An Alternative Production Method For Collagen To Obtain Scaffolds

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Study: Collagen is a basic structural element in native extra cellular matrices, and its abundant presence in natural tissues, composing 30% by weight of body protein tissues, predestines it as a polymer for biomedical materials and tissue engineering matrices. It is generally extracted from the natural tissues by treatments with acid or alkali, enzyme, and microorganisms. However these methods are generally depend on batch type and reactants, time and energy consuming, and highly costly methods. In this paper, we discuss an alternative method that could be applied on different tissues to extract collagen. It decreases the time and energy consumption and the usage of environment hazardous chemicals.

Methods: In this study, we developed an improved method that reduces the time needed to extract this protein and increase the efficiency (Figure 1). The results were compared with the one obtained from the traditional methods. The alternative method uses traditional extraction buffers combined with forceful agitation and centrifugal filtration to obtain highly-pure, soluble collagen extraction.

Results: This method is simple to perform using standard methods and equipment found in many laboratories. By employing high-speed agitation, this protocol reduces the time necessary to isolate solution, collagen extraction from approximately 7 days to less than 3 hr.

Conclusions: This paper indicates that these waste materials of animals have potential in supplementing the skin of land vertebrates as a source of collagen. The end product (collagen) could be used in many different applications, ranging from drug carrier systems to tissue scaffolds and reconstructive surgery.

Evaluation Of The Potential Of 3d-Membranes For Artificial Lungs

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Study: Until today hollow fibers are the state of the art core element of extracorporal membrane oxygenator (ECMO) devices, which are restricted to short term applications up to a few weeks. Over the last decade, substantial improvements in 3D-printing technology were achieved that allows the fabrication of novel three-dimensional membranes with almost no limitations in shape and design. 3D-membranes with a blood flow adapted design promise low pressure loss paired with high gas transfer efficiency and better hemocompatibility. Subject of this study is the evaluation of the potential of three-dimensional membranes for artificial lungs.

Methods: The membrane designs under investigations come in the form of triply periodic minimal surfaces. Initially, Schwarz-P, Schwarz-D and Gyroid geometry were parametrized using CAD tools. Computational fluid dynamics simulations were combined with a gas transfer model to estimate oxygenation performance, pressure loss and hemocompatibility of the proposed 3D-membranes. In addition, the results are compared with a hollow fiber reference geometry. Design of experiments (DoE) and multi-objective optimization was used to infer optimal scaling and geometry parameters for each of the stated designs for low flow and high flow. Mesh independency was assured prior to the study. The hydraulic performance of the initial and optimized membrane designs was tested in vitro.

Results: All suggested designs indicate a lower pressure drop and lower shear stress values. After optimization, the Schwarz-P design outperforms the hollow fiber configuration by 44% at high flow and almost 94% at low flow in gas transfer efficiency according to the numerical results. However, a comparable high ratio of stagnation volume occurs. 3D-Membranes were evaluated numerically regarding their potential use in artificial lungs. According to the results the 3D-membranes possess high potential as core technology for more efficient and probably more hemocompatible artificial lungs.
Transmission Electron Microscopy Of Explanted Intravascular Medical Devices
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Study: Plastic embedding and micro-ground sectioning (vs. traditional paraffin histology) is often preferred for histology analysis of implanted medical devices. In devices with metal and hard plastic components, micro-grinding preserves the tissue-device interface, allowing for assessment of tissue reaction and ingrowth into the device. However, the plastic embedding medium used to create micro-ground sections may prevent penetration of some stains, which results in inconsistent staining that can preclude a thorough pathology analysis of tissue substrate morphology. To combat this issue, transmission electron microscopy (TEM) can be used on targeted areas within micro-ground, plastic-embedded samples to validate light microscopic findings based on substrate morphology.

Methods: Formalin-fixed vessels containing implanted occlusion devices were embedded in hard plastic resin and micro-ground to ~60 μm-thick sections. Slides were stained and evaluated using light microscopy. After identification of targeted region(s) of extracellular matrix (ECM), the plastic embedded section was remounted to accommodate ultra-thin ~80A sectioning. Ultra-thin sections were mounted and stained with lead citrate and uranyl acetate for TEM. ECM morphology was evaluated in similar regions with both TEM and light microscopy.

Results: In micro-ground sections, trichrome inconsistently stains collagen (Fig A); however, the same region of ECM ultrastructurally is identified as collagen (Fig B; 5000x). Fibrin was also identified by TEM in other regions of ECM in which light microscopy trichrome staining was unclear. These findings can be used to more accurately assess tissue substrate morphology and the healing response of host tissues to the medical device. This method can be applied to micro-ground sections of other hard-substance containing specimens in which a distinction between histologically similar materials (e.g., fibrin vs. collagen) is important.
Predicting Plasma Free Hemoglobin Levels In Patients Due To Medical Device Hemolysis

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Study: Blood passage through medical devices can cause hemolysis and increased plasma free hemoglobin (pfH), which may lead to adverse effects such as renal injury. As a new blood-contacting device is developed, its hemolytic potential is assessed in vitro under clinical-use conditions by measuring the rate of pfH generated in a recirculating blood flow loop. To help determine device safety and to spur innovation, it would be beneficial to directly relate measured in vitro hemolysis levels to actual clinical performance.

Methods: To assist in this process, we developed a biokinetic model linking in vivo hemolysis rates to time-dependent pfH concentrations, while accounting for plasma haptoglobin (Hpt) that can bind and safely eliminate pfH. The model was parameterized using studies that characterized the evolution of pfH and Hpt following the introduction of pfH in humans, and evaluated by predicting hemolysis rates, pfH, and Hpt levels in three patient groups during, and up to 48 hr after, CPB surgery.

Results: The congruity of the model with the clinical data suggests that it can infer in vivo hemolysis rates and provide insight into pfH concentrations that may cause concern. The model was subsequently used to assess acceptance threshold hemolysis values proposed in the literature (i.e. normalized index of hemolysis (NIH) = 0.01 and 0.1 g/100L, and pfH > 20 mg/dL) and the impact of patient weight on pfH accumulation. Simulating an adult exposed to the threshold hemolysis rates, total and unbound pfH reached steady-state levels within 24–48 hr. Using physiological scaling, the model predicted that at NIHin vivo = 0.07 g/100L the INTERMACS hemolysis criterion of pfH > 20 mg/dL would be breached in an 80 kg adult; more importantly, the pfH level would be nearly three-fold greater in a 10 kg pediatric patient. Pending further clinical verification, the model may assist in the development of new blood-contacting medical devices for different patient populations.
**Effect Of Driving Pressure On VAD Flow Fields**  
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**Study:** In order to achieve more mobility of the predominantly young patients supported by EXCOR® blood pumps, an alternative driving concept is being investigated. The new driver provides the possibility of an active lifestyle adapted to the patients age and satisfies the user need of a quiet therapy environment. At the same time, the proven performance with respect to pump thrombosis and hemolysis of the EXCOR® blood pump should not be affected by the driver. In contrast to the current (Ikus) driver design, the functionality of the new driver is based on a compact and light weight servo-controlled piston. The new design features a closely controlled temporal pressure distribution which allows a gentle operation of the blood pump valves.

**Methods:** This study aims to verify the similarity of the flow field within the EXCOR® blood pump driven by the two different drivers. An in vitro flow visualization technique using High Speed Particle Image Velocimetry (PIV) was carried out by Berlin Heart. A scheme of the test setup is shown in the figure.

Besides the determination of the time resolved absolute velocity values, other problem-related differential quantities as the local vorticity distribution can be derived from the vector fields. Due to the high temporal resolution of the data obtained with the High Speed PIV-System, a detailed insight into the temporal evolution of the pump flow is possible.

**Results:** The results comprise videos of the time resolved velocity fields. The videos show a phase lag in the characteristic flow behaviour between the two drivers. This is due to the different applied pneumatic pressure curves. In turn, phase related differences in local velocity magnitudes and time-scales can be observed. However, as indicated by the figures, the cycle based time mean values and the standard deviation of the velocity vector field infer a compensation of these differences within a pump cycle.

**Conclusion:** We conclude that the washout of the EXCOR® blood pump and the peak shear stresses are very similar for both driver concepts.
Direct 3D Printing Of An Anatomical Model For Flow Visualization Experiments

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Study: Transparent models of the vasculature are often used to investigate the hemodynamic performance of medical devices such as intracranial stents, inferior vena cava (IVC) filters, and artificial heart valves. Unfortunately, the complex shape of vascular structures makes fabricating these models difficult. An emerging solution to this problem is additive manufacturing using transparent polymers.

Methods: We outline and demonstrate a process for using 3D printing to build moderately complex, optically clear models suitable for flow visualization experiments. Specifically, we use a commercial inkjet (PolyJet) printer and stock resin (VeroClear) to fabricate an idealized model of the IVC. The model includes noncircular vessel cross-sections and centerline curvature. Parts are printed with layers oriented 45 degrees to the flat visualization surfaces to optimize optical transparency. After printing, parts are sanded and polished to achieve glass-like interior and exterior surface finishes (Figure 1a) and fused together using a cyanoacrylate adhesive. Two-dimensional particle image velocimetry (PIV) measurements are then acquired using an index-matched fluid composed of water, glycerol, and sodium iodide. Velocity data are recorded for two flow rates (one and six liters per minute) and six image planes (coronal and sagittal in the left and right iliacs and the infrarenal IVC).

Results: Excellent optical clarity is achieved after post-processing the 3D printed components, and high-quality velocity measurements are obtained for all planes and flow rates considered. Interestingly, the iliac bifurcation generates a jet-like flow pattern in the downstream flow at the higher flow rate (Figure 1b). Future work will explore alternative methods to manual sanding and polishing for improving the surface finish of printed parts.

Static Cold Storage Versus Dynamic Hypothermic Ex-Situ Perfusion On Rat Hind Limb Allografts

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Study: The standard of care for preservation of vascularized composite tissue allografts (VCA) prior to transplantation is static cold storage (SCS). A dynamic hypothermic ex-situ perfusion system reduces the metabolic rate of muscle cells, and removes toxic metabolites from the circulation. The use of such system as an alternative to SCS may prolong allograft survival and function in the long-term. The aim of this study is to determine the effect of dynamic hypothermic ex-situ limb perfusion on the survival and long-term function of VCAs using rat hind-limb allograft transplantation model.

Methods: Thirty-five male Lewis rats (250 ± 25gr) were divided into 4 groups. Group 1 served as denervation control group. In group 2, 5 hind limbs were immediately transplanted to the recipient (isograft control) without dynamic perfusion. In group 3, five donor limbs were preserved at 4°C using HTK solution for 6 hours and transplanted (SCS group). In group 4 using the same preservative solution, five limbs were continuously perfused at 10–15°C for 6 hours and transplanted. Sciatic nerves were repaired in all groups. Muscle injury and function were assessed using sciatic function index (SFI), EMG, muscle histology, and metabolomics analysis at 3 months.

Results: All recipients in groups 1 and 2 survived, while groups 3 and 4 had 40% and 20% mortality rates at the early postoperative period. The average SFI in for group 2, 3 and group 4 were -54.5 ± 4.2, -84.3 ± 5.9, and -66.4 ± 3.9, respectively. The average muscle injury score of group 2, 3 and group 4 were 40.1 ± 9.2, 89.3 ± 8.9, and 47.7 ± 5.6, respectively (p<0.05). EMG and metabolomics results are pending. SCS is unable to protect muscle viability and function at 6 hours. Dynamic hypothermic ex-situ perfusion appears to provide for better viability and function in this model. Further studies are needed to explore longer perfusion periods (12–24 hours) in order achieve clinically significant prolongation of allograft survival.
Assessment Of Healing Response To Intravascular Devices Using Transmission Electron Microscopy

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Study: Assessment of the host tissue healing response to an implantable medical device provides useful data that can aid in FDA evaluation of device safety. Defined healing metrics may be used to quantify this data and elucidate trends of cellular infiltration and tissue ingrowth over time. Hard plastic embedding is preferred for hard material medical devices (e.g. metals and many plastics) as it maintains the device-tissue interface and allows in situ evaluation of the host response; however, variable stain penetration with special stains used to assess healing tissue morphology (e.g. trichrome) can preclude assessment of healing. Transmission electron microscopy (TEM) can be applied to and correlated with specific regions of plastic-embedded slides to identify components of the extracellular matrix, which can confirm findings on light microscopy and validate a defined metric for assessment of tissue healing.

Methods: Light microscopy was performed on plastic-embedded, H&E-stained slides from an intravascular occlusion device study at 30, 60, and 90-day time points. Extracellular matrix morphology was evaluated and a numeric healing score was given for each slide in different regions of the vessel and intravascular device. TEM was performed on targeted sections of slides at each time point and used to assess substrate morphology and validate tissue healing scores.

Results: The extracellular matrix at earlier time points comprises a greater degree of fibrin, whereas the later time points show greater deposition of more mature collagen. TEM of the substrate verifies the trend of increasing collagen at later time points, which correlates positively with the defined healing scores and validates their use. TEM can be used to confirm light microscopy findings of plastic-embedded devices, and is particularly useful for validating healing metrics applied to determine device safety when special stains are inconsistent.

