiotomy shock (1), and graft dysfunction (1). Three patients were undergoing active CPR at the time of VAECMO placement. Overall 3 of 9 patients (33%) survived to discharge (one remained hospitalized). Efficacy of LV decompression was addressed in 3 patients who received VAECMO followed by pLVAD. Clinical indications to add pLVAD included poor oxygenation due to pulmonary edema (2) and refractory ventricular fibrillation (1).

Conclusion: Use of VAECMO and pLVAD can optimize hemodynamics in RCS by unloading the LV and improve cardiogenic pulmonary edema in the setting of LV distension. (Figure 1)

<table>
<thead>
<tr>
<th>Patient</th>
<th>Indication for pLVAD</th>
<th>Time to pLVAD (hr)</th>
<th>Heart Rate (BPM)</th>
<th>Respiratory Rate</th>
<th>CKB (Pulmonary Edema)</th>
<th>MB</th>
<th>Pre- and Post-pLVAD</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Worsening Pulmonary Edema</td>
<td>21.2</td>
<td>109</td>
<td>71</td>
<td>12</td>
<td>12</td>
<td>Improved</td>
</tr>
<tr>
<td>B</td>
<td>Worsening Pulmonary Edema</td>
<td>32.4</td>
<td>137</td>
<td>70</td>
<td>16</td>
<td>13</td>
<td>Improved</td>
</tr>
<tr>
<td>C</td>
<td>Refractory Ventricular Fibrillation</td>
<td>2.4</td>
<td>83</td>
<td>86</td>
<td>23</td>
<td>18</td>
<td>Improved</td>
</tr>
</tbody>
</table>

PATHOLOGY OF VENTRICULAR ASSIST DEVICES

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Background: Cardiovascular disease has consistently been a leading cause of death in industrialized countries. While heart transplantation is the preferred treatment for refractive heart failure, the lack of donor hearts available has given rise to Ventricular Assist Devices (VADs) for possible treatment options (Bridge-to-Decision, Bridge-to-Transplant, Bridge-to-Recovery, Destination Therapy). In order for VADs to become commercially available in the US, they must be approved by the FDA. Currently, pathology evaluation of VADs is not a specific requirement for submission to the FDA. Methods: We have developed a thorough technique for VAD evaluations, and performed this on over 700 VADs. External surfaces are first evaluated and then the VAD is disassembled to examine internal surfaces. Unexpected material within the device is collected and undergoes gross and light microscopic analysis (X-Ray/CT or electron microscopic evaluation if necessary). Each abnormality is given a nonparametric value based on size/location/extent using a predetermined scoring metric. Analysis: A statistical analysis is performed on the nonparametric values to determine the significance and correlations of deposits/abnormalities. Results: Post/peri-explant blood was often throughout VADs and the occurrence was treated as noise in the data. Antemortem fibrin blood thrombi were often seen in pumps that also had abrasions due to contact involving rotating surfaces. Conclusions: Pathology evaluation of VADs yields important information about VADs themselves; however, further bench top testing is necessary to elucidate how fibrin thrombi interact with VADs, and any correlations between fibrin thrombi and occurrence of power spikes and/or pump failure.
LEFT VENTRICULAR ASSIST DEVICE IMPLANTATION OR HEART TRANSPLANTATION IN ISCHEMIC HEART FAILURE AFTER PREVIOUS CORONARY ARTERY BYPASS GRAFT AND MITRAL VALVE SURGERY IS STILL A CHALLENGE


Objectives: Left ventricular assist device (LVAD) and heart transplantation (HTX) are end-stage therapies in patients following mitral valve surgery (MVS) and coronary artery bypass grafting (CABG). However, the outcome of this scenario is completely unknown.

Methods: We identified 8 highly risk patients at a mean age of 61.9±5.6 years and a mean EF of 20.6±4.3% with impaired left ventricular (LV) function after MVS and CABG. Patients treated by LVAD had an intermascular level 1 or 2, and the procedure was performed urgently, whereas the others were listed as high urgent for HTX. Clinical data and outcome were retrospectively gathered with a mean time span of 3.3 years (range 0.03-10.1 years).

Results: Five patients received a LVAD (3 HM I, 1 Incor, and 1 HM II) at a mean postoperative time of 50.6 days (range 6-184 days). For one of the HM I patients the device was a bridge to transplant therapy. All others were final destination therapy. 3 Patients received a HTX at a mean postoperative time of 4.5 years. 30 day mortality of all LVAD patients was 20%. Mortality at 60, 90 and 365 days was 40%, 80% and 80% respectively. The patient who survived received his HTX 146 days post LVAD surgery and is still alive. After HTX no patient died within the first 30 days. The long term mortality at 180 days, 1 and 5 years was 0%, 33.3% and 33.3% respectively.

Conclusion: VAD and HTX are the last options in patients with impaired LV function after CABG and MV surgery. However patients who needed an LVAD had a poor outcome but heart transplantation may offer the best alternative to these sick patients.

IMPROVING PATIENT SELECTION IN LVAD CANDIDACY: ENHANCING TEAM DECISION-MAKING, PATIENT EDUCATION, AND INFORMED CONSENT

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Background: Cognitive impairment is present in up to 58% of patients with end-stage heart failure and may be a contraindication for left ventricular assist device (LVAD). However, there are currently no guidelines for standard evaluation to inform patient selection. The purpose of this study was to evaluate VAD Family Teaching, a new formal protocol, used to assess ability to learn the device while providing device specific education in order to improve patient candidacy for LVAD implant.

Method: A hands-on simulation protocol was developed to target questionable candidates given identified cognitive risk. From May 2012 to December 2012, eight patients completed this new protocol; recruitment is ongoing. Nine patients previously implanted with cognitive impairment are used as a comparison group for multiple clinical outcomes including post-implant LOS, readmissions, infections, and emergent contacts.

Results: Five patients (62.5%) with questionable candidacy were identified as appropriate candidates for LVAD. Two patients (25%) were ultimately deemed inappropriate based on protocol performance (e.g., made fatal errors). One patient declined implant based on demands of the device. Comparative analyses are ongoing to evaluate outcomes for patients participating in the protocol versus patients previously implanted.

Conclusions: Preliminary implementation of our protocol has enabled the identification of appropriate candidates, despite cognitive risk factors. Without VAD Family Teaching, patients may have otherwise been identified as too high-risk for LVAD implant. This protocol also enhances the process of informed consent for patients and their supports.

MECHANICAL CIRCULATORY SUPPORT: EMERGENCY PROCEDURES AND EDUCATION OF COMMUNITY SERVICES

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Introduction: In Germany approximately 700 pts. with ventricular assist devices are living at home. Life-threatening complications are rare with modern devices, but it is important that medical and paramedical personnel correctly assess emergency situations and react to them optimally.

Methods and Results: We developed an educational program for fire brigade paramedics, medical personnel and police, including airport based units. Additionally, a special checklist for emergency situations and specific cards were developed and introduced into routine. For 1 year we have provided a 24h emergency hotline to answer all questions concerning VADs from paramedics, physicians, other hospitals, family doctors, patients and relatives (Fig.1) with a mean of 20 tel. calls per month. Fig. 2 shows the main reasons for calling the hotline.

![Graph showing who called the VAD hotline](image1)

**Figure 1:** Who called the VAD hotline?

![Graph showing reasons for calling the VAD hotline](image2)

**Figure 2:** Reasons for calling the VAD hotline.

Conclusion: A special education program for the community and a VAD hotline should be established by every hospital running an MCS program.

ASAIO CARDIAC ABSTRACTS
TROIODAL CONVOLUTION BLOOD PUMP FOR ECLS SYSTEM
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A new blood pump for extracorporeal life support systems (ECLS) named Troidal Convolution Pump (TCP) that has proper hydraulic performance against the high pressure loss in the case of Percutaneous Cardio-Pulmonary Support (PCPS) application was developed. The pump principle is similar to the cascade pump. The blood is given static pressure by the multiple centrifugal forces during spiral turning in the pump room. The inlet of the blood pump is located on the side wall of the pump housing. There are two semicircular blood pump rooms to keep equilibrium in the axis symmetry. There are two pump outlets located at the top surface of the pump in the axial direction to diffuse the blood to the oxygenator. The impeller is suspended by a monopivot bearing for long-term use and driven by magnet coupling using permanent magnets. The impeller consisted of 20 vanes, and its diameter was 66 mm. TCP in the mock circulatory system perfused 5 L/min against 350-mmHg pressure head at 2450-rpm motor rotation. One of the advantages of TCP is that it operates in relatively low rotation in the same impeller diameter as a centrifugal pump. That means low shear stress for the blood and eliminating wear of monopivot.

EFFECTS OF OPTIMAL MEDICAL MANAGEMENT AND LOWERING LVAD SPEED ON AORTIC VALVE FUNCTION
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Aortic insufficiency (AI) in patients with LVAD-support is well known phenomenon that can lead to an ineffective LVAD output. The aim of our study was to examine AI development under optimal medical therapy (MT) and simultaneously lowering LVAD support. Methods: Echocardiograms of 12 LVAD patients (pts) were reviewed for demographics and medications. Medications were uptitrated to MAP of 80mmHg. LVAD speed (RPM) was reduced in 6 pts at 6, 12 and 18 months (mo) according to our outpatient protocol including LVEDD, LV-EF, aortic root diameter (ARD), AV opening. AI was graded: none, mild, moderate, severe. Results: At baseline mean LVEDD was 67±7.3, mean LV-EF (21±9.6), AV opened regularly (4/12 (33%) pts), partially opened (1/12 (8%)pts), didn’t open (7/12(67%)pts), mild AI was in 9/12 (75%)pts, no AI had 3 pts, mean ARD was 31±0.3. At 6 mo AV opened regularly (6 pts), AI was mild, LV-EF (34±10.1), mean ARD and LVEDD didn’t change. At baseline RPM was 6825/min, at 6mo reduced to 6100/min. After RPM reduction AV opened regularly. 2 mo later LVEDD was (70±8.7), LV-EF decreased, AI was moderate, mean ARD dilated (35±0.4). AV partially opened (1pt), regularly (5 pts). RPM-Elevation to 6800/min. After LV-EF and LVEDD recover RPM was reduced at 12 and 18 mo. 5 pts tolerated reduced RPM for only 2 mo, 1 pt didn’t tolerate because of infection. At 12 and 18mo LVEDD reduced to 63±8, LV-EF was 42±2.4, mean ARD was 32±0.5, AI remains mild, AV opened regularly in 5 pts, partially in 1pt. Conclusion: Our results suggest slower progression in AI grade at optimal MT and regular AV opening. Decreased RPM was tolerated for only 2mo, fractional reduction of RPM has to be investigated in further studies.

MEDIA COVERAGE OF REVISED ACT ON ORGAN TRANSPLANTATION IN JAPAN
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Background: In Japan, Act on Organ Transplantation was revised in 2009 and enforced in 2010 to achieve self-sufficiency in organ donation. It had a certain impact on clinical situations. However, it is unknown how the public pay attention to the revision. Meanwhile the media plays an important role in dissemination of such medical information among the public. Therefore the objective of this study is to assess the impact of the revision through media coverage.

Materials and methods: We investigated serial changes in the number of newspaper articles and web pages via a Japanese newspaper database and Google search, respectively. The key words included “heart transplantation” or “artificial heart”. The study period was from January 1, 2007 to December 31, 2011.

Results: The total number of the newspaper articles and the web pages were 2134 and 347366, respectively. The monthly number of the newspaper articles jumped up from around 40 before the revision to 70 just after it, while it returned straightforward to the previous level. The contents of the newspaper articles in peak months also changed: “transplant tourism” was the major content before the revision, while topics regarding the act become major after it. After the monthly number of the web pages increased from approximately 2000 to 6000 gradually until July 2010, it increased sharply to over 12000.

Discussion: The numbers of newspaper articles and web pages increased corresponding to specific events. The former responded temporally to the events as compared to the latter increasing continuously. These differences were attributed to the features of media, yet revealed was the revision attracted the public interest in both newspapers and internet.
ENHANCEMENT OF THE MYOCARDIAL PERFUSION BY A NOVEL CARDIAC CYCLE-SYNCHRONIZED ROTATION CONTROL MODE IN A CONTINUOUS-FLOW LVAD IN CHRONIC ISCHEMIC HEART FAILURE MODEL

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Objectives: We have previously developed a novel pump control system in a continuous-flow LVAD, and demonstrated that we can change the heart load, cardiac oxygen consumption and coronary flow by changing its rotational speed (RS) in synchronization with the cardiac cycle. In this study, we assessed the coronary flow and myocardial perfusion in chronic ischemic heart failure (CHF) models.

Materials Methods: CHF was introduced in 6 adult goats (57.5 ± 5.1 kg) by coronary microsphere embolization (50 m, 0.258 ± 0.023 million) to the left anterior descending artery and subsequent rapid ventricular pacing for 4 to 6 weeks. Then, the EVAHEART was implanted via left thoracotomy and effects of different 2 modes, Continuous (constant RS) and Counterpulse mode (increase RS in diastole), were examined. We injected colored microsphere in each drive mode at full bypass condition in order to evaluate the segmental myocardial perfusion.

Results: The coronary flow in the Counterpulse mode was higher than that in the Continuous mode (150.5 ± 61.5 vs 123.8 ± 64.3 ml/min). We also found the distribution of coronary perfusion was different between two modes. In the Counter-pulse mode, the ratio of endocardial myocardial perfusion was slightly enhanced as compared with that in the Continuous mode, especially in the non-ischemic region (55.4 ± 0.3 vs 52.1 ± 0.2%).

Conclusions: The counterpulse mode of continuous-flow LVADs enhanced the coronary perfusion and changed the myocardial perfusion. This novel drive mode may provide a favorable blood supply to the myocardium and offer the possibility to promote cardiac recovery.

THREE CASES OF SUB-ACUTE STENT THROMBOSIS AFTER DIFFERENT TYPES OF DRUG-ELUTING STENTS IMPLANT TO ANGIA PECTORIS

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In the era of the drug-eluting stent, sub-acute thrombosis has been a very serious issue in the percutaneous coronary intervention (PCI). 2 cases of angina pectoris (AP): one biolimus-A9-eluting stent (BES) was implanted for the mid-stenotic left anterior descending artery (LAD), and the other zotarolimus-eluting stent (ZES) was implanted for the proximal-stenotic LAD. After PCI, anemia, hives and liver dysfunction occurred as the side effects due to clopidogrel. We changed anti-platelet medicine, clopidogrel, to cilostazol. After that, the side effects disappeared. In additional PCI, the one BES was deployed for the mid-stenotic lesion in the left circumflex artery (LCX). Within 30 days after PCI, they complained of a chest pain and we diagnosed it as an acute myocardial infarction (AMI). Emergent CAG revealed total thrombotic occlusion in-stent sites: in BES of both LAD and LCX, and ZES of LAD. They underwent intracoronary aspiration thrombectomy and additional stents were implanted the thrombotic lesions of both LAD. Aspiration only was performed for the thrombotic lesion in LCX. 1 case of AP, sirolimus-eluting stent (SES) was implanted for the distal-stenotic LCX. 17 days after PCI, he was admitted to our hospital because of AMI. Emergent CAG revealed a thrombotic occlusive lesion in the stent site of LCX. Intravascular ultrasound findings of stent thrombosis before PCI are related to an incomplete stent apposition and positive vessel remodeling. Then we deployed a bare-metal stent in the thrombotic occlusion stent after balloon angioplasty. We reported these three cases of sub-acute stent thrombosis after three different types of drug eluting stents.

HYDROGEN GAS SUPPRESSES SYSTEMIC INFLAMMATORY RESPONSE DURING CARDIOPULMONARY BYPASS IN A RAT MODEL

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Backgrounds: Systemic inflammatory responses in patients receiving cardiac surgery with the use of the cardiopulmonary bypass (CPB) significantly contribute to CPB-associated morbidity and mortality. In recent study suggested cytoprotection effect of hydrogen gas (H2). We hypothesized that insufflated H2 would provide systemic anti-inflammatory and anti-apoptotic effects during CPB, therefore reducing proinflammatory cytokine levels. In this study, we examined the protective effect of H2 on a rat cardiopulmonary bypass model.

Methods: Rats were divided into three groups: The SHAM group, received surgical preparation only; a CPB group, CPB was initiated and maintained for 60 min; and a CPB + H2 group in which H2 was given into an oxygenator during CPB for 60 min. We collected blood samples before, 20 and 60 min after the initiation of CPB. We measured the serum cytokine levels of (TNF-α, IL-6, IL-10) and biochemical markers (LDH, AST, ALT). We also measured the wet-to-dry weight (W/D) ratio of the left lung after 60 min after the initiation of CPB.

Results: In the CPB group, the cytokine and biochemical marker levels significantly increased 20 min after the CPB initiation and further increased 60 min after the CPB initiation as compared with the SHAM group. In the CPB + H2 group, however, such increases were significantly suppressed at 60 min after the CPB initiation. Although the W/D ratio in the CPB group significantly increased as compared with that in the SHAM group, such an increase was also suppressed significantly in the CPB+ H2 group.

Conclusions: We suggest that H2 insufflation is a possible new potential therapy for counteracting CPB induced systemic inflammation.
VALIDATION OF A NOVEL ASSAY FOR PREDICTING NON-SURGICAL BLEEDING RISK IN VENTRICULAR ASSIST DEVICE RECIPIENTS

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Objective: All continuous flow left ventricular assist device (CF-LVAD) recipients develop an Acquired von Willebrand Syndrome (AVWS) associated with gastrointestinal (GI) bleeding and epistaxis. Our objective was to validate a novel assay’s (ALPEIVA) ability to discriminate between patients with and without non-surgical bleeding events post CF-LVAD implantation.

Methods: A total of 29 patients implanted with CF-LVADs (2010-2012) had pre and post implant evaluation for: high molecular weight multimer analysis (HMWM), von Willebrand factor antigen (vWF:Ag), Factor VIII, and ALPEIVA. Results were compared between patients with GI/epistaxis bleeding events and those without.

Results: 9 (31%) of the 29 patients had GI or epistaxis bleeding post-implant. All 29 patients demonstrated HMWM loss consistent with AVWS. ALPEIVA and vWF:Ag levels were significantly higher in subjects who experienced GI bleeding or epistaxis (Table 1).

Table 1: Comparison of CF-LVAD recipients with and without bleeding complications

<table>
<thead>
<tr>
<th>Summary Statistic</th>
<th>No bleeding (n=20)</th>
<th>Bleeding (n=9)</th>
<th>Mean ± SD</th>
<th>Mean ± SD</th>
<th>p-value</th>
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</thead>
<tbody>
<tr>
<td>Gender - Male (%)</td>
<td>17 (85%)</td>
<td>7 (70%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DT / BTT</td>
<td>11 / 9</td>
<td>5 / 4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age [years]</td>
<td>57.00 ± 11.69</td>
<td>59.56 ± 11.73</td>
<td>0.59</td>
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<tr>
<td>Implant duration at lab draw [months]</td>
<td>5.97 ± 2.08</td>
<td>7.10 ± 3.22</td>
<td>0.35</td>
<td></td>
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</tr>
<tr>
<td>INR</td>
<td>1.62 ± 0.33</td>
<td>1.81 ± 0.58</td>
<td>0.39</td>
<td></td>
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</tr>
<tr>
<td>Factor VIII [%]</td>
<td>173.95 ± 53.43</td>
<td>186.78 ± 46.97</td>
<td>0.53</td>
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</tr>
<tr>
<td>vWF:Ag [IU/dl]</td>
<td>171.45 ± 64.62</td>
<td>260.11 ± 64.96</td>
<td>0.00020</td>
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<td>ALPEIVA [U/l]</td>
<td>117.15 ± 33.55</td>
<td>179.44 ± 64.40</td>
<td>0.00010</td>
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Conclusions: The ALPEIVA assay is significantly higher in CF-LVAD recipients who experience GI bleeding and epistaxis events post-implant. This commercially available automated assay provides the first analysis capable of discriminating between CF-LVAD recipients with and without bleeding complications, in order to individualize anticoagulation management and reduce bleeding complications for these patients.

A SMALL, THIN, NOVEL, MAGLEV VENTRICULAR ASSIST DEVICE FOR MILD HEART DISEASE PATIENTS

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A small, thin, novel, maglev ventricular assist device (VAD), which can be implanted under the thorax muscle layer, has been developed for mild heart disease patients. The regenerative pump, which has the inlet and outlet ports in the same plane, and a radial type self-bearing motor are adopted to reduce the axial thickness of the device. Rotation coils to produce 3-phase 8-pole magnetic field and levitation coils to produce 2-phase 6-pole magnetic field are wound separately in the stator. The plus minus two-pole algorithm is adopted to levitate and rotate the impeller. Two radial degrees of freedom of the impeller and rotation of the rotor are controlled actively with electric magnets constructed on the stator. Axial position and tilt motion of the impeller are stabilized passively with self-restoring characteristics of the magnets to simplify the control system. The outer diameter and the axial thickness of the maglev VAD are 59 mm and 22 mm, respectively. The maglev VAD is successfully levitated and rotated up to a rotational speed of 2,600 rpm under the pumping operation. The maximum head pressure and the maximum flow rate are 260 mmHg and 6 l/min, respectively. The targeted pump performance, which is a head pressure of 100 mmHg and a flow rate of 2 l/min, of the maglev VAD is achieved with a rotating speed of 2,000 rpm and a power consumption of 4.5 W. The maximum radial oscillating amplitude of the impeller is 17 mm with a rotating speed of 2,000 rpm. The proposed maglev VAD has excellent levitation performance and sufficient pump performance as a ventricular assist device.
THE GROWING PROCESS OF STABLE NEOINTIMAL TISSUE AROUND TITANIUM-MESH COVERED LVAD INFLOW CANNULA
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Stable neointimal tissue around the inflow cannula could prevent wedge thrombus formation among the patient supported by LVAD. We evaluated the growing process and stability of neointimal tissue around titanium-mesh covered LVAD inflow cannula.

Titanium pins covered with or without titanium-mesh were developed to mimic the inflow cannula of LVAD (length: 20mm, width: 3mm, wire diameter: 85 μm, volumetric porosity: 40-70%). Both pins were covered with MPC to prevent acute massive thrombus formation. Pins were inserted into the apex of Japan-white rabbit. Rabbits were bled for 1 week, 2 weeks, 1 month, 3 months, 6 months and 1 year, respectively. After sacrificed, the neointimal tissue was evaluated in MMA resin specimen.

28 rabbits were used in this study (mesh 15, smooth 13). After 1 week from implantation, both pins were covered with thrombus, but mesh-covered pin clearly prevented the massive thrombus formation. After 2 weeks until 1 month, granulation tissue was growing around the mesh-covered pin and then they were contracted to fibrotic tissue from after 3 months to 1 year. Myofibroblasts were infiltrated into granulation tissue and they were differentiated to the smooth muscle cells. The surface of neointimal tissue was covered with aligned endothelial cells and platelet adhesion was prohibited on the mesh-covered pin. Neocapillaries were observed and increased in the fibrotic tissue around the mesh-covered pin but not around the smooth-surface pin.

Titanium mesh induced stable neointimal tissue even at acute phase to chronic phase compared to smooth surface titanium. This surface modification could prevent the wedge thrombus formation in the patients supported by LVAD.

IMPACT OF PRE-OPERATIVE ACE INHIBITOR EXPOSURE ON THE INCIDENCE OF POSTOPERATIVE REFRACTORY VASOPLEGIA IN PATIENTS UNDERGOING LEFT-VENTRICULAR ASSIST DEVICE IMPLANTATION
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Purpose: The purpose of this study was to determine the effect of pre-operative ACE inhibitor exposure on vasopressor requirements in patients undergoing continuous flow left ventricular assist device (CF-LVAD) placement.

Methods: In this retrospective study, patients implanted with a CF-LVAD between January 1, 2010 and December 31, 2011 who were exposed to ACE inhibitors within 72 hours before surgery (CASE) were matched 1:1 based on age, gender, and INTERMACS classification to patients not exposed to ACEI (CONTROL). The primary outcome was the number of vasopressor medications needed for support during separation from cardiopulmonary bypass. Secondary outcomes were the time to resolution of vasopressor dependent shock, ICU length of stay, incidence of acute kidney injury, and in-hospital mortality.

Results: Of 52 patients screened, 5 CASE patients were identified (mean age 54.4, 100% male, median INTERMACS score 3) and matched to 5 CONTROL patients. CASE patients required significantly more vasopressor agents for hemodynamic support than CONTROL patients (mean 3.8 ± 0.8 versus 1.8 ± 0.4, respectively; p=0.0015). There was a trend toward longer time to resolution of vasopressor dependent shock in CASE than CONTROL patients (median 43 ± 71 hrs vs. 15 ± 2.6 hrs, respectively; p=0.17), and ICU length of stay (mean 11 ± 5.6 days vs. 5.6 ± 2.7 days, respectively; p=0.08). One CASE patient experienced an acute kidney injury; all patients survived to hospital discharge.

Conclusion: Pre-operative ACE inhibitor exposure was associated with higher vasopressor requirements in the immediate postoperative period.
FULL-SIZE TRIDIMENSIONAL SIMULATOR OF THE HUMAN CHEST FOR CONTINUOUS-FLOW TOTAL HEART REPLACEMENT DEVICE STUDY

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Introduction: Severe biventricular systolic dysfunction is more common than isolated severe LV dysfunction in the main Advanced HF Units of Brazil. This issue is due to Chagas Disease and other dilated cardiomyopathy etiologies, frequently referred in end stages. As the prognosis for primary BIVAD support is inferior to cardiac replacement with TAH, it’s justifiable to consider TAH for our advanced HF biventricular patients. Materials and methods: We developed a full-size tridimensional simulator of the human chest based on the dataset of ECG-gated multi-detector row computed tomography (MDCT) scan previously acquired with a 64-detector row CT (Toshiba, Aquilion; slice thickness 64 x 0.5 mm). Images were reconstructed in axial, sagittal and coronal reformation planes in purpose to limit the model of a 58-year old female in the inferior, superior, anterior, posterior and lateral extremities. Reconstruction of the aorta, pulmonary artery, left and right atria remnants and diaphragm was obtained by multiaplanar oblique reformation and three dimensional volume rendering reconstructions printed in the same fashion (1:1 ratio to patient dimensions), now in a 3-D printer. Results: This model avoids the use of human cadavers; allows surgeons to plan grafts, atria adapters, inflow and outflow cannulla and pumps positions for each patient; separates the atria to facilitate anatomic placement of axial pumps; allows combinations to mock-loop circuits to study fluid dynamics of CF TAH assays. Conclusions: Cardiac computer angiotomography images were useful to develop a full-size tridimensional simulator of the human chest applicable for CF TAH replacement device study.

WIRELESS POWER TRANSMISSION FOR VENTRICULAR ASSIST DEVICES

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Background: Previously, a transcannular energy transmission system (TETS) was developed for a pulsatile total artificial heart and left ventricular assist device (LVAD). The TETS was successfully implanted in over 100 animals, and accumulated 24.9 patient-years in clinical trials in 36 LVAD patients. The TETS demonstrated excellent patient acceptance, reliability, and absence of adverse tissue reactions. Here we present recent work for adapting this technology for use with rotary VADs. Methods: Circuit analysis and finite element analysis were used to design smaller coils while maintaining tolerance to coil misalignment. Due to the reduced power consumption of rotary devices, the TETS was redesigned from a peak power of 80W to 17W. Results: The diameter of the subcutaneous coil was reduced from 70 mm to 56 mm; thickness was reduced from 19 mm to 6 mm. The operating frequency was increased from 200 kHz to 550 kHz to allow smaller coils and more variance in the coil displacement. The updated system demonstrated maximum continuous power capability of 17W into a resistive load. Performance was verified using a HeartMate II® pump operating at 5L/min and 100 mmHg. Measured DC-DC efficiency was 80% at 10 mm coil separation and 76% at 20 mm. Voltage regulation was maintained at 15.2 +/- 0.35 V over the full range of coil displacements and loads. Conclusion: TETS technology previously developed for pulsatile systems was successfully adapted to the reduced power consumption of rotary pumps. In addition, coil size was reduced, and tolerance to misalignment was improved.

OUTCOMES FOLLOWING HEARTMATE II LEFT VENTRICULAR ASSIST DEVICE IMPLANTATION IN PEDIATRIC PATIENTS

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Objective: The Heartmate II (HM II) axial-flow ventricular assist device is an established therapy for the treatment of adults with heart failure. However, its use in pediatric patients is limited. We report our outcomes following implantation of the HM II in 9 children, including the youngest reported to date. This is the largest reported pediatric series to date. Methods: Since 2010, the HM II has been implanted in 9 pts < 18 years of age. Diagnoses included dilated cardiomyopathy in 8 pts and end-stage heart failure following aortic stenosis palliation in 1 pt. Indications for implantation were bridge to transplant in 4 pts, destination therapy in 3 pts, and bridge to decision in 2 pts. Mean body weight was 63.3 kg (34.5-141 kg) and mean age was 14.8 (9-18 years, median 15). Two pts were on extracorporeal membrane oxygenation at the time of implant. Results: One pt died on postoperative day 138 due to device thrombosis. Three pts required postoperative exploration for mediastinal bleeding. One pt required device replacement for pump thrombosis 3 months after implantation. One pt had gastrointestinal bleeding which had resolved by medical treatment. Three pts were successfully bridged to transplantation (42, 109 and 174 days after implant). Four of the remaining 5 pts are currently outpatients (36-703 days, average 266) with no significant functional limitations. One pt remains hospitalized for early post operative recovery. Conclusion: The HM II can be safely implanted in pediatric patients as a bridge to transplant or as outpatient destination therapy in patients as young as 9 years old. Postoperative bleeding and device thrombus remain a major source of morbidity.
THE EFFECTS OF CONTINUOUS AND INTERMITTENT REDUCED SPEED MODES ON GASTROINTESTINAL PERFUSION IN AN OVINE MODEL

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Gastrointestinal (GI) bleeding complications after continuous flow left ventricular assist device (CFLVAD) implantations were reported in 20-30% of patients. The purpose of this study is to assess the effects of the continuous and intermittent reduced speed modes on GI perfusion of a healthy ovine model implanted with a CFLVAD. Four sheep (56±4 kg) were implanted with HeartWare HVAD Pump® in the LV apex to descending aortic position. Renal and upper/lower GI perfusions were measured using C62 PET/CT and microsphere techniques under the following conditions: baseline (pump-off), low (2300±500 RPM) and high (3500±500 RPM) speeds at both continuous and intermittent reduced speed modes. Intermittent reduced speed was implemented using an algorithm that temporarily decreases pump rotational speed. Aortic, right atrial and LV pressures, CFLVAD flows, and arterial and portal vein blood gas samples were recorded at baseline and at each speed. GI and renal perfusions measured via microsphere technique increased 30-50% at all speeds compared to baseline. PET/CT measurements followed the same trend. The portal vein/aortic oxygen pressure ratio increased in all speeds. There was no significant difference between continuous and intermittent reduced speed modes in terms of perfusion and venous oxygen pressure. Our results showed immediate increase in renal and GI perfusion at all speeds. The immediate increase in portal vein oxygen pressures may suggest opening of GI arteriovenous shunts in response to mechanical stimuli developed by continuous and intermittent reduced speed modes.

SUCCESSFUL TREATMENT OF AORTIC CANNULA DETACHMENT WITH TOTAL ARTIFICIAL HEART

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44 years old male, on April 2011, underwent Berlin Heart Excor LVAD implantation with the diagnosis of non-ischemic cardiomyopathy. He has a history of pump thrombosis on September 2012, due to depletion of battery charge resulting transient ischemic attack and femoral artery embolism. Pump head exchange and femoral embolectomy was performed. On December 2012, patient suffered of leakage around apical cannula exit site. Computed tomography showed blood leakage from the aortic cannula anastomosis. An emergency call for organ donation was made for the patient. Mediastinal hematoma was progressed and a pulsatile pouch which is appeared in lower sternum. Echocardiography showed mediastinal hematoma related with aortic anastomosis. Clinical worsening of patient and poor function of right ventricle, urgent implantation of total artificial heart (TAH) was planned. Cardiopulmonary bypass (CPB) was started via femoral artery and vein cannulation. Patient was cooled, venting tube was placed via apical cannula and arterial balloon occluder was placed to the aorta, via arterial cannula. Resternotomy was performed but bleeding persisted. Temperature was dropped until 20°C and circulatory arrest (TCA) was started. Distal part of ascending aorta was dissected and clamped. TCA was terminated in 8 minutes. Syncardia, total artificial heart was implanted under CPB at 34°C. Sternum was kept open but reexploration is needed for hemorrhage at 48th hour. Cannula detachment is a serious complication of paracorporeal devices. This complication can be treated definitively with heart transplant or TAH.

FIRST IMPLANTATION OF A HEARTWARE RIGHT VENTRICULAR ASSIST DEVICE FOR RIGHT VENTRICULAR FAILURE CAUSED BY SEVERE IDIOPATHIC PULMONARY HYPERTENSION


Introduction. Patients suffering from primary pulmonary hypertension (PPH) are at increased risk for right ventricular (RV) failure leading to death. We report on a patient with RV failure due to PPH who was supported with an implantable primary RVAD using a HeartWare HVAD.

Case Report. The RV function of a 70-year-old male patient with PPH worsened despite optimal medical treatment over the past 10 years. The patient was admitted to hospital in NYHA class IV, with peripheral edema and arterial oxygen saturation of 87%. Intensified medical treatment failed and he received a HeartWare HVAD for support of the right ventricle (RVAD), implanted through a median sternotomy and without the use of cardiopulmonary bypass. The RVAD cannula was placed in the right atrium and the outflow cannula was anastomosed to the pulmonary artery. For better positioning of the pump, the right portion of the pericardium was dissected and the pump placed into the right pleural space; the pericardium was adapted around the pump. Following a short stay in our intensive care unit the patient was moved to a normal ward.

Conclusion. Primary RVAD implantation in patients suffering from PPH with failing RV using a HeartWare HVAD is feasible.

INCIDENCE OF POSTOPERATIVE BLEEDING IN PATIENTS WITH A HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM WITH SEALED GRAFTS


Introduction: The implantation of ventricular assist devices is an effective surgical treatment option for patients with terminal heart failure. However, the incidence of post-operative bleeding has remained high. Since the beginning of 2011 a sealed inflow graft was added to the HeartMate II LVAS (Thoratec) making both grafts (inflow and outflow) sealed.

Methods: The primary study objective was to compare the amount of chest tube drainage at 48 hours between two groups: 20 patients implanted with non-sealed inflow and outflow grafts (retrospective data) and 20 patients implanted with the sealed inflow and outflow grafts (prospective) while using our standard institutional anti-coagulation protocol in both groups. Patients were excluded from this study if they had a suboptimal pre-operative anti-coagulation status, sepsis or infection before implantation. Additional secondary parameters included number of transfused units of PRBC and FFP and days of ICU stay.

Results: A preliminary review and analysis was performed. The data of 20 HeartMate II patients with non-sealed grafts (75% male, median age 57 years, 45% DCMP, 45% ICMP, 75% INTERMACS category 2 and 3) was compared to that of 12 HeartMate II patients implanted with sealed grafts (100% male, median age 58 years, 50% DCMP, 50% ICMP, 92% INTERMACS category 2 and 3). The chest tube drainage at 48 hours was lower in the sealed graft group: 1425 ml vs 1750 ml. The additional secondary parameters will be reported after completion of study enrolment.

Conclusion: This preliminary analysis indicates that introduction of the HeartMate II sealed grafts did lead to decreased postoperative bleeding at 48 hours.
LATE CAUSE OF RIGHT HEART FAILURE IN A LVAD PATIENT: AORTIC ROOT THROMBUS
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41 years old man received HeartMate II LVAS implantation as a destination therapy. His has a history of Buerger Disease. At 16th day, pericardial effusion expanded and pulsatility index decreased. Although it was removed, while INR is 1.7, he suffered suddenly onset chest pain. He evaluated as an inferior myocardial infarction according to ECG and troponin level.
Echocardiography showed right ventricular failure. Computed tomography showed wide thrombus formation on aortic root. (Figure 1)

Thrombus was removed successfully. (Figure 2)

Follow-up echo showed improvement in right ventricular function.
HeartMate II is a continuous flow pump used for end-stage heart failure.
Although there isn’t a consensus, some authors reported low thromboembolic events with the INR1.5 to 2.5, we reported a case developed aortic root thrombus caused right ventricular failure. We would like to point that aortic root thrombosis can occur in early follow up period.
Absent of aortic valve opening, high pump speed and low INR level may lead thrombus formation on aortic root. Reducing pump speed till aortic valve opens may prevent.

A PROPOSAL OF FLEXIBLE CONTROL ALGORITHM FOR ARTIFICIAL HEART BASED ON STOCHASTIC METHOD
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Introduction: Adaptively controlling an artificial heart (AH) in the realistic situation would be difficult because it is necessary to model the whole including the AH and the cardiovascular dynamics. To solve this problem, we propose flexible control method for an AH based on stochastic model. In this study, we sought to investigate whether our proposed method can be used to adaptively control an AH in the simple case of a continuous flow VAD.

Methods: The flow rate control algorithm was constructed on the basis of a stochastically control model dx(t)/dt=A [−dU(x)/dx]+ η (x(t); a control variable for the rotational speed, U(x): tentative objective function with the extremum of the potential at x=c, A: evaluation function to indicate the desirability of a current state, η: noise). “c” was updated on the basis of the value of “A” in order to approximate the extreme of the real potential. “A” was experimentally designed to increase when the pump output approached arbitrary target values. The validity of the constructed algorithm was examined in a mock circuit.

Result: The adaptive behaviors to inflow obstruction (unexpected disturbance) were found as follows: 1) “c” became dominant by a decline of “A”, 2) “c” decreased temporarily depending on changes of “A”, 3) the negative pressure of the inlet was canceled by a temporary decline of “c”, 4) Subsequently “x” increased again. As a result, in response to a low flow state with the different causes, the flow rate reached a target value with adaptive behavior.

Conclusion: The constructed algorithm realized adaptive flow rate control in the situation of mock circuit without designing the detailed control rule based on the model the control target.
TEMPORAL TRENDS IN HEARTMATE II LVAD SUSPECTED PUMPTHROMBUS EVENTS AND PUMP REPLACEMENTS - THE INTEGRIS BAPTIST MEDICAL CENTER EXPERIENCE

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Purpose: An increase in LVAD implants per year and corresponding increase in patients supported can lead to the perception of increased adverse event rate. Therefore, we reviewed of our experience with the HeartMate II with regards to pump thrombosis and pump replacement from 1/2010 - 12/2012.

Methods: We reviewed data from HeartMate II patients experiencing suspected pump thrombosis events (SPTE), defined as elevated plasma free hemoglobin and evidence of LVAD dysfunction (power spikes, high power, and/or onset of heart failure symptoms), or who required pump replacement. We also recorded anticoagulation status, pump parameters, infection history, recent disruptions of anticoagulation, interventions, event outcome, patient outcome, history of gastrointestinal (GI) bleeding, use of Factor VII, and heart failure etiology. 2010 served as baseline for comparison to 2011-2012 with no significant changes in patient management in that time.

Results: Five SPTEs occurred in 2010 in 52 total patients, with no pump exchanges, but 2 patients expiring related to pump malfunction. The remaining events were treated with Integrilllin and Heparin or Angiomax. There were 16 SPTEs in 112 patients in 2011-2012. Two patients accounting for 4 events had confirmed inflow obstruction resolved with surgery. The remaining 12 events occurred in 10 patients with 5 resulting in pump replacement. 5 of 12 events resolved with increased anti-thrombotic therapy, with 3 also receiving thrombolytics.

Conclusion: In our experience the HeartMate II pump replacement rate has increased; however, the rate of suspected pump thrombosis events has not significantly changed.

BIVACOR - IMPLANTABLE ROTARY TOTAL ARTIFICIAL HEART

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An implantable prototype of the single device BIVACOR® rotary TAH was constructed for in-vivo evaluation. The device integrates a MAGLEV system to actively or passively translate impeller position to alter left and right outflow, whilst arterial pulsatility can be induced via cyclic speed changes. The purpose of this study was to evaluate the in-vivo performance of the device in calves.

Animal trials in three calves (75-95Kg) were conducted. The purpose was to evaluate device fitting in a closed chest and short term hemodynamic performance. To this end, maximum outflow, the effectiveness of the flow balancing controller, and the level of arterial pulsatility was recorded. The first two animal trials were acute non-recovery, whilst the animal was woken and allowed to stand for 5 hours in the third trial. During in-vivo testing, the device simultaneously provided up to 10 L/min outflow from both left and right sides of the device. The flow balance controller could prevent negative arterial pressures at extreme ratios of SVR:PVR. Finally, pulse pressures of 120/80 mmHg and flows of 5 L/min at 2500 RPM +/- 500 RPM at 30 cycles per minute could also be achieved. Sufficient, balanced, and pulsatile cardiac output can be delivered from the BIVACOR® TAH. These in-vivo results encourage further progression to a longer term chronic animal model.

FIRST ANALYSIS OF ARTIFICIAL MYOCARDIUM APPLIED TO CHRONIC HEART FAILURE IN CANINE MODEL

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Objectives: We have been developing artificial myocardium (AM) made of shape-memory alloy fibers as an application to a cardiac support device contracting on the epicardium of the failing heart. In this process, how to adjust and configure AM bands to a failing heart is one of the primary issues as the installation of AM might cause ventricular diastolic dysfunctions due to incomplete fittings of AM bands. However there is few study concerning about the effect on chronic heart failure and the optimized configuration of AM. In this study, we examined the effect of AM for chronic heart failure in canine model.

Method: The heart failure was achieved by rapid pacing for 4 weeks. Prior to the experiment, we confirmed that the ejection fraction (EF) declined below 30%. After thoracotomy, AM was installed with an oblique fashion and the cardiac function was monitored to obtain the changes under the assistance of AM.

Result: The shape of failing heart became spherical rather than ellipsoid by rapid pacing. Left ventricular end-diastolic dimension decreased by 36.9% (35.5mm → 22.4mm) at AM installation, and EF was improved from 21.5% to 40.6% with a support of AM. Additionally, mitral regurgitation was ameliorated by the approximation of the papillary muscles with AM installation. And end-systolic maximal elastance (Emax) was also improved by 69.5% (Emax 2.10 mmHg/ml at baseline, 3.56 mmHg/ml at AM activation).

Conclusion: Artificial myocardium could improve the cardiac functions for a failing heart as a left ventricular support device. The optimization of AM configuration as well as the synchronous motion will amplify the contracting effect to support the cardiac function.

ISCHEMIC BOWEL IN PATIENTS WITH MECHANICAL CIRCULATORY SUPPORT

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Introduction: Mechanical Circulatory Support (MCS) improves both survival and quality of life in patients with advanced heart failure. Despite advances in technology and patient care, gastrointestinal complications occur and contribute to adverse outcomes.

Methods: Data was retrospectively reviewed on patients from 2000-2012 who were implanted with MCS devices at a single center.

Results: 375 patients were supported with 490 MCS devices at our institution. 420 Left Ventricular assist devices (LVAD), 18 Right Ventricular assist devices (RVAD), 49 Bi Ventricular assist devices and 3 total artificial hearts (TAH). 6 patients (21%), 3 men and 3 women were identified with ischemic bowel disease, mean age 66.6 years (59-83). Five of 6 patients with ischemic bowel had MCS for an ischemic cardiomyopathy. Five patients were supported with continuous flow pumps for which 2 required Bi-VAD continuous flow pumps. One patient was on a pulsatile LVAD. In 2 patients ischemia was isolated to the small bowel while the other 4 had ischemia involving the cecum and ascending colon. Four patients presented in cardiogenic shock required emergent MCS and were treated with vasoactive drugs. Two patients developed ischemic bowel at 77 and 127 days post implant. Four patients were treated with bowel resection. Five of 6 (83%) patients expired.

Conclusion: Ischemic bowel disease is a rare but lethal condition for patients supported with mechanical circulatory support. Despite bowel resection, mortality is high.
COMPUTATIONAL FRAMEWORK TO PREDICT PULSATILE PRESSURE AND POWER FOR AXIAL-FLOW LVADS OPERATING IN PULSATILE MODE

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Whether pulsatile pressure is necessary in the cardiovascular system to maintain homeostasis is a question that has only recently become relevant. Pulsatility can be diminished or completely abolished with axial-flow ventricular assist devices or axial-flow total artificial hearts. Operating axial-flow pumps in pulsatile mode can generate a pulsatile pressure, but at a cost of increased power consumption. Although mock circulations and animal models provide necessary tools to characterize the interaction of cardiac assist devices and the cardiovascular system, they are not sufficient; the many variables influencing the interaction either cannot be measured or controlled, and the generality of results is limited. We therefore developed a realistic human arterial system model to predict pulsatile pressure and oscillatory power dissipation resulting from the complex interaction of the ventricle, arterial system and axial-flow pump. We also developed a simpler algebraic approximation for the special case that an imposed pulsatile flow has a low frequency or the arterial system is fairly stiff. Higher arterial compliances or pulse frequencies increases efficiency of the pump but decreases pulsatile pressure. This framework provides the means to predict optimal amplitudes and frequencies of imposed pulsatile flow in particular patient populations.

WORLDHEART LEVACOR CLINICAL EXPERIENCE

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Purpose: We present the largest single center experience with the Worldheart Levacor mag-lev centrifugal LVAD and novel system features, some of which were introduced clinically for the 1st time.

Methods: The Levacor was implanted in 6 patients (4M:2F), ages 32-67, during a bridge-to-transplant trial. Unique aspects of the Levacor system included 1)Mag-lev rotor with optimized flow paths, 2)LV-cannulation approach enabling rapid deployment, 3)Modular, replaceable percutaneous lead, and 4)Controller with internal reserve battery.

Results: Six patients were supported for 8.3 yrs: 3 were transplanted at 7, 8 & 30 mos, 1 remains on support at ~2.8 yrs, 1 died at home at 7 mos of undetermined cause, and 1 had support withdrawn at 1.5 yrs due to complications post-CVA. Experience with unique features of the Levacor included: 1)Improved hemocompatibility with preservation of vWF multimers in all patients and no GI bleeding events, 2)Implant cardiopulmonary bypass (CPB) time averaging only 25 mins, 3)Replacement of a failed percutaneous lead without pump exchange, and 4)Controller internal reserve battery allowing safe single battery operation and improved quality of life.

Initially, the controller displayed heating and frequent alarms, resolved by subsequent upgrades. 3 patients experienced CAVs – 1 with confirmed lupus anticoagulant, 1 with atrial thrombus embolization, and 1 of unknown origin. Only 1 CVA resulted in persistent disability.

Conclusion: While the Levacor trial was halted, this single center experience provides a basis for investigation of new features including improved hemocompatibility, faster implantation with shorter CPB duration, modular system components for less-invasive replacement, and a battery within the controller.

TRANSPAPITAL TO AORTA DOUBLE LUMEN CANNULA BASED NEONATE LVAD ACHIEVES TOTAL LV UNLOADING

Dongfang Wang, Mark Plunkett, Louis Bezold III, Croft Cherry, Joseph Zwischenberger. University of Kentucky College of Medicine.

The paracorporeal ExCor is the only approved pediatric LVAD. However it requires invasive median sternotomy, and is difficult to implant and remove in neonate. We are developing a less invasive and reliable TransApical to Aorta (TAA) double lumen cannula (DLC) based LVAD for neonate. The DLC is designed to be inserted from the apex though the LV, crossing aortic valve to ascending aorta. The TAA DLC drainage lumen opening is located in the LV and the infusion lumen opening in the aorta. Coupled with a commercial blood pump, blood is withdrawn from the LV and infused into the aorta to unload the LV through a single cannulation.

Method and material: The 16 Fr cannula consists of a main DLC body and extension infusion cannula (EIC) with stainless steel reinforced polyurethane construction. The infusion lumen was a thin eccentric membrane sleeve, extending out of the DLC main body, and becoming a reinforced EIC.

Result: The bench test in 37% glycerin showed 1,100 ml/min flow against 200 mmHg in infusion side and 100 mmHg in drainage side. The TAA DLC was tested in 3 new born lambs (2.5-4.0 kg) through left thoracotomy. The TAA DLC was inserted from apex to LV, passing aortic valve to ascending aorta. A CentriMag pump was connected, pumping blood from the LV to the Aorta. All three lambs achieved 80-200 ml/kg pumping blood flow, decreasing LV pressure for LV unloading. Our data demonstrated that LV peak pressure was lower than aortic systolic pressure, indicating all the cardiac output through DLC LVAD system for total LV unloading.

Conclusion: Our TAA DLC based neonate LVAD was proved efficient, less invasive, and easy to implant/remove.

IMPELLA PEDIATRIC INSERTION TECHNIQUES

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Background: The Impella Pediatric is a catheter-based percutaneous ventricular assist device for treatment of acute heart failure (Figure 1). The device is based on the Impella 2.5, provides flows of up to 2.5 L/min and up to 7 days of support.

Insertion Techniques: Based on ventricular and ascending aorta geometry the proposed target population for this device is 10-25 kg (0.5-1.0 m² BSA). Challenges remain to insert the device into small patients using peripheral arteries.

CT scans measurements from 17 pediatric patients using Mimics software (Materialise NV, Belgium) revealed carotid artery diameters between 4.0 and 5.7 mm for 10 kg patients. Data from the literature suggests that common carotid artery luminal diameter of 10 kg pediatric patients is between 5.2 and 5.9 mm, and between 4.1 and 4.9 mm. Femoral artery measurements were not possible since the scans were limited to the thoracic region; however, aortic arch width measurements between 45 and 60 mm may limit femoral insertion to patients ≥20 kg, and ≥15 kg with a softer catheter.

Acute studies (N = 2) were completed in an ovine model (N=2, 31-32 kg) and porcine model (N=2, 18-20 kg). The 12 Fr Impella Pediatric was inserted through 13 Fr sheaths into the carotid and femoral arteries and provided up to 2 L/min of support for 5 hours. Vessel diameter was approximately 5 mm in these animals.

Evaluation in preserved specimens (5-25 kg patients) showed that the rigid length of the motor and the catheter diameter may prevent carotid insertion in 10 kg patients.

Conclusion: Carotid insertion appears feasible for ≥15 kg patients, while ≥10 kg patients may require direct aortic insertion. Femoral insertion with the current catheter appears feasible for ≥15-20 kg patients.
DESIGNING THE IMPELLA PEDIATRIC FOR SMALLER PATIENTS

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Background: The Impella Pediatric is a percutaneous ventricular assist device for treatment of acute heart failure. The device is based on the Impella 2.5 and provides flow up to 2.5 LPM for up to 7 days of support. The proposed patient population range between 10-25 kg.

Problem: Design challenges around anatomy, insertion, and maximum flow need to be addressed for both pediatric and adult patients. One aspect of pediatric VAD design concerns the minimum flow required by a small pediatric patient. Flow must be maximized for larger patients while providing an appropriate minimum device flow for smaller patients.

Patients need 75-100 mL/kg to fully unload the left ventricle. Impella Pediatric patients require 0.75-2.5 LPM of flow for full support. In small patients who do not require full support the device must provide a minimum mean flow <0.75 LPM.

Design Considerations: Flow varies over the cardiac cycle by the differential pressure (dP) across the inlet (left ventricle) and outlet (aorta). Maximum dP occurs during diastole and varies between 60-100 mmHg. Minimum pump speed must consider this dP. Mean flow should be ≥ 0 LPM over the cardiac cycle.

The minimum speed was determined to be 29 krpm using a MathCAD simulation. This speed delivers flows of 0-1.5 LPM for dP of 0-60 mmHg with a net mean flow >0 LPM. Under certain blood pressure conditions retrograde flow may still occur elevating the risk of left ventricle overload and hemolysis.

Conclusion: The Impella Pediatric design must address many factors to provide maximum flow for the larger patients while accommodating the flow needs of smaller patients.

A PRACTICAL DOUBLE LUMEN CANNULA BASED CAVOPULMONARY ASSIST DEVICE REVERSES FAILING FONTAN CIRCULATION

Guodong Gao, Dongfang Wang, Mark Plunkett, Cherry Croft, Joseph Zwischenberger. University of Kentucky College of Medicine.

We are developing the double lumen cannula(DLC) based Cavopulmonary assist (CPA) device for failing Fontan circulation.

Method and material: The DLC is the key, inserted from right jugular vein into superior vena cava (SVC), crossing total cavopulmonary connection (TCPC) anastomosis to inferior vena cava (IVC). Total venous blood is withdrawn from both IVC and SVC through one drainage lumen and pumped back directly into the pulmonary artery (PA), achieving CPA. One of the 27 Fr working prototypes has been made with main body of thin stainless steel reinforced polyurethane. Infusion lumen are membrane sleeve within main body, extending out between SVC and IVC drainage openings, and bifurcating into left and right PA. (Figure 1)

We also have developed a clinically relevant sheep TCPC model with failing Fontan circulation to test CPA device.