A Protocol For Automated Adaptive Discretization Of Complex Geometry

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Study: This study aims to summarize our experiences with iterative adaptive meshing and suggest preliminary guidelines that facilitate the generation of a converged adapted mesh. While several studies have utilized adaptive meshing algorithms to optimize the discretization of complex patient specific geometry, they rarely describe the parameters supplied to the meshing algorithm.

Methods: The SimVascular package includes an adaptive meshing algorithm (AMA) which performs an a posteriori evaluation of the Mean Interpolation Error (MIE) of a finite element solution. Our protocol utilizes this AMA to iteratively reduce the MIE by progressively refining the mesh through each iteration. The AMA is applied to the steady flow solution of an isotropic mesh for the initial iteration and attempts to reduce the MIE by a reduction factor (R). Constraints for the size of the adapted mesh elements generated by the AMA are specified by the minimum & maximum edge size parameters. In the subsequent iteration, the minimum edge size parameter is reduced by a refinement factor (F) and the process of the first iteration is repeated. The protocol continues in a similar manner for a user specified number of iterations.

Table 1

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Recommendations</th>
<th>Trial 1</th>
<th>Trial 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isotropic Mesh Edge Size</td>
<td>Crucial to solution convergence. Set Courant number ≤ 0.5</td>
<td>1.25 mm</td>
<td>0.5 mm</td>
</tr>
<tr>
<td>Maximum Edge Size</td>
<td>Set equal to Isotropic mesh edge size</td>
<td>1.25 mm</td>
<td>0.5 mm</td>
</tr>
<tr>
<td>Initial Minimum Edge Size</td>
<td>Set to 0.75–0.5 times the isotropic mesh edge size, based on desired upper bound of mesh size.</td>
<td>0.938 mm</td>
<td>0.25 mm</td>
</tr>
<tr>
<td>MIE Reduction Factor (R)</td>
<td>0.75 suggested, may be reduced to 0.5 if Min Edge size Reduction factor is small.</td>
<td>0.5</td>
<td>0.75</td>
</tr>
<tr>
<td>Min. Edge Size Reduction factor(F)</td>
<td>0.5–0.85 suggested; use the least possible value that does not result in unacceptably large adapted meshes</td>
<td>0.75</td>
<td>0.5</td>
</tr>
</tbody>
</table>

Fig 1. A) Final adapted mesh for trial2 (left), and view of stent face highlighted on the left, showing mesh refinement (right). Evolution of the MIE and the pressure at the SVC face for (B) trial1, (C) trial2.
Effects Of Animal Blood Type On In Vitro Dynamic Thrombogenicity Tests Of Biomaterials

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Study: We investigated the effects of animal blood type on the thrombogenicity assessment of blood-contacting materials in a dynamic flow loop system.

Methods: Three common blood types were examined: donor sheep, donor pig, and slaughterhouse pig blood. Donor blood was drawn into containers with ACDA, shipped overnight, and used within 36 hrs. Slaughterhouse pig blood was collected from a local abattoir with ACDA plus heparin, and used within 12 hrs. Immediately before starting each dynamic flow test, the blood was recalcified and heparinized to a donor-specific concentration (donor sheep: 1.4 - 1.8 U/mL, donor pig: 3.5 - 7 U/mL, slaughterhouse pig: 3.0 - 4.5 U/mL). The target heparin level was based on a static pre-test in which latex tubes were incubated in recalcified blood to assess thrombus coverage under a series of heparin concentrations. Whole blood was recirculated at room temperature through a PVC tubing loop for 1 hr at 200 mL/min using a roller pump. Each loop contained a 12 cm long test article introduced through the tubing wall. Six materials were investigated: a positive control latex, a negative control polytetrafluoroethylene (PTFE), a non-medical grade silicone (NM-Sil) comparator, and three medical grade materials (silicone, high-density polyethylene (HDPE), and polyether block amide (PEBAX)). The percent thrombus surface area coverage, thrombus weight, and platelet count reduction were examined.

Results: For all blood types, latex had the greatest amount of thrombus formation (P < 0.01 compared to all other materials, Figure 1). For donor sheep blood only, NM-Sil was found to have intermediate thrombogenicity with significantly more thrombus surface coverage and platelet reduction than PTFE, HDPE, and PEBAX (P < 0.05). All blood types used in this flow loop test system enabled the differentiation between thrombogenic and thrombo-resistant materials. However, donor-specific anticoagulation levels and thrombosis marker sensitivity were dependent on the animal blood type.

Combined Action Of Biochemical Agonists And VWF-Mediated Shear Activation In Stenosis

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Study: Pathological shear conditions occurring in severe stenoses promote increased platelet aggregation through the action of von Willebrand Factor (vWF). We performed numerical simulations of thrombus formation in the context of arterial coarctation under a combined action of soluble platelet agonists and vWF.

Methods: Blood is treated as a multi-constituent mixture comprised of a linear fluid phase and a thrombus (solid) phase. The chemical and biological species are modeled using a system of coupled convection-reaction-diffusion (CRD) equations. The model incorporates biochemical and mechanical platelet activation, where the latter is implemented as a shear stress accumulation function. vWF activity is enabled in regions of high shear and enhances the platelet shear stress accumulation leading to activation.

Results: The simulations demonstrated excellent agreement with experimental observations and highlighted the role of vWF in the context of arterial coarctation under a combined action of soluble platelet agonists and vWF.
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An Experimental Study Of The Embolus Trapping Efficiency Of The FDA Generic Inferior Vena Cava Filter

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Study: Inferior vena cava (IVC) filter placement is often performed when patients cannot tolerate anticoagulation therapies for deep vein thrombosis and pulmonary embolism. IVC filters are used to prevent thromboemboli from traveling to the pulmonary system. The objective of this study is to characterize the embolus trapping efficiency of the FDA generic IVC filter created by the FDA.

Methods: The generic IVC filter is made of nitinol and consists of 16 identical struts equally spaced in a conical fashion around the hub. The filter is placed in the infrarenal region of an optically accessible anatomical model of the IVC. The blood analog fluid is 40% glycerin/60% water by weight. Nylon spheres (ρ=1.142 g/cm³) of diameters 3 mm, 4.5 mm, and 6 mm (n=5 each) are injected into either the left or right iliac entrances for each trial. The mean flow rate is 6.26 +/- 0.10 LPM to simulate physiological exercise conditions.

Results: In this study, we characterize the embolus trapping efficiency of the FDA generic IVC filter. The trapping efficiency has thus far been shown to depend on embolus size and the iliac vein from which the embolus originates. Specifically, the trapping efficiency of the filter for the 3 mm diameter spheres was 90% from the left iliac (2 of 5 captured) and 0% from the right iliac (0 of 5 captured). The trapping efficiencies for the 4.5 mm and 6 mm spheres were 100% for both veins. Future work will consider characterizing the performance using deformable bovine blood clots.

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Novel Tissue-Engineered Heart Valve Without Any Foreign Bodies

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Study: We are developing a novel autologous tissue-engineered heart valve (Biovalve) with a unique in-body tissue engineering. This is expected to be a viable bioprosthesis keeping better biocompatibility. In this study, we developed a conduit-type valve without any foreign bodies and tested the feasibility and long-term availability in large animal experiments.

Methods: We created plastic molds for Biovalves with 3D printer easily and quickly considering the recipient character. We embedded them in the subcutaneous spaces of adult goats about 2 months. After extracting the molds with the tissue en-block and removing the plastic molds only, Biovalve with tri-leaflets similar to those of the native valves were constituted from completely autologous connective tissues and fibroblasts. Total 19 conduit-type Biovalves were implanted in the apico-aortic bypass or the pulmonary artery of goats, (8 and 11, respectively). No anticoagulants were used after implantation.

Results: Biovalves were successfully implanted and showed smooth movement of the leaflets with a little regurgitation in angiogram, and the maximum duration reached to 2 years 6 months. Histological examination of the Biovalves showed the autologous cells covering the laminar surface of the valve leaflets as the endothelium and also getting inside to construct characteristic tissues like native leaflets. In conclusion, the Biovalves have a potential to be used for viable bioprosthetic valves and to keep better function and biocompatibility longer than current ones.

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Development Of A Collagen-Based Angiogenic Growth Factor Delivery System For Use In Tissue-Engineered Specimens

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Study: A rate-limiting step in engineering complex organs and tissues is the creation of an intact vasculature. Decellularization of non-transplantable organs seemingly provides a solution to this, as the larger vascular branch architecture is preserved. However, decellularization renders the microvasculature insufficient, as it removes the smaller vessel structure completely, and therefore cannot supply the metabolic demands of the tissue. Currently, re-endothelialization of decellularized matrices alone has not yielded sufficient regrowth of microvasculature. The purpose of this study was to develop a method for enhancing vascular regeneration in decellularized matrices, by creating a collagen-based angiogenic growth factory delivery system that induces microvascular growth, to eventually be applied into a decellularized matrix.

Methods: Type 1 porcine collagen gels (2.4 mg/ml) were constructed either with growth factors (Vascular Endothelial Growth Factor, Angiopoietin 1, Platelet Derived Growth Factor B; GFs), or without growth factors (control). Human umbilical vein endothelial cells (HUVECs; Passage 3 or 4) were serum starved and seeded either on top of collagen gels, or encapsulated within. Medium was changed every day. Gels were imaged using a Zeiss multiphoton microscope on days 3, 7, 14, and 21.

Results: HUVECs seeded on collagen gels containing GFs formed more tubules and invaded further into the gels than HUVECs on control gels (Figure 1, Figure 2). The morphological and organizational change of the endothelial cells and formation of circular structures show evidence of the early stages of microvessel formation. These results indicate that using a controlled GF release collagen-based system may increase microvascular growth in vitro, laying the groundwork for eventual use in acellular scaffolds.
**Design And Electromagnetic Simulation Of A Novel Stacked Motor For The Cleveland Clinic Continuous-Flow Total Artificial Heart**

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**Yaksh Magnetic Solutions, Lilburn, GA,**

**R1 Engineering, LLC, Euclid, OH,**

**Biomedical Engineering, Cleveland Clinic, Cleveland, OH.**

**Study:** The Cleveland Clinic continuous-flow total artificial heart (CFTAH) contains a single motor with only one moving part, the rotor. The rotor drives both the left and right side centrifugal pumps with impellers mounted on opposite ends. The left and right inlet pressures are balanced as the axial movement of the rotor modulates the performance of the right pump in response to the difference in inlet pressures. The rotor’s axial range of motion is limited by the magnetic restoring force exerted by the stator on the magnets inside the rotor. Greater than normal axial hydraulic forces can occur during extreme operating conditions, such as inlet suction or hemodynamic excursions that happen during surgery. The axial magnetic restoring force required to prevent the rotor from moving too far, potentially causing the impellers to contact the pump housings, is greater than that which would normally be generated by a motor of this size. The purpose of this work was to design a novel stacked motor that produces the required axial restoring force while still meeting the torque, efficiency, size and weight targets.

**Methods:** ANSYS modeling and simulation software was used to produce a 3D model (Figure 1) of the stacked motor. The initial model parameters were based upon previous non-stacked motor designs. The maximum allowable size and power were fixed and other motor parameters were varied to achieve simulation outputs that met targets.

**Results:** The target peak torque was >= 8 oz-in at 3 A average current. The target axial force curve has minimal axial force when the rotor is in its nominal operating region, and a steep slope as the rotor reaches 0.12" axial displacement. The chosen parameters for the motor resulted in a simulated peak torque of 10.0 oz-in @ 3 A average current, and axial force of 10.45 N @ 0.12" axial displacement (Figure 2). The torque meets the target value and the axial force is a significant improvement over the previous (non-stacked) design.

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**Comparison Of Two Arterial Cannulae For Cardiopulmonary Bypass Using Computational Fluid Dynamics**

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**DIMEG, University of Calabria, Arcavacata di Rende, ITALY.**

**Study:** To assess, using a patient-specific computational fluid dynamics (CFD) analysis, hemodynamics of two different arterial cannulae routinely used during cardiopulmonary bypass (CPB). The two cannulae were similar except for the distal end, with a straight or curved tip.

**Methods:** A 3D real aorta model was generated from CT images using segmentation and reverse engineering techniques. Two 22 Fr cannulae were modeled and inserted in the ascending aorta, 2 cm above the ST junction perpendicular to the aortic wall. The assumption of identical boundary conditions was chosen for both simulations in order to analyse the only effects of cannula’s geometry on hemodynamics. Flow was delivered through the cannula assuming the ascending aorta below the cannulation site was cross-clamped, as during open heart surgery.

**Results:** The curved tip cannula caused a swirling flow with stasis in ascending aorta below the cannulation site and flow separation in supra-aortic vessels, whereas the straight tip produced more flow recirculation in the ascending aorta and an orderly flow pattern in the supra-aortic vessels. Interestingly, a greater percentage of the total output directed towards the supra-aortic vessels with the curved tip cannula (50% Vs 30%) was observed. Similarly high wall shear stress (WSS) was obtained nearby the take off of the innominate artery and right carotid artery with curved tip instead it was located on the posterior wall of the aorta opposite the cannulation area with the straight one. In conclusion, this non-invasive assessment showed that using different cannula tips offers specific advantages during CBP. The straight one seems to generated a more steady flow patterns with good recirculation also in the ascending aorta. On the other hand, the curved tip, even though seems potentially more thrombogenic offered an enanched flow output selectively to the supra-aortic vessels.
Blood Pump Rotor Eccentricity And Hemolysis Evaluation

**Study:** A rotary blood pump consists of a rotor and a pump housing, which are perfectly concentric in an ideal scenario. This paper presents a non-linear relationship between rotor eccentricity and pump hemolysis found through testing and CFD analysis.

**Methods:** Turbulence is characterized by large fluctuations in vorticity, where part of kinetic energy is ultimately dissipated into internal energy by viscous diffusion. The vorticity transport equation is shown in equation (1), in which the last term on the RHS represents viscous dissipation function. Volume integral of specific dissipation rate is proposed to predict hemolysis change due to eccentricity.

\[
\frac{D\omega}{Dt} = -\omega(\nabla \cdot \mathbf{v}) + \left( \frac{\nabla \rho \times \nabla p}{\rho^2} \right) + \left[ \omega \cdot \nabla \mathbf{v} \right] + \left( \nabla^2 \omega \right)/Re
\]

Impeller pumps were fabricated with different levels of eccentricity between rotor and stator. A CFD RANS-model was setup to analyze impeller/housing effect. 6 cases of different eccentricity levels were simulated with the same settings. Hemolysis testing was conducted with porcine blood.

**Results:** Fig. 1 shows eccentricity vs volume integral of specific dissipation rate ratio in CFD and MIH ratio in testing. The nonlinearity between eccentricity and hemolysis is clearly demonstrated by both. With an eccentric impeller, the smaller impeller-housing gap on one side causes higher shear stress and bigger gap side sees more recirculation. Both conditions lead to elevated hemolysis. Fig. 2 shows the specific dissipation rate plot where high rates reside near walls, impeller-pump housing gap, recirculation and wake regions in fluid field. In summary, this study shows the nonlinear relation between rotor eccentricity and hemolysis. A small amount of eccentricity can be tolerated while MIH will increase nonlinearly once eccentricity exceeds a threshold. Volume integral of Specific Dissipation Rate in k-w RANS-model displays a similar nonlinear increase when compared to MIH ratio. It can be a practical indicator to estimate hemolysis in blood pump design.
Simulation In Surgery: Models For Ventricular Assist Device Implant Training

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Study: One critical determinant of successful ventricular assist device (VAD) implantation is the location and positioning of the device relative to the patient’s cardiac and vascular anatomy. Proper orientation and coring/suturing techniques can make the difference between implant success and failure. Repetitive training on high quality simulation models can improve surgical efficacy, minimizing patient time under anesthesia and overall occurrence of adverse events. However, current models (e.g. cadaveric hearts) are expensive, impractical, and poorly representative of the complex cardiovascular pathology seen in VAD patients. Therefore, a need exists for low-cost, realistic cardiac models for VAD implant training.

Methods: As a proof of concept, a digital cardiac model was acquired and optimized for 3D-printing. Inner and outer geometry shells were printed using a Form 2 printer; respective molds were produced. To determine a casting material most similar to tissue, puncture testing was performed on 1.5 mm thick silicone samples (control, mesh-enhanced, and fiber-enhanced). The ideal silicone variant was cast via a modified lost-wax casting technique. Resulting models underwent qualitative assessments of suitability for surgical training.

Results: PFHb over 6-hour in vitro test was shown in Fig. 1. At nominal condition, the NIH and MIH were 0.0058 ± 0.0013 g/100L and 0.5436 ± 0.1497 (n=9, 2 preliminary tests were also included in the statistics). There was no significant difference between any two devices (P>0.05). Experiment concerning different work point was performed at two devices (U160001 and U160003). The average NIH at low flow work point was 0.0164 ± 0.0046 g/100L (n=4) and the average MIH increased to 1.4389 ± 0.2899 (n=4). The results indicate consistency between the CH-VAD pump units. Hemolysis level increased at low flow condition compared to nominal operating point. The low in vitro hemolysis level demonstrates the superior hemocompatibility of CH-VAD.

In Vitro Hemolysis Evaluation Of CH-VAD, An Ultra-Compact Fully Magnetically Suspended Left Ventricular Assist Device

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Study: CH-VAD (CH Biomedical, Suzhou, China) is an ultra-compact (190g, 49mm diameter, 26mm height) centrifugal blood pump with fully magnetic suspension and CFD-optimized flow path. It was designed to minimize pump size, facilitating pericardial placement, without compromising suspension stiffness, system efficiency, and most importantly blood compatibility. In this study, we present the hemolysis level of multiple CH-VAD pumps at various work points tested in vitro.

Methods: Seven CH-VAD pump units were tested in circulation loops at the nominal work point (5 L/min at 100 mmHg). Among the seven pump units, two were tested at low flow work point (2 L/min at 123mmHg) for two repetitions. Heparinized fresh porcine blood (500 ± 25 ml) was circulated in the loop, maintained at 37ºC, for 6 hours. Blood samples were collected every 60 min conforming to the ASTM standards. Plasma free hemoglobin (PFHb) was then measured to calculate the normalized hemolysis index (NIH) and modified hemolysis index (MIH).

Results: PFHb over 6-hour in vitro test was shown in Fig. 1. At nominal condition, the NIH and MIH were 0.0058 ± 0.0013 g/100L and 0.5436 ± 0.1497 (n=9, 2 preliminary tests were also included in the statistics). There was no significant difference between any two devices (P>0.05). Experiment concerning different work point was performed at two devices (U160001 and U160003). The average NIH at low flow work point was 0.0164 ± 0.0046 g/100L (n=4) and the average MIH increased to 1.4389 ± 0.2899 (n=4). The results indicate consistency between the CH-VAD pump units. Hemolysis level increased at low flow condition compared to nominal operating point. The low in vitro hemolysis level demonstrates the superior hemocompatibility of CH-VAD.
Assessment Of VAD Hydraulic And Blood Damage Performances By Means Of Dynamic Pressure Simulations

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Study: The aim of this work is to investigate the hydraulic and blood damage performance of Ventricular Assist Devices (VAD) under pulsatile conditions using Computational Fluid Dynamics. This pulsatile model (PM) is a useful tool in predicting VAD performance, providing clinicians with a better understanding of flow rate estimation and the risk of thrombus formation, compared to the current constant pressure condition modelling. This novel approach potentially eliminates the need for mock circulatory pulsatile loops during VAD development, hence reducing costs. Furthermore, this PM could provide greater detail of blood flow behaviour, as well as quantifying accessible parameters, such as fluid efficiency, force and shear stress.

Methods: The fluid domains of CentriMag, HeartMate II (HM2) and HVAD were extracted from the CAD files, and numerical simulations were performed using ANSYS CFX. Grid independence was ensured, and the sampling frequency was chosen based on available computational resources. Dynamic pressure behaviour simulating heart failure conditions, at different pump speeds, was investigated. A total of five cardiac cycles were simulated and analysed for each condition. The calculated dynamic pressure-flow (HQ) loops were compared against static HQ conditions, and the regions of potential thrombus formation were assessed.

Results: The effect of the pulsatile condition was observed to operate around a certain range within the static HQ solution (Image 1). Varying pump speed shifted the range and altered the size of the loop (Image 2). Within each cycle, fluid efficiency, forces and shear stresses were calculated, and flow patterns analysed. Critical areas for thrombus formation in the HM2 were identified around the front bearing, in the blade channels and diffuser gap region; in the HVAD around the cutwater, top of blades and bottom channels. Ongoing work is focused on validating this PM and investigating HM3, HVAD, HM2 at different speeds and pulsatile conditions.
Surface-Engineering Of Small Intestinal Submucosa Via Carboxylic Acids For New Regenerative Vascular Grafts
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Study: Regenerative vascular grafts (VG) made of small intestinal submucosa (SIS) have been manufactured and evaluated before. Although the coagulation cascade is important for healing processes, it could lead to thrombus formation (TF) and reduced patency rates. To overcome this issue, we conjugated two Carboxylic Acids (CA) on SIS VG: oleic acid (SIS-OA) and lauric acid (SIS-LA).

Methods: Dried tubes and unrolled sheets of wet SIS were immersed in PBS (pH 7.0) with 6 Eq of a CA, added with N,N-Dimethylformamide, and the molar addition of EDC to covalently conjugate CA molecules via amide bonds (Fig 1).

Results: Scanning electron micrographs (SEM, n = 4; Fig 2) and X-ray photoelectron spectroscopy (XPS, n = 9), were conducted to analyze changes on the SIS after surface modifications.

Platelet deposition was analyzed via Lactate Dehydrogenase Assay (LDH, n=9; Fig 3) on modified surfaces, pristine SIS, and commercial ePTFE for comparison.

All conjugations led to significantly lower platelet deposition than pristine SIS (Fig 3). However, only conjugation of SIS-OA on dried SIS resulted in significantly lower platelet deposition levels than those observed for ePTFE (81% less). SEM showed that even after conjugation of CA, surfaces appeared homogeneous. Water was detrimental for conjugation most likely due to the blockage of active amine groups. XPS analyses for dried SIS-OA, showed that Nitrogen and Oxygen contents remained at about the same level of control samples, while Carbon slightly decreased, which can be attributed to the reduction of the accessible Carbon on SIS surface by the presence of the conjugated molecules. These results suggest that even after low conjugation levels, hydrophobic molecules are capable of mitigating TF formation. However, further investigation is needed to elucidate the mechanistic details behind controlling platelet-surface interactions.
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A Surrogate Modeling Approach To Predict Device-Specific Hemolysis Power Law Coefficients In Blood-Contacting Medical Devices

Study: Predicting mechanical hemolysis in medical devices using computational fluid dynamics (CFD) is extremely challenging. Historically, the most popular approach is a stress-based power law model derived from an empirical correlation between hemolysis and the flow-induced stress and exposure time. Empirical model coefficients are traditionally determined from global hemolysis measurements in simplified blood shearing devices under uniform shear conditions and with well-defined exposure times. Such global empirical coefficients are then applied to predict hemolysis in a device with complex hemodynamics. The applicability, however, of using such idealized global empirical coefficients in a real device with non-uniform shear and varying exposure times is currently unknown and may be one of the reasons why accurately predicting absolute hemolysis levels is so challenging.

Methods: Using analytical solutions for the non-uniform shear flow present in a small capillary tube we first develop a generalized approach for determining device-specific hemolysis power law coefficients. As a practical approach for use in real devices, we then develop, verify, and demonstrate a framework that combines CFD and Kriging surrogate modeling to determine device-specific coefficients that yield hemolysis predictions that match in vitro test data.

Results: For flow in a small capillary tube we show that device-specific coefficients are significantly different from traditional coefficients obtained from idealized uniform shear experiments, and that using such idealized coefficients leads to highly inaccurate hemolysis predictions. The Kriging surrogate modeling framework is successfully verified and demonstrated as a powerful practical approach for determining device-specific coefficients in medical devices. Future work will apply surrogate modeling to more complex devices and extend the framework to other continuum-based hemolysis models.

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The Effects Of Different Blood Sampling Sites Of A Closed-Loop Artificial Endocrine Pancreas In Critically Patients
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Study: We have reported that the usefulness of a newly developed and commercialized closed-loop artificial endocrine pancreas, STG-55 (Nippon Medical Systems Co., Ltd., Tokyo, Japan) in the blood glucose management in critically ill patients. This system must be connected to the patients with 20-G intravenous catheter to take blood samples continuously (2ml/h) for successively measuring blood glucose levels. However, it is sometimes very difficult to insert a catheter into good sampling vein. To compare the accuracy of three different blood sampling sites of a closed-loop artificial pancreas in peripheral forearm vein, continuous renal replacement circuit, and cardiopulmonary bypass circuit.

Methods: This study was approved by the Institutional Review Board, and written informed consent was obtained from all participants. The artificial pancreas was connected to forearm vein (n=12), continuous renal replacement circuit (n=10), and cardiopulmonary circuit (n=12) with 20-G venous catheter. The blood glucose levels with three different blood sampling sites were determined immediately after sample collection with ABL3 acid-base laboratory analyzer for correlation analysis.

Results: The correlation coefficient (R2) was 0.966 in forearm vein, 0.995 in continuous renal replacement circuit, and 0.946 in cardiopulmonary circuit. However, mean difference from ABL3 is 11.6 ± 5mg/dl (mean±SD) in continuous renal replacement circuit, -27.8 ± 8mg/dl in cardiopulmonary circuit. The blood glucose measurements in three different blood sampling sites with the STG-55 are consistent with intermittent measurement. In the case of extracorporeal circuit blood sampling, STG-55 may still be useful for continuous blood glucose management.
Ex Vivo Culture Platform To Characterize And Monitor The Onset, Progression And Treatment Of Vascular Pathologies

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Study: Nowadays, there is increasing interest in the use of ex vivo tissue culture models for evaluation of pathology progression and vessel reaction to treatments, which is hardly possible real-time and at different timepoints in vivo and in vitro. At the same time, promising imaging techniques have been developed to improve diagnosis and treatment of vascular diseases, but not applied in ex vivo models yet. Therefore, our aim was to combine these two aspects by developing a long-term ex vivo vascular platform in which novel online imaging techniques and biological assessments can be incorporated, to get information on healthy, pathological and treated vessels already during culture, for application in surgical planning and device testing.