Result: Bench test has been done in TCPC simulation loop, demonstrating 4.5 l/min pumping flow against 30 mmHg. P. The latest animal prototype of the DLC based CPA device has been tested in our adult TCPC sheep model (n=3). It pumped 3.0 to 4.3 l/min blood flow, increased systolic pressure from 38-60 mmHg to 86-129 mmHg, decreased CVP from 13-18 to 6-7 mmHg, achieving total CPA and successfully reversing failing Fontan circulation.

Conclusion: Our DLC based CPA device is a practical and efficient way to achieve total CPA.
LEFT VENTRICULAR END DIASTOLIC DIMENSION ASSESSMENT DURING ECHOCARDIOGRAPHIC SPEED OPTIMIZATION OF HEARTWARE VENTRICULAR ASSIST DEVICE

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Purpose: Recent studies involving continuous flow left ventricular assist devices (LVADS) have demonstrated the utility for speed ramp protocols involving echo assessment of the dynamic interactions of left ventricular dimensions, valve function, and right ventricular morphology. The HeartWare (HVAD) continuous flow device utilizes a centrifugal pump mechanism and dynamic interactions unique to the HVAD have not been well described. We sought to describe the influence of HVAD speed ramping on left ventricular end-diastolic dimension (LVEDD) in relation to valvular function and right ventricular morphology.

Methods: We utilized previously reported speed ramp protocols as an effort to optimize HVAD performance while measuring sequential changes in LVEDD, aortic valve opening, aortic regurgitation, mitral regurgitation, and right ventricular structure and function by assessing leftward septal shift.

Results: Seven ramp tests were retrospectively analyzed. Upitation of speed was associated with decreased frequency of aortic valve opening, reduced mitral regurgitation, and increased leftward shift of the interventricular septum. However, LVEDD did not decrease significantly despite escalating speed. (Figure 1)

Conclusion: For HVAD speed optimization, LVEDD may be a less useful marker of LV decompression. This finding requires further study.

THE PATIENT-SPECIFIC CARDIAC SUPPORT DEVICE FOR DILATED HEART FAILURE PATIENTS

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Background: The Acorn CorCap is a cardiac supporting device (CSD) for dilated heart failure patients to prevent cardiac remodeling. There are two drawbacks of CorCap. One is to need adjustment of size and shape by surgeon which diverse the constrain level, and the other is to envelope the both ventricles evenly which interfere the diastolic function of the right ventricle (RV) more than that of the left ventricle (LV).

Methods Results: We developed the patient-specific CSD to overcome these drawbacks. The 3-dimensional (3D) patient-specific heart model is created from MRI images. Then, the design paper for computer assisted knitting machine (Shima-Seiki, Japan) is created. The patient-specific CSD will be produced within an hour after start for knitting. The size of the net can be changed easily by changing the size of the design paper. Ten percent reduction of the net size will produce the optimal contact pressure of 4 mmHg on patient-specific polyurethane model when the net is produce by 6-0 polyester suture threads. We apply the finite element analysis (FEA) to the patient-specific 3D model using Simlab and Ansys. The contact pressure on cardiac surface, the wall stress of RV and LV are simulated in Ansys.

Conclusion: Our patient-specific CSD can set the different constrain level on RV and LV without surgical adjustment, which solves the two weak points of CorCap.

Acknowledgement: This study is partially funded by Ministry of Economy, Trade, and Industry, Japan as a part of “Program to support collaboration between hospitals and businesses for development and improvement of medical equipment and devices to solve unmet medical needs.
IN VITRO AND IN VIVO EVALUATION OF A COMPACT WEARABLE PNEUMATIC DRIVE UNIT FOR A VENTRICULAR ASSIST DEVICE
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Purpose: To improve the QOL of the patients with a pneumatically driven extracorporeal ventricular assist device (VAD), we have been developing a compact wearable pneumatic driver (WPD) that enables greater freedom of movement and longer battery run time than the conventional pneumatic VAD drivers. This study describes the evaluation of pump and battery performances, durability and stability for WPD.

Methods: The size and weight of WPD are 21x11x25 cm and 4.75 kg, respectively. The WPD consists of an air pressure generation unit and battery power supply unit. The air pressure generation unit is constructed from a cylinder piston, a crankshaft, a brushless DC motor and non-circular gears. The battery power supply unit is composed of two lithium-ion batteries (Rating 14.4 V, 4400 mAh), a DC-DC converter, a power source selector and a controller of batteries. The pump performance and durability of WPD was examined using a mock circuit. The animal test (left heart bypass model) was performed using a calf to assess the pump and battery performances of WPD in a more realistic setting.

Results: More than 6 L/min of pump output was obtained at the after-load of 100 mmHg at beating rate of 100 bpm. The WPD was able to pulsate more than 1 year without device failure or the wear of non-circular gears. The WPD was able to maintain stable hemodynamics for 28 days (mean AoP= 86±10 mmHg, mean bypass flow=4.1±0.4 L/min, mean power consumption=13.2±0.4 W, and beating rate=70 bpm), and the battery unit could operate the WPD for longer than 5 hours stably.

Conclusion: The developed compact WPD showed stable pump and battery performances and durability for improving the QOL of the patients.

EVALUATION OF PLATELET AGGREGATION IN PATIENTS SUPPORTED BY CENTRIFUGAL CONTINUOUS FLOW LEFT VENTRICULAR ASSIST DEVICE
Kenji Suzuki, Tomohiro Nishinaka, Takuma Miyamoto, Yuki Ichihara, Masahide Komagamine, Yukiko Yamada, Kenji Yamazaki. Department of Cardiovascular Surgery, The Heart Institute, Tokyo Women’s Medical University, Tokyo, Japan.

Objective: Shear stress of blood flow in left ventricular assist device (LVAD) can cause activation of platelets, thereby promoting thrombotic events. In this study, we evaluated the platelet aggregation in patients supported by a centrifugal continuous flow LVAD.

Methods: The study group consisted of 12 patients (9 men and 3 women) supported by an EVAHEART centrifugal continuous flow LVAD for more than 6 months (average 386.7±140.4 days), and with an anticoagulation regimen of warfarin (targeted PT-INR = 2.5 - 3.5) and aspirin. Blood from the patients was sampled at 1 week (7.17±1.70 days), 1 month (29.5±3.06), 3 months (99.3±19.47) and 6 months (184.4±13.28) after LVAD implantation. Platelet aggregation was assessed by laser light-scattering methods with 2.0 µg/ml adenosine 5'-diphosphate.

Results: Laser light scattering intensity at 3 and 6 months showed significant increment compared with that at 1 week in large (50-70 µm) aggregate generation (P<0.0029 and 0.0158 respectively), but not in small (9-25 µm) and medium (25-50 µm). (Table 1)

<table>
<thead>
<tr>
<th>Laser light scattering intensity (x10&lt;sup&gt;5&lt;/sup&gt;)</th>
<th>1 week</th>
<th>1 month</th>
<th>3 months</th>
<th>6 months</th>
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<tbody>
<tr>
<td>Small</td>
<td>2.12±0.83</td>
<td>2.78±1.56</td>
<td>3.2±0.96</td>
<td>2.56±0.85</td>
</tr>
<tr>
<td>Medium</td>
<td>1.22±0.68</td>
<td>1.70±1.14</td>
<td>2.33±0.87</td>
<td>1.51±0.83</td>
</tr>
<tr>
<td>Large</td>
<td>2.12±1.99</td>
<td>3.01±2.93</td>
<td>5.01±1.80</td>
<td>4.13±2.18</td>
</tr>
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</table>

Conclusions: Platelet aggregation at 3 and 6 months after LVAD implantation showed significant increment compared with that at 1 week.

THE EFFECT OF SPEED MODULATION INDUCED PULSATILITY ON HEMOLYSIS USING A HEARTMATE II® LVAD
Megan A Stauffer, Joshua P Cypyk, Choon-Sik Jhun, Gerson Rosenberg, William J Weiss, Christopher S Hollenbeak, Branka Lukic. Surgery, Penn State College of Medicine, Hershey, PA.

Purpose: Despite the wide-spread use of continuous flow LVADs, maintaining pulsatile flow within a patient’s cardiovascular system could potentially alleviate some common side effects associated with continuous flow pumps. The goal of this study was to evaluate the effect of pulsatility, induced by speed modulation of the HeartMate II®, on hemolysis. Methods: A low volume (370 ml), passive filling, mock circulatory loop with fresh bovine blood at 37°C was used. The continuous flow condition was operated at a speed of 10000 rpm and the pulsatile flow condition was operated using sinusoidal speed modulation at 60 bpm with an average speed of 10000 rpm and an amplitude of 3000 rpm. Six, 6 hour experiments with randomly assigned 30 minute intervals of pulsatile and continuous flow were conducted. The nominal mean flow and head pressure were 5 L/min and 83 mmHg throughout the continuous flow condition and 4.9 (3-7) L/min and 88 (40-150) mmHg throughout the pulsatile flow condition. Results: The Mean±SE of the Normalized Index of Hemolysis (NIH) for all experiments combined was 0.015±0.002 mg/dL for continuous flow, and 0.015±0.002 mg/dL for pulsatile flow. The mean NIH value from each of the six individual experiments ranged from 0.007 to 0.025 mg/dL for continuous flow (SE 0.005) and from 0.011 to 0.025 mg/dL for pulsatile flow (SE 0.006). Paired T-tests showed no statistically significant differences between the two flow conditions within any individual experiments. Conclusion: Pulsatility, induced by speed modulation, has no statistically significant effect on hemolysis at the stated conditions for a HeartMate II® LVAD.
IS FAST TRACK ANAESTHESIA IN LEFT VENTRICULAR ASSIST DEVICE IMPLANTATION FEASIBLE AND REASONABLE?
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Objective: Left ventricular assist device (LVAD) implantation has become a crucial option in end-stage heart failure therapy. Experience has grown, but it is remarkable that anaesthesiological management of this special patients and their advanced needs have not been examined profoundly yet. Especially postoperative right ventricular (RV) failure is feared. Fast track procedures, including early extubation have been well established in cardiac surgery and were proven to be effective. We assumed that RV function benefits from early extubation.

Methods: From 01/2008 to 11/2012 we implanted 77 continuous flow LVADs. Out of these, 13 patients (INTERMACS level 3 or 4) were treated as “fast-track”. This included extubation in the theatre or up to 6 hours postoperatively.

Results: 10 patients were male, average age was 61±10 yrs on day of implantation. 3 patients suffered from DCM the others from ICM. Mean left ventricular ejection fraction was 48±4%. 9 of 13 pts. had an impaired RV function. We implanted 12 Thoratec Heartmate II and 1 Heartware HVAD device. All patients were extubated within 4 hours. The mean stay on ICU was 53±41 hours and the mean stay in hospital after implantation was 23±9 days. We did not record any postoperative RV failure. The 30-day survival was 100%. After one year of support, 11 of 13 patients were alive. The current mean time on device is 413 days.

Conclusion: In our study, we showed that fast track anaesthesia in LVAD implantation is feasible in selected patients. In every case, a sufficient RV function was preserved. Prospective investigations should examine if fast track regimen contribute to saving the right ventricle.

REACHING OPTIMAL BLOOD PRESSURE CONTROL IN PATIENTS SUPPORTED BY VENTRICULAR ASSIST DEVICES: UTILIZING A VAD HYPERTENSION PROTOCOL
Karen A Sche hein, Robert A Gordon, Andrew Sauer, Travis Abicht, Edwin C McGee. Bluhm Cardiovascular Institute, Northwestern Memorial Hospital, Chicago, IL.

Ventricular assist devices (VADs) are widely utilized in the treatment of advanced heart failure. Although the size and efficiency of the pumps have improved, substantial morbidity continues to plague the VAD population. Among the most detrimental problem in the continuous flow population is hypertension with resultant hemorrhagic stroke. We feel that strict management of hypertension in VAD patients may decrease the risk of hemorrhagic stroke.

At our institution a VAD Hypertension Protocol was instituted to provide clear mean arterial pressure (MAP) parameters, to outline guidelines to optimize oral antihypertensive medications, and to appropriately triage hypertensive crisis in order to provide timely and effective treatment. The hypertension protocol, broken down for both the inpatient and the outpatient setting, addresses treatment of both symptomatic and asymptomatic hypertension. Mirroring our recovery protocol, the hypertension protocol elaborates on the titration of medications to achieve optimal blood pressure control as well as promotion of native heart function. The hypertension protocol will remain an important tool to ensure optimal care of VAD patients supported with continuous flow devices. We plan to study the impact of the hypertension protocol on adverse events in our VAD population. (Figure 1)

CLINICAL EXPERIENCE WITH STERNOTOMY VERSUS LESS INVASIVE SUBCOSTAL APPROACH FOR EXCHANGE OF THE HEARTMATE II LEFT VENTRICULAR ASSIST DEVICE
Behzad Soleimani, Lauren C Price, Edward R Stephenson, Aly El-Banayosy, Walter E Pae, Heart and Vascular Institute, Penn State Hershey Medical Center, Hershey, PA.

Purpose: The safety and efficacy of exchange of the HeartMate II left ventricular assist device through a less invasive subcostal approach remains unclear. Methods: We reviewed the records of 17 patients who required exchange of their HeartMate II device at our institution since 2007. We divided the cohort to those exchanged through subcostal (SC) versus median sternotomy (MS) approach and obtained data pertaining to their short and long term outcomes. Results: Nine patients had pump exchange through MS versus 8 that had the SC approach. The mean support duration with the first pump was 540±450 days. The reason for exchange was electromechanical failure (7), thrombosis (8) and infection (2). There were no 30-day perioperative deaths with either approach. Compared with sternotomy, patients with subcostal approach had significantly shorter operative times (131 versus 222 minutes; p=0.001), lower re-operation rates for bleeding (0 versus 4.4%; p=0.05) and required fewer transfused blood products (packed red cells 3.5 versus 7.1 units, p=0.05; cryoprecipitate 50.7 versus 209.3 mL p=0.01; platelets 292 versus 762 mL, p=0.05). Additionally, patients with subcostal approach had shorter postoperative intensive care unit stays (5 versus 13.8 days, p<0.05) and total hospital stays (16.4 versus 27.2 days, p<0.05). Long-term survival after mean follow up of 260 days for the subcostal group and 322 days for the sternotomy group was 75% and 33% respectively. Conclusions: Exchange of the HeartMate II pump can be accomplished with a low morbidity and mortality and good long-term outcomes, through a less invasive subcostal approach.
IS EARLY POWER DYSFUNCTION A BENIGN PHENOMENON AFTER HEARTMATE II IMPLANT?
Alana A Lewis, Nicholas A Haglund, Mary Beth Davis, Daniel J Lenihan, Mary E Keebler, Mark A Wigger, Thomas G DiSalvo, Kelly H Schiendorf, Simon Maltias, Cardi thoracic Surgery, Vanderbilt University Medical Center, Nashville, TN; Cardiology, Vanderbilt University Medical Center, Nashville, TN.

Introduction: Early (1 month) power dysfunction (PD) has been recently reported as a frequent observation after continuous flow left ventricular assist device (CF-LVAD) implantation. We sought to clarify the frequency of PD undergoing CF-LVAD implantation, and correlate PD with thromboembolic events (TE).

Methods: From April 2011 to November 2012, we analyzed data collected for elective patients undergoing elective implantation of a HeartMate II CF-LVAD. Patients were assessed according to the identification of early PD. Patient characteristics, hemolysis-related parameters, and thromboembolic (TE) outcomes were assessed longitudinally.

Results: Thirty-three patients aged 33.5±9.5 years old were identified. Mean LVEF was 15.9±6.1%, and mean INR was 2.4±0.5. Over 1000 pump parameters were analyzed over 255±150 days (median 205). Fourteen patients (42%) were found to have early PD, while 19 had normal pump recordings. Interestingly, patient in the early PD group showed higher pump power measurements throughout the study period (PD=7.4±0.8, and no PD=6.7±0.6; p<0.001). Despite these differences, hemolysis-related parameters (LDH, platelet count, INR, plasma free hemoglobin, bilirubin, and creatinine) remained comparable between groups. Clinically relevant thromboembolic events were also similar (PD=3 patients; no PD=4 patients). In this study, early PD was not associated with differences in TE outcomes.

Conclusion: PD is common after CF-LVAD implantation, and it is associated with higher pump power measurement after implant. PD is not associated with a higher incidence of TE events. Further studies are needed to clarify the clinical implications of these findings.

DURABILITY TESTING OF THE PENN STATE PEDIATRIC VAD

Purpose: Durability testing of the pneumatic Pediatric VAD started early in the pump development stage. The goal was to evaluate the pump’s reliability and make incremental changes in the pump design. Method: The first two durability tests were conducted on the performance mock circulatory loop. All subsequent tests were conducted on modified Penn State TAH durability test stands. Each stand had two open loops for simulating systemic circulation consisting of spring-loaded arterial compliance, systemic resistance, PVAD, and 8mm ID, 10cm and 21cm long inlet and outlet cannulae. The pumps were submerged in 37C saline, which was also the pumping circulating fluid. The systolic drive pressure was 250 mmHg and the diastolic pressure was -50 mmHg. The pump rate and systolic duration were set to 100 beats/min and 300ms. The mean arterial pressure was kept at 75(85/65) mmHg. Results: A total of 13 tests were conducted including three ongoing tests. There were no pump failures. Test durations ranged from 54 to 87 days after which the pumps were electively stopped and thoroughly examined. The pump sac and diaphragm scuffing apparent during early testing led to the sac, diaphragm, and control ring design changes. Test 11 is still ongoing after 425 days of uninterrupted running, while ongoing tests 12 and 13 have run for 347 and 297 days with some interruptions for driver repair, and pump examination. The modified Bjork Shiley valves used in test 11 were also used in tests 6-10 for a total of 710 days. Conclusion: The latest PSU Pediatric VAD durability tests demonstrated the pump’s high reliability.

DYNAMIC HYDRAULIC RESPONSE IN THE HVAD® CENTRIFUGAL PUMP
Michael C Brown, Carlos Reyes, Fernando Casas, Jeffrey A LaRose. HeartWare, Inc.

Purpose: Rotary blood pumps have inherent hydraulic performance that is unique to the design of each pump. This study explores the concept of dynamic hydraulic response, or the ability of a pump to produce a desired pressure-flow (HQ) relationship using automated rotational speed changes.

Methods: The HeartWare® Ventricular Assist Device (HVAD), a centrifugal rotary blood pump, was run in a steady-state flow loop while recording pump flow, inlet pressure, and outlet pressure. Pump flow was measured using a Transonic flow probe and inlet/outlet pressure were measured using BD pressure transducers. A flow range of 0 to 10 L/min was recorded by adjusting loop resistance as necessary. Using a custom LabVIEW application and characterized HVAD HQ curves, pump rotational speed was programmatically adjusted to provide the target differential pressure for a given flow.

Results: While adjusting flows from 0 to 10 L/min, the HVAD Pump was capable of producing the target pressure within 5% for each flow. Figure 1 shows the target HQ response and speed required to produce the target pressure. (Figure 1)

Figure 1. Target HQ Response & Required Speed

Conclusion: This study demonstrates that with dynamic hydraulic response, a rotary blood pump may not be limited to the HQ response of its design. Further testing will be conducted to determine the feasibility and effectiveness of dynamic hydraulic response in a pulsatile environment.

COST-EFFECTIVENESS OF VENTRICULAR ASSIST DEVICE IMPLANTATION IN MEDICARE RECIPIENTS: IS IT SUSTAINABLE?
Michael E Bowdish, Felicia S Schenkel, Uzma Quersh i, Sanjit Mahanti, Tarek Salaway, Mark L Barr. Department of Surgery, Keck School of Medicine of USC, University of Southern California, Los Angeles, CA.

Objective: The cost-effectiveness of ventricular assist device technology remains unproven. The objective of this study was to examine the cost-effectiveness of ventricular assist device implantation in medicare recipients.

Methods: This is a single-center retrospective study of our prospectively collected data base of ventricular assist device recipients. All patients undergoing ventricular assist device implantation between July 2010 and December 2012 were included. Direct costs, net revenue, and contribution margin are reported for both private and public payers.

Results: During this time period, 75 VADs were implanted at our institution. Most patients were quite ill, with 70% being INTERMACS Classification 1 or 2. Most were male (75%). 80% were considered destination therapy or bridge to candidacy unlikely or moderately unlikely. Average age was 60 +/- 13 years. 27 (37%) patients were medicare beneficiaries, while 60% have private insurance, and the remainder had Medicaid. Estimated implant costs were similar between groups at $284, 973 +/- 167,895. Reimbursement, however, varied greatly, with medicare contribution margins near zero dollars, and private payer contribution margins ranging from zero to over $500,000.

Conclusions: Implantation of ventricular assist devices in medicare recipients is at best, cost neutral. The financial success of ventricular assist device programs is presently being driven by private payers. The growing population of destination therapy patients, who are all mostly medicare recipients, has drastic implications on VAD programs, as the cost of implanting devices in these patients quickly exceeds current reimbursement.
CHALLENGES IN ESTABLISHING NEW CENTER FOR ADVANCED TREATMENT OF END-STAGE HEART FAILURE

Rodney Thomas,1 Biswajit Kar,2 Pranav Loyalka,3 Rajko Radovancevic,3 Igor Gregoric.1 1Memorial Hermann Hospital-TMC, Houston, TX; 2Center for Advanced Heart Failure, The University of Texas Health Science Center at Houston, TX.

Background: Until May 2012, the largest not-for-profit health system in SE Texas did not have mechanical circulatory support and heart transplantation as a treatment option for patients with end-stage heart failure. We describe rapid construction of an advanced heart failure program.

Methods: Hospital administration conducted analyses and in December 2011 decided to establish the Center for Advanced Heart Failure. The initial phase of the Center began in late March 2012. During April and May 2012 a core team was composed of 3 cardiologists, 1 cardiovascular surgeon, 3 mechanical circulatory support personnel, 2 ventricular assist device (VAD) coordinators, and 2 heart transplant coordinators. All of the key personnel had at least 5 (5–25) years of experience in mechanical circulatory support and heart transplantation. In addition, over 180 nurses were hired for a newly developed 50 bed unit. We carried out intensive training and preparation in the departments of anesthesiology, respiratory critical care, pathology, blood bank, nutritional and social services.

Results: Pending JCAHO approval, since the first LVAD implant on 5/08/2012 through 12/31/2012, we have implanted 11 LVADs (10 HeartMate II 1 HeartWare). Also, we implanted 1 SynCardia total artificial heart, 26 TandemHeart, 6 Centrimag (Levitronix) and 7 Impella 2.5 VADs. After conditional approval from UNOS was obtained on 9/21/2012, we transplanted 10 hearts through the end of 2012.

Conclusion: With strong determination and the support of hospital administration, as well as enthusiastic effort from the entire experienced team, it is possible to establish an advanced heart failure program in a short period of time.

PATHOLOGICAL OBSERVATION IN THE GOAT FOLLOWING PROLONGED VENOARTERIAL BYPASS USING AN EXTRACORPOREAL MEMBRANE OXYGENATION

Toshihide Mizuno, Nobumasa Katagiri, Tomonori Tsukiya, Yoshiaki Takewa, Eisuke Tatsumi. Dept. of Artificial organs, National Cerebral and Cardiovascular Center Institute; Suita, Osaka, Japan.

Prolonged venoarterial (VA-ECMO) is becoming a potent therapeutic option in treating the patients with severe respiratory and circulatory failure. However, the chronic effect of this bypass modality has not yet been fully clarified. Recently, we have developed an extremely durable and thrombo-resistant ECMO system, and succeeded over a month continuous heparin-less VA-ECMO in a series of animal experiments. This paper presents the pathological findings observed in the cardiopulmonary tissue of these animals. Five healthy goats (BW: 19-25 kg) underwent VA-ECMO for scheduled periods of 15-36 days. All animals demonstrated good general condition during the course of the experiment. The bypass blood flow was maintained at 62.3-77.1 mL/min/kg. In histopathological findings, however, the lungs of all animals showed severe alveolar fibrosis with topical atelectasis. Von Willebrand factor on the endothelial cells in the alveolar capillaries were increased as compared with those of the normal goats. The ultrastructure of these cells showed ischemia-induced endothelial swelling. The pathological findings indicated that the vascular endothelial phenotypes had changed from respiratory type to nutrient type. Furthermore, right ventricular was dilated, and localized fibrosis and atrophy of cardiac muscle were observed in these wall. These atrophic foci were mainly scattered with fatty degeneration and proliferation of collagen fibers along perivascula area directly under the epicardium. The results of this study indicated that the VA-ECMO might cause localized fibrosis in both pulmonary and cardiac tissue due to ischemia accompanying reduced pulmonary blood flow.

THE INFLUENCE OF MECHANICAL CIRCULATION SUPPORT DEVICE ON LUNG TRANSPLANTATION

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Introduction: The waiting time for lung transplantation is approximately 3 years due to the extreme donor shortage in Japan. The recipient is commonly too ill, and the use of mechanical circulatory support (MCS) is frequently required for oxygenation and hemodynamic support in lung transplantation. MCS, however, can lead to several complications. We sought the influence of MCS for the patients requiring lung transplantation.

Patients: From 2000 to 2013, 48 pts were transplanted in our hospital. An average of waiting time was 1144 days. The indications included lymphangiopleomymatosi (n=26), primary pulmonary hypertension (n=8), and the others (n=14). Female (n=39) was dominant. MCS was established by small graft end-to-side anastomosis to femoral artery for arterial return to prevent lower extremities malperfusion.

Results: 31 pts (65%) were supported by MCS during surgery and 12 of them were supported after surgery (14.5 days). 12 of 17 bilateral transplant pts and 19 of 31 single transplant pts were supported by MCS. 10 pts underwent MCS installation prior to general anesthesia due to unstable condition. There were no pre-operative hemodynamic and respiratory parameters to predict the MCS installation. The ischemic time of donor lung was significantly longer in pts with MCS after surgery (p=0.03). Over-all survivals were 81% and 62% at 1 and 5 years. Survival of pts with MCS (73 and 30% at 1 and 5 years) was significantly lower than pts without MCS (94 and 94%) (p=0.008). Lower extremities malperfusion occurred in only a patient.

Conclusions: MCS is necessary to carry out lung transplantation for too ill pts; however, it should make an effort to avoid MCS installation if at all possible.

AIR AND GROUND TRANSPORTATION OF EXTRA CORPOREAL MEMBRANE OXYGENATION DEPENDENT PATIENTS

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Background: Many centers cannot offer prolonged cardiopulmonary support, mechanical device therapy, or perform organ transplantation. As one of the busiest ECMO centers in the Southwest United States (N=35 for 2012), our facility has been consulted regarding ECMO dependent patients who require advanced organ failure therapy, and the present study describes our experience providing interfacility transport for these patients.

Methods: Since 2006, we performed interfacility transport for 10 ECMO dependent patients. We retrospectively reviewed the medical record of these patients.

Results: Indication for ECMO was respiratory failure in 2 and cardiac failure in 8. Median age was 44 years (range 0.02 – 85 yr), and 8 were female. ECMO had been initiated by the referring facility in 5 patients. 3 patients failed to wean from cardiopulmonary bypass, and were placed on ECMO by our transport team while still in the operating room. For 1 case, ECMO was initiated in the ICU of the referring facility by our transport team. 8 patients were transported via ground, with a median transport distance of 5.6 miles (range 4.3 – 116 miles). 2 patients were located 243 and 209 miles away, and were transported via airplane. There were no untoward events during transfer. 4 (40%) patients died prior to hospital dismissal.

Conclusion: Air and ground transport of ECMO dependent patients is safe and effective. Collaboration with a center that offers robust cardiopulmonary support expertise may allow a center without these services to consider them for their patients. While there have been spectacular successes, enthusiasm should be tempered due to the high mortality associated with this critically ill cohort.
ANTITHROMBIN USE IN ADULT ECMO PATIENTS IS ASSOCIATED WITH A REDUCTION IN BLOOD PRODUCT USAGE
Paul E Nolan,1 Molly E Oldeen,2 Mary C Smith,3 Zain I Khalpey,3 Grant H Skrepnek,1 Douglas F Larson.2,3 Pharmacy Practice and Science, University of Arizona, Tucson, AZ; 2Pediatric Cardiac Surgery, Mater Children’s Hospital, South Brisbane, Queensland, Australia; 3Surgery, University of Arizona, Tucson, AZ.

Purpose: of Study: Clotting and bleeding complications remain problematic in adult ECMO patients. Heparin is generally used to minimize clotting. However, heparin’s anticoagulant activity is largely dependent upon adequate levels of antithrombin (AT). The purpose of this study was to compare requirements for selected blood products administered to adult patients supported by ECMO and supplemented with AT (i.e., plasma-derived) to those not supplemented with AT.

Methods: This was a single center study of adult patients requiring ECMO and supplemented (n = 35) or not supplemented (n = 6) with AT. Demographic, laboratory and clinical results, as well as requirements for PRBCs, Platelets and FFP, were prospectively collected and retrospectively compared. Student t-test was used to compare continuous variables whereas the Chi Square test was used to compare categorical variables. P value < 0.05 was considered to be statistically significant. This study was approved by the IRB of the University of Arizona.

Summary of Results: Patients supplemented with AT required significantly fewer units of PRBCs as compared to those not supplemented with AT (2.81 ± 0.30 PRBC units/day vs. 7.02 ± 1.25, p = 0.00002). Platelet transfusions were also significantly fewer in patients receiving AT (0.77 ± 0.17 vs 2.93 ± 0.37, p = 0.00003). In addition, units of FFP administered to patients receiving AT were significantly less (1.11 ± 0.21 vs. 4.61 ± 1.26, p = 0.00001).

Conclusions: Supplementation of AT in adult ECMO patients appears to reduce patient requirements for PRBCs, platelets and FFP. Clinical and economic outcomes need to be studied as a function of the use of AT.

A WIRELESS ULTRA-COMPACT PULSATILE DRIVER FOR CONTINUOUS FLOW LEFT VENTRICULAR ASSIST DEVICES
Sam Asgari, Pramod Bonde. Artificial Heart Laboratory, Yale School of Medicine, New Haven, CT.

Purpose: The durability afforded by frictionless, single moving part technology is undermined by a steady attrition in survival related to infections, aortic incompetence GI/intracerebral bleeds due to non-physiological flow and externalized components. We have previously demonstrated the feasibility of wireless power systems (FREE-D system), in the current investigation, we demonstrate creating physiological conditions in terms of flow and pulse pressure with a user friendly graphic interface.

Methods: The HVAD pump (HeartWare Inc) was connected to a wireless driver (WD), Fig 1. We employed signal processing and filtering methods to further analyze the received data. Pulsatility was achieved by changing the LVAD speed during cardiac cycle. Flow was estimated by changes in power and speed (validated by Transonic probe).

Results: The system proved to be remarkably safe, accurate and efficient. Fig 1 shows that the WD can produce the same pump speed and flow rate at a lower power than the HVAD controller and allows pulse pressure/flow adjustment.

Conclusions: We have demonstrated the versatility of a driver that can create physiological flow. Combining wireless powering and communication abilities of this ultra-compact driver with the durability of a single moving part pumps has the potential to prolong patient survival and overall acceptance of this technology. (Figure 1)
INTRA-OPERATIVE COAGULATION-BASED HEMOTHERAPY PROTOCOL DECREASES OVERALL BLOOD UTILIZATION WITH LEFT VENTRICULAR ASSIST DEVICE IMPLANTATION

Elena Nedelcu,1 Igor D Gregoric,2 Rajko Radovancevic,1 Kerry Welsh,1 Yu Bai,1 Kimberly K Klein,3 Biswajit Kar,2 Pranav Loyalka,2 Manish Patel,2 Ovidiu Moise,2 Nghia D Nguyen,1,3 Department of Pathology and Laboratory Medicine, University of Texas HSC at Houston - Memorial Hermann Hospital Texas Medical Center, Houston, TX; 2Center for Advanced Heart Failure, University of Texas HSC at Houston - Memorial Hermann Hospital Texas Medical Center, Houston, TX; 3Department of Cardiovascular Anesthesia, University of Texas HSC at Houston - Memorial Hermann Hospital Texas Medical Center, Houston, TX.

Background: Bleeding complications and blood transfusion administration are associated with increased morbidity and mortality after major cardiac surgery. We developed an intra-operative algorithm for transfusion support using integrated analysis of functional hemostatic assay results and transfusion triggers.

Methods: We reviewed medical records of patients who underwent left ventricular assist device (LVAD) implantation at our center from May 2012 to January 2013 and received intra-operative coagulation-based hemotherapy. Recommendations for transfusion were sequentially made in four operative phases based on integrated analysis of laboratory data, including CBC, DIC panel, antithrombin III, VerifyNow-P2Y12, VerifyNow-ASA, and thromboelastography. Blood transfusion requirements were recorded for each case and transfusion rates were compared with published data.

Results: The coagulation-based hemotherapy protocol was applied to 17 patients who underwent LVADs implantation over the study period. Patients received an average of 5.9±4.5 RBC units, 5.3±3.3 FFP units, 2.3±1.6 platelet doses and 0.2±0.4 cryoprecipitate doses intraoperatively and less than 2 total blood products within the post-operative 48-hour period (0.8±1.8 RBC units, 0.2±0.93 FFP units, 0.6±1.9 platelet doses and 0.1±0.2 cryoprecipitate doses). The cumulative transfusion rate of patients undergoing this protocol was 15.4 units, much lower than the previously published transfusion rate of 37 or 91.3 units.

Conclusion: Coagulation-based hemotherapy protocol developed at our center effectively decreases blood transfusion requirements with LVAD implants.

VENTRICULAR WORK AS A FUNCTION OF MVAD® PUMP SPEED: A COMPARISON BETWEEN HEALTHY AND ACUTE HEART FAILURE MODELS

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Purpose: This study characterized left ventricular work as a function of pump speed in animals implanted with the HeartWare MVAD Pump. The pump parameters and native heart response were compared in healthy and acute heart failure (HF) porcine models.

Methods: The MVAD Pump was implanted as a BVAD in 2 healthy and 2 HF porcine models. Acute heart failure was induced in animals via ligation of the LAD. Flow probes (Transonic Systems Inc.) and PV catheters (CD Leycom™) were placed to measure pump outflow and left ventricle parameters. Pump rotational speed was increased from 10K to 20K RPM in increments of 1K RPM. Stroke work and dP/dt were calculated. A standard correlation using a second order polynomial model and a one-way ANOVA analysis were performed to determine correlation and statistical significance between speed, stroke work, and dP/dt in both models.

Results: There is a strong correlation between pump speed and stroke work, as well as pump speed and dP/dt in both animal models. The statistical analyses performed yielded p values < 0.001 and R² values > 0.900 for the two models studied.

Conclusion: This preliminary data indicates a correlation between pump rotational speed and left ventricular unloading in healthy, and to a higher degree, in HF animal models. (Figure 1)

CAUTION: Investigational device. Limited by United States law to investigational use.
CIRCADIAN RHYTHM IS ONE OF THE FACTORS INFLUENCING THROMBUS FORMATION IN AN EXTRA-CORPOREAL LEFT VENTRICULAR ASSIST DEVICE

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1Department of Thoracic and Cardiovascular Surgery, Graduate School of Medical Science, Saga University, Saga, Japan; 2Department of Thoracic and Cardiovascular Surgery, Faculty of Medicine, Saga University, Saga, Japan.

Purpose: Although the usage of implantable LVADs became a standard practice, extra-corporal LVAD provides an opportunity to observe thrombus formation in the pump. The purpose of this study was to elucidate the factors influencing the thrombus formation. We especially focused on a circadian rhythm of the thrombus formation, because we had had an impression of seeing larger thrombus early in the morning. Methods: We retrospectively studied an extra-corporal pump (NIPRO LVAD) used for a 27-year-old man with dilated cardiomyopathy. We obtained sketches of the thrombus attached to the pump membrane. These sketches were done 3 times a day (day, night and early morning). From July 2009 to September 2010, we scanned 963 sketch records of thrombus in the LVAD pump. We then measured the area of the thrombus with commercially available software and expressed as percentages compared to the entire area of the device membrane. We also examined the correlations between thrombus area and PT-INR, platelet count (plt), C-reactive protein level, white blood cell count (WBC) and fibrinogen level. Results: There were significant correlations between thrombus area and PT-INR (p=0.002), plt (p=0.004), and WBC (p=0.013). Thrombus area was significantly larger (p=0.038) early in the morning (2.08%), compared to the area at night(1.77%), which indicated the presence of circadian rhythm. Conclusion: The thrombus area in the LVAD pump was influenced dynamically with coagulation and inflammatory properties. In addition, circadian variation in thrombus formation was observed, which warrants further understanding of circadian rhythms in the patients with LVADs.

HEART ASSIST 5 LEFT VENTRICULAR ASSIST DEVICE EXPERIENCE IN TURKEY

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Background: Fifty- six Heart Assist 5 (Micromed Cardiovascular Inc, Houston, TX) LVAD pts had been implanted since 5/2009 worldwide. Methods: We evaluated 5 Heart Assist 5 LVAD pts with two and three-dimensional TTE and TEE parameters between 11/2011 and 11/2012. The pre-op TTE; the quantification of LV and RV function, presence of AR MR and PFO, peri-operative TEE; inflow cannula, septum position, the surgical results of LVAD implantation. The mean age of the pts; 52±13 (34-64) yrs, CI; 2.04±0.4 (1.5-2.6) L/min/m², the mean CO; 3.7±0.7 (2.6-4.2)L/ min, the mean EF; 23±5 (18-28)%; RVFAC; 43±9 (35-55)%.

Results: One patient had AVR during LVAD implantation, had excess current alarms and increased power which was suspected for possible thrombus. The close follow-up with TTE to clear LV for thrombus formation and inflow cannula position maintain the septum in midline position preventing the suction cascade. (Figure 1)

One patient had been supported for more than 1 year, 2 pts supported more than 8 months, and the other 2 pts supported 2 months. Follow-up speed change studies of 4 patients showed that the mean speed; 9800±600 (9500-10400) rpm, the mean CO;4,7±0,3 (4.3-5.0) at post-implant 3 month.

Conclusion: We believe that TTE has major role for managing LVAD patients for optimal settings. Large series is mandatory for the assessment of echocardiographic studies of Heart Assist 5 LVAD.

ASAIO CARDIAC ABSTRACTS
EFFECTIVE PERIOPERATIVE BILIRUBIN PLASMA- ADSORPTION IN A TOTAL ARTIFICIAL HEART RECIPIENT: REPORT OF THE FIRST CLINICAL APPLICATION

Marrianna Buonocore,1 Cristiano Amarelli,1 Claudio Marra,2 Gianpaolo Romano,1 Ciro Maiello,1 Manuela Angelone,2 Antonio De Pietro,3 Nicola Galdieri,1 1Cardiothoracic and Respiratory Sciences, Second University of Naples, Naples, Italy; 2Cardiovascular Surgery and Transplants, Monaldi Hospital-Azienda Ospedaliera dei Colli, Naples, Italy; 3Intensive Care Unit in Cardiac Surgery, Monaldi Hospital-Azienda Ospedaliera dei Colli, Naples, Italy.

Total artificial heart (TAH) replaces the heart with 2 pneumatic pumps and 4 tilting disk mechanical valves. It was hypothesized that patients receiving TAH support have persistent hemolysis that resolves after heart transplantation (HT). In the acute postoperative phase bilirubin overload related to hemolysis may be detrimental in patients with multiorgan insufficiency.

Out of 3 implant of TAH in a single center experience 2 patients had significant hemolysis in postoperative course. In a 68 years old man, with preoperative stage III renal insufficiency, early hepatic dysfunction and severe pulmonary hypertension, we registered 3 days after TAH implantation a severe increase in bilirubin level suspected for sepsis, biliary obstruction or ongoing liver dysfunction. Examinations disclosed significant hemolysis and systemic inflammation with positive blood cultures. Antibiotic therapy was promptly started and after 2 days of progressive increase of bilirubin (>20mg/dl) compassionate plasma absorption was instituted. We performed five plasma absorption treatments, lowering bilirubin levels after each session. Absorption therapy was stopped on the 11st post-operative day with bilirubin 12.1mg/dl. Renal and hepatic functional parameters rapidly returned to normal ranges and after 58 days the patient was discharged in rehabilitation regimen. The patient is now on waiting list for HT, bilirubin level is 1.6mg/dl with a slightly low apotoglobin and an increased LDH level.

Peri-operative hyperbilirubinemia may be detrimental after TAH implantation, temporary plasma absorption treatment may preserve organs from its toxic effects.

BIOCOMPATIBILITY PROFILE COMPARISON BETWEEN AN INTEGRATED PEDIATRIC PUMP-LUNG (PEDIPL) AND A PEDIATRIC AXIAL FLOW VENTRICULAR ASSIST DEVICE (VAD) IN AN OVINE MODEL

Yang Liu,1 Shuqiong Niu,1 A Claire Watkins,1 Pablo G Sanchez,1 Robert Jarvik,2 Stephen Franklin,1 David Vaifades,1 Zhongjun J Wu,1 Bartley P Griffith,1

1Department of surgery, University of Maryland School of Medicine, Baltimore, MD; 2Jarvik Heart, Inc., New York, NY.

The large surface area of hollow fiber membranes in the integrated pediatric pump-lung device has been a major concern for its long-term biocompatibility and durability. In this study, the biocompatibility profile was compared between the newly developed PediPL and an axial flow VAD with a much smaller blood contacting surface in the thirty-day study duration in a juvenile ovine model. The PediPL and Jarvik 2000 infant VAD were implanted in six juvenile sheep for 30 days and 60 days, respectively. Blood biocompatibility of the two devices in the animals was compared for the first 30 days. Measures of biocompatibility included plasma free hemoglobin (PFH), platelet activation, liver function, renal function and blood count. There was no significant difference in PFH levels between the PediPL and VAD groups (10.45 ± 6.53 vs. 11.47 ± 5.60 mg/dL, p>0.05). Platelet activation was higher in the VAD group than in the PediPL group at 2 hours after implant surgery (8.74±2.23 vs 4.23±2.60, p<0.05) and at the first post-operative day (8.93±2.41 vs. 3.99±2.47, p<0.05). However, there was no significant difference between the two groups thereafter. There was no significant difference in tests of liver and kidney function (ALT, AST, BUN and creatinine) between the two groups at any time point (p>0.05). All values were within the normal ranges. In summary, there was no significant difference in the biocompatibility profile between the PediPL and VAD groups. The results from this study suggest that a large blood contacting surface area of the PediPL did not impart negative effect towards the device biocompatibility.
ANALYSIS OF A NEW ALGORITHM FOR GASTROINTESTINAL BLEEDING (GIB) IN VAD PATIENTS; A FASTER, CHEAPER WAY FOR DIAGNOSIS AND TREATMENT

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Purpose: GIB has a reported incidence of 18%-40% in patients receiving therapy on ventricular assist devices (VAD). With the introduction of non-pulsatile VADs, clinicians will increasingly have to face this diagnostic and therapeutic challenge. We implemented a new algorithm for management of GIB in VAD patients focused on deep bowel enteroscopy (DBE) being performed within 24 hours of presentation. We then reviewed the cost effectiveness of adhering to our algorithm in comparison to the standard one used today.

Methods: 84 patients underwent VAD placement of which 59 were non-pulsatile. 45 individual GIB episodes were observed and were separated into two groups. Group 1: GIB managed with a standard protocol that did not follow our algorithm. Group 2: GIB episodes that followed our algorithm. Total number of tests performed, transfusions administered, and hospital charges were compared between the two groups.

Results: GIB episodes where our algorithm was followed (Group 2) underwent less procedures and received less transfusions compared to Group 1. (Table 1)

<table>
<thead>
<tr>
<th>Results</th>
<th>Group 1</th>
<th>Group 2</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ave # of Procedures</td>
<td>3</td>
<td>1.14</td>
<td>p &lt; 0.05</td>
</tr>
<tr>
<td>Ave # of PRBC</td>
<td>4.95</td>
<td>1.29</td>
<td>p &lt; 0.05</td>
</tr>
<tr>
<td>Ave Cost per Episode ($</td>
<td>5013</td>
<td>2002</td>
<td>p &lt; 0.05</td>
</tr>
</tbody>
</table>

The total charges for the diagnosis and treatment of GIB is $6000 lower per episode when patients followed our DBE focused algorithm.

Our new algorithm for the diagnosis and treatment of GIB in VAD patients based on the performance of DBE at the onset of bleeding allows for a more rapid diagnosis and treatment. Following the algorithm results in fewer transfusions, fewer diagnostic tests and a substantial cost savings per episode of bleeding.

SINGLE CENTER EXPERIENCE ON DIFFERENT ANTICOAGULATION PROTOCOLS IN THE MANAGEMENT OF VENO-ARTERIAL ECMO

Cristiano Amarelli,1 Angelo Caiazzo,2 Giuseppe Petrone,3 Gianpaolo Romano,1 Claudio Marra,4 Antonella Capasso,4 Nicola Galdieri,2 Ciro Maiello,1 1Cardiovascular Surgery and Transplants, Monaldi Hospital-Azienda Sanitaria dei Colli, Naples, Italy; 2Intensive Care Unit in Cardiac Surgery, Monaldi Hospital-Azienda Sanitaria dei Colli, Naples, Italy.

ECMO is an effective strategy to warrant an optimal peripheral perfusion in acute cardiogenic shock (ACS). Coagulative disorders, Ventilator Associated Pneumonia and infectious complications are the most common causes of death in such patients. Use of bivalirudin has been advocated to avoid heparin induced thrombocytopenia and its complications but there are not enough data to support this policy.

In a tertiary care center for Heart Transplantation (HT) and Cardiovascular Surgery during the last three years 22 pts were implanted with Levitronix ECMO (20 central and 2 peripheral cannulation) and treated either with bivalirudin (10 pts) aiming to reduce coagulative disorders or with heparin (12 pts) for short support. All patients were extubated immediately after implantation whenever neurologically feasible. Weaning was performed according to the Aissouli’s criteria at minimal ECMO flow.

The indication for ECMO were 9 Primary Graft Failures, 4 post-cardiomyopathy, 5 acute complications of myocardial infarction and single cases of Acute Myocarditis, Acute Rejection and ACS.

ECMO was always successful to warrant optimal perfusion. Significant bleedings were shown (3 pts) only in the heparin groups. One ECMO (postcardiomyotomy) was futile due to Cerebral Anoxia. Three patient underwent successful HT and 3 patient underwent Interventricular Septum Closure. Mortality on ECMO was 25%. Hospital mortality was 40%, in 3 cases due to poor residual myocardial function after effective weaning.

A novel approach in the management of ECMO based on bivalirudin reduces bleedings and coagulative complications, although hospital mortality remains still high due to the poor preoperative conditions.
ASSESSMENT OF ANTICOAGULATION MANAGEMENT AS A MEASUREMENT OF PUMP THROMBUS RISK

G Andrew Wright, Abdullah G Kfouri, Sean P McCandless, Renee A Merchel, Annicka K Carter, Sandi Stoker, Bruce B Reid, William T Caine, Stephen E Clayson, Rami A Alharethi. Artificial Heart Program, Intermountain Medical Center, Salt Lake City, UT.

Background: Thrombosis in left ventricular assist device (LVAD) patients is a serious complication and must be detected quickly to ensure patient safety. Systemic anticoagulation and antiplatelet medications are used to decrease this risk. The aim of our study was to determine any correlation between either the percent of time patients spend within therapeutic INR range (%TTR) or Aspirin dose (ASA) and HeartMate II LVAD thrombosis at our center.

Methods: The Artificial Heart Program was queried for HeartMate II LVAD explants from 2010 to 2012. Patients were stratified into two groups: Group 1) those without a confirmed clot and Group 2) those with a confirmed clot. Laboratory values, ASA and comorbidities were collected. %TTR for each patient was calculated using the Rosendaal method. All statistics were performed by using a two sided Student’s t-test (p-value<0.05 was significant).

Results: 24 patients qualified for the study. Of these, 8 patients had confirmed pump thrombosis. All patients were on ASA and both groups had similar rates of comorbidities. Of all statistics performed, only LDH upon admission for explant was significant. (Table 1)

<table>
<thead>
<tr>
<th>Group1(n=16)</th>
<th>Group2(n=8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age(mean)</td>
<td>n=5±3D</td>
</tr>
<tr>
<td>Male(%)</td>
<td>84</td>
</tr>
<tr>
<td>INR</td>
<td>1.7±1.25</td>
</tr>
<tr>
<td>Mean Support(day)</td>
<td>2.0±0.19</td>
</tr>
<tr>
<td>%TTR</td>
<td>51±4.4</td>
</tr>
<tr>
<td>Time INR&lt;2.0</td>
<td>41±15.4</td>
</tr>
<tr>
<td>LDH</td>
<td>870±318</td>
</tr>
<tr>
<td>% with 325 mg dose ASA</td>
<td>60 75</td>
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</tbody>
</table>

Conclusion: There appears to be no correlation between %TTR or ASA dose with risk of thrombus formation. A larger sample study is needed to evaluate %TTR and other risk factors for HeartMate II pump thrombosis.

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</table>

SYN CARDIA TOTAL ARTIFICIAL HEART PATIENT SUPPORTED MORE THAN 700 DAYS IN TURKEY

Deniz Suha Kucukkalou,1 Erman Pektok,1 Zumrut Tuba Demiroz,1 Nurcan Arat,1 Ferahe Ece,1 Cavlan Ciftci,1 Osman Bayindir,1 Nurcan Yazicioglu,1 HEART TRANSPLANTATION MCS, Sisli Florence Nightingale Hospital; 2 CARDIOLOGY HEART FAILURE, Sisli Florence Nightingale Hospital; 2 PULMONARY DISEASE, Sisli Florence Nightingale Hospital; 4 ANESTHESIA ICU, Sisli Florence Nightingale Hospital.

Background: The SynCardia Total Artificial Heart (SynCardia Systems Inc, Tuscon, Arizona) TAH-t has been implanted worldwide as a BTT. Our aim is to present first Turkish TAH-T patient who had been supported more than 700 days as an out-patient. Method: 45-year-old gentleman had idiopathic cardiomyopathy. He admitted to our hospital with severe biventricular failure with INTERMACS level I-II. At February 2011, his echocardiographic and cardiac catheterization was; his EF was 20%, LVEDD was 84mm, LVESD was 72mm, severe mitral, aortic and tricuspid regurgitation, sysPAP was 70mmHg, his CI was 1.9L/min/m², PCWP was 34 mmHg. He had SynCardia TAH-T implantation March 2011. He was extubated at post-op 4th day and was discharged from hospital post-op 50th day with portable Freedom Driver. The patient was 90 kg when he was discharged and gained weight, was 130 kg during last 2 year period.

After several consultations he was planned to have gastric by-pass surgery to lose weight to be able to have a donor heart. Results: He is the longest supported TAH patient more than 700 days in Turkey. His end-organ function recovered after implantation of TAH and made him available to have a donor heart. Conclusion: We believe that TAH-T support save life of end-stage heart failure patients who weren’t candidate for left ventricular assist device (LVAD) and give them a hope for future.
ARTERIAL PRESSURE ACCOMMODATION TO POSTURAL CHANGES IN CALVES IMPLANTED WITH A CONTINUOUS FLOW TOTAL ARTIFICIAL HEART

Steven M Parnis, William W Cohn, Aaron Palmer, Fernando Reyes, Kelly M Handy, Jo A Winkler, OH Fraizer. Center for Cardiac Support, Texas Heart Institute, Houston, TX.

Purpose: Short-term autonomic response for the adaptation of arterial pressure (AoP) is intended to correct temporary imbalances in pressure associated with postural change. The ability of the baroreceptor system to maintain constant arterial pressure may be altered by the elimination or reduction in pulse pressure in calves implanted with continuous flow total artificial hearts (CFTAH). We measured AoP in calves implanted with a CFTAH to observe the difference in arterial pressure and the time for the AoP to return to baseline during a change in posture from a lying to standing position. Methods: In a series of calves we observed and measured AoP, right and left filling pressures (LAP,RAP) and right and left pump flows throughout the duration of studies for up to 92 days in calves with a CFTAH. Results: Over the course of each study, large variations (p) in AoP (30-50 mmHg) and LAP (10-15 mmHg) were observed during postural changes from lying to standing positions, but very little change from standing to lying positions. Throughout postoperative week one, arterial pressure recovery time (AoP before standing until stable AoP was achieved) varied from 2-13 minutes, and over time the p decreased (15-30 mmHg) with faster recovery times (2-5 minutes). Recovery times varied for each animal and were not consistent. Conclusion: In calves implanted with a CFTAH, a large decrease in AoP was measured from a lying to standing position in the first postop week. These changes markedly reduced over time possibly indicating a resetting of the baroreceptor system and a compensation for the elimination of a pulse pressure following implantation of a CFTAH.