Methods: Porcine carotid arteries from slaughterhouse were cultured for 10 days in a custom developed ex vivo vascular platform. Arteries were divided into 3 groups: healthy, pathology-induced and stented vessels (n=3 per group). During culture, intravascular ultrasound and optical coherence tomography were used online to determine vessels’ structure and composition. In addition to these, dissipative particle (DPD) method is used for simulating the aggregation process of activated platelets, which was proposed by our previous investigations. By using this computational model, number of activated platelets with aggregation is evaluated. Computational objects are 5 kinds of orifice pipe flows. And the orifice flows with small leakages is also used for observation of thrombus formation.

Results: Total number of activated and aggregated platelets was evaluated with time. The rate of deposited and aggregation for activated platelets was compared with our previous data of thrombus formation rate. It was found that the tendency of predicted rate of deposited and aggregation increases with shear rate as same as the experiments. As for the leakage flows, there is a possibility to use the length ratio of wake and recirculation behind leakage as an index of thrombus formation rate.

This work was supported by the European Commission within the Horizon 2020 Framework through the MSCA-ITN-ETN European Training Networks (project number 642458).
How Well Understood Is The Mechanism Of Plasma-Free Hemoglobin Mediated Vasoconstriction?


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Study: Plasma-free hemoglobin (PHb) is associated with numerous conditions including hemoglobinopathies, ABO incompatibility, transfusion of older stored RBCs, mechanical hemolysis in CPB, ECMO and VADs, and more recently during Hb-based blood substitute therapy. PHb in excess of the haptoglobin-binding capacity resulting in serious clinical sequelae driven by oxidative, inflammatory and vasoactive events. While the link between PHb-mediated redox changes and inflammation has been well established, the mechanism of vasoconstriction is still under investigation. The proposed direct and indirect nitric oxide scavenging, calcium influx, hyperoxia, eicosanoids-, 8-isoprostane- and ET-1-formation or RAAS activation cannot explain all the observed adverse hemodynamic events.

Methods: This study examined the role of serotonin (5-HT) in PHb-mediated vasoconstriction. Platelets are the source of many vasoactive factors, including 5-HT that impacts vascular tone via activation of Rho-kinase in vascular smooth muscle. We compared the effects of different doses of PHb on human platelet aggregability and release of 5-HT. We also monitored the platelet response following incubation with collagen and PHb to mimic vascular endothelial injury. Platelet aggregation was performed using the Platelet Ionized Calcium Aggregometer (Chrono-Log, Co., Haverstown, PA). 5-HT was measured by commercially available ELISA kit (Rocky Mountain Diagnostics, Inc., Colorado Springs, CO).

Results: It was found that PHb accelerates quick release of 5-HT ($p<0.01$). Collagen increases PHb stimulatory effects on platelet aggregability ($p<0.01$) and 5-HT release ($p<0.01$). The observed effects were time ($R^2=0.957$) and dose dependent ($R^2=0.948$). 5-HT could be an early factor in PHb-mediated vasoconstriction.
Comparison Between Three Impellers For A Transventricular Assist Device (TVAD)

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Study: The main cause of death in most countries of the world is cardiovascular diseases. Heart transplant or/and the usage of a Ventricular Assist Device (VAD) is often a form of treatment for severe heart diseases. The objective of this study is to analyze and to compare three different impellers for a new type of VAD, the Transventricular Assist Device (TVAD) concerning their hydrodynamic performances to choose the best axial impeller design and to guide a future study using finite element methods.

It is known that one of the important parameters affecting the performance of an axial pump is the propeller’s pitch. Thus, in order to find an optimal value, 3 different propeller’s pitches were tested experimentally. TVAD shall be implanted through left ventricle apex, crossing left ventricle, where it takes blood, and crossing aortic valve to pump blood to ascending aorta in a minimally invasive procedure, reducing post-surgical difficulties and improve patient’s recovery.

Methods: TVAD with three types of impellers (A, B and C, Figure 1) were created using SOLIDWORKS software and prototypes were manufactured by 3D printing. With those prototypes, In Vitro tests were conducted to analyze and compare their hydrodynamic performance curves. We obtained results as total pressure head (ΔP) versus Flow (F) for several rotational speeds.

Results: The rotors showed different hydrodynamic performances. Rotor A presented worse performance curves. Rotor B presented better performance than Rotor C for higher flow and rotor C presented better performance for lower flow. Conclusion: Rotor B is better for left ventricular assistance providing physiological pressure and flow in lower rotational speeds. Future studies will be performed using rotor designs similar to Rotor B, including Hemolysis tests.
A Comprehensive Platform For Enhanced Islet Cell Delivery: Update From The Drive Consortium
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Study: Islet cell transplantation is a promising treatment for type 1 diabetes mellitus (T1D), but current strategies require immunosuppression and have been plagued by poor islet cell retention and reduced implant viability. Technologies to assist the delivery and engraftment of islets in extrahepatic sites are necessary for widespread clinical adoption of islet transplantation. Here we provide an update from Diabetes-Reversing Implants for enhanced Viability and long-term Efficacy (DRIVE), a European Consortium supported by EU Horizon 2020 funding. The objective of DRIVE is to develop a platform for islet cell transplantation that improves cell retention and viability, is delivered in a minimally invasive fashion, and negates the need for systemic immunosuppression.

Methods: DRIVE partners have developed a multicomponent platform to improve islet cell delivery. Technologies under development include β-Gel, a support matrix for islet cell growth, β-Shell, an immunoprotective macroencapsulation device, and TheraPocket, a procedure for delivering islet cells to a target implant site in the anterior abdominal wall. Significant progress has been made in developing DRIVE technologies for improved islet cell transplantation. Preclinical studies to evaluate the therapeutic effectiveness of the DRIVE platform are ongoing.

3D Printed Mock Ventricular Assist Device For Benchtop Testing
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Study: As the number of patients receiving ventricular assist device (VAD) therapy increases, improvements to current VAD designs are continuously being made. Many of these improvements aim to decrease pump failure due to pump thrombosis and thrombotic occlusion. Typical benchtop systems for testing VAD thrombosis and thromboembolic events are expensive and unreliable; pump thrombosis is unpredictable and may take long periods of time to develop. First generation prototype testing of VAD designs are expensive and may be limited in quantity reducing the amount and quality of device testing prior to pre-clinical trials. The goal of this study is to create various functional but inexpensive and rapidly-produced VAD prototypes for testing in a functional flow loop. This allows rapid and relatively inexpensive testing of VAD designs, and allows data accumulation for prediction of VAD thrombosis and embolic sensitivity.

Methods: Three dimensional VAD models of varying impeller and housing types were created using SolidWorks software and then printed using a FormLabs stereolithography 3D printer. The pumps were based on typical centrifugal-flow pump designs. While clinical VADs employ various forms of magnetic impeller levitation, the prototype VAD impellers were directly connected to electric drive motors via a rotating shaft. Some impeller movement was allowed to simulate the motion of magnetically levitated impellers. The 3D printed prototype impellers differed in blade number, angle, size and height for future analysis.

Results: The pumps were assembled from 3D printed components and connected to an external electric motor for preliminary bench testing. Inexpensive and rapid prototype testing was possible due to the ability to design, 3D print and change impeller designs within a single VAD housing unit. Future capabilities include testing various VAD designs (centrifugal, axial, impeller blade changes) through a motor driven flow loop to determine differences in power, RPM and flow rate for comparative analysis.
Revisiting The Definition Of Surplus Hemodynamic Energy (SHE) - Are We Using The Right Pulsatility Index?
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Study: Surplus Hemodynamic Energy (SHE) has become a popular index when discussing pulsatility in the perfusion modes provided by mechanical circulatory support devices (MCSDs). SHE has been also used to evaluate the effect of inotropic agents. SHE has been defined as $\text{SHE} = \left(\frac{\int (P \cdot F \, dt)}{\int F \, dt}\right) - \text{MAP}$, where $P$ is pressure, $F$ is flow, and MAP is mean arterial pressure. However, multiplying the coefficient 1,332 to convert the pressure on the right-hand-side equation to energy is not appropriate. We intend to revisit the definition of this commonly adopted index, propose a new index reflecting the underlying physics, and compare the efficacy of two indices.

Methods: Using the similarity of the non-linear and periodic oscillation properties of the cardiovascular system and an AC circuit, we defined a new index $\text{SHE}_{\text{NEW}} = \left(\int (P \cdot F \, dt) - \text{MAP} \cdot \int F \, dt\right)$. This expression better represents the concept of “surplus” energy, which indicates the difference between the total energy and the “DC” energy of the system. In the Fourier analysis representation, this is the sum of the energy across all frequencies minus the energy at 0 Hz. We took parameters from the clinical data published by Lim et al. evaluating the effect of Dopamine, Ephinephrine, and Esmolol on the Hemodynamic Energy (ASAIO J. 2007) and computed SHE and $\text{SHE}_{\text{NEW}}$. Correlation coefficients between the inotropic agent levels and the two indices were calculated and compared.

Results: Correlation coefficients between inotropic agents’ level and the indices were 0.69, -0.84, and 0.93 for SHE vs 0.92, -0.96, and 0.97 for $\text{SHE}_{\text{NEW}}$ in Dopamine, Ephinephrine, and Esmolol groups, respectively. This proves the efficacy of $\text{SHE}_{\text{NEW}}$ and utilization of this index does not require more computation compared to current indices, such as SHE and energy equivalent pressure (EEP). In conclusion, $\text{SHE}_{\text{NEW}}$ is potentially a superior index representing pulsatility in the cardiovascular system.

The “Molecular Signature” Of Dynamic Shear-Mediated Platelet Activation in Mechanical Circulatory Support
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Study: Shear-mediated platelet activation (SMPA) is a primary driver of thrombotic complications in mechanical circulatory support (MCS). Conventional assays of platelet activation have limited ability under shear conditions to detect: 1. early excessive levels of platelet activation, and to differentiate 2. shear- vs biochemical agonist-mediated activation. We previously demonstrated, under constant shear, using a hemodynamic shearing device - a laboratory modified cone and couette viscometer, that a preferential “molecular signature” exists for SMPA. Specifically, phosphotidylserine externalization (PSE) and platelet surface thrombin generation, both contributors to pro-thrombosis, were observed; without P-selectin exposure or GPIbIIia activation - common markers of biochemical activation. We now extend and validate this work, testing the hypothesis that this molecular signature is observed under actual VAD-mediated dynamic shear.

Methods: Human gel-filtered platelets (GFP) (20k plts/ul) were circulated through a VAD loop system consisting of non-thrombogenic tubing and a cfVAD (Heart Assist V, 8000 rpm) for up to 60 min. GFP samples were fixed for flow cytometry detection of PSE (annexin V binding), P-selectin, or GPIbIIia activation. GFP procoagulant activity was detected via chromogenic platelet activation state (PAS) assay.

Results: Dynamic shear stress exposure of GFP led to an exponential increase in PSE, with 7.0 ± 0.7% annexin V-positive platelets (60min) vs 0.5 ± 0.1% annexin V-positive in non-sheared controls (Fig 1A). Simultaneously, neither P-selectin exposure nor integrin GPIbIIia activation was detected. VAD-sheared platelet procoagulant activity was also elevated, with a 7-fold increase of PAS at 60 min vs non-sheared control (Fig 1B). Thus the “molecular signature” of shear is observed under both constant and dynamic, VAD-mediated shear, raising the potential for utility as a useful clinical biomarker in MCS.

Figure 1. Phosphatidylserine externalization (A) and procoagulant activity (B) of platelets recirculated through the VAD-employing model circulatory system (n = 4 & 6. M ± margins of error; one-way ANOVA: * p ≤ 0.05, ** p ≤ 0.01).
Fabrication Of Hollow Fiber Bioreactor For Functional Bioartificial Organs

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Study: Bioreactor provides mechanical stimulants and biochemical supplements during cell culture with various benefits for cell survival, proliferation and tissue maturation. Bioartificial organs are supposed to have a homogeneous distribution of nutrient as well as oxygen inside for desired tissue or cell products. The concept of hollow fiber bioreactor has similarity to native blood vessels in organs. The cells cultured on the outer surface of hollow fibers and the oxygen is carried through the inner surface. As a result, cells or tissues provided oxygen and nutrients uniformly. Despite of these benefits, Hollow fiber bioreactor is hard to use in laboratory due to the complicated fabrication techniques. In this paper, we developed simple method to make hollow fiber bioreactor module for functional bioartificial organs.

Methods: Cylindrical configuration was selected because of the advantage in high surface to volume ratio. Since wetting problem of micro pores in hollow fibers is one of the major limitation of bioreactor performance, polymethylpentene(PMP) membrane was chosen because of appropriate wetting resistance for long term use. The fibers are filled in the cylindrical module and sealed with resin using centrifugal force. To verify our hollow fiber bioreactor, the mesenchymal stem cells were seeded in interspacing of the PMP fibers and cultured for a predetermined period. Cell proliferation was analyzed after perfusion culture.