APPLICATION OF EXTRACORPOREAL MEMBRANE OXYGENATION DURING SYNCardIA TOTAL ARTIFICIAL HEART IMPLANTATION

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Background: The SynCardia Total Artificial Heart TAH-t (SynCardia Systems Inc, Tuscon, AZ) has been used as a BTT. Methods: 61-year-old gentleman had ischemic cardiomyopathy and admitted to our hospital with severe biventricular failure with INTERMACS level I-II. His cardiac catheterization; PAP was 74/30 mmHg, CI was 1.3L/min/m², and his EF was 15% and TAH implantation at March 2011. While weaning from CPB, the TAH-t was allowed to take over patient’s circulation. After single strokes, a significant amount of fluid was noted in his endotracheal tube. Despite the addition of positive end-expiratory pressure and maximization of ventilator support. The patient continued to have large amount of fluid in his endotracheal tube with PaCO2 of > 80 and PaO2 < 40 mmHg. The patient was re-heparinized, ECMO was connected to cannulas via right and left femoral veins. The ECMO circuit consisted of Centrimag Blood Pump (Levitronix, Waltham, MA). ECMO support was run 2.5 to 4.0 L/min with target TAH-t support 1.5 to 2.5 L/min. His ECMO support was weaned at post-op 7th day. (Figure 1)

He was supported with TAH-t for more than 30 days and died from sepsis and multi-organ failure. Conclusion: The use of ECMO during implantation of a TAH-t may improve patient outcomes, provide oxygenation and a safe circulatory support in emergent cases of hemodynamic instability and respiratory failure.
LINEARLY ACTUATED VOLUME DISPLACEMENT PUMP FOR VENTRICULAR ASSIST

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A linearly actuated piston pump (LAPP) is being developed for potential use as a ventricular assist device (VAD). Rotary blood pumps (RBP), either axial or centrifugal flow, have replaced earlier generations of volume displacement (V-D) VADs. RBPs are attractive because of their small size and durability. However, they are associated with gastrointestinal hemorrhage and aortic valve insufficiency. A small V-D pump that provides physiologic pulsatile flow with low shear forces acting on the blood may avoid or minimize these complications.

This device promises durability with only one moving part and two 19mm b-leaflet valves. These advancements make this pump an improvement from earlier V-D VADs. The LAPP can be used to study arbitrary pulse waveforms, with adjustable acceleration and deceleration. The ejection volume (EV), waveform, and ejection rate (ER) can be adjusted to accommodate a wide range of physiologic conditions. In its present form, EV ranges from 20-50 mL per beat with an ER of 100 bpm. In addition to providing the necessary flow, the LAPP must be minimally hemolytic.

Two initial in vitro tests were performed: HeartMate I (control) and LAPP. The custom mock loop had two thin-wall silicone compliance chambers each with relaxed volumes of 200 mL in series with the LAPP. Flows and differential pressures were measured and found to be within physiologic ranges. Modified index of hemolysis (MIH) for the HeartMate I was 11.7±7.12, while MIH for the LAPP was 35.2±6.11. Future work is ongoing to increase the electromechanical efficiency of the device, miniaturize the controller, and lessen hemolysis.

INCIDENCE AND CHARACTERISTICS OF VASCULAR COMPlications WITH SHORT-TERM VAD SUPPORT

Annicka K Carter, James Revenaugh, Renee A Merchel, Bruce B Reid, William T Caine, Sean P McCandless, Stephen E Clayson, GA Wright, Brad Rasmussen, Sandi Stoker, Deborah Budge, Rami A Alharethi, Abdullah G Kfouri, Mechanical Circulatory Support, Intermountain Medical Center, Salt Lake City, UT.

Background: Short-term ventricular assist devices (VADs) can support patients through high risk cardiac procedures and it is vital to have the appropriate cannula size to provide adequate flow; cannula size potentially increases risk for limb vascular complications. This study comparatively examines temporary VAD cases to characterize vascular complications at our center. Methods: The Artificial Heart Program database was queried for short-term VAD patients between June 2007 and Oct 2012. Femoral inserts and patients with no recorded cannula size were censored. Bleeding or ischemia caused by the VAD cannula was collected. Cannula size was normalized to the patient’s body size by dividing cannula gauge by body surface area. Analysis of vascular complication was completed using a Student’s t-test. Results: 65 patients were included. 31% received a TandemHeart®, 29% Centrimag®, 18% Impella®, 17% RotaFlow®, and 5% Biomedicus®. Vascular complications occurred in 7 patients (2 limb ischemia, 1 arterial occlusion, and 4 hemorrhages). (Table 1)

Conclusion: In this exceedingly high-risk population, lower limb vascular complications occur infrequently and don’t seem to be affected by VAD type or cannula size. When indicated, adjusting cannula size for each patient’s body surface area seems appropriate and relatively safe.
REPAIR OF LEFT VENTRICULAR ASSIST DEVICE DRIVELINE DAMAGE DIRECTLY AT THE TRANSCUTANEOUS EXIT SITE

Heinrich Schima,1,2,4 Martin Stolber,1,2 Thomas Schloeglhofer,2,4 Zeno Hartner,1 Thomas Haberl,1 Daniel Zimpfer,2,3 1Center of Med. Physics and Biomed. Engineering, Med. Univ. Vienna, Vienna, Austria; 2Dept. of Cardiac Surgery, Med. Univ. Vienna, Vienna, Austria; 3Ludwig-Boltzmann-Cluster for Cardiovasc. Research, Vienna, Austria.

Purpose: Transcutaneous drivelines remain a weak spot of the therapy. First, they can get an entry point for infections, and second cable lesions and even electrical failures due to material fatigue and eventual carelessness can occur. In an HVAD patient, the outer driveline cable sheet ruptured directly at the exit site, where the standard repair procedure with self-fusing tape may lead to biocompatibility problems and irritation of the skin entrance. Therefore a new procedure was developed using a special sleeve expander tool and a highly expandable latex tubing to stabilize the defect in a flexible and biocompatible manner.

Methods: A patient experienced a fracture of the outer sheath of an HeartWare HVAD-driveline directly at the skin entrance (approximately 15 mm long, 5 mm distal from the skin). The metal strands and the electrical functionality were not affected, therefore a pump exchange was not indicated. After considering several conventional solutions for repair as not applicable, a new approach was developed: A sleeve expander tool was applied, which allowed radial stretching of the latex tubing. After preparations of the tool and the cable site, the pump was briefly disconnected, the tubing moved over the connector and released at the site of fracture.

Results: The problem could be solved keeping the cable’s flexibility and without additional risks for the skin. Within a yet three months (ongoing) follow-up the skin entrance returned to perfect condition.

In conclusion, this method allows a quick stabilization and repair of damaged driveline isolation near the exit site, resulting in a biocompatible surface and consistent flexibility of the cable.

CLINICAL COMPARISON OF THE CENTRIMAG® AND THE ROTAFLOW® CENTRIFUGAL FLOW DEVICES

Annicka K Carter, Shane S Froebel, Bruce B Reid, Sean P McCandless, Renee A Merschel, GA Wright, Mark Goddard, Stephen E Clasoy, Rami Alharethi, William T Caine, Deborah Budge, Brad Rasmussen, Sandi Stoker, Abdallah G Kfoury. Artificial Heart Program, Intermountain Medical Center, Salt Lake City, UT.

Background: The Centrimag (CM) has been proven safe and effective for cardiopulmonary support (CPS). The RotaFlow (RF) is a centrifugal pump that costs our center only 2% of the price of the CM and has been shown in model studies to have better mechanical performance. This study aims to compare the clinical outcomes of patients on each device.

Methods: The Artificial Heart Program database was queried for CPS centrifugal pump patients from 2008 to Jan 2013 and stratified by device. Baseline demographics and outcomes were collected. To determine pump efficiency we divided pump speed by flow and measured levels of plasma-free hemoglobin. To compare, a two-sided Student’s T-Test and Kaplan-Meier survival and log-rank analysis were used (p-value<0.05 significant).

Results: Fifty-eight patients qualified. The average age and % male were 55±16 years and 60%. Both groups had similar profiles. 59% of the CPS cases were inserted femorally. Both groups had comparable transitions to durable VAD (RF 16.7%, CM 12.8%) and heart transplant (RF 16.7%, CM 10.3%). No significant differences were found. (Table 1)

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>RotaFlow (n=10)</th>
<th>Centrimag (n=48)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plasma Free Hemoglobin (mg/dL)</td>
<td>10 ± 7.8</td>
<td>11 ± 25.1</td>
<td>0.37</td>
</tr>
<tr>
<td>Pump Efficiency (rpm/ml/L)</td>
<td>846 ± 109</td>
<td>930 ± 195</td>
<td>0.18</td>
</tr>
<tr>
<td>Vascular Complications (%)</td>
<td>11.1</td>
<td>7.5</td>
<td>0.66</td>
</tr>
<tr>
<td>F/HOF 1 week post</td>
<td>7.5 ± 7.7</td>
<td>6.4 ± 6.4</td>
<td>0.58</td>
</tr>
<tr>
<td>Morbidity (%)</td>
<td>56.0</td>
<td>51.3</td>
<td>0.76</td>
</tr>
</tbody>
</table>

Conclusion: The comparison of the two devices suggests that the RF matches both the clinical performance and pump efficiency of the more established CM. Because the RF is less expensive, this analysis may suggest it is a more economical option.
THE DEVELOPMENT OF A MINIATURISED MYOCARDIAL ANALYSIS SYSTEM AS A NOVEL EXPERIMENTAL TECHNIQUE FOR HEART TISSUE RESEARCH
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Purpose: A novel micro total analysis system, the MMAS, has been developed to maintain human heart tissue in a biomimetic environment closely correlating with the actual in-vivo conditions, harnessing the inherent advantages of microfluidic technology. "Lab on a chip" or miniaturisation analysis systems are becoming a recognised technique in translational medicine. Methods: Right atrial tissue was dissected to a 2x2x2 mm3 size, and placed in the MMAS. The tissue was perfused with buffer, at 37°C. The tissue was equilibrated, and kept alive for 5 hours, finally being destroyed by a detergent, Triton X-100. The experiment was divided into three time periods: 0-100 minutes, the equilibration period; 100-300 minutes, the maintenance period; 300-360 minutes, the insult period. Tissue activity of Lactate Dehydrogenase (LDH), Creatine Kinase (CK), and aerobic metabolism were measured. Results: See Table 1.

<table>
<thead>
<tr>
<th>LDH and CK Activity Profiles</th>
<th>Equilibration Period</th>
<th>Maintenance Period</th>
<th>Insult Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>LDH activity (Um/l g tissue)</td>
<td>50-100</td>
<td>0-10</td>
<td>~100</td>
</tr>
<tr>
<td>CK activity (U/L) (p&lt;0.05)</td>
<td>0-500</td>
<td>0-50</td>
<td>50-700</td>
</tr>
</tbody>
</table>

The oxygen metabolism showed a drop in oxygen tension in the buffer, of between 1.5 and 5 kPa, as it flowed across the tissue; compared to the control, this was between 0.5 and 1.5 kPa in an empty MMAS (n=4). Conclusions: This is the first known demonstration of a micro total analysis system, the MMAS, to maintain human heart tissue. Preliminary evidence suggests that the system provides complementary experimental technology. The MMAS may be easily used to study other experimental conditions such as ischaemia/reperfusion injury and pharmacological drug testing.

HIGHER EXPRESSION OF AGNOR AND NOR ASSOCIATED PROTEINS IN BLOOD LEUKOCYTES OF HEART FAILURE PATIENTS SUPPORTED BY CONTINUOUS FLOW LEFT VENTRICULAR ASSIST DEVICES (LVADS)
Mubarak A Chaudhry,1 Mahmoud Loubani,1 Erik N Sorensen,2 Nicholas Hivlava,2 Erika D Feller,3 Bartley P Griffith,1 Zhongjun J Wu.1 1Department of Surgery, Artificial Organ Lab, University of Maryland School of Medicine, Baltimore, MD; 2Department of Clinical Engineering, University of Maryland Medical Center, Baltimore, MD; 3Department of Medicine, University of Maryland School of Medicine, Baltimore, MD.

Background: Leukocytes are cells of the immune system involved in defending the body against both infectious disease and foreign materials. High levels of argyrophilic nucleolar organizer region (AgNOR) and related proteins in blood leukocytes indicate abnormal cellular processes and altered functions. The aim of the study was to investigate the effect of LVAD implantation on expression of AgNOR proteins in blood leukocytes of heart failure (HF) patients. Methods: 9 HF patients implanted with continuous flow LVAD and 6 healthy volunteers were recruited for the study. Blood samples were collected from the volunteers and HF patients before and after LVAD implantation. AgNOR cytochemical staining and immunocytochemistry of nucleolar protein nucleolin and nucleophosmin in blood leukocytes were used to examine ribosome biosynthesis. Results: HF patients had higher AgNOR proteins in blood leukocytes than healthy volunteers. Significant increase was observed in the number of AgNOR dots per nucleus, their size, and the percentage of NOR-occupied nuclear area in circulating leukocytes of HF patients after LVAD implantation (p<0.01, compared with pre-LVAD patients). The amounts of nucleolar proteins were also higher among LVAD recipients. Spearman correlation analysis established a positive association between AgNOR values and post-operative follow-up time up to 3 months (r =0.429, p<0.01). Conclusions: Our result showed that LVAD may trigger immunologic response that increase AgNOR and NOR associated proteins in nuclei of blood leukocytes of HF patients indicating persistent inflammatory condition.

COMPARISON OF TWO IMPELLERS FOR THE JARVIK INFANT PUMP: A COMPUTATIONAL FLUID DYNAMIC (CFD) STUDY
Jiafeng Zhang,3 Katharine H Fraser,1 John Teal,1 Robert Jarvik,2 Bartley P Griffith,1 Zhongjun J Wu.1 1Surgery, Artificial Organs Laboratory, University of Maryland School of Medicine, Baltimore, MD; 2Bioengineering, Imperial College London, London, United Kingdom; 3Jarvik Heart Inc., New York, NY.

Although multiple ventricular assist devices (VADs) are available for adults with heart diseases, few VADs for children and infants have been developed. Because of the heart size, VADs for infants have to be much smaller than those for adults. The Jarvik 2000 infant VAD is being developed based on a tiny axial-flow blood pump with a size of an AAA battery, and a weight of 11 g. In this study, flow characteristics of the Jarvik infant VAD with two different impeller designs were analyzed with computational fluid dynamics. One impeller has taller blades (approximately 0.3 mm taller) and smaller stators than the other. The Jarvik infant VAD with two impellers were meshed by Ansys and simulated by Fluent 14.0 using k-ω(κ-omega) turbulence model. For the same rotating speed and flow rate, CFD simulations slightly under-predicted pressure differences between the inlets and outlets compared with the experimental results. Although the differences of the CFD predicted maximum velocities are less than 2% for the two impellers, the flow patterns are noticeably different. There are more recirculation zones in the area between blades and stators in the pump with the shorter blades, which may potentially increase blood damage. The overall scalar shear stress distribution showed negligible difference. The volumes with shear stress larger than 150 Pa in two pumps are similar (~4.7% of the total volume in the shorter blades pump and ~4.4% in the taller blades pump). In summary, the taller impeller blade design is preferred for the Jarvik infant VAD.
MODIFIED TANDEMHEART VENTRICULAR ASSIST DEVICE FOR PEDIATRIC CIRCULATORY SUPPORT

Development of pediatric ventricular assist device (VAD) circuits to accommodate lower flow rates and pressures has been challenging. We present the results of modifying a readily available adult VAD to support infants and children. We modified the TandemHeart VAD (CardiacaAssist, Pittsburgh, PA) circuit design to include a recirculation shunt with variable restriction to allow greater flow ranges in children. Flow rates and pressures were initially studied. (Figure 1)

<table>
<thead>
<tr>
<th>RPM</th>
<th>3/16” Short</th>
<th>1/4” Short</th>
<th>3/16” Short</th>
<th>1/4” Short</th>
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<tbody>
<tr>
<td>2500</td>
<td>2200</td>
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<tr>
<td>3500</td>
<td>2200</td>
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</tr>
<tr>
<td>5000</td>
<td>3700</td>
<td>4300</td>
<td>790</td>
<td>710</td>
</tr>
</tbody>
</table>

Hemolysis studies were performed using whole bovine blood to compare plasma free hemoglobin levels between modified and unmodified VAD circuits. The modified VAD was surgically implanted in 7 piglets (6-14kg) and supported them for 6 hours. End organ perfusion was monitored and the circuit was inspected for clot formation at study end. The modified VAD circuit did not increase levels of hemolysis and provided full hemodynamic support. It was subsequently used clinically on a 10kg patient with restrictive cardiomyopathy who was supported 5 days without complication until heart transplantation. Because of its simplicity, lower complication rates, greater patient flow range, and lower cost, centrifugal pumps such as the modified shunt TandemHeart VAD should be given consideration as alternatives to ECMO and standard pulsatile VADs in children.

VENO-VENOUS EXTRACORPOREAL MEMBRANE OXYGENATION SUPPORT AFTER TOTAL ARTIFICIAL HEART IMPLANTATION
Sean P McCandless, Bruce B Reid, Mark Goddard, Rami Alharethi, Deborah Budge, Sandi Stoker, Shane Froebe, Brad Rasmusson, William T Caine, G Andrew Wright, Annicka K Carter, Stephen E Clayson, Abdallah G Kfouri, Artificial Heart Program, Intermountain Medical Center, Salt Lake City, UT.

Purpose: The Syncardia™ total artificial heart (TAH) has been effective in providing biventricular circulatory support in patients until transplant with end-stage heart failure. We report a rare clinical occurrence in a patient after TAH implantation.

Report: A 31 year old male who underwent an aortic valve and aortic root replacement failed to wean from cardiopulmonary bypass and was managed on vено-arterial (VA) extracorporeal membrane oxygenation (ECMO) via central cannulation for 6 days. He was then implanted with a TAH due to prolonged failure of cardiac recovery. Preoperatively, there was concern that the patient’s pulmonary function would be inadequate secondary to acute respiratory failure and possible pulmonary vascular thrombosis. The TAH implantation was complicated by severe hypoxemia, which was unresponsive to positive end-expiratory pressures of 20 cm H2O and the use of nitric oxide. Veno-venous (VV) ECMO support was then initiated with a 31-French bi-caval dual lumen catheter inserted via the Superior Vena Cava. Pulmonary function gradually improved; VV ECMO weaning trials occurred where sweep was decreased from 8.0 to 0.5 liters per minute and ECMO FiO2 from 100% to 21% without any issues. On postoperative day (POD) 10, VV ECMO support was explanted, on POD 12, the patient’s chest was closed, and the patient was extubated on POD 37. On POD 87, the patient received a heart transplant with an uneventful postoperative course.

Conclusion: We were able to support a TAH patient with severe hypoxemia by VV ECMO. Therefore, we propose consideration of temporary VV ECMO support in patients undergoing TAH implantation who have severe but reversible lung injury.

A COST REDUCING ECMO MODEL: A SINGLE INSTITUTION EXPERIENCE
En Yaw Hong, Suzanne Wallace, Amy Tropea, Jaime Byrne, Hitoshi Hirose, Harrison T Pitcher, Nicholas C Cavarocchi. Division of Surgical Cardiac Care Unit, Department of Surgery, Thomas Jefferson University, Philadelphia, PA.

Background: The demand for ECMO support has grown. Its provision remains limited due to several factors (high cost, complicated technology, lack of expertise) which increase healthcare cost. Our goal was to assess if an ICU run ECMO model (without continuous bedside perfusion) would decrease costs while maintaining patient safety and outcomes. Method: We performed a retrospective review that analyzed the cost and safety benefits of a newly implemented ICU-run ECMO unit from 2011-2012. The program consisted of a dedicated ICU involving multidisciplinary providers (ICU RN, mid-level providers and intensivists). In year one, we introduced an education platform, new technology and dedicated space. In year two, the multidisciplinary providers (MDPs) adopted continuous bedside perfusion support. New management algorithms designating MDPs as first responders were established. The primary end point included total cost, while the secondary end points were the RN ratios and patients’ safety. We compared these parameters with the previous model. Results: During the study period, 75 patients were placed on ECMO (mean days: 10). The total hospital expenditure for the previous ECMO model was $623,070 compared to $302,328 respectively, showing a 46.8% decrease in cost. This cost decrease was attributed to a decreased utilization of perfusionist services and the introduction of longer lasting and more efficient ECMO technology. We did not find any significant changes in RN ratios or any differences in outcomes related to ICU safety events. Conclusion: We demonstrated that the ICU run ECMO model managed to lower hospital cost by reducing the cost of continuous bedside perfusion support with no loss in safety or outcomes.
AN EX-VIVO PERFUSION MODEL FOR VALIDATION OF NIRS OXYGEN SATURATION IN EXTRACORPOREAL SYSTEMS AND CORRELATED TO CLINICAL METHODS- ELIMINATING THE GUESS WORK

Jeffrey P Sites. Preclinical Translational Services, Wake Forest University Health Sciences, Winston Salem, NC.

Noninvasive sensor technology relying on Near Intra-red Spectroscopy (NIRS) is an important option for fast, accurate and portable applications to patients in both a hospital and a trauma environment. Testing of these devices under proper conditions to determine linearity and accuracy under a variety of conditions must include a means to control the device-tissue interface as well as the tissue environment and metabolism to develop a variable condition model that is reproducible.

NIRS technologies used for extracorporeal circulation are similarly limited being expected to mirror the tissue conditions via the blood path coming from the body and after the gas exchange interface of the blood oxygenator, represent arterial conditions returned to the perfused body. This presentation presents an ex-vivo model created to provide concise tissue and blood conditions perfusing an isolated muscle, using a new noninvasive, extracorporeal in-line metabolic monitor, and evaluating blood gas values under varying conditions every 3 minutes, and correlating this to an IL GEM 4000 blood gas machine with co-oximetry, over a 4-5 hour period. (Figure 1)

This model demonstrated that NIRS methodologies can be very accurate- in specific, the Spectrum Medical M3 monitor was found to be accurate to +/- 1% of laboratory controls.

EFFECT OF CANNULA IMPLANTATION SITE AND CARDIOMYOPATHY ETIOLOGY IN THE REMODELING HISTOPATHOLOGICAL CHANGES AT LEFT VENTRICULAR ASSIST DEVICE (LVAD) IMPLANTATION

Ana Maria Segura, Ibrahim Aboshady, OH Frazier, L Maximillian Buja. Texas Heart Institute, Houston, TX.

Purpose: We aimed to assess the impact of cannula placement site (apical/diaphragmatic) and cardiomyopathy (CMP) type (ischemic=I, non-ischemic=N) in histopathology at the time of LVAD implantation

Methods: We studied 60 LV samples from terminal heart failure patients with LVAD support. Computerized morphometry was used to evaluate the extent of fibrosis and hypertrophy (cytoplasmic diameter=CD; nuclear diameter=ND) according to cannula placement site and CMP type

Results: Thirty-one patients (21 men, 10 women; age 57±15 y) underwent apical implantation; 29 underwent diaphragmatic implantation (23 men, 6 women; age 53±12 y). Twenty-five (14/31 apical, 11/29 diaphragmatic) had history of ischemic CMP. Groups were comparable in regard to hemodynamic parameters, hypertension, diabetes. We found more fibrosis in all samples of ischemic CMP patients than non-ischemic patients (21.8%±16.6 vs15.0%±11.0, P=0.042). Apical cores from ischemic CMP patients were the most fibrotic. There were no significant differences in hypertrophy. (Table 1)

(Table 2)

Conclusion: Cannula placement site and CMP type should be considered when interpreting LV samples at LVAD implantation. Apical cores from ischemic patients are the most fibrotic samples. Diaphragmatic samples and N-I CM patients’ apical LV cores may provide a better substrate for structural remodeling analysis.

THE MVAD® PUMP: FLOW ESTIMATION THEORY OF OPERATION

Fernando Casas, Carlos Reyes, Justin Wolman, Jeffrey LaRose. Advanced Product Development, HeartWare Inc., Miami Lakes, FL.

Purpose: Flow estimation in sensorless axial flow blood pumps has been a known challenge in the field of mechanical circulatory support. The flow estimation theory of operation for the MVAD® pump was formulated and feasibility tested. Methods: The MVAD pump is a full output blood pump supported by a contactless passive hybrid hydraulic magnetic suspension system. In the MVAD pump, due to its unique suspension system, the impeller is allowed to move axially. The flow estimation strategy was developed using motor current and an additional degree of freedom derived from the impeller’s axial motion and expressed in the motor’s Back Electromotive Force (BEMF). The behavior of the BEMF is non-linear however single-valued with respect to flow. The BEMF was used in conjunction with the motor current to provide average flow estimates throughout the operating range of the MVAD. Measured flow was mapped via performance tables to motor current and BEMF values for a range of viscosities, pump speeds, and flows. Preliminary testing was conducted in an instrumented mock loop running a glycerin-water mixture at 37°C. Results: The flow estimation strategy for the MVAD was successfully developed using the motor’s current and BEMF. The additional information derived from the BEMF behavior has the potential to allow for better average flow estimate tracking performance when compared to methods based solely on motor current.

CAUTION: Investigational device. Limited by United States law to investigational use.

ASAIO CARDIAC ABSTRACTS
FINITE ELEMENT INVESTIGATION OF NOVEL DESIGNED THRE-DIMENSIONAL BICUSPID VALVE FOR RIGHT VENTRICULAR OUTFLOW TRACT RECONSTRUCTION
Guangyu Zhu,1 Masakazu Nakao,2 Qi Yuan,2 Joon Hock Yeo,3 Cardiothoracic Surgery, KK Women’s and Children’s Hospital, Singapore, Singapore; 2School of Energy and Power Engineering, Xi’an Jiaotong University, Xi’an, Shaanxi, China; 3School of Mechanical and Aerospace Engineering, Nanyang Technological University, Singapore, Singapore. Bicuspid expanded polytetrafluoroethylene (ePTFE) valved conduit is a viable option for the right ventricular outflow tract (RVOT) reconstruction. However, the geometry of valve leaflet will have significant impact on the hemodynamic performance of the valve. A valve designed or created inappropriately may lead to the risk of reoperation due to regurgitation or valve malfunction. In this study, the authors present a novel designed three-dimensional bicuspid valve, which can provide an enhanced performance in the finite element investigation as compared to conventional designs. A series of different valve leaflet designs incorporating the aortic root of 25 mm in diameter were created. Leaflet geometry was designed based on parameters including conduit size, valve length and valve area. Dynamic behavior of the designs was analyzed using finite element method. The physiological pressure loading was applied on the valves throughout a cardiac cycle. After several iterations of numerical simulation and optimization, one optimal design was identified. The maximal leaflet coaptation area of the bicuspid valve was 80 mm². When fully closed, no gap which may cause regurgitation was observed and the free edges of the valve formed an S-shaped coaptation line, characterized by counterclockwise twisting motion, which is a sign of good coaptation of the leaflets. The highest stress occurred in the dynamic procedure was 3.84 MPa. The finite element simulation revealed the feasibility of the new designed three-dimensional bicuspid valve and confirmed that this design could provide a reliable performance under physiological loading.

SYMPTOM BURDEN AND MENTAL HEALTH AFTER MECHANICAL CIRCULATORY SUPPORT: PATIENT PERSPECTIVES
Kathleen L Grady,1 Susan Magasi,2 Sarah Buono,2 Tanisha Abraham,3 Clyde Yancy,1 Edwin McGee, Jr.1 Surgery, Division of Cardiac Surgery, Northwestern University, Chicago, IL; 2Occupational Therapy, University of Illinois at Chicago, Chicago, IL; 3Medical Social Sciences, Northwestern University, Chicago, IL. No surveys measure health-related quality of life (HRQOL) of advanced heart failure (HF) patients (pts) with mechanical circulatory support (MCS). This abstract reports pt perspectives on 2 HRQOL domains: symptoms and mental health. Methods: Using qualitative methodology, we conducted semi-structured interviews with 13 pts (7+bridge to transplant [BTT] and 6=destination therapy [DT]). Interviews were 30-60 minutes, audio-recorded, and transcribed verbatim. Data were analyzed using a 2-phase coding strategy. Results: Pts reported most HF symptoms abated early post MCS (shortness of breath, paroxysmal nocturnal dyspnea, fluid weight gain, poor appetite, weakness, difficulty sleeping, and daytime drowsiness). Some HF symptoms (fatigue and poor energy) persisted for several weeks to months. MCS-specific symptoms (bleeding [per nose and gastrointestinal], dizziness/syncope, driveline/pocket infection, neck/shoulder discomfort with carrying equipment, and difficulty sleeping with a driveline/equipment) and surgical pain were also reported. Pts, pts were positive and grateful for the device but had depression and frustration, related to MCS self-care, loss of independence, symptoms, and negative body image. Early post-MCS pts had anxiety about MCS-related self-care; later post-MCS, pts, fear about MCS malfunction arose. BTT and DT pts were anxious/uncertain about waiting for a heart and life expectancy, respectively. Conclusions: Most HF symptoms resolved after MCS, and new symptoms arose. Negative and positive emotions were present after MCS, related to adjusting to life with MCS and issues specific to BTT and DT. These data will inform development of an instrument to measure MCS HRQOL.

PROLONGED EX-SITU HEART PERFUSION IN SWINE
Benjamin Bryner, Cory Toomasian, Yao Nie, Alvaro Rojas-Pena, Gabe E Owens, Martin L Bocks, Robert H Bartlett. Extracorporeal Life Support Laboratory, University of Michigan, Ann Arbor, MI. Purpose: Cold preservation is the standard of care for heart transplantation; but it is limited to six hours. A continuous ex-situ organ perfusion system could substantially expand the recipient pool. Methods: Swine were used as heart and blood donors. Reconstituted cellular perfusate (hemoglobin ~ 3-4mg/dl) was made from autologous plasma and red blood cells. The perfusion circuit consists of a membrane oxygenator and a pulsatile pump (MC3 Corp. Ann Arbor, MI) (figure 1). (Figure 1) Perfusate was delivered at a mean perfusion pressure of 60-80 mmHg into the aortic root. Initial experiments were conducted at 20°C and 30°C, followed by two at 37°C. Biochemical sampling occurred hourly. Perfusion continued for a goal of 12 hours, followed by histologic analysis. Results: At 20°C and 30°C, flows of 150-200cc/min were achieved, but the hearts did not regain sinus rhythm despite electrical cardioversion. At 37°C, both hearts displayed sinus rhythm on EKG (figure 2) with flows of ~200cc/min. Lactate rose minimally and oxygen delivery was appropriate. Histologic analysis showed varying degrees of myocardial hemorrhage and edema. Conclusions: A pulsatile pump with blood-derived perfusate provided 12 hours of ex-situ cardiac perfusion. Normothermic perfusion supported sinus rhythm and prolonged ventricular contraction. Future studies will examine non-blood perfusate, effects of cardioplegia, and functional assessment of perfused hearts.
IS VENTRICULAR REMODELING MORE SEVERE IN PATIENTS ≥70 YEARS OLD REQUIRING LVAD SUPPORT?
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Purpose: Patients ≥70 years old have increased risk of severe heart failure due to myocardial ischemia. We aimed to compare histologic remodeling in ischemic cardiomyopathy (CMP) patients ≥70 years old with 2 groups of younger patients (50-69, 40-49y).

Methods: We included 48 patients (42 men, 6 women) with left ventricular assist device (LVAD) support. Ten patients were ≥70 years old (mean, 73±3), 29 were 50-69 years old (mean, 60±5), 9 were 40-49 years old (mean, 45±3). We quantitatively analyzed LV cores at the time of implantation evaluating fibrosis and hypertrophy with computerized morphometry.

Results: Patients of all age groups had similar degrees of fibrosis and hypertrophy. Patients ≥70 years old did not have more severe fibrosis (p=0.38) or hypertrophy (cytoplasmic diameter, p=0.41; nuclear diameter, p=0.37) than younger patients (40-69y). (Figure 1) (Figure 2)

Conclusion. Independent of age group, all patients, including ≥70 years old, showed similar extensive remodeling at the time of LVAD implantation. Age did not correlate with severity of remodeling in ischemic CMP.

SIMULATION-BASED TRAINING FOR VENTRICULAR ASSIST DEVICE EMERGENCY EDUCATION IN A PEDIATRIC INSTITUTION
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Ventricular assist device (VAD) emergency education is critical to a successful pediatric VAD program. Through the use of simulation training it is possible to recreate VAD emergencies that may arise. The specific aims of this project were to improve VAD proficiencies while identifying latent safety threats (LSTs) therefore enabling the team to recognize and mitigate system problems before they cause harm to VAD patients.

Our study was a prospective in situ simulation-based evaluation. Subjects were providers from the VAD, Emergency Services and Cardiac Intensive Care teams at Cincinnati Children’s Hospital. To conduct a simulation, the Heartmate II (Thoratec, Pleasanton, CA) mock loop was inserted into a simulator mannequin, SimMan 3G (Laerdal, Wappingers Falls, NY) and made to alarm in the emergency room. The simulations were video recorded and followed by standardized debriefings and education.

To date, five simulations have been completed. Average time to alarm resolution was 7:57 (7 minutes, 57 seconds). Mean time to arrival in ED was 8:08 for VAD physician. The ED care team correctly identified the alarm in 3 (60%) simulations. Six team-level knowledge deficits included not knowing where to assess for pump flow via auscultation and not knowing where to find appropriate pager numbers. Four LSTs were identified, including specialty resource nurses unaware of need to perform online education and ACLS algorithms missing from ED.

Early experience has demonstrated that multidisciplinary simulation-based ventricular assist device training is feasible, well received and an effective method for identifying gaps in education and teamwork within a pediatric institution.
LONG-TERM OUTCOMES IN PATIENTS WITH ADVANCED HEART FAILURE LIVING ALONE WHILE SUPPORTED WITH LEFT VENTRICAL ASSIST DEVICES

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Background: Our institution cares for many VAD patients that live alone and sustain autonomy. We evaluated the comparison of those VAD patients that lived alone to those that did not by utilizing a retrospective design.

Methods: LVAD database from a single center was reviewed between 2008-2011. Univariate statistical methods and Kaplan-Meier Survival curves were used for analysis. Data analyzed included: gender, age at implant, race, device explant date, living arrangements, occurrence of driveline infection, occurrence of bleeding events, number of re-admissions, length of stay, and average length of stay. Outcomes were determined by documented diagnoses and re-admissions.

Results: 46 patients were included in the analysis. The VAD patients that lived alone experienced fewer occurrences (47.8%) of driveline infections as compared to those patients not living alone (65.2). The patients that lived alone experienced a higher occurrence of GI bleeding (43.5%) as compared to those that did not live alone (8.7%). Both groups were re-admitted at an equal amount (91.3%). The average number of readmissions of those living alone were higher (5.4) compared to those not living alone (4.4); however, the length of stay in the hospital of those that lived alone was less, 6 days to compared to 9 days, for those that did not.

Conclusions: The goal of our program plans for the VAD patient that lives alone returns to a life living alone after the determination of homeostasis and autonomy. With such studies exploring the living situation of the VAD patient, insight to potential outcomes may be utilized in directing patient selection and care planning after implant.

ASSOCIATION OF CENTRAL ECMO AND IMPELLA IN THE SAME PATIENT: THE RIGHT WAY TO MYOCARDIAL RECOVERY?

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Cardiogenic shock (CS) still carries a high mortality risk; ECMO is becoming the standard of treatment of CS as bridge to recovery (BTR) or to decision. Impella System(IS) is an attractive, ease and effective system for left ventricular(LV) dysfunction. Superior LV-unloading has been shown using IS, while ECMO warrant better perfusion. The association of ECMO and IS has been advocated to combine the efficacy of both techniques. A 20-30 year experiencing sudden dyspnea was referred to a local hospital for pericardiacentesis. After the procedure LV contractility rapidly declined despite increasing inotropic support, so IS 2.5L was implanted to maintain circulation. For ongoing right ventricular failure patient was referred to our hospital with indication to ECMO implantation and/or Transplantation. ECMO with Levitronix was implanted via median sternotomy to warrant optimal perfusion and to lower the risk of leg complications. IS was left in place to warrant myocardial unloading aiming BTR. A fine needle biopsy of LV showed minimal necrosis (with a high likelihood of Myocardiacpericarditis) and encouraged the feasibility of BTR. ECMO implantation was complicated from a severe coagulopathy requiring massive blood product administration and reexploration for tamponade. BNP dosage rapidly decreased during the first postoperative week and ECMO was removed on day 6. On day 7 IS was percutaneously removed. This report further support the synergistic effect of IS and ECMO to warrant both myocardial unloading and optimal peripheral perfusion. IS implantation as first step of treatment of CS or in combination with ECMO should be considered when dealing with a potentially reversible pathology.

CLINICAL USE OF INDIGENOUSLY PREPARED DECELLULARISED PORCINE PULMONARY ARTERY XENOGRAFTS

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Introduction: Xenografts gain importance in right ventricular outflow tract reconstruction(RVOT) as homograft availability is unpredictable. Surgical outcome of patients undergoing RVOT using decellularized porcine pulmonary artery xenografts with nanocoating with collagen fibres (NPAX) and without coating (PAX) was assessed. Methods: Hospital database was accessed retrospectively for patients who underwent RVOT using PAX and NPAX. Data studied included age and diagnosis at surgery, perioperative mortality, follow up clinical status, right ventricular and conduit function, need for conduit replacement. Results: From Aug 2005 to April 2011, 80 patients underwent RVOT using PAX (n=64) and NPAX (n=16). Mean age at surgery was 9.3±9.0(0.16–45) yrs. Operative procedures included correction of pulmonary atresia (n=63), Ross procedure (n=10) and truncus repair (n=7). Mean size of conduit was 17+/-3(7–23 mm) and follow-up duration 26.5+/-19.6 (3-67 months). 12 patients with PAX and 2 with NPAX died in the early post-operative phase. Deaths were not conduit-related. 41 patients (50%) were asymptomatic and without conduit related problems on follow up. There was no infection, thromboembolism or calcification. 12 patients (15%) needed conduit replacement. 2 patients died at replacement. Conduit stenosis occurred in 6 cases, conduit dilatation occurred in 12 and significant regurgitation in 10. Conclusions: Decellularised porcine pulmonary artery xenograft is a viable alternative to homograft in RVOT reconstruction. Advantage is easier availability in all size ranges. These patients need regular follow up to detect early conduit dysfunction.

HYBRID CARDIOVASCULAR SIMULATOR VALIDATION TESTS

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Objectives: A Hybrid (numeric and physical) Cardiovascular Simulator (HCS) was constructed in order to evaluate Left Ventricle Assist Devices (LVAD). However, HCS behavior needs to be validated to be used as a tool for LVAD assessment.

Background: HCS model has a physical section composed by: reservoir, mimicking a passive left atrium; pumping chamber with two bileaflet valves, as left ventricle; an air tight compliance chamber; a proportional valve as systemic vascular resistance; and a set of tygon tubes. The electromagnetic actuator of pumping chamber, air volume inside the compliance chamber and the proportional valve are controlled by computer through the numeric section which is composed by: vena cava; right heart; pulmonary artery; lungs and pulmonary vein. All compartments of numeric section have been programmed in LabVIEW®. Interaction between both sections is made through pressure and flow signals which are acquired at physical section by sensors through an acquisition board. According to literature, validation of cardiovascular simulators is made verifying if the system is capable to follow the Frank-Starling law when left ventricle pre-load, afterload and elastance changes are imposed. Results: Effect of changes in left ventricle pre-load, afterload and elastance was observed through Pressure x Volume loop analysis. Conclusion: During validation test we could observe that HCS behavior under preload, afterload and elastance changes were coherent with results from literature using computational cardiovascular simulators. We conclude that as HCS is validated it can be used as tool in LVAD studies.
PRELIMINARY DRIVELINE INFECTION RESULTS FROM THE MULTICENTER SILICONE-SKIN-INTERFACE (SSI) REGISTRY

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Purpose: Single center experience has suggested encouraging reduction in driveline (DL) infection rates after changing the surgical tunneling technique to keep the entire velour portion in the subcutaneous tunnel, resulting in a Silicone-to-Skin Interface (SSI) at the exit site. To assess the long term freedom from DL infection associated with this technique, a multi-center SSI registry was initiated.

Methods: SSI is both a prospective and retrospective observational registry of HMII pts. The retrospective cohort consists of 200 pts on HMII support for at least 10 months at the time of enrollment. The prospective cohort consists of 200 pts enrolled at the time of implantation. One year freedom from DL infection was determined in the first 99 pts enrolled in the retrospective cohort. Results were compared to data from an earlier HMII DT clinical trial where a small section of the velour portion of the DL was externalized in all pts.

Results: Between Mar and Dec 2012, 99 pts (46% BTT, 54% DT) with an average age of 59 yrs (range: 26-79) were enrolled. The mean follow-up was 16 mos (range: 8-31 mos; cumulative: 132 pt-yrs of support). There were 11 DL infection events (0.083 events/pt-year) in 8 patients, with time to event ranging from 2.1 to 13.8 mos. The actuarial freedom from DL infection at 12 mos was 94.4%. This compares to 77.0% in the DT clinical trial.

Conclusion: These preliminary results suggest that leaving the full length velour portion of the DL below the skin is associated with reduced DL infection at one year. Complete analysis of the data collected from all 400 patients will help establishing a best practice for DL tunneling and exit site management.

"IN VIVO" TEST ACQUIRING ELECTROCARDIOGRAM SIGNAL FOR ROTATIONAL SPEED CONTROL OF AN IMPLANTABLE CENTRIFUGAL BLOOD PUMP

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This paper presents an "In Vivo" Test aiming to acquire electrocardiogram (ECG) signal directly from myocardium using two stainless steel rings attached to the inlet cannula of an Implantable Centrifugal Blood Pump (ICBP), under development in our laboratories to be used as a Left Ventricular Assist Device (LVAD) for long-term support. ICBP successful operation depends also on an appropriate rotational speed control system, ensuring: 1) no reverse flow through the pump during left ventricle diastolic phase and 2) aortic valve correct opening, avoiding later valve stenosis. ECG signal can be used to enable ICBP rotational speed adjustment according to heart rate variation. Furthermore, the ICBP electronic controller will act synchronously with natural heart, changing LVAD behavior in different instants of a cardiac cycle. "In Vivo" test was conducted with a pig (+70 kg). ECG signal was acquired with the aid of LabView software (National Instruments, Austin) and an acquisition board (8009, National Instruments, Austin). The software has an acquisition module and signal filtering module. A low-pass type filter was used to eliminate high frequency noise. The filtered ECG signal was satisfactory for ICBP electronic controller. (Figure 1)

REPAIR OF LEFT VENTRICULAR PSUEDOANEURYSM DUE TO ATRIOVENTRICULAR DISSOCIATION FROM MITRAL VALVE ENDOCARDITIS

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Infective endocarditis is an endovascular microbial infection of intracardiac structures facing the blood including infections of the large intrathoracic vessels and of intracardiac foreign bodies (1). Atrioventricular dissociation with left ventricle aneurysm is very uncommon in infective endocarditis. It usually presents in myocardial infarction. (2) Left ventricular aneurysm in endocarditis has been described following aortic valve replacement.(3) The transoesophageal echocardiography was crucial to pre operative assessment and as seen from the pictures above illustrated the anatomy well. Cardiac Computed Tomography has also been reported to demonstrate the anatomy in left ventricular aneurysm due to endocarditis.(4)

This case illustrates the successful repair of left ventricular pseudoaneurysm with bovine pericardial patches (Baxter Healthcare Corp., Edwards Division, Santa Ana, Calif) used to buttress the and restore atrioventricular continuity and stable result obtained up to 1 year post procedure.

To our knowledge, this is the 1st report of atrioventricular dissociation leading to left ventricular pseudoaneurysm formation from group B streptococcus infective mitral valve endocarditis and its successful repair with 1 year follow up.
EFFECT OF WARM PERFUSION OF DONOR LUNGS USING THE ORGAN CARE SYSTEM® ON IMMUNE MEDIATOR RELEASE DURING PRESERVATION

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Purpose: Warm perfusion of donor lungs for transplantation (Tx) using Organ Care System® (OCS) may provide superior preservation compared to standard cold preservation (SOC). Release and composition of donor-derived soluble immune mediators (IM), triggering allorecognition and inflammation after Tx, might be differentially affected. We analyzed 55 soluble IM in preservation solutions (PS) and peripheral blood (PB) of recipients.

Methods: IM were quantified at protein level (pg/ml) by Luminex-based multiplextechnology in PS using OCS (n=11) or warm preservation in OCS (n=13), both based on low potassium dextanar solution. Differences were assessed by Mann–Whitney U and ROC/AUC statistics.

Results: Unexpectedly huge differences were found between concentrations in PS. Highest statistical differences with higher release in OCS were: IL-6 p=0.0001, IL-10 p<0.0001, IL-17 p=0.0003, IL-16 p<0.0001, IFN-γ p=0.0001, IL-1RA p=0.0004, CXCL8 p=0.0001, CXCL10 p=0.003, CCL5 p=0.0001, CCL5 p=0.0004, HGF p=0.0004, G-CSF p=0.0001, Ang-2 p<0.0001, Follistatin p=0.0004, PDGF-b p=0.0001. Inverse distribution was observed for bFGF p=0.005 and very low significance for GM-CSF p=0.03. ROC analyses revealed AUC values between 0.74 -1.0. High concentrations in PS of OCS induced lower delivery/expression of IM in PB after Tx, clearly detectable by comparing OCS with SOC.

Summary: Donor-derived IM remained low in SOC, whereas OCS potentially depleted them from the lung with accumulation in PS. This ‘dialysis’ effect may indicate anti-inflammatory properties. Further studies on clinical outcomes of patients transplanted with OCS vs SOC preserved lungs are warranted.

PATIENTS WITH EXTRA CORPOREAL LUNG ASSIST AS BRIDGE TO LUNG TRANSPLANTATION VERSUS PATIENTS WITHOUT – A SINGLE CENTER EXPERIENCE


Objectives: With increasingly frequent mechanical lung assist (MLA); extracorporeal membrane oxygenation (ECMO) or extracorporeal lung assist (ECLAJ) is temporary used as a bridge to lung transplantation (LTX). This study was designed to evaluate the impact of preoperative MLA on operative outcome including longer term survival in patients undergoing in comparison to patients undergoing LTX without preoperative MLA.

Methods: A total of 143 patients underwent LTX at our institution form 2002 to 2011. 43% (n=62) of patients presented with idiopathic pulmonary fibrosis of whom 71% (n=102) presented severely elevated pulmonary artery pressure. Results: Overall 15 patients (22%) required pre LTX MLA support (age 44 ±13 years, double-LTX 73.3%, female gender 53%) whereas 130 patients did not (age 52 ±11 years, double-LTX 41.5%, female gender 36.9%). Preoperative death occurred in 2 patients in the MLA group. In one patient MLA was successfully weaned and the patient underwent subsequent LTX. All patients in the MLA group were intraoperatively supported with continuous ECMO. One patient had to be supported with MLA after LTX for a period of 8 days. The short-term and mid-term postoperative survival of the MLA patient group was not significantly different from the non-MLA group (LogRank p=0.28). The 30-day, 90-day and 1-year survival was 95%, 90% and 71% in the patients without MLA compared to 85%, 77% and 68% in the MLA group.

Conclusions: MLA has no impact on postoperative outcome in LTX patients. It is however a valuable tool as bridge to LTX in instable patients.

DEVELOPMENT OF A LIQUID-LIQUID OXYGENATOR WITH MICRO-DROPS OF BLOOD

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Recently, a membrane oxygenator is used to long-term cardiopulmonary support such as ECLS (Extra-corporeal Life Support). The membrane oxygenator reached a satisfactory level with basic life support such as gas exchange and pressure drop in open-heart surgery; however, it is difficult to maintain durability and basic performance. In this study, we developed a new oxygenator without hollow fibers to improve these problems. In the new oxygenator, blood contacts with Perfluorocarbon (PFC) directly. PFC is immiscible with aqueous solutions and has a high specific gravity and high gas solubility. We cut blood into micro-diameter to improve gas exchange performances. The micro-drops of blood have large contact surface area per unit volume in PFC. The blood came floating to the surface of the PFC chamber because of the difference of their specific gravity. We conducted in-vitro experiment to measure the performance of the oxygenator. Evaluations of gas exchange performance and hemolysis property were measured. Experimental conditions were as follows: initial blood oxygen pressure of 35±5 mmHg, initial blood carbon dioxide pressure: 45±5 mmHg, hematocrit value: 40±2 %, initial PFC oxygen pressure: more than 750 mmHg, initial PFC carbon dioxide pressure: less than 5 mmHg and PFC flow rate of 1.0, 1.5 l/min. We have used silicone membrane oxygenator made by Fuji Systems Corp. to regulate PFC gas pressure. As a result, PaO2 and PaCO2 were maintained in the normal value (PaO2>80 mmHg, PaCO2<40 mmHg) during experiments. The plasma free hemoglobin level was less than 50 mg/dl after 60 min circulation. These results show that the performance of the oxygenator is comparable to that of conventional membrane oxygenators.
EFFECT OF ATRIAL SEPTOSTOMY SIZE ON HEMODYNAMICS DURING MOCK CIRCULATION SIMULATION OF EXTRACORPOREAL MEMBRANE OXYGENATION SUPPORT FOR PEDIATRIC SYSTEMIC VENTRICULAR FAILURE

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Extracorporeal membrane oxygenation (ECMO) provides cardiopulmonary assistance for a failing heart or lungs in pediatric patients. In an ECMO patient with two ventricles and no intraatrial communication, left atrial and pulmonary hypertension (LAH, PH) may occur with systemic ventricular failure. Using a pediatric mock circulation that mimics hemodynamics, key anatomic structures, pneumatic ventricles, and ECMO cannulation sites, we investigated what size atrial septal defect (ASD) was needed to reduce LAH and PH and restore hemodynamics in a 4 to 5 kg infant. After establishing baseline conditions (aortic pressure, AoP, 80 mm Hg; cardiac output, CO 1.00 L/min; left atrial pressure, LAP 8 mm Hg; and pulmonary artery pressure, PAP 20 mm Hg), heart failure was created by reducing the left pulmonary drive pressure resulting in AoP 54 mm Hg, CO 0.62 L/min, LAP 28 mm Hg, and PAP 36 mm Hg. ECMO circuit flow was generated between a 10 Fr. inflow cannula in the right atrium and an 8 Fr. outflow cannula in the carotid artery of the model. An ECMO flow of 420 mL/min created increases in AoP to 76 mm Hg, LAP to 42 mm Hg, and PAP of 44 mm Hg. Creation of an ASD provided no hemodynamic benefit below 3 mm diameter. An ASD of 3.7 mm reduced the LAP to 29 mm Hg and PAP to 38 mm Hg with small additional benefit with ASD up to 7 mm as atrial pressures equilibrated. Reducing systemic afterload did not result in added benefit. This simulation demonstrates that creation of an ASD of at least 3.7 mm diameter is needed to provide beneficial reduction of LAH and PH during ECMO support of a failing systemic ventricle.

PRACTICAL OPERATING METHOD OF VENO-VENOUS EXTRACORPOREAL MEMBRANE OXYGENATION AIMING FOR EFFECTIVE OXYGENATION

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Background: Veno-venous extracorporeal membrane oxygenation (VVECMO) is increasingly used for adult respiratory failure patients. However, it is not clear whether sufficient oxygenation was achieved in all cases. The some factors such as cannula position and recirculation, which occurs when oxygenated blood by ECMO recirculate into ECMO circuit, may induce ineffective oxygenation. The objective of this study is to investigate practical operating method of VVECMO for effective oxygenation.

Method: VVECMO was performed in five goats (mean body weight, 64 ± 4 kg). We changed the position of return cannula in the inferior vena cava (IVC), the right atrium (RA) or the superior vena cava (SVC), whereas the position of drainage cannula was fixed in the IVC in all cases. We changed the bypass flow from 1 - 4 L/min in all positions, and compared ECMO recirculation rate and pulmonary arterial (PA) oxygen saturation which represented oxygenated blood by ECMO and unoxygenated venous blood. In another experiment, we investigated whether oxygen delivery by ECMO in each condition could cover the demand of the systemic organs by measuring of arterial oxygen pressure.

Result: In the groups of IVC return cannula, the recirculation rate was the highest, and the PA oxygen saturation was the worst among three positions. On the condition which is bypass flow under 2 L/min, oxygen delivery to systemic organs was not enough.

Conclusion: The oxygenation by VVECMO is considerably influenced by both cannula position and bypass flow rate which are closely related.

INCORPORATING GAS AND HEAT EXCHANGE BY INDUCING PHYSIOLOGICAL PULSATILITY INTO A HEAT EXCHANGING OXYGENATOR

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Purpose: Large surface areas and high filling volumes are associated with adverse effects within cardiopulmonary devices. By inducing pressure pulses with physiological frequencies within a heat exchanging oxygenator, efficiencies can be improved and hence reduce these areas and volumes.

Methods: A single silicone tube (Ø 2mm, WT 130µm) was placed central in an oxygenator fiber bundle and sealed in a small casing. Tempered water was pumped inside this tube to facilitate heat exchange. In-vitro tests were done following the ISO7199, using porcine blood. Three operating points for constant flows, using a DP2 blood pump, were compared with corresponding pulsatile flows. The latter were generated by periodically pumping water through the tube to collapse and expand it (40-120 BPM). Combined with valves at the oxygenator’s inlet and outlet, blood flows pulsatile through the oxygenator.

Results: Heat exchange efficiency was improved to K=18.4±0.6 for pulsatile flows compared to 5.4±1.1 for constant flows. CO2 and O2 exchange could be improved by at least 18% and 25% respectively by pumping with the silicone tube compared to continuous flow from the DP2.