Results: The cells proliferated in high population density in the cylindrical hollow fiber bioreactor. These results imply that the hollow fiber bioreactor developed with simple fabrication methods can be applied to functional bioartificial organs for instance artificial liver, pancreas and kidney. Furthermore, it can be parlay highly efficient cell culture performance into the massive cell culture production system. This research was supported by the Ministry of Health & Welfare, Republic of Korea (HI14C0746, HI14C0517)

Virtual Anatomic Fitting Of A Centrifugal LVAD: An Inlet Cannula Study


Study: A virtual anatomic fitting study was conducted, in order to achieve an optimized inlet cannula design for a centrifugal LVAD under development in our institutions.

Methods: Virtual model construction was made using images from Computed Tomography (CT) scan. Selected patient was a male (weight: 55 Kg, age: 79 years) with a diagnosed heart failure caused by aortic valve stenosis. CT images were processed into two separated 3D solids: one containing regions with blood only and another with all other tissues. Both 3D solids were created using Mimics Research 18.0.0.25 (Materialise, Leuven Belgium), a medical image processing software. A cylinder shape form represented our device’s inlet cannula, dimensions of this cylinder were: height of 40.5 mm and diameter of 12 mm. Inlet cannula model was positioned at the left ventricle apex of the virtual anatomic model. Registered measurements included: inlet cannula portion that was located inside the ventricle and inlet cannula angles. In addition, dimensions of the region outside the heart, where our device could be placed, were registered. All measurements were held in three anatomical planes.

Results: Registered measurements from the portion of the inlet cannula located inside the ventricle were: Coronal plane 23.5 mm, Sagittal plane: 24.6 mm, Axial plane: 28.2 mm. Angles between the inlet cannula model and sternal bone were: Axial plane: 90.5º, Coronal plane 41.2º, Sagittal plane: 41.4º. Data from the dimensions of the region outside the heart are presented in Table 1.

Conclusion: Our results indicated that our device’s inlet cannula may be implanted in this patient without been directly obstructed by adjacent tissues inside the ventricle. In addition, there are enough space in the region outside the heart to allocate our device in this patient.

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<th>Anatomical Plane</th>
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High Hydrostatic Pressure (HHP) Engineering-Based Acellular Scaffolds For Airway Reconstruction In Porcine Model
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Study: We have been studying the effect of high hydrostatic pressure (HHP) ranging from 100 to 1,000 MPa on various mammalian cells and tissues. Over 500 MPa, the cell membrane was destroyed, which enhanced decellularization efficacy. Based on these HHP effects, we succeeded to prepare various acellular tissues: heart valve, blood vessels, peripheral nerves, dermal tissues.

Methods: In the present research, we tried to reconstruct the airways by using HHP-decellularized trachea in porcine model. Tracheal cartilage reconstruction is an essential approach for the treatment of tracheal congenital abnormalities or injury. Here, we evaluated the potency of allogeneic decellularized trachea as novel support scaffolds. Six weaned pigs were subjected to transplantation with allogeneic tracheal graft patches onto artificial defects.

Results: After 11 weeks, the tracheas were evaluated by bronchoscopy and histological studies. No pigs showed airway symptoms during the observation period. The tracheal lumen restored by fresh graft patches showed more advanced narrowing than that treated with decellularized grafts with bronchoscopy. Histologically, fresh grafts induced typical cellular rejection, whereas the effects of decellularized grafts were lower. In addition, immunohistochemistry demonstrated regenerating foci of recipient cartilage along with the adjacent surface of decellularized tracheal grafts. These finding strongly indicated that the HHP treatment for decellularization can maintain the function of the trachea ECM and can be used as effective materials for restoring impaired trachea.

Embedding Medium Composition Can Affect Assessment Of Subcutaneous Medical Device Biocompatibility Using Standardized Scoring Schemes
M. T. O'Brien, R. N. Mowry. Medical Device Pathology, Charles River Laboratories, Frederick, MD.

Study: Medical device biocompatibility can be evaluated using a variety of histological scoring schemes, such as provided by ISO 10993–6 for comparing biocompatibility of an implanted medical device to a control or reference item. However, embedding medium can affect interpretation of biocompatibility using a standardized scoring system.

Methods: Six (6) subcutaneously implanted glucose sensors collected from a guinea pig model were evaluated for biocompatibility: three (3) sensors contained a standard (control) hydrogel formulation and three (3) sensors contained a novel (test article) hydrogel formulation. Two (2) control group sensors and two (2) test article group sensors were submitted for standard paraffin histology requiring device removal during sectioning. One (1) control and one (1) test article sensor each underwent hard plastic resin embedding for retention of device and surrounding tissue within thick plastic (~50 µm) sections. All sensors were evaluated microscopically using routine H&E staining and scored using the 10993–6 implantable device biocompatibility rubric.

Results: Biocompatibility scoring differed between paraffin- and plastic resin-embedded specimens despite identical sectioning sites. Findings in this study indicate that embedding medium composition can have an impact on biocompatibility evaluation and the medium employed should be reported when assessing biocompatibility to ensure equal comparison, as biocompatibility scoring conducted in one embedding medium (e.g. paraffin) may not be directly relatable to scoring of similar devices using a different embedding medium such as plastic resin.
**ASAIO BIOENGINEERING ABSTRACTS**

**Benchtop Model For Examining Ventricular Assist Device Response To Embolic Particles**

M. Billiot,1 S. L. Jessen,1 J. Gigiotti,2 F. J. Clubb, Jr.,1 B. R. Weeks1.

1Biomedical Engineering, Texas A&M University, College Station, TX, 2Veterinary Pathobiology, Texas A&M University, College Station, TX.

**Study:** Ventricular assist device (VAD) thrombosis is a consistent concern for clinicians and VAD manufacturers. As such, VAD thrombosis is an active area of research. Research goals include detection of VAD thromboembolic events and prevention of complications from thromboembolism. The goal of this project is to create a benchtop model to simulate VAD thromboembolism and characterize VAD flow response to embolic particles of varying size and composition.

**Methods:** As a proof of concept, a mock-VAD was created to simulate centrifugal pump flow. A simple flow loop was created with a main reservoir that connects to the inflow of a mock-VAD. An electromagnetic flow meter is installed at the outflow of the mock-VAD. An access port is placed proximal to the mock-VAD inflow for de-airing the flow loop; this port also serves as the selection site for embolic material. VAD output flow rate is continuously recorded prior to and throughout introduction of embolic material into the flow loop.

**Results:** The benchtop model provides a convenient and effective means of monitoring VAD flow rate while interacting with embolic material. Future studies will include monitoring VAD RPM to correlate flow and impeller rotational speed as the VAD encounters embolic material. This proof of concept benchtop VAD model paves the way for use of clinically available VADs to recreate embolic events in a controlled, in vitro environment. Data generated from these VAD thromboembolism experiments should be useful in detecting and managing thromboembolic complications in VAD patients.

**Validation Of Bayesian Models For LVAD Mortality At Single Implant Center**

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**Study:** MyCORA is a decision support tool for risk stratification in patients undergoing a left ventricular assist device (LVAD) implant. The tool uses Bayesian models to predict mortality at several time points post-LVAD implant. The models were learned from over 10,000 patients and validated in another 2000 patients within the INTERMACS registry. While use of this large dataset provides the most robust model, it obscures institution-dependent differences in patient selection, care, and outcomes. To be confident in the use of the myCORA mortality models at a given clinical site, validation of the models on site-specific data is required. This study uses a data set of 100 patients from Allegheny General Hospital (AGH) in Pittsburgh to evaluate the model performance in predicting mortality.

**Methods:** Retrospective data from 100 patients implanted at AGH between 2014 and 2015, with a 1 year follow up, was used to evaluate the Bayesian models. Survival predictions were made for each patient using the myCORA Bayesian models for mortality at 1, 3, and 12 months post implant. The area under the receiver operating characteristic (ROC) curve was used to evaluate model performance for comparison to the original model validation results.

**Results:** The AGH patients had similar demographics to the patients in the training dataset, except for a higher proportion of INTERMACS profile 2 patients (48% at AGH, compared to 35% in INTERMACS). The mortality models for all three time points performed better with the AGH patient dataset than in the original validation cohort: ROCs were 78% versus 70%, 76% versus 71%, and 75% versus 69% at 1, 3 and 12 months after LVAD implant, respectively. Bayesian models for predicting mortality during the first year after LVAD implant perform with confidence when applied to dataset from a single implant center.

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**Table 1. Key Parameters of Spiral Groove Bearing**

<table>
<thead>
<tr>
<th>Groove Type</th>
<th>Spiral angle $\alpha$</th>
<th>$b_1/b_2$</th>
<th>$a_1/a_2=\gamma$</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>10°</td>
<td>2.2 / 1.0</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>10°</td>
<td>3 / 1.4</td>
<td>1.15</td>
</tr>
<tr>
<td>3</td>
<td>15°</td>
<td>2.2 / 1.0</td>
<td>1.15</td>
</tr>
<tr>
<td>4</td>
<td>15°</td>
<td>3 / 1.4</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>20°</td>
<td>2.2 / 1.0</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>20°</td>
<td>3 / 1.4</td>
<td>1.15</td>
</tr>
</tbody>
</table>
Artificial Thrombi For In Vitro Ventricular Assist Device Testing

J. M. Gigliotti,1 S. Jessen,1 K. T. Ortiz,2 C. N. Kaufus,1 F. J. Clubb, Jr.,1 B. Weeks3. 1Veterinary Pathobiology, Texas A&M University, College Station, TX, 2College of Veterinary Medicine, Texas A&M University, College Station, TX.

Study: Prevention, detection and management of thromboembolic complication is a significant challenge in the clinical application of ventricular assist devices (VADs). An apparatus to test the VAD’s response to thromboembolism would enable iterative design changes that could lead to increased tolerance of embolic material. A standardized, well-defined artificial thrombus should be an integral component of such a benchtop model. The aim of this project is to establish a repeatable procedure for developing fibrin thrombi that have physical, gross, and histologic features resembling thrombi recovered from explanted VADs.

Methods: Bovine blood collected with citrate anticoagulant was centrifuged and divided into aliquots comprising varying ratios of red blood cells to plasma. Aliquots were distributed evenly among four artificial thrombosis configurations. Calcium chloride was then added to overcome the citrate chelation of calcium and initiate clotting. Tested configurations were: an open beaker on a lab-grade shaker table, a closed loop of tubing rotating at a 23° angle, a rotating petri dish in contact with blood in a glass beaker at room temperature (22°C), and the same rotating-dish apparatus at 38°C.

Results: Histological analysis with PTAH staining revealed clots created in a warm water bath at 38°C resemble reference thrombi. The closed loop and room-temperature rotating petri dish systems also produced fibrin matrices histologically consistent with reference specimens. Clots with higher plasma:RBC ratios grossly and histologically resemble the reference specimens better than those with greater proportions of RBC. This in vitro method of fibrin clot formation offers a means of creating artificial thrombi of consistent, well-defined physical, gross, and histological characteristics for benchtop testing of VAD thromboembolism.

The Biomimetic Modification With Surface Texturing And Nitric Oxide Release To Improve Hemocompatibility Of Biomaterials For Blood-Contacting Medical Devices

L. Xu, C. Siedlecki. Department of Surgery, Penn State University, Hershey, PA.

Study: The use of blood-contacting medical devices such as intravascular catheters, stents, valves, and ventricular assist devices is an important part of modern cardiovascular-healthcare strategies. However, device associated thrombosis and infection are recognized as significant issues impairing the long term use of these devices, and causing significant morbidity/mortality. Biomimetic strategies are effective approaches to control biological responses on surfaces, thereby improving the hemocompatibility of biomaterials.

Methods: Inspired from nature, we have developed surface textured polyurethane (PU) biomaterials with submicron-sized pillar patterns via a soft lithography two-stage replication process and demonstrated the significant improvement in the resistance to platelet and bacterial adhesion/biofilms of biomaterials. In this work, we further developed PU biomaterials with surface texturing and nitric oxide (NO) release to mimic the natural blood vessel inner surface.

Results: A long term release of NO was obtained by impregnation with NO donor, S-nitroso-N-acetylpenicillamine (SNAP) in PU polymers which lasted up to 38 days. Both surface texturing and NO release exhibited synergistic or additives effects on bacterial adhesion and inhibited biofilm formation for more than 28 days. The tests of platelet adhesion and activation, blood coagulation, and contact activation of coagulation factor XII demonstrated that these biological responses were all significantly reduced compared to the materials without modification or a single treatment alone. Results suggested that biomimetic modification by surface texturing and NO release was a promising approach to develop biomaterials for blood contact medical devices that can potentially significantly decrease the risk of device-related thrombosis and infections.
Modeling And Optimization Of A Pediatric Artificial Lung Based On Circular Blood Flow Paths


Study: We recently demonstrated an artificial lung (the MLung) design based on concentric gating to lengthen the blood flow path, increase flow velocity, and induce secondary flows to improve local mixing, which results in improved overall efficiency. In this work, we optimized this design for pumpless pediatric applications. The desired specifications are 0.75 L/min rated flow at a pressure drop (∆P) ≤ 5 mmHg.

Methods: Based on previous data, a device with surface area (SA) of 0.28 m² has a rated flow of 2 L/min at a ∆P of 100 mmHg. By interpolating to the desired rated flow, our basis for this optimization is a SA = 0.1 m². The Carman-Kozeny equation and flow simulations (Solidworks) were used to estimate ∆P and identify potential areas susceptible to clot formation. The fiber bundles were modeled as an isotropic porous media. A custom fiber mat with low density (6 fibers/cm) was assumed as well as a two-inlet design to reduce ∆P due to parallel blood flow paths. Fiber length was varied (Figure 1), and the resulting fiber bundle dimensions (to reach SA of 0.1 m²) were calculated. Benchtop performance testing was performed.

Results: A fiber bundle length of 4 cm meets the required size and pressure specifications (Table 1). The simulated velocity profile indicates potential stagnation points near the gates susceptible to clot formation (Figure 2). A prototype device was built using available fiber mat (~20 fibers/cm), as a 6 fiber/cm fiber mat was not readily available. A segmented packing configuration was used to achieve an effective fiber density corresponding to a fiber mat of 6 fibers/cm. The resulting prototype exchanged 20 mL/min of O₂ at a blood flow rate of 0.75 L/min (est. rated flow ~0.4 L/min) and ∆P of 16 mmHg (Figure 3). Pending work includes fabrication of the optimized MLung using a 6 fiber/cm fiber mat which is expected to improve performance, benchtop validation, and in vivo testing.

Table 1. Optimized Pediatric MLung Dimensions

<table>
<thead>
<tr>
<th>Fiber length (cm)</th>
<th>Housing ID (cm)</th>
<th>Bundle width (cm)</th>
<th>Priming volume (mL)</th>
<th>Expected ∆P (mmHg, at .75 L/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>5</td>
<td>.57</td>
<td>57</td>
<td>4.5</td>
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</tbody>
</table>
Contact Activation Of Blood Plasma Coagulation

C. Siedlecki, L. Xu. Department of Surgery, Penn State University, Hershey, PA.

Study: Material-induced thrombosis through the intrinsic pathway of blood plasma coagulation cascade is initiated by contact activation of the blood zymogen factor XII (FXII, Hageman factor). This event in turn triggers a series of zymogenic conversions eventually leading to thrombin production. Contact activation of FXII is affected by both material surface properties and solution composition. Further, FXII can be activated via at least three biochemical pathways: autoactivation, reciprocal activation, and autohydrolysis. This study reviews current understandings of FXII contact activation including new insights into the activation process.

Methods: FXII activation is studied through a variety of analytical tests for protein structure, functional tests for protein activity, and modeling techniques that allow for measurements of active FXII produced following contact with various material surfaces. By careful control of material surface properties and test solution composition, activation levels are discerned in a manner that allows us to deduce the roles of the different potential activation processes.

Results: Results suggest that activation of FXII arises from random structural perturbations of FXII, generally not involving the enzymatic-like cleavage events that give rise to alpha- and beta-FXIIa forms. Rather, these structural perturbations result in full length activated FXIIa that can be procoagulant (leading to formation of a clot), amidolytic (leading to cleavage of chromogenic substrates designed to react with the active enzyme) and potentially even procoagulant. The ratios of the different forms in the solution appears to be influenced by the material surface properties. Overall, the results suggest that FXII activation is a largely random event making it extremely difficult to control using traditional surface modification approaches.

Continuous Estimation Of Dynamic Differential Pump Pressure With A Rotary Piston Pump

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Study: Implanted pressure sensors are prone to thrombus formation and have difficulties with reliability as measurements drift over time. Non-invasive estimation methods have been proposed for continuous flow devices, but they are typically only useful under steady state conditions and with known viscosity. The TORVAD is a rotary piston pump with positive displacement flow. Therefore, motor current can be directly transduced into pressure when pumping is temporarily paused. Estimation techniques could be used to obtain dynamic differential pump pressure throughout the entire pumping cycle and not just when the pump is paused, which could allow for continuous estimation of important hemodynamic parameters.

Methods: Reduced order observers are estimators that take the limited measurements already acquired by the device (in this case motor currents and motor positions) and then use a real-time model of the system (which can be run on the device controller) to make estimates of variables that are not directly measured (in this case the differential pressure across the pump). An observer is designed for the TORVAD using control systems engineering methods by creating a linearized state space model of the pump and treating the differential pressure as an exogenous disturbance. Matlab is used to design the observer and then simulate the dynamic pressure estimation over a range of hemodynamic and operating conditions.

Results: Simulation results demonstrate accuracy of ±2 mmHg for dynamic pressure estimation using the reduced order observer, insensitive to blood viscosity. This pressure can be used to improve the piston motion control of the device through disturbance rejection, continuously monitor patient hemodynamics, and provide feedback for physiological control.
Physiological Control With A Synchronous Positive Displacement Rotary Piston Pump
J. R. Gohean,1 E. R. Larson,1 M. Kurusz,1 R. G. Longoria,2 R. W. Smalling1, 1Windmill Cardiovascular Systems, Austin, TX, 2Mechanical Engineering, University of Texas at Austin, Austin, TX, 1UTHealth/ McGovern Medical School, Houston, TX.

Study: Speed modulation of continuous flow devices is limited by rotor inertia and power requirements. The TORVAD is a rotary piston pump capable of precisely shaping the flow profile of 30 ml positive displacement ejections. The device has an integrated epicardial ECG sensing lead for detecting rate and rhythm changes, and motor current can be transduced to estimate dynamic differential pump pressure without the need for adding additional sensors. These measurements can be used as feedback for physiological control by adjusting pump parameters such as asynchronous or synchronous flow, pump ejection time, synchronous phasing within the cardiac cycle, and event response to premature ventricular contractions (PVCs), suction, and ventricular fibrillation (V-fib).

Methods: Acute bovine studies (n=3) were performed to study synchronous phasing. Pump ejections were phased from 0 to 100% of the RR-interval in 10% increments and hemodynamics were measured after stabilization. Event response to PVCs, suction, and V-fib was also tested. In addition a computational model of the cardiovascular system was used to study physiological control capabilities of synchronous support including phasing (when to pump during cardiac cycle), pulsatility (how quickly to pump), and rate (how often to pump).

Results: Acute animal experiments confirmed computational predictions that an early diastolic counterpulse maximizes aortic valve flow and cardiac output. The pump detected and took immediate actions to respond to PVCs (skipping the pump ejection after the PVC when ventricular volume is low), suction (slight reversal of the pump stroke followed by several seconds of low flow), and V-fib (asynchronous flow up to 5 L/min to provide full support). Computational models demonstrated more physiologically shaped ventricular function curves for synchronous counter-pulsation compared to continuous flow. These results demonstrate the adaptability of physiological control with a rotary piston pump.

"Digital Reflexes": Quantitation And Signatures Of Superficial Reflexes via Stretchable Electronic Wearable Sensors
R. C. Slepian,1 H. L. Swanson,1 A. M. Thompson,1 K. R. Ammann,2 A. Sweedo,2 R. Walk,3 B. M. Coull, M. J. Slepian3, 1Physiology, University of Arizona, Tucson, AZ, 2Biomedical Engineering, University of Arizona, Tucson, AZ, 3Medicine, University of Arizona, Tucson, AZ, 4Neurology, University of Arizona, Tucson, AZ.

Study: Measurement of superficial reflexes is a fundamental element of the neurologic exam performed by health personnel worldwide to evaluate upper vs lower motor neuron disorders. Detection of reflex abnormalities is of particular value as changes may predate overt symptoms and signs of a given disorder. The most common superficial reflexes tested are deep tendon reflexes (DTRs), subjectively assessed via limb/appendage movement and muscle contraction post hammer strike, rated on a 0 - 5 scale. This approach, while historic and universal is fraught with limitation due to: poor performance technique, subjective interpretation of movement, inter-observer variability, and inconsistencies in serial assessment. We tested the hypothesis that assessment of DTRs utilizing wearable sensors, able to assess limb/appendage 3D motion and muscle EMG, would provide a means of quantitation as well as defining motion and EMG "signatures" of a given reflex.

Methods: Stretchable electronic motion sensors (BioStamp, MC10), with contained tri-axial accelerometers and EMG signal detection were applied to: 1. distal limb/appendage (to assess movement); 2. relevant muscle (EMG) and; 3. strike hammer (to assess coordinate strike vs reflex time lag). Biceps, Triceps, Patellar and Achilles reflexes were assessed in 6 subjects (3M/3F, age 18 - 25, n = 3 repeats/subject) following standardized hammer strike, with data wirelessly transmitted and then analyzed.

Results: 1. For all reflexes tested, digital signal data of limb/appendage movement (x,y,z) and EMG was successfully obtained and analyzed. 2. Signals allowed quantitation of movement (dimension data), acceleration, muscle contraction and timing of events 3. Reproducibility of signals was observed for each individual 4. Each reflex yielded a characteristic motion signature (figure = Patellar). This approach is a step towards standardization, reduced inter-observer variability and meaningful serial assessment.
CFD Integrated Optimization Platform For A Fontan Circulatory Assist Device
C. Scheib, R. Newswanger, W. Weiss, G. Rosenberg, C. Jhun. Surgery, Penn State College of Medicine, Hershey, PA.

Study: Thrombus formation, Acquired von Willebrand Syndrome (AvWS), and hemolysis are frequent adverse events associated with cardiovascular assist devices and are primarily dependent on shear stress (SS), strain rate (SR), and turbulent energy dissipation (EPS). These fluid properties can both be approximated and predicted with experimental flow visualization and computational fluid dynamics (CFD), respectively. The current study is developing a fully automated CFD Integrated Optimization Platform (CFDIOP) seeking to minimize the adverse events mentioned above based upon the principles of fluid dynamics for a failed Fontan circulatory assist device.

Methods: The pump’s rotor is created through CAESES (Friendship Systems, Potsdam, Germany), a 3D parametric design optimization tool. Coupling CAESES with Converge CFD (Convergent Science, Madison, WI) completes the CFDIOP for rotor studies. This platform allows CFD setup, control, and execution to be conducted directly through CAESES. The solver predicted output is used for evaluating the relationship of pump performance and fluid dynamic response by creating 3D surfaces that compare HQ against a third evaluation (pump efficiency, EPS, SS, SR). The EPS around the blades was used as the objective function to drive parameter sensitivity studies, along with the design-of-experiments (DOE) based optimizations set to minimize the selected objective evaluations.

Results: The CFDIOP was tested and revealed the inner radial offset and suction profile of the blades were the most EPS sensitive parameters, along with producing a design that reduced the EPS predicted by the nominal design by 5.6%. Implementing SS and SR as additional optimization evaluations will further define their relationship with the blade geometry and ultimately the disruption of formed elements in blood. The CFDIOP is capable of discovering the least blood-traumatic rotor blade geometry within given flow conditions in a time efficient manner, expediting the search for a safer pump.

An Algorithm For Coupling Multi-Outlet Experimental Sections To Numerical Physiology Simulations For A Hybrid Cardiovascular Model
E. Mirzaei, E. Kung. Mechanical Engineering, Clemson University, Clemson, SC.

Study: Numerical and experimental methods have been widely used in cardiovascular biomechanics. Each of them, however, has its own advantages and disadvantages. Numerical simulation of objects such as ventricular assist devices (VAD) that consist of moving parts is still a challenging and sometimes impractical task. In-vitro experiments, on the other hand, suffer from the excessive number of components and connections required to build an intricate in-vitro vascular network. Such shortcomings motivate the development of a new technique for combining numerical and experimental methods in a hybrid framework. This study presents an algorithm for coupling non-deformable multi-outlet experimental sections to numerical physiology models.

Methods: To demonstrate the concept of multi-outlet coupling, a 3-outlet (two inlets, one outlet) experimental section consisting of a linear resistance on inlet 1 and a continuous flow VAD on inlet 2 together with the lumped-parameter network (LPN) model of a Fontan patient is considered (Fig. 1). For every inlet of the experimental section there exists a unique flow waveform that results in the same pressure change from the inlet to the outlet in both the experimental and numerical models; this is the solution flow waveform. Using Broyden’s method, an iterative algorithm is developed that identifies the solution flow waveforms starting from random initial ones.

Results: To verify the reliability of the coupling algorithm, we used mathematical surrogates to simulate the experimental section; we couple the mathematical surrogates of the experimental section (i.e. VAD and linear resistance) to the lumped-parameter network (LPN), providing the true solution of a “virtual” coupled system. Then, solutions obtained from the coupling algorithm are compared against the true solution (Fig. 2). RMSE values of 0.0482 mL/s and 0.0073 mmHg for flow and pressure waveforms, respectively, demonstrate good accuracy of the coupling algorithm.
Disruption Of von Willebrand Factor In Turbulent Flow

Study: Acquired von Willebrand syndrome (AvWS) associated with continuous-flow left ventricular assist devices (cf-LVAD) still remains a major complication. AvWS primarily due to a loss of the high molecular weight multimer (HMWM) of the von Willebrand factor (vWF) is known to be dependent on shear stress and exposure time (t_{exp}) in laminar flows. However, the flow around the rotors in most cf-LVADs is highly turbulent, and a detailed understanding of the effect of turbulence on the disruption of HMWM is still lacking. As turbulence energy dissipation (TED) is postulated to be a better metric than Reynolds stress for predicting the damage of formed elements in blood, this study examined the disruption of HMWM in turbulent flows relating to TED using a custom submerged jet apparatus. Inhibition of ADAMTS13 with 10 mM EDTA enabled us to investigate the mechanism of cleavage of vWF with regard to mechanical and enzymatic aspects.