Conclusions: The in-vitro results prove that pulses caused by a pumping tube inside a heat exchanging oxygenator, improve gas- and heat exchange efficiency. This might be explained by an improved flow distribution through the device, which could also reduce risk of recirculation areas and shunt flows.

Summary: This abstract describes a method to improve gas and heat exchange by inducing a physiological blood pulse inside a heat exchanging oxygenator. This principle could improve flow fields in future cardiopulmonary devices.

1H-NMR ANALYSIS OF THE INTERACTION AMONG PERFLUORINATED LIQUIDS AND POLYMERS IN A VENTILATOR PROTOTYPE FOR TOTAL LIQUID VENTILATION

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Purpose of the Study: Aim of this study was the analysis of the interactions among different perfluorinated liquids (PFs) and the polymeric components of our new ventilator prototype for Total Liquid Ventilation (TLV). Indeed, no data are available about the effect of a prolonged exposure of polymers to PFs, which is crucial in view of in vivo application.

Methods: Three PFs suitable for TLV were chosen: Fluonert FC770 (3M™ Electronic Materials), Galden® HT170 (Selvay Speciality Polymers), Perfluor (Exfluor Research Corp). Five polymeric components of the TLV prototype were analysed: tubes (polyvinylchloride: PVC), oxygenator housing (polymethylmethacrylate), oxygenator membrane (composite of polydimethylsiloxane), one-way valve housing (polycarbonate) and membrane (polydimethylsiloxane). For each PF a series of 5 vials was prepared, each containing one polymeric sample. A control vial in absence of polymeric sample was also prepared for each PF. The vials were thermostatted at 37°C for 28 days.

The PFs were analysed by proton nuclear magnetic resonance (1H-NMR) at day 0, 1, 7 and 28. Infrared attenuated total reflectance (IR-ATR) and mass analysis on the polymeric samples were performed at day 0 and 28.

Summary of Results: 1H-NMR showed an increase in hydrogen content in the samples containing PVC and Perfluor. No significant alteration in PFs was observed in the other samples. No IR spectra variation and minimal (<2%) mass alteration was observed in all polymers.

Further analyses are ongoing to assess the maximum duration of a polymeric-based TLV device before the occurrence of polymer degradation, to avoid possible toxic effects.
COMPARISON OF THE FLUIDYDYNAMICS INDUCED IN THE BRONCHIAL BIFURCATION BY DIFFERENT PROTOTYPES FOR TOTAL LIQUID VENTILATION
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Purpose: The optimization of the fluidodynamics in the tracheobronchial bifurcation during Total Liquid Ventilation (TLV) with liquid perfluorocarbons, is fundamental to improve the treatment. Aim of this study is to compare the effects exerted on preterm airways by using two TLV prototypes: a volume controlled piston pump and a newly developed pressure controlled pump (Pro-Li-ve).
Methods: A 3D model of the tracheal bifurcation was obtained by computer tomography images, scaled to represent preterm neonatal size, and interfaced to a model of endotracheal tube. The geometry was discretized into 468000 tetrahedral elements and used to perform simulations (Fluent 14.1, ANSYS Inc).
Unsteady-state simulations were performed to replicate the flow rate profiles generated by the two prototypes, at the same tidal volume (TV). A lumped parameter model implemented to simulate the lung impedance was coupled to the model to obtain realistic pressure. The k- turbulent model and the laminar model were used to simulate inspiration and expiration, respectively.
Summary of results: The model allows reliable simulations of the tracheal pressure obtained during previous experimental trials. The main percentage (58%) of the flow rate is conveyed to and from the right bronchus with both prototypes. The model also permits to quantify the airway Wall Shear Stresses (WSS). The maximum WSS are located on the internal side of the bronchial bifurcation during inspiration, when the PFC inflow impacts on the carina. Comparable mean WSS during inspiration were obtained with the two devices (WSS=23Pa for the volumetric prototype and WSS=26Pa for Pro-Li-ve, both at TV=10 ml).

DEVELOPMENT OF AN INTRAVASCULAR MEMBRANE OXYGENATOR WITH SMALL AXIAL PUMP
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Purpose: An intravascular membrane oxygenator (IVOX) is an intracorporeal, hollow-fibers membrane oxygenator and CO2 removal device that is surgically inserted into a vena cava. There is no extracorporeal circulation device and circuit of blood. Inlet and outlet gas conduits exit from a small skin incision. About 15 years ago, the clinical testing of IVOX was halted because this design did not allow for sufficient gas exchange. In this study, we have fabricated a novel intravascular membrane oxygenator with small axial pump. The axial pump is placed behind the membrane oxygenator. The pump could flow blood 0.5-1 L/min in a vena cava. The device is expected to allow for more efficient gas exchange. It could support not only gas transfer performance but also blood circulation performance.
Methods: The membrane oxygenator was fabricated with woven micro porous hollow fiber membranes (225 μm outer diameter). The total fiber surface area was 0.3 m² and the length of the fiber bundle was 200mm. The axial flow pump consisted of an impeller, a diffuser, and a small motor. The small motor has a diameter of 4 mm and a length of 16.8 mm. It was inserted into the diffuser. Outer diameter of the impeller and the diffuser was 14 mm. The potential of device was evaluated by the in vitro experiments.
Results: Our new device has efficient gas exchange performance during experiments. The device could flow blood around 1 L/min.
Conclusion: We developed the novel intravascular membrane oxygenator with small axial pump. The device is useful as a gas exchange device and for medical treatment required assisted circulation.

EVALUATION OF SILICONE HOLLOW FIBER MEMBRANES FOR TOTAL LIQUID VENTILATION OXYGENATOR
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Purpose: Total liquid ventilation (TLV) is an effective treatment for severe respiratory failure such as acute respiratory distress syndrome and idiopathic respiratory disease syndrome. However, there still remains the problem about CO2 removal from the living body. The CO2 removal performance depends on the pressure difference between liquid side and gas side in a membrane oxygenator during TLV. In this study, we developed a membrane oxygenator for TLV (LV-OX) to remedy this problem. Methods: The LV-OX was made optimizing flow condition with computational fluid dynamics, and designing its configuration for perfluorocarbon (PFC) evenly flowing through the membrane portion in oxygenator. Furthermore it has a low priming volume to minimize the amount of PFC needed. The hollow fiber membrane of the LV-OX was used for silicone hollow fibers (SHF). This SHF is 0.3 mm inside diameter, 0.4 mm outside diameter and 50 μm thicknesses. The membrane area of 1.0 m², filling rate of SHF is approximately 40% for housing, and the priming volume of PFC is 97 mL. We examined gas exchange performance in in vitro experiments, and compared the performance with ECMO 0800 membrane oxygenator (ECMO-0800). Gas exchange performance was evaluated PFC flow rate of Q=1.0, 2.0, 3.0 L/min with V/Q=1. 2. Results: CO2 transfer rate of the LV-OX (60 mL/min) was higher than that of ECMO-800 (41 mL/min). Gas exchange performance of the LV-OX was increased by approximately 50% compared with the ECMO-0800 in V/Q=2. Conclusion: The newly developed LV-OX had a high gas exchange performance and suggested that it will useful as an oxygenator for TLV.

NOVEL SMALL-ANIMAL EX-VIVO LUNG PERFUSION AS A PLATFORM FOR ORGAN MODIFICATION IN LUNG TRANSPLANTATION
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Background: There is a paucity of suitable lungs available for transplantation. 17% of lungs are able to be utilized leading to a proracted wait-list time or patients dying awaiting transplant. Ex-Vivo Lung Perfusion (EVLP) is an approach to increase the donor pool which currently focuses on organ assessment. We sought to develop a small-animal EVLP model as part of a program to rescue organs for transplantation and create a platform to assess and potentially modify lungs in preparation for transplant. Methods: EVLP through an isolated Heart-Lung Perfusion system (Harvard Apparatus, Holliston, MA) was performed on 6 Sprague Dawley rats. The perfusate (Steen Solution™, Vitrolife Sweden AB) consisted of balanced salt solution containing dextran & 7% albumin. Ventilator/pulmonary hemo-dynamics (endpoints: PaO2, FiO2, Perfusion Flow Rate, Perfusion Pressure, Tidal Volume, Tracheal Pressure) were assessed. Results: 3 rats were able to be successfully perfused up to 2 hours. As successful perfusion, duration increased. 3 rats were not able to be perfused [inability to perfuse was due to cannula malposition (x 2) & pulmonary edema (x 1)]. Tracheal pressures increased (5 mmHg to 18 mmHg), Tidal Volumes averaged 1.2 cc, & mean PaO2/FiO2 ratio 585. Conclusion: In time, this model allows 1) continuous assessment of lung function, 2) ventilation mechanic changes, 3) continuous monitoring of pulmonary vascular hemodynamics, and 4) potential modification of organs through preservation solution. EVLP is cost-effective to evaluate new preservation approaches to reduce ischemia/reperfusion injury & has the potential to modify the organ to minimize transplant-induced inflammatory reaction.
DEVELOPMENT OF A BIOMIMETIC MICROFLUIDIC OXYGEN TRANSFER DEVICE
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The demand for advancement in blood oxygenation technology is rising with the growing number of patients suffering from acute and chronic lung diseases, such as in the recent pandemic of H1N1 influenza virus. Currently established treatments such as mechanical ventilation and ExtraCorporeal Membrane Oxygenation (ECMO) are of limited use due to system complexity and safety concerns. In particular, hollow fiber oxygenators used in ECMO therapy and cardiac bypass surgery require high levels of anticoagulants associating with significant blood health related deleterious side effects. More biomimetic flow properties and a reduction in blood prime volumes in oxygenation devices would improve the patient safety and expand the use of this technology. We have designed a multilayer microfluidic blood oxygenation device with lower blood prime volume and improved blood health conditions relative to current approaches. Here we address the scaleup of a device capable of delivering high oxygen transfer rates with low prime volume at blood flow rates up to 100mL/min, demonstrating the potential for clinical applications. We compare scaling effects in footprint design as well the approach for stacking multiple layers. In order to further enhance the biomimetic properties of these devices, we have also endothelialized the membrane on the blood layer to leverage the cell’s ability to inhibit coagulation. We present a comparative blood oxygenation study based on blood testing of devices with endothelialized membranes and acellular devices. After undergoing blood testing, absolute visual confirmation of fibrin clot formation was observed; while minimal to non-existent such formation was visible in the cell seeded devices.

ELEVATED LEVELS OF SPHINGOLIPIDs CORRELATE WITH GOOD CLINICAL OUTCOMES IN PATIENTS WITH SEVERE ARDS ON ECMO SUPPORT
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Background: Sphingolipids such as sphingosine-1-phosphate (S1P), ceramide, or sphingomyelin are essential constituents of plasma membranes and regulate many (patho)physiological cellular responses inducing apoptosis and cell survival, vascular permeability, mast cell activation, and airway smooth muscle functions. Increased levels of S1P have been shown to confer protection in ischemia reperfusion injury by receptor-mediated inhibition of necrosis and apoptosis. We report two patients who required ECMO support for severe ARDS in which we, measured sphingolipid concentrations from BAL.

Methods: BAL was obtained from two study patients and centrifuged to obtain supernatant. This supernatant was analyzed for sphingolipids using liquid chromatography/tandem mass spectrometry (LC/MS/MS) to measure the concentrations of different sphingolipid species and (13)C-isotopic enrichment of 16:0-ceramide.

Results: Our data showed that in Patient 1 the sphingolipid concentration peaked on day 2 (Figure 1), and in patient 2 it peaked on day 4 and decreased profoundly on day 7 (Figure 2). Both patients had a good clinical outcome and survived.

Conclusions: Sphingolipid concentration peaked on days 2 and 4 in patients with severe ARDS on ECMO, a detailed study to ascertain the prognostic value of sphingolipids is required.[figure1]

RELATIONSHIP BETWEEN FREQUENCY MODULATION AND TOTAL LUNG VOLUME
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We used an elementary circuit similar to the basic blocks of a High Frequency Oscillator and connect the system to an isolated Ex-Vivo sheep lung. we used air flow of 12 litres per minute, pressure of 4 joules and circuit oscillator with 50% duty time. Total lung volumes were measured at different oscillation frequencies from 1 Hertz to 20 Hertz.

Total lung volume increased linearly with increased frequency from 1 Hertz to 5 Hertz then started to decline slowly between 11 Hertz and 15 Hertz then the total lung volume declined sharply at 16 Hertz and higher.

Between 5 Hertz and 10 Hertz, Total lung volume decreased by almost 1000 ml. Our Ex vivo study suggests that using frequency modulation before transferring patients from HFO to Conventional ventilation may improve the success rate.

Also Using frequency modulation during the most of the HFO time may prove physiologically better to the ailing lung.

Both possibilities need to be confirmed by in-vivo studies.
BIOMARKERS OF LUNG INJURY AFTER INITIATION EXTRACORPOREAL CO2 REMOVAL IN ACUTE EXACERBATION OF COPD

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Background: Severe exacerbation of chronic obstructive pulmonary disease (COPD) requiring mechanical ventilation is associated with a high mortality and morbidity. We used extracorporeal CO2 removal (ECC02R) to facilitate rapid discontinuation of mechanical ventilation for acute hypercapnic respiratory failure due to COPD exacerbation. We would like to report that a strategy of extracorporeal CO2 removal and early discontinuation of mechanical ventilation results in rapid attenuation of Angiotopiten-2 (Ang-2) and the receptor for advanced glycation end products (RAGE). Methods: Serum specimens were collected on consecutive days from study subjects and centrifuged to obtain supernatant which was frozen at -80 degrees centigrade, thawed at room temperature, and analyzed using ELISA immunoassay quantikine kits for human RAGE and human Ang-2 (Rand D Systems). Results: Study subjects had mechanical ventilation discontinued within 24 hours after initiation of ECC02R. Daily reduction in serum ANG-2 occurred in both subjects. (Figure 1) RAGE increased on day two followed by a rapid attenuation. (Figure 2)

Conclusions: Extracorporeal CO2 removal facilitates rapid endotracheal extubation and is associated with attenuation of Ang-2 and RAGE, serum markers of lung injury, in patients with acute exacerbation of COPD.

THE USE OF GMP-PRODUCED MULTISTEM® CELLS IN COMBINATION OF EXTRA CORPOREAL MEMBRANE OXYGENATION IN ARDS

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Acute Respiratory Distress syndrome (ARDS) is a common clinical entity and a major cause of morbidity and mortality. Despite advances in intensive care management and ventilator support techniques, mortality rates have remained high. Extracorporeal membrane oxygenation (ECMO) may provide an alternative support therapy to minimize the trauma caused by mechanical ventilation when the conventional ventilator support has failed. However, trials evaluating ECMO in ARDS didn’t demonstrate benefit because of the limited nature of the oxygenation, CO2 removal and high rate of bleeding complications. A novel potential therapy for ARDS is the use of bone marrow derived mesenchymal stem cells (B-MSC) which effects not only by modulating inflammation but also by protecting local endothelium and epithelium. We designed an animal model to assess the effect of stem cells in combination with ECMO treatment in ARDS. 11 sheep received 2.5-3.5µg/kg E. coli endotoxin to create ARDS. 5 animals who received endotoxin only were considered as control group. 3 sheep received veno-venous ECMO support that was established between superior vena cava and main pulmonary artery 1 hour after the end of the endotoxin infusion. 3 sheep received a dose of 40 million of clinical grade gmp-produced Multistem® cells (Athersonys, Inc.) intratracheally one half-hour after the end of the infusion endotoxin, followed by ECMO treatment. PO2 and plasma neutrophil levels, BAL, and postmortem histopathology were studied. The results of this pilot experiment showed that combination of stem cells with ECMO treatment may be useful in future studies investigating the diagnosis, treatment and the prevention of ARDS.

EVALUATION OF LONG-TERM DURABILITY OF AN ANTITHROMBOSGENIC-COATED ECMO SYSTEM WITH GYRO PUMP

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ECMO systems are applied for life-threatening severe respiratory and/or circulatory failure. However, conventional ECMO systems have poor durability and antithrombogenicity for long-term use. We have been developing an ultra-durable heparin-free ECMO system. The system consists of a compact oxygenator (BIOCUBE®) made of PMP membrane in which micropores are blind-ended at the blood contacting surface to prevent plasma leak, and the entire blood-contacting surface is coated with a novel heparin-bonding material (T-NCVC®). This study reports a newly development of ECMO system consisting of Gyro pump® coated with T-NCVC and evaluations of its long term durability and antithrombogenicity on chronic animal experiments. Heparin-free veno-arterial bypass ECMO was carried out during 1, 2 and 3 weeks animal experiments using 3 goats weighing 57-58 kg. Systemic anticoagulation was not conducted, except for one-shot heparin injection at cannulation. As a result, 3 weeks heparin-free ECMO could run. 2.1 - 3.0 L/min of bypass flow rate was maintained, and gas transfer was kept sufficient level without device exchange in any case. Gyro pump has 2 pivot bearings at the top and bottom of impeller shaft. Post 1 week ECMO, a bit of thrombus was observed at the top of the shaft. Post 2 and 3 weeks ECMO, no thrombus was observed in each pump. There was no thrombus in a hollow fiber bundle and on outlet side of each oxygenator, in spite of small thrombi were scattered on inlet side. In conclusions, the ECMO system with Gyro pump has enough durability and antithrombogenicity for 3 weeks cardiopulmonary support.
14-DAY IN VIVO TESTING OF A COMPLIANT THORACIC ARTIFICIAL LUNG

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A 14 day recovery experiment was performed in sheep (60-70kg, n=4) to assess the long term function of a compliant thoracic artificial lung (cTAL). The cTAL was connected to the circulation in a pulmonary artery to left atrium attachment mode via 18 mm vascular grafts with no pulmonary banding to divert flow. Throughout the course of each experiment only one device was used. Post-surgery, sheep hemodynamics (mean arterial pressure, MAP; cardiac output, CO), organ function (BUN, creatinine, AST, ALT) and cTAL function (blood flow rate, oxygen transfer, and resistance) were evaluated. One sheep was euthanized on day 6 after lung attachment due to a bradycardiac arrhythmia; the remaining three sheep survived for 14 days. The MAP was stable, averaging 104.9±2.6 mmHg over 14 days. The CO started elevated at 9.3±1.42 L/min, declined gradually, and reached a stable average of 5.0±0.3 L/min over the last 8 days. BUN and creatinine were unchanged and within normal ranges throughout. ALT and AST were elevated over the first 3 days but declined thereafter. The cTAL performance was very stable in all aspects. cTAL flow rate started at 3.7±0.4 L/min and averaged 3.3±0.2 L/min; cTAL resistance was 0.90±0.11 mmHg/ml/min; and cTAL oxygen transfer was 185±52 basal and averaged 188±24 mili/min. Upon explant, the first cTALs featured small regions of clot formation at the sides where it was fixtured. This was remedied and the last three devices were almost completely free from clot. Overall, the cTAL was able to maintain excellent function over the course of a 14 day experiment. Future studies will examine extending its use beyond one month.

SEVEN-DAY IN VIVO EVALUATION OF A LOW-FLOW ACTIVE-MIXING EXTRACORPOREAL CARBON DIOXIDE REMOVAL SYSTEM (ECO2R) FOR PEDIATRIC RESPIRATORY SUPPORT

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Adult ECO2-R devices and pediatric oxygenators share the common objectives of low blood flow and low priming volume while safely maintaining sufficient respiratory support. The objective of this work was to conduct initial feasibility studies to determine if a highly efficient active mixing adult ECO2-R system can safely be translated directly to the pediatric population. Methods: Eight healthy juvenile sheep (22-33 kg) were connected to the Hemolung Respiratory Assist System (ALung Technologies) via independent 8-10Fr perfusion/drainage cannulae in the right external jugular (REJ) for up to 7 days. Circuit flow was maintained by the Hemolung integrated pump. Anticoagulation was maintained with heparin to target an aPTT of 1.5-2.3X baseline. Summary of Results: All eight animals were successfully connected to the circuit, five of which were treated for the full seven-day period. None of the three studies ending prematurely were related to device functionality. The mean of the seven-day average flow rates was 290 ± 10 ml/min excluding one animal, where flow was increased up to 480 ml/min to reduce cranial swelling. Average CO2 removal rates were 59 ± 5 ml/min and returned blood O2 saturation remained at 100%. Conclusions: The Hemolung provided clinically relevant levels of CO2 removal and fully oxygenated the blood, at appropriate pediatric flow ranges in each animal receiving treatment for seven days. These study outcomes suggest that the potential exists for use of the Hemolung in a venovenous pediatric configuration to safely provide respiratory support utilizing a significantly less complex system than traditional ECMO.

PLANAR PDMS/SILICON ASYMMETRIC MEMBRANES FOR EXTRACORPOREAL MEMBRANE OXYGENATION

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Purpose: We aim to minimize the membrane surface area required for adequate oxygenation of blood in neonatal patients on ECMO support, thereby reducing exposure to foreign surfaces and associated thrombogenesis. Polydimethylsiloxane (PDMS) membranes are sufficiently gas permeable to meet neonatal oxygen and carbon dioxide requirements of 100 and 80 ml/min, respectively, in a small form factor, but thin PDMS membranes require mechanical support. Novel silicon micro pore membranes (S Mem) fabricated by our group provide a rigid, planar substrate for the PDMS membrane while offering negligible resistance to gas transport.

Methods: Finite element modeling was conducted using ANSYS (Canonsburg, PA) to analyze the deformation of the PDMS membrane supported by S Mem under a load of 77.6 cmHg. To fabricate the asymmetric membranes, PDMS was spin-coated on a silicon wafer, transferred, and then bonded to the S Mem supported on O2 plasma treatment. Membrane thickness was measured by profilometry and SEM. Permeability to O2 and CO2 was measured by a bubble flow meter. Oxygenation of heparinized human blood was evaluated with a blood gas analyzer and ex vivo test circuit.

Results: Modeling results indicated that, under high pressure, the PDMS layer would deform less than 50 nm out of plane. Profilometry and SEM showed a uniform 4.2 m thick layer of PDMS on the S Mem. Permeability to O2 and CO2 were 7.17±1.92 and 44.8±8.47 ml min^-1 m^-2 cmHg^-1, respectively. Oxygen saturation of human blood was achieved with no gross clots for 90 minutes.

Conclusions: Our results show that the asymmetric PDMS/S Mem membranes are capable of constituting a neonatal ECMO support system with a small membrane surface area (less than 0.2 m2).
TWO DECADES’ EXPERIENCE WITH INTER-FACILITY TRANSPORT ON EXTRACORPOREAL LIFE SUPPORT

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Purpose: In the U.S., extracorporeal life support (ECLS) for patient transport has been limited to a few centers. We reviewed our institution’s experience with transport on ECLS to facilitate transfer of critically ill patients.

Methods: Review of an institutional registry of inter-hospital transports on ECLS from 1990-2012, and comparison with data from the international ELSO registry.

Results: ECLS teams traveled to evaluate 236 critically ill patients for cannulation. Six patients died before transfer. Ten were too stable to require ECLS. One patient died during transport. 220 patients were transported on ECLS; they represent 11.3% of all ECLS cases at our institution.

Forty-two transfers were by helicopter, 23 by airplane, and 152 by ambulance. 135 survived to discharge (62%). Average age was 26.5 ± 19 years; 79 (36%) were < 18 years old. Venoarterial ECLS was used in 114 patients (52%), of whom 57 (50%) survived to discharge. Venovenous ECLS was used in 107 (48%); of these, 78 (73%) survived. Survival ranged from 20-76% by age and indication for ECLS. (Table 1)

183 (84%) were in-state transfers. Travel distance did not impact survival (mean = 181km among nonsurvivors, 189km among survivors) and 7 successful transfers were >1000km.

Conclusion: Transport on ECLS is safe in a critically ill population. Survival is comparable to age- and treatment-matched ECLS patients at large.

### ASAIO PULMONARY ABSTRACTS

OXYGENATOR AND HEAT EXCHANGER MODULES FOR A MODULAR CARDIOPULMONARY SUPPORT SYSTEM

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Purpose: For CPS there are only few oxygenator sizes for a disproportionate range of patient sizes. The systems are generally not adaptable to changing patient conditions during therapy and, additionally, a HLM system cannot be used postoperatively as an ECLS system. This is a downside for patients in terms of priming volume and hemodilution.

To address these concerns, we support the continued development of a modular system with small and independent oxygenator and heat exchanger modules which can be added to and removed from the system. These modules must be easy to manufacture for economic viability.

Methods: Simple oxygenator and heat exchanger modules with two different housing parts were designed and manufactured. A simplified potting technique to aid manufacturing was developed. Five oxygenators and one heat exchanger module were tested for efficiency. For 800 mL/min blood flow, the calculated gas exchange efficiency was 44 mL O2/min and 40 mL CO2/min and the heat exchanger performance was calculated to be a factor of 65 %.

Results: In vitro gas exchange efficiency results demonstrated an average of 40 mLO2/min and 37 mLCO2/min for blood flow of 800 mL/min. Average priming volume for the oxygenator modules was 33 mL. Heat exchange results show a performance factor of 43.3 % with a priming volume of 29 mL.

Conclusions: The results for the oxygenator modules show that gas exchange needs to be improved by approximately 10 % to reach the designated efficiency. The heat exchanger module performance must be improved by 50 %. The simplified potting procedure may reduce manufacturing costs but could also be responsible for the underperformance of the gas and heat exchange modules.
POLYMYXIN B-HEMOPERFUSION AND ENDOTOXIN ACTIVITY ASSAY IN KIDNEY TRANSPLANTS

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Introduction. Our principal end point was to use a new Endotoxin Activity Assay (EAA) which has been developed to rapidly detect endotoxin activity (EA). Furthermore we aim to prove the validity and safety of removal of endotoxins using Polymyxin-B based hemoperfusion (PMX-DHP). Finally, survival, endotoxin activity and graft function was monitored at 30 days of follow up. Material and Methods. Eighteen recipients with EA>0.60 were enrolled in this study and received treatment to remove endotoxins. Each treatment was performed for two hours with a blood flow rate of 100 ml/min. All the patients were treated with PMX-DHP until an EA<0.4 was found. Results. Two PMX-DHP treatments were performed on 8 patients [median EA =0.72(0.61-1.22)], three treatments on 6 patients [median EA =0.85(0.77-0.92)] and four treatment on 4 patients [median EA =1.11(0.95-1.22)]. At the end of the endotoxin removal therapy, the median EA level was 0.33[0.29-0.39]. The stabilization of hemodynamic (p<0.005) and inflammatory frameworks (p<0.001) were immediately observed after the PMX-DHP. At 30 days of follow up all patients were alive with a good graft function and low level of endotoxin activity.