Methods: Destruction of HMWM was performed by injecting 2 ml of phosphate buffered saline through a 0.33 mm diameter nozzle into a 30 ml receiver syringe containing 7 ml of pooled human platelet-poor plasma solution. Flow conditions of Re = 10400, 25000, and 29000 with t_{exp} of 0.74, 0.31, and 0.27 sec, respectively, were tested. Identical flow conditions were repeated with 10 mM EDTA added to the plasma solution. In order to relate the percent destruction of HMWM (D_p) to TED, a series of computational fluid dynamics (CFD) simulations was performed using Autodesk® CFD (Autodesk Inc., San Rafael, CA).

Results: As shown in the figure, a linear increase in D_p over TED (dD_p/dTED = 1.86 × 10^{-6} /m^{2}/s^{3}), R^2 = 0.99 was observed at the flow conditions tested without EDTA. With 10mM EDTA, no disruption of HMWM was observed. The results of the study may provide useful guidance for improving the design of cf-LVADs where turbulence is expected. The inhibition study by EDTA confirms that disruption of HMWM is not mechanical but enzymatic at given flow conditions.

Computational Prediction Of The Effect Of Left Ventricular Assist Device Therapy On Right Ventricular Mechanics
K. Lim, J. Park. IT Convergence Engineering, Kumoh National Institute of Technology, Gumi, Gyeongbuk, KOREA, REPUBLIC OF.

Study: Although the quantitative analysis of the hemodynamic factors related to the right ventricle (RV) after left ventricular assist device (LVAD) implantation is critical, previous studies have focused only on the alteration of the ventricular shape and lack quantitative analysis of the various hemodynamic parameters. Therefore, in this study, various hemodynamic parameters related to the RV were quantitatively analyzed under normal, heart failure (HF), and HF incorporated with continuous flow LVAD conditions by using a computational model.

Methods: We combined a three dimensional finite element electromechanical model of ventricles, which is based on human ventricular morphology captured by magnetic resonance imaging (MRI) and diffusion tensor MRI, with a lumped model of the circulatory system and continuous flow LVAD function in order to construct an integrated model of an LVAD implanted in the cardiovascular system.

Results: Under HF condition, the left ventricular end systolic pressure decreased and the left ventricular end diastolic pressure increased. The pressure in the right atrium (RA), RV and pulmonary artery (PA) also increased compared to the normal condition. When the continuous LVAD was applied, LVAD decreased end systolic pressures of the RA (29%), RV (63%), and PA (71%) but increased right ventricular ejection fraction (40%) while stroke work is reduced (67%) compared to HF condition without LVAD. In addition, end systolic ventricular tension and strain decreased under LVAD treatment. In an ideal case, LVAD enhance CO and mechanical unloading of the LV as well as those of the RV and prevents pulmonary hypertension that can be induced by left HF.
A Modified Definition Of Ejection Fraction For Continuous Flow Left Ventricular Assist Devices As A Determinant For Heart Recovery

V. Siruvallur Vasudevan, M. A. Simaan. Electrical and Computer Engineering, University of Central Florida, Orlando, FL.

Study: In the planning of strategies for treatment of heart failure patients, left ventricular ejection fraction (LVEF) is used as an important determinant. Traditionally, LVEF is defined as the ratio of stroke volume to the left ventricular end-diastolic volume. For patients implanted with a Continuous Flow Left Ventricular Assist Devices (CF-LVADs) as a bridge-to-recovery, the presence of the pump alters the volume of blood available both at the end of the systole and diastole. This impacts the measurement of LVEF, as the measured value might not completely eliminate the effects of the pump. Such a measurement used as a determinant for heart recovery might not be accurate to understand the status of the left ventricle.

Methods: An alternative definition for LVEF for bridge-to-recovery patients would be the ratio of blood pumped out of the left ventricle through the aortic valve to the volume of blood available in the left ventricle immediately before the ejection phase within the cardiac cycle. In our work, we investigate the modified definition of LVEF, with speed of the LVAD as the control parameter using a validated mathematical model.

Results: Our results show that the LVEF decreases as the speed of the LVAD increases, becoming 0 at the speed that causes the aortic valve to permanently close (as illustrated in Figure 1). A possible advantage of using this definition would be in monitoring the recovery progress of the patient’s left ventricle. When the activity of the patient’s changes, our results show that the LVEF also changes accordingly (as illustrated in Figure 2). With a fixed speed, if the patient changes from normal activity to heavy exercise, the LVEF increases leading us to conclude that, the modified definition of LVEF can be used as a determinant for heart recovery and planning strategies for LVAD patients. This is illustrated in Figure 3, which shows the relationship between the new definition of LVEF and the peak elastance of the ventricle.
Numerical Simulation For Thrombosis Under Non-Newtonian, Pulsatile Blood Flow
L. Yang, S. Deutsch, K. B. Manning. Biomedical Engineering, The Pennsylvania State University, University Park, PA.

Study: Thrombosis is a common complication resulting from interaction between blood and cardiovascular devices. To evaluate the risk of thrombosis in these devices, our lab previously developed a numerical model that simulates thrombus deposition and growth in a two-dimensional domain. However, the model assumes blood is Newtonian and flow is steady, while pulsatile flow was applied in validation experiments. To introduce the non-Newtonian and pulsatile flow effects on thrombus growth, the Carreau and Cross-Power models are added individually to the existing model for comparison, under pulsatile flow.

Methods: Applying a thrombosis model, flow is simulated in an asymmetric expansion using OpenFoam. The numerical model calculates species (e.g. platelets) in bulk concentrations through a convection-diffusion equation and includes an aggregation intensity term, a scalar that quantifies thrombosis. All species are coupled to the modified Navier-Stokes equations so that the velocity field is influenced by the thrombus growth. Blood viscosity is represented by the Carreau or Cross-Power models. At the inlet, blood flow is defined as fully developed, laminar (Re=540), and pulsatile (15.1 s\(^{-1}\) frequency). For validation, the simulated thrombus growth is compared with in vitro magnetic resonance imaging data.

Results: Both viscosity models predict that thrombosis will occur at the site of expansion over time, which is observed experimentally. Comparing with the original thrombosis model, the Cross Power simulation under pulsatile flow results into the thrombus growth matching the experimental data better. Assuming blood to be non-Newtonian and inlet flow to be pulsatile improves the exiting thrombosis model, providing more accurate results.

Fluid Dynamics Of The Pulsatile Penn State Pediatric Ventricular Assist Device At Elevated Beat Rate Conditions
S. V. Ponnaluri, C. Dawson, M. B. Gallagher, B. C. Good, S. Deutsch, K. B. Manning. Department of Biomedical Engineering, The Pennsylvania State University, University Park, PA.

Study: Congenital heart disease is the leading cause of infant death annually, with over 36,000 newborns in the United States, where heart transplantation is the only option for many. Despite their shorter median time to receive a donor heart relative to adults, children face the highest wait-list mortality rate of 13%. To address this, a pneumatic, pulsatile pediatric ventricular assist device (PVAD) was developed. Prior in vitro hemodynamic studies for the Penn State PVAD have used a beat rate of 75 bpm, however, beat rates can vary greatly. Therefore, this study aims to quantify the fluid dynamics in the PVAD at elevated beat rates using particle image velocimetry (PIV).

Methods: An acrylic model of the Penn State 12cc PVAD was placed in a mock circulatory flow loop to obtain desired physiological conditions. To ensure consistency between beat rates, a systolic duration of 43% of the total cardiac cycle was used. A blood analog was created to mimic the viscoelastic properties of pediatric blood at 40% hematocrit. PIV was used to image the flow of three planes of the PVAD at the elevated beat rate of 100 bpm and then compared to data at 75 bpm.

Results: At both beat rate conditions, a strong inlet jet was formed at the start of diastole and transitioned into a solid body rotational flow towards the end of diastole. During systole, this rotational flow deteriorated as an outlet jet formed. However, with an increased beat rate, there was an overall magnitude increase, a stronger inlet jet and a stronger rotational flow that lasted longer into systole. These changes to the fluid dynamics create more favorable conditions to reducing thrombus formation.
VA ECMO Restores Systemic Circulation In Severe Cardiogenic Shock But Exacerbates LV Distension: A Numerical Simulation Study

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Study: For severe cardiogenic shock (CS), VA ECMO is the fastest way to reestablish collapsed systemic circulation, but is unable to unload the LV, resulting in LV distension. In this study, we simulated VA ECMO-supported severe CS to evaluate the degree of LV distension.

Methods: The numerical lumped-parameter model of human circulatory system included the bronchial circulation and coronary circulation with Thebesian veins (Fig 1A). The healthy circulation was simulated with the parameters of cardiac output (CO), mean aortic pressure (mAoP), mean pulmonary artery pressure (mPAP), end diastolic LV pressure (EDLVP), right atrial pressure (RAP), and end diastolic LV volume (EDLVV). In severe CS, compromised CO was input at 1.3 l/min. Femoral VA ECMO was input into the above CS model with ECMO blood flow similar to normal CO (5.0 l/min).

Results: The mathematical model simulated circulation of healthy, severe CS and severe CS plus VA ECMO (Table 1). The parameters of healthy circulation were in the physiological range. Cardiogenic shock was simulated with a decreased mAoP (48 mmHg), increased EDLVP and increased EDLVV. VA ECMO normalized collapsed circulation of cardiogenic shock (mAoP 107 mmHg). However, VA ECMO further increased EDLVP (from 42 to 74 mmHg) and EDLVV (from 206 to 234 ml) with P-V loop right-up move (Fig 1B), demonstrating exacerbation of LV distension.

Conclusion: VA ECMO restores systemic circulation in severe CS, but does not unload LV, exacerbating LV distension.

<table>
<thead>
<tr>
<th>Table 1</th>
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<tbody>
<tr>
<td>CO (l/min)</td>
<td>Healthy</td>
<td>5.4</td>
</tr>
<tr>
<td>mAoP (mmHg)</td>
<td>79</td>
<td>48</td>
</tr>
<tr>
<td>mPAP (mmHg)</td>
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<td>41</td>
</tr>
<tr>
<td>RAP (mmHg)</td>
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<tr>
<td>EDLVP (mmHg)</td>
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<td>42</td>
</tr>
<tr>
<td>EDLVV (ml)</td>
<td>153</td>
<td>206</td>
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Quantification Of Flow And Thrombus Development Using Micro-Particle Image Velocimetry
T. R. Harkins, J. E. Myśliowski, K. B. Manning. Department of Biomedical Engineering, The Pennsylvania State University, University Park, PA.

Study: Cardiovascular disease is the number one cause of death in the United States, affecting over 600,000 people annually. Many cardiovascular diseases are thought to be caused by a microcirculatory dysfunction. Few studies have investigated conditions that lead to the development of a microsopic blood clot. Micro-particle image velocimetry (μPIV) provides the ability to quantitatively measure microflow alongside thrombus development. Using a newly developed μPIV platform, we aim to capture the real time in vitro formation of a thrombus and better understand the micro-scale factors related to thrombus growth.

Methods: For thrombus studies, plasma is perfused by a calibrated syringe pump through a 0.7mm x 0.7mm micro-channel at a rate of 4μL/min. This plasma is seeded with ghost RBCs infiltrated with fluorescent tracer particles (1 μm in diameter) at 20% hematocrit. Emission light from a 2D plane is focused using a microscope and is acquired by a camera for processing later. By cross-correlating the displacement of particles, the velocity can be obtained. As a comparison to the experimental velocity data, COMSOL was used to simulate flow conditions within the microchannel.

Results: The system is able to quantitatively measure flow and compared well to the COMSOL model under the same flow conditions. The data demonstrate the technique’s ability to generate stable flows within the micro channel. Thrombus formation was confirmed using time-lapse, fluorescent images.

Comparison Of Newtonian And Viscoelastic Blood Models In The FDA Benchmark Centrifugal Pump
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Study: The U.S. Food and Drug Administration (FDA) developed a benchmark centrifugal blood pump to provide experimental data to support computational fluid dynamics (CFD) validation. In the experimental and CFD studies, a Newtonian fluid was used while for measuring hemolysis porcine whole blood was used. Therefore, to better predict blood pump hemodynamics and compare hemolysis results, a generalized Oldroyd-B (GOB) viscoelastic blood model will be used in a CFD solver to model the centrifugal blood pump and compare to Newtonian simulation results.

Methods: Using OpenFOAM (OpenCFD Ltd), transient simulations were performed for FDA Case 1 (Q=2.5 L/min and Ω=2500 rpm) and FDA Case 4 (Q=6 L/min and Ω=2500 rpm) to directly model the rotation of the rotor with a sliding mesh approach. The Newtonian and GOB blood models were used to simulate the experimental data from the porcine blood properties and a set of previously fit GOB coefficients, respectively. For predicting hemolysis, an Eulerian approach was used with a Giersiepen power law model to determine a normalized index of hemolysis (NIH).