Conclusion. The EEA could be considered a diagnostic test to detect endotoxin activity early or may be used to clarify the role of endotoxin translocation and can help us to determine the correct timing for intervention. Accordingly, larger multicenter clinical trials will be necessary to accurately assess the benefits of EAA plus DHP-PMX for transplant patients with suspect of sepsis.

INVESTIGATIONS ON THE NEPHROTOXIC POTENTIAL OF DIALYSATE TAKEN FROM HIGH CUT-OFF HEMODIALYSIS TREATMENTS IN PATIENTS WITH LIGHT CHAIN INDUCED MYELOMA KIDNEY


Purpose. Acute kidney injury is a common complication in multiple myeloma (MM), usually caused by cast nephropathy a direct consequence of high serum free light chain (FLC) concentrations present in these patients. In this condition FLC induced cell stress responses are frequently seen in proximal tubular cells (PTCs). Removal of circulating FLC with high cut-off hemodialysis (HCO-HD) has recently been studied and rapid reduction in serum FLC levels was associated with improved likelihood of kidney function recovery. The aim of this investigation was to study renal epithelial cell toxicity of dialysate obtained from HCO-HD treatments of MM patients.

Methods. Spent dialysate collected from HCO-HD treatment sessions of patients with FLC induced AKI were concentrated by filtration with a 5 kDa cut-off membrane and exposed to HK-2 cells, a proximal tubule epithelial cell line from human kidney. The effects on cell morphology and activation were studied by microscopy and by measurement of cytokines in the supernatant using enzyme-linked immunosorbent assay. FLC concentrations were determined by nephelometry, using a particle-enhanced immunoassay.

Results. Incubation of the FLC containing concentrates (25 μmol and 50 μmol) with HK-2 cells induced the release of proinflammatory cytokines (IL-6, IL-8, TNF, MCP-1) and lead to morphological alterations of the cells. There was a considerable variability among the dialysates obtained from different patients. The amount of FLC that stimulated expression of inflammatory cytokines in the PTCs was well within levels that are seen in patients with MM.

ECS-ASSISTED DONATION AFTER CARDIAC DEATH IN A NON-ANTICOAGULATED PORCINE MODEL AFTER 60 MINUTES OF WARM ISCHEMIA

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Extracorporeal Support (ECS) resuscitates abdominal organs in donors after cardiac death (EDCD) with minimal impact on the donor pool using controlled DCD (cDCD). Uncontrolled DCD (uDCD) represents a major potential organ source, but ECS use is questionable in this setting due to prolonged warm ischemia (WI) times. This study evaluates post-transplant function of kidneys from a porcine model of uncontrolled ECD after 60 minutes of WI with addition of thrombolytics. Methods: A porcine (25-30Kg) model of DCD by apnea was used with the extension of WI to 60 minutes. ECS was initiated via the iliac vessels for 4hrs at room temperature with addition of streptokinase 2,000,000 IU. Target ECS flows were >50mL/min/kg at mean perfusion pressures of 65-75mmHg. Kidneys were procured after 4 hours, flushed with HTK, stored, and transplanted into healthy nephrectomized recipients (25-30 kg). Postop serum Creatinine (Cr) was checked daily. Adequate graft function was defined as Cr <5mg/dL in the first 72hrs. No immunosuppression was used. Results: Target ECS flow was met in all donors (n=6) within 60 minutes at mean perfusion pressures of 65-75 mmHg. 12 kidneys were transplanted. Recipient Cr on postoperative days 1, 2, 3, and 4 were 2.7, 3.2, 3.0, and 2.3, respectively. One pair of renal grafts failed. All pigs were directly observed producing copious urine.

Conclusion: ECD can be used with thrombolytics to adequately resuscitate organs prior to transplantation in uDCD after 60 minutes of WI, and result in functional organs. This addresses a major logistic limitation for the use of ECD in uDCD donors, and could have a major impact on the organ donor pool.

ESTIMATION OF EQUIVALENT CONTINUOUS CLEARANCE FOR HEMODIALYSIS PATIENTS FROM MIDWEEK AND WEEKLY MEASUREMENTS

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Equivalent continuous clearance (ECC) defined as the removed mass per dialysis cycle time (one week) per a reference solute concentration, Cₘᵦ, in serum, where ref may denote peak average (pa) concentration (as for standard K, stK) or time average (ta) concentration (as for equivalent renal clearance, EKR), needs frequent measurements throughout the weekly cycle of dialysis. Can the evaluation be reduced to the “sub-cycle” of midweek dialysis and the following interdialytic interval?

Eighteen patients on HD were examined during three consecutive HD sessions of one week (with the interdialytic breaks of 2-2.3 days). Serum urea (U), creatinine (Cr) and phosphate (iP) concentrations were measured before, at 1, 2 and 3 h, at the end and 45 min after each session, and every 0.5 h in dialysate. Weekly ECCₘᵦ was 7.1 ± 1.4, 5.7 ± 1.6, 4.9 ± 1.6 and ECCₘᵦ was 10.8 ± 1.9, 7.0 ± 1.8, 6.9 ± 2.3 mL/min, whereas the respective midweek values were significantly higher by 20 – 25% (p < 0.01), except for IP ECCₜₐ that was on average only 16% higher (NS). The weekly values of ECCs correlated well with the respective midweek values with r² in the range 0.82 – 0.86, except for IP ECCₚ with r² = 0.62, and may be calculated from the midweek values using the linear regressions.

We conclude that the weekly ECC values for U, Cr and iP, although generally lower than the respective midweek ECC values, can be calculated from the midweek ECC by linear regression.
ASSESSMENT OF PHOSPHATE REMOVAL BY EQUIVALENT CONTINUOUS CLEARANCE IN PATIENTS ON HEMODIALYSIS

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The kinetics of plasma phosphate during hemodialysis (HD) is much different than that of standard adequacy markers, as urea and creatinine. We propose to apply equivalent continuous clearance (ECC) defined as the removed mass per dialysis cycle time (1 week) per a reference serum phosphate concentration Cr,ref, where ref may denote peak average (pa) concentration (as for standard K, stdK) or time average (ta) concentration (as for equivalent renal clearance, EKR).

Eighteen patients on HD were examined during three consecutive HD sessions of one week (with the interdialytic breaks of 2-2-3 days). Serum urea (U), creatinine (Cr) and phosphate (IP) concentrations were measured before, at 1, 2 and 3 h, at the end and 45 min after each session, and every 0.5 h in dialysate. ECCU was 7.1 ± 1.4, 5.7 ± 1.6, 4.9 ± 1.6 ml/min and ECCr was 10.8 ± 1.9, 7.0 ± 1.8, 6.9 ± 2.3 ml/min for U, IP and Cr, respectively. Total IP ECC parameters were corrected to diffusible IP, as 15% of IP in plasma is bound to plasma proteins, and the corrected values were 6.8 ± 1.8 for pa and 8.3 ± 2.1 ml/min for ta. IP ECCPa correlated with U ECCPa (r² = 0.22, p < 0.005), IP ECCr, with Cr ECCr (r² = 0.27, p = 0.03), U ECCPa with Cr ECCpa (r² = 0.86, p < 0.001), and U ECCr with Cr ECCr (r² = 0.65, p < 0.001).

We conclude that IP ECCPa and ECCr are between those calculated for U and Cr, in agreement with the molecular mass of phosphate. The weak correlations of ECC between IP and U and Cr, in contrast to very strong correlations of ECC between U and Cr, reflect the specific kinetics of phosphate during HD.

IMPACT OF STERILIZATION ON POLYMER MEMBRANES AND PLATELET INTERACTION


Purpose: Use of electron-beam (e-beam) sterilized haemodialysis membranes was associated with risk of thrombocytopenia which was published in 2011 (Kiakii et al, JAMA, October 19, 2011-Vol 306, No. 15). The present study was about the impact of e-beam on polymer membranes and its impact on platelet adherence, aggregation and activation as well as the underlying changes in the polymer and the mechanisms leading to platelet drop. The effect of e-beam radiation was compared against unsterile and steam sterilized membranes.

Methods: Flat sheet membranes were subjected to steam and e-beam sterilization and also left unsterile. Platelets of human whole blood were allowed to interact with the membranes during a period of 60 minutes in a laboratory setting. Platelet loss was measured by platelet counts in blood samples for 16 different donors. Platelet activation and aggregation was studied with SEM, immunolabeling and flow cytometry. Surface energy, roughness and surface chemical composition of the membranes were studied with contact angle measurements, SEM, AFM and XPS.

Results: E-beam sterilized and unsterile membranes caused the platelets to drop to a level of 82 % and 80% of their original number, respectively, which were significant (Kruskal-Wallis). Platelet counts were 93% after contact with steam sterilized membranes (no significance; p = 0.05). Steam sterilized membranes had lower surface energy and slightly different membrane surface composition compared to e-beam and unsterile membranes. Attached platelets were rather clustered on steam sterilized membranes and had an outspread morphology on e-beam and unsterile membranes. No differences could be shown regarding platelet activation or aggregation.

MATHEMATICAL MODEL OF THE DIFFERENT ON-LINE HDF THERAPIES

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Background. Renal insufficiency has a large medical and social impact. Despite the developments in technology, dialysis is still associated with a non-negligible rate of morbidity. A better response to dialysis could be gained by tailoring it on the single patient and choosing among alternative methods. Many mathematical models have been developed so far to describe body fluid and solute kinetics during Standard Hemo-Dialysis, while On-line Hemo-Dia-Filtration (HDF), has been poorly investigated from this point of view. This work aims to provide a tool to allow correct HDF choice.

Materials and Methods. The data from 24 dialysis sessions, recorded at San Faustino Dialysis Center, Milan (Italy), were used to develop and validate the model. The diffusive and convective interactions occurring among the patient, the dialysis filter and the on-line system for the production of fluids were considered. The effects of pre- and post-dilution techniques were investigated. Three parameters, related to mass transfer at the cell membrane, capillary wall permeability and thickness of the protein layer inside the filters, were used to tune the model.

Results. Sodium and Chloride concentrations calculated by the model showed deviations lower than 3% with respect to the corresponding clinical measurements, while other solutes deviation was always less than 20%. Different electrolyte distribution and their electric charge resulted to be the most important factors affecting the effectiveness of pre- or post-dilution settings.

Conclusions. The developed model allows to describe electrolytes and fluid transfer in the dialysis patient and to evaluate the effects of different HDF settings being helpful in dialysis therapy planning.
ROTORy BLOOD PUMP PROMOTES RAPID DILATION OF PORCINE PERIPHERAL VEIN

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Purpose: The preferred form of vascular access for hemodialysis is the arteriovenous fistula (AVF). Flow Forward Medical’s Arteriovenous Fistula Eligibility (AFE) System™ is designed to dilate peripheral veins prior to AVF surgery by increasing vein wall shear stress (WSS) and stimulating vascular remodeling, thereby increasing AVF eligibility and improving AVF maturation.

Methods: A prototype AFE System was built comprising a small extracorporeal centrifugal blood pump, cuffed and heparin-coated inflow and outflow conduits, and a power base unit. In a 28 kg pig, the device was implanted in a right jugular vein to left saphenous vein (SV) configuration and the SV was treated with a WSS of approximately 4 Pa for 9 days.

Results: Pump flow increased from 270 mL/min to 947 mL/min and the SV segment dilated from 3.8 mm to 11.8 mm over 9 days of treatment, without angiographic evidence of stenosis. At necropsy, the dilated SV was easily mobilized and manipulated. Thrombus was noted in the ligated jugular vein and around the intravascular portion of the inflow conduit, consistent with known hypercoagulability of the pig. Emboli were seen in the lung. (Figure 1)

Conclusion
This pilot study demonstrated a 300% increase in vein diameter over 9 days of treatment in a porcine model, easily exceeding the minimum 6 mm vein diameter required for new AVF maturation. A larger nonclinical study is planned.

CLASSIFYING THE MEMBRANES FOR BLOOD PURIFICATION BY A SIMPLE AND WELL-KNOWN METHOD

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Purpose: Membranes for blood purification are generally classified as low-flux, high-flux, protein leaking and high cut-off membranes. The characterization is achieved by a variety of methods, ranging from water permeability to removal of different toxins in order to describe the performance across the relevant size spectrum. The aim of this analysis is to establish a simple methodology for classification based on the well-known in vitro dextran filtration measurements.

Methods: The sieving profile for 20 blood purification devices from different manufacturers and different types was measured by filtration of dextran mixtures with molecular weight of the fractions covering the range from 6 to 500 kDa, under constant shear rate and with ultrafiltration rate set at 20% of the blood side entrance flux. To eliminate the differences among devices the experiments were carried out in mini-modules with surface area of 280-300 cm².

Results: Dextran sieving curves were characterized by the molecular weight cut-off (MWCO), i.e., the molecular weight at which the sieving coefficient is 0.1, and by the newly defined weight retention onset (MWRO), i.e., the molecular weight at which the sieving coefficient is 0.9. Defining two points on the sieving curves describes the shape of the curve, widening the methodology by alluding to the pore sizes of the membrane and its pore size distribution. A graph of MWCO vs. MWRO shows the landscape of blood purification membrane types, clearly differentiating among the membrane types and ranges can be defined. Further classification of newly developed membranes can be easily achieved by this meaningful representation based on one well-known in vitro method.
HOW TO CALCULATE KT/V IN DIALYSIS PATIENTS WHO ARE NOT ON ROUTINE 3 TIMES/WEEK DIALYSIS REGIMEN?
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Introduction: Renal or extrarenal blood detoxification is defined as clearance (K) which may be applied continuously or discontinuously. Consequently KT/V is the dose of any kind of artificial kidney therapy. It is a matter of debate how KT/V in patients on regular artificial kidney therapy should be evaluated especially when it differs from routine 3 times/week treatment including residual renal function. In this study 5 different methods are compared.

Methods: 6 anuric RDT patients have been dialyzed consecutively 3x4 h for one week and 6x2 h in another week. Pre- and post-dialysis blood samples and body weight are taken at each dialysis session. The same dialyzer and blood flow has been applied in each dialysis. KT/V has been evaluated using the formal two compartment urea kinetic model of Stiller based on a weekly therapy cycle. The Stiller model also provides data on protein catabolic rate (PCR), time average concentration (TAC) and on prescribed and delivered clearance. Data were compared with Daugirdas formulae (spKT/V) and (Daug 2012) as well as Leyboldt and FHN prediction formulae to calculate standard KT/V (stdKT/V).

Results: In 3x4 h dialysis Kt/V-Stiller and spKT/V are 1.44 and 1.45. StdKT/V is 2.00 (Leyboldt) and 2.13 (FHN). In 6x2 h dialysis Kt/V-Stiller is 1.6 and KT/V (Daug 2012) is 0.87. StdKT/V is 2.95 (Leyboldt) and 3.04 (FHN), respectively. In the Stiller model PCR is 0.99 and 1.17 g/(kg x day) and TAC 14.95 and 15.12 mmol/l.

Conclusion: If dialysis frequency is different from 3 times/week dose of therapy KT/V should be calculated using formal urea kinetics based on a weekly cycle instead of using approximation formulae.

MEASUREMENT OF INTRA-PERITONEAL VOLUME DURING CONTINUOUS FLOW PERITONEAL DIALYSIS (CFPD)
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Background: During CAPD or standard cycle therapy the peritoneal volume (PV) of fluid is drained with each cycle so that the PV is known. In contrast, during Tidal PD or CFPD it is much more difficult to determine PV and this lack of information has limited the application of these more effective therapies. Knowledge of the PV is important in order to maintain adequate volume for solute transfer while not endangering the patient with excess volume.

Method. We investigated PV measurement based on the response in outflow dialysate to step changes of a chemical marker concentration in the inflow dialysate in a simulated patient. It consists of a PVC bag filled with partially filled Penrose tubing to simulate peritoneum and bowels; it has volume and surface area of a normal patient. Inflow and outflow curled Tenckhoff catheters are at opposite ends of the simulator. Step changes of input marker are made every 15 - 20 minutes.

Observations and Results. Outflow response to a step change in the marker concentration of the inflow dialysate has an expected sigmoid shape indicative of a system that is at least second-order. A second order system would consist of two hypothetical volumes: 1) the bulk volume through which the dialysate travels quickly from inlet to outlet and 2) the less-accessible spaces between the bowels. Parameters of the first phase of the response curve show the best correlation to the PV. Over a PV range of 500 to 2,000 mL, parameters of the response are able to predict the PV within 10 % of the actual volume.

Conclusion: PV during CFPD may be measured by varying inflow concentration of a chemical marker and analyzing its concentration profile in the outflow dialysate.

SEQUENTIAL PERITONEAL EQUILIBRATION TEST: REPEATED ASSESSMENT OF PATIENTS ON CONTINUOUS AMBULATORY PERITONEAL DIALYSIS
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Sequential peritoneal equilibration test (sPET, Galach et al, 2013) is based on the consecutive performance of peritoneal equilibration test (PET, 4 h, glucose 2.27%) and mini-PET (1 h, glucose 3.86%), and the estimation of parameters of the three pore (3p) model. It enables the assessment of the functional transport barrier for fluid and small solutes and the following of its changes with the vintage time.

Sixteen patients (age 61.1±15 y, 7 females, vintage time 28±24 months) were examined using sPET twice with the interval of at least 5 month (7.6±2.0 months). There was no difference between the observational parameters (urea and creatinine D/P, sodium dip, glucose D/DO, net UF,) measured in the two examinations and their values for small solutes were well correlated between the examinations, but not net UF. Among the estimated parameters of 3p model, the significant difference between the two examinations was found only for hydraulic conductance (LpS, 0.042±0.033 for 1st examination vs. 0.030±0.021 mL/min/mmHg for 2nd examination, p=0.03) and peritoneal fluid absorption rate (PerAbs, 1.6±1.3 for 1st examination vs. 1.1±0.7 mL/min for 2nd examination, p=0.05). The two fluid transport parameters did not correlate with D/P creatinine, but the decrease in LpS values between the examinations was observed mostly for patients with low D/P creatinine.

We conclude that the changes in fluid transport parameters, as assessed by 3p model, may precede the changes in small solute transport parameters, but the systematic assessment of fluid transport status needs specific clinical and theoretical tools besides the standard tests.
A STRATEGY FOR ELIMINATING PASSENGER LEUKOCYTES IN HUMAN ALLOGRAFTS

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Transplantation is unique immunologically due to both donor and recipient antigen presenting cells present at reperfusion. As part of the normal immune surveillance, passenger leukocytes (PL) are trapped in the renal parenchyma at procurement. Upon reimplantation, PL migrate to secondary lymphatics where recipient immune cells recognize PL via direct antigen presentation and there is an up-hill battle to prevent rejection. Strategies preventing allorecognition, positively impact outcomes. Using an acellular, near-normothermic perfusion technology; Exsanguinous Metabolic Support (EMS), we evaluated feasibility of removing PL from human kidneys.

Methods—Biopsies were taken pre and post EMS (up to 48hrs). Frozen representative sections of the kidneys were used to determine the number and location of the PL using an indirect immunofluorescence assay with CD4 antibody and Alexafluor488 secondary antibody along fluoroshield plus DAPI.

Results—There was a significant reduction in the number of resident PL post EMS. (Figure 1)

Findings mirrored the increasing concentration of PL in the circulating EMS after perfusion. PL were isolated from the perfusate and quantified at 1.02x10^6. Conclusion—This study demonstrates the feasibility of depleting renal allografts of PL pretransplantation during a period of EMS perfusion. We are currently evaluating non-toxic adjunct techniques for further enhancement of depletion.

MICROFLUIDIC DEVICES FOR MECHANOTRANSDUCTION STUDIES IN POLARIZED KIDNEY EPITHELIAL CELLS

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Kidney epithelial cells are sensitive to their surrounding mechanical microenvironment. Changes in fluid flow and shear stress on the apical surface of tubular epithelial cells affect transport, protein expression, protein trafficking, and cytokine production. Studying these processes in polarized epithelial cells can be challenging given the paucity of devices that allow application of controlled shear stress in cells grown on porous substrates that are needed for proper cell polarization. We have developed a set of microfluidic devices to allow differentiated growth of polarized kidney epithelial cells on synthetic porous substrates to evaluate the effects of fluid shear stress on various epithelial cell functions. Cells are grown on porous inserts that can be removed from the device for pre- and post-flow cell characterization. The modular design allows higher throughput than what is possible using standard microfluidic devices. One of the designs is compatible with inverted fluorescence microscopy and can be used for live cell imaging. These devices could have a wide range of applications for mechanotransduction studies in polarized epithelial cells.

DIALYZER REPROCESSING WITH A TWO-PHASE CLEANING SYSTEM — INITIAL ASSESSMENT IN DIALYSIS CLINICS

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Purpose: Reprocessing of dialyzers with peracetic acid requires manual pre-cleaning which increases infection risk. Clearance of higher molecular weight (MW) solutes decreases markedly after only a few reuses with peracetic-acid based methods. A two-phase cleaning process (ClearFlux™ Dialyzer Reprocessing System, CF) was used to reprocess dialyzers. Performance of dialyzers reused in this manner was assessed in terms of maintenance of total cell volume (TCV), number of reuses, and cost.

Methods: High-flux dialyzers were used to perform dialysis and then reprocessed using CF or conventional peracetic acid reprocessing for a period of 9 months. TCV, clearance of middle molecules, reuse numbers and other parameters were studied. Cost analysis was based on data from actual usage in dialysis clinics.

Results: Two-phase dialyzer reprocessing showed that: 1) manual pre-cleaning of used dialyzers was eliminated, allowing sinks dedicated to this purpose to be removed from clinics; 2) during reuse, >90% of patients maintained TCV between 95-100% of baseline; 3) average reuse number increased from 5-8 to >30; 4) no fiber leaks were reported. The clearance of a 10 kDa dextran probe (beta-2 microglobulin = 11.8 kDa) was reduced by 78% in dialyzers reprocessed by conventional peracetic acid methods, but was unchanged from baseline values with CF. Cost analysis revealed a savings of 40% versus single-use and 25% versus conventional reprocessing.

Conclusions: When CF is employed, dialyzer TCV and reuse numbers, as well as clearance of larger MW solutes are maintained to a much greater extent than with conventional reprocessing. Cost analysis indicated significant savings.
PRELIMINARY ASSESSMENT OF SILICON NANOPORE MEMBRANES FOR HEMODIALYSIS
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Purpose: Silicon nanopore membranes (SNMs) with compact geometry and uniform pore size distribution have previously demonstrated a remarkable capacity for hemofiltration. We aim to assess the existing SNMs for use in hemodialysis.

Methods: A flow cell with parallel plates was mounted with polyethylene-glycol coated SNM chips. The average pore size was 6.5nm ± 0.6 and effective surface area was 1.73 cm². A total of 13ml of artificial serum (Cr: 10mg/dL, BUN: 88mg/dL, PO₂: 5mg/dL, alb: 3g/dL) or 30ml of heparinized bovine whole blood was recirculated and dialysate (140mEq NaCl) flowed in a single-pass counter-current fashion. The flow rate of blood and dialysate was 25ml/min to maintain pressures < 30mmHg. Solute clearance (K) was calculated by fitting concentrations measured at 2 and 5 hr (n=3) to an exponential decay function: C(t)=Cᵢe⁻ⁿᵗ/V, Cᵢ: initial concentration, t: time, V: volume. Diffusivity (D) was calculated by multiplying by the thickness (400nm).

Results: Reduction in all species was significant (p<0.05) except for albumin. The single pass dialysate effluent was below detection, but diffusion into dialysate was confirmed using recirculated dialysate.[table1][table2] We demonstrated that SNM are capable of selective diffusion of key species pertinent to hemodialysis while retaining larger macromolecules. Future iterations will increase surface area, optimize membrane design, and flow paths allowing for improved clearance.

MEMBRANE VS. CENTRIFUGE BASED THERAPEUTIC PLASMA EXCHANGE – A RANDOMIZED PROSPECTIVE CROSS-OVER STUDY
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Background: Therapeutic plasma exchange (TPE) is either performed using a highly permeable filter (mTPE) or a centrifugation device (cTPE). We aimed to do the first ever head to head comparison. Methods: 21 patients (51.6 ± 13.5 years; 10 F) were enrolled in this randomized, prospective, paired, cross-over study. First treatment (either mTPE or cTPE) was chosen by an online randomization list followed by the other mode for the 2nd treatment. Primary endpoints: plasma removal efficiency with 1.2 x of the total plasma volume exchanged. 2ndary endpoints: total amount of removed IgG + fibrinogen. Further, the treatment effect on platelet count was evaluated. Results: cTPE had a higher plasma removal rate than mTPE. (Figure 1)

Both devices led to similar reduction of IgG, 63.3 % (mTPE) and 67.8 % (cTPE). Clearance of fibrinogen was higher with cTPE (64 ± 9% vs 56 ± 16%, p<0.05). Platelet loss during TPE with the mTPE was nearly double of that with cTPE (15 ± 9% vs 7 ± 9%, p<0.05). Processed blood volume required to remove 1.2 x TPV in mTPE was significant higher than with cTPE, (19.855 ± 3.423 L vs 6.456 ± 1.230 L, p<0.05). Plasma removal efficiency was significantly higher in cTPE vs. mTPE (84 ± 11% vs 27 ± 5%,p<0.05). Conclusion: Higher plasma removal efficiency and lower treatment time make cTPE an attractive procedure for institutions performing TPE on a regular basis.
Progress toward closing the loop of an artificial pancreas (AP) has been hampered for years by significant time delays inherent in the current, indirect, subcutaneous tissue fluids-based glucose sensing and medications infusing approach. Developers have been burdened with the requirement to create an extremely complex algorithm that predicts vital physiological blood data as much as an hour hence, to safely treat volatile insulin dependent diabetics, based on derived blood data from as much as an hour in the past. Consider instead, direct blood access for a real time, blood-based artificial pancreas (BBAP). Reconsider the blood-based Biostator’s notable bedside success using a real time venous sugar “clamping” algorithm that was little more complicated than a thermostat. Consider also the precedent of ubiquitous successful emergency collateral vein obliteration, to speed flow, in hemodialysis patients, whose gold standard AV fistulae are either slow to mature or failing. Describe potential criteria for creation of an elective, identical, In Situ Debranched Vein Fistula Graft (VFG) for BBAP access. Review the Biostator’s clinical results. Describe and illustrate the design of an A/V pressure driven arm or forearm worn BBAP. The Biostator has been successful in clinical-experimental "clamping" of blood glucose levels in numerous patients. The BBAP is direct and real time and avoids the difficulty of having to try to safely predict the future and treat volatile insulin dependent diabetes patients based on stale data from the past. Serial (as needed) VFG’s and synthetic grafts (as may ultimately be required) offer the possibility of lifetime blood access for an exceedingly sensitive and imminently powerful BBAP.
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