Results: Comparing the velocity fields between the two blood models, differences were observed in the trailing blade regions and in the outflow jet. The viscoelastic blood model showed more coherent flow patterns in both regions while predicting lower peak velocities for Case 1 (6.81 m/s vs. 7.6 m/s) but higher peak velocities for Case 4 (9.05 m/s vs. 8.58 m/s). Additionally, large differences in NIH were predicted between the two models with the Newtonian model’s NIH value over an order of magnitude lower (1.8e-4 g/100L vs. 2.6e-4 g/100L). The viscoelastic results were very similar to a previous Centrimag centrifugal pump CFD study (1e-4 g/100L).
Study: Surgical technique for ascending aortic replacement has remained unchanged for over a half a century. Automated aortic graft anastomosis has the potential to reduce procedural times and morbidity. A major impediment to automated aortic graft anastomosis is creating an end to end anastomosis without luminal compromise. We present our design of an automated Dacron graft placement with conformational felt sandwich.

Methods: Based on isolated ascending aortic aneurysm patients (n=50) a 3D model was developed with a hollow interior. Using computational designs, a modular multi-component device was developed. Rapid prototyping achieved by 3D printer (100 micron resolution). A specially woven Dacron graft with flared ends was designed. A specially arranged configuration of staples to allow aorta to expand during systole without compromising hemostatic seal was designed.

Results: Ascending aorta was excised one cm from the innominate, a modular anvil with incorporated conformational felt was then clasped around the aorta, aortic wall was everted on to the anvil and engaged in the spikes (Figure). The pre-loaded Dacron graft was then lowered and positional pins engaged, clockwise movement achieved accurate apposition. The handle was depressed to discharge a specially arranged staples to achieve a hemostatic seal. The procedure is repeated by engaging the aorta above the Sino tubular junction. The automated anastomosis obtains a hemostatic seal with a conformational felt on the outside of the aorta (Figure). An automated aortic graft anastomosis can improve operational ease and reduce procedural times while obtaining reproducible results.

Study: Introduction: An Intravascular Ventricular Assist System (IVAS) was developed to provide chronic counterpulsation support timed to subcutaneous ECG in heart failure patients. The IVAS includes (1) a 50-cc intravascular pump; (2) three bipolar subcutaneous leads to provide three different ECG vectors for counterpulsation timing chronically; (3) a skin interface device for grounding and communication between the ECG leads and the external NuPulseCV drive unit (NDU); and (4) a portable NDU that processes the ECG signal and trigger IVAS inflation and deflation.

Methods: The IVAS was implanted with long term subcutaneous ECG leads in thirteen patients (M=11, F=2). The efficacy of the subcutaneous ECG leads for timing IVAS inflation and deflation, noise artifacts, lead failure and potential loss of signal due to mechanical flexing of the lead were recorded for implantation durations of up to ~2 months.

Results: The subcutaneous leads provided a reliable trigger for effective counterpulsation support. IVAS support augmented cardiac index by 39%, cardiac power index by 35%, and diminished pulmonary wedge capillary pressure by 22% compared to baseline values. A minor temporary signal degradation that did not adversely affect IVAS triggering efficacy was observed during the first seven days post-implant, potentially due to the healing process. No long-term loss of ECG signal, lead failures, or post explant complications due to lead removal were observed. Conclusions: The IVAS subcutaneous ECG leads provided a continuous, long term ECG trigger for effective counterpulsation therapy.
Portable Pneumatic Driver For Long-Term Counterpulsation Support

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Study: Counterpulsation therapy is currently limited to short-term use for treatment of heart failure. An implantable Intravascular Ventricular Assist System (iVAS) is being developed to expand counterpulsation as a long-term therapeutic option. A portable drive unit is a key requirement for ambulatory chronic counterpulsation support.

Methods: A small (97mm (3.8") x 165mm (6.5") x 203mm (8.0")) light-weight (6.5 lb) NuPulseCV drive unit (NDU) was developed to actuate the 50-cc iVAS pump. The NDU utilizes bellows, whose volume is matched to the pump, to prevent overinflation. The NDU actuates the pump using room air, eliminating the need for helium tanks. The NDU is worn in a satchel over the shoulder for portability and ambulation. The effectiveness and portability of the drive unit was evaluated in thirteen patients (M=11, F=2) for up to two months in a US feasibility clinical trial.

Results: The NDU provided effective counterpulsation support as evidenced by statistically significant improvements in cardiac index (39%) and cardiac power index (35%) over baseline values. All patients were ambulatory within 24 hrs of implantation, 11 were able to move to a step-down unit, and 2 were discharged home. The 6-min walk test improved from 1159 to 1349 ft. The NDU was able to provide support for up to 6 hrs on one set of batteries, promoting patient freedom. Conclusions: The iVAS NDU enabled patient ambulation while providing effective counterpulsation support in heart failure patients.

Overcoming The Limits Of Design: Magnet 3D Printing For Rapid Development Of Turbodynamic Ventricular Assist Devices

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Study: Conventional manufacturing methods are the bottleneck in the development of turbodynamic ventricular assist devices (VAD), as adaptations in design often require production steps with long lead times. The shift to agile, fast and test driven development practices renders the use of additive manufacturing techniques necessary. When designing new rotor geometries, a major restriction is the (1) boundedness of shapes of embedded magnets and (2) the need for their separate assembly. The current work presents a proof-of-concept of a fully 3D printed magnetic rotor. Polymer bonded isotropic hard magnets are co-printed directly into the final thermoplastic part on an end-user fused deposition modelling printer.

Methods: Three challenges are targeted: (1) magnet-filament production, (2) ability to print via layer by layer extrusion and co-printability with the main building material and (3) post-print magnetization. Isotropic NbFeB powder thermoplastic composite is extruded to filaments on a twin-screw compounder. The filaments are printed on a desktop printer which is capable of printing multiple materials simultaneously. ABS is used as the rotor body material. The magnetic domains are magnetized in a pulse coil after printing.

Results: A functional prototype of a fully 3D printed and magnetically driven rotor with embedded magnetic domains, is successfully manufactured. Our study shows the feasibility of 3D printing arbitrarily shaped magnets directly into a thermoplastic rotor for the use in an electromotor. This method could potentiate the usefulness of 3D printing in the development of new VAD designs. Therefore, it could enable faster iteration cycles and postpone the shift to conventional manufacturing methods to later development phases. Once the disqualifiers of 3D printing for the use in blood carrying implants, such as inferior surface qualities, are overcome, 3D printing of magnets could open the door for more complex and customized VAD designs.
Investigation Of Polyethylene Glycol (PEG) Coatings On Polydimethylsiloxane (PDMS) For Membrane Oxygenator Applications

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Study: To address the limited blood compatibility of current extracorporeal oxygenation (ECMO) systems, significant work has focused on soft lithographic microchannel devices, which intend to mimic lung capillaries. These devices use PDMS as a membrane material for its high gas permeability, as well as its amenability to microfabrication. We are developing a blood oxygenator that similarly uses PDMS bonded to silicon membranes to conduct gas exchange. The PDMS can be modified with hemocompatible coatings that decrease membrane fouling and prevent channel occlusion. Here we investigate the effects of PEG formulations on membrane hydrophilicity and fouling resistance.

Methods: PEG-silane was applied to PDMS-coated silicon and cast PDMS substrates using three protocols varying in PEG concentration. The PEG layers were characterized through contact angle for wettability, and visualized with atomic force microscopy (AFM). Finally, the layers were evaluated for protein fouling by surface antibody assay of adsorbed albumin.

Results: Application of PEG stably reduced contact angle on PDMS substrates in all formulations. AFM scans indicate the presence PEG-silane multilayers ranging from 10–50 nm thick on the surfaces in a concentration-dependent manner, particularly for cast PDMS. While none of the PEG multilayer formulations resisted protein fouling on PDMS-coated silicon, the multilayers at higher thicknesses (~50 nm) on cast PDMS were able to provide high resistance to protein adsorption. This data demonstrates the impact of coating coverage and thickness on its utility to resist protein fouling, and similar methods could be used to examine other coatings for PDMS oxygenators.

Novel Right Sided Pulmonary To Left Atrial Mock Circulatory Loop (MCL) For Experimental Testing Of Mems Sensors And Catheter-Based Devices


Study: Objective: To develop an in vitro testing platform for pre-clinical development of MEMS and catheter-based devices.

Methods: We constructed a silicon circulatory loop (MCL) with a pneumatically actuated ventricle and primed with a blood analog solution to model the adult right heart to left atrium system. The MCL was instrumented with pressure, volume, and flow sensors to tune the MCL to match clinically-relevant hemodynamic parameters and quantify performance characteristics of MEMS and catheter-based devices (figure). To demonstrate efficacy of the MCL, volume, compliance, and resistance elements were controlled to simulate healthy, HF, hyper- and hypotension, and hyper- and hypovolemia. To demonstrate utility, a PA catheter was introduced through a vascular port for appropriate placement within a pulmonary vascular equivalent.

Results: Hemodynamic data for RV, PA, PCWP, and LA were collected in 30 sec epochs at 400Hz and analyzed. Clinical conditions for an average adult (BSA 2.0 m$^2$) were successfully replicated: healthy (in mmHg: RA 2–6, RVSP 20–25, RVDP 0–8, mean PA 10–20, LA 5–10, CO 4–6 L/min, 70 BPM, eject duration 300 msec); HF (in mmHg: RVSP 25–50, RVDP 25–35, mean PA 30–40, LA >10, CO <3.8 L/min, 80 BPM, eject duration 300 msec); pulmonary hypertension (in mmHg: RVSP >70, mean PA >40, LA <10, CO 4–6 L/min, 80 BPM, eject duration 300 msec), and left HF (LA > 16 mmHg). Conclusion: The MCL accurately reproduced right heart physiologic conditions and demonstrated its utility as a training tool and experimental platform for testing clinical hypotheses and assessment of device performance in clinically-relevant hemodynamic conditions.

Equipment:

1. Right Atrial
2. Right Ventricular Pressure
3. Mean RA Pressure
4. RV Flow sensor
5. RV pressure sensor
6. Pulmonary capillary pressure
7. RV pressure sensor
8. Right ventricular flow
9. Right atrial pressure detail
10. Access port for left device access
11. Pulmonary Compliance
12. Pulmonary capillary resistance
13. Left atrial pressures
14. Pulmonary Resistance
15. Intraventricular shunt
16. Systemic flow return to RA

Equipment:

A. Transesophageal Flow Meter
B. DPM – Data Acquisition System
C. Patient Monitor
D. Automatic Blood Flow Injector
E. Automatic Blood Flow Injector
F. Manometer
Galvanotaxis: An Electroceutical Strategy For Modulating Cell-Selective Migration

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Study: Percutaneous coronary intervention (PCI), the primary therapy for obstructive coronary artery disease, remains limited by arterial re-narrowing (restenosis). The advent of drug-eluting stents (DES) have reduced restenosis rates from 40% (angioplasty alone) to below 10% post-procedure. Despite improvement, DES remain limited by late thrombosis, due to the non-specificity of drugs eluted, which limit smooth muscle cell (SMC) ingrowth but also endothelial cell (EC) lateral growth needed for preventing thrombosis. Here we introduce a galvanotactic approach with potential selectivity for limiting SMC growth while simultaneously enhancing EC growth. Galvanotaxis uses direct current electric fields (DCEFs) to drive wound healing. While this concept has been studied on many other tissues (i.e. bone, skin), the differential effect on vascular SMCs and ECs has not been explored. In this study, we aim to identify the ability of DCEFs to selectively direct vascular wound healing.

Methods: A chamber designed in our lab was used to expose cells to uniform DCEFs. Saline solution and agar salt bridges mediated DCEFs to cell media, preventing electrolysis. Cells were seeded at 50k cells/ml for 4 hours in the chamber. A range of DCEFs (0 - 200 mV/cm) were then applied to the saline solution. Time-lapse imaging allowed tracking of cell movement over 4 hours.

Results: ECs were responsive to galvanotaxis, with a positive correlation of migration towards the cathode (-) with increasing DCEF magnitude. In contrast, SMCs were less responsive to galvanotaxis, with no significant correlation to DCEF magnitude, but often migrating towards the anode (+). ECs also increased travel distance with increased DCEF magnitude while SMCs did not. Our findings suggest galvanotaxis may serve as a cell selective alternative to drugs. With further translation, galvanotaxis may be useful in minimizing SMCs ingrowth at the luminal arterial surface while directing ECs to re-establish a non-thrombogenic endoluminal layer.
Evaluation Of Flow Modulation Approaches In Ventricular Assist Devices (VADS) Using An In-Vitro Endothelial Cell Culture Model (ECCM)

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Study: The purpose of this study is to use human aortic endothelial cells (HAECs) cultured within an Endothelial Cell Culture Model (ECCM) (fig.1) to: (A) identify and validate biomarkers of pulsatility and (B) determine if introduction of artificial pulsatility using flow modulation approaches can mitigate changes in endothelial cells seen with continuous flow ventricular assist devices (CF-VADs).

Methods: Comparison of HAECs cultured within the ECCM (normal pulsatile vs. CF-VAD flow) and aortic wall samples from patients (normal pulsatile vs. CF-VADs) confirms that both the Nrf-2 activated anti-oxidant response and eNOS/ET-1 signaling pathways are deferentially regulated. Two additional flow modulation protocols were introduced to attempt to reduce oxidant response: synchronous (SYN, 80 bpm, 20 mmHg pulse pressure) and asynchronous (ASYN, 40 bpm, 45 mmHg pulse pressure).

Results: To determine if artificial pulsatility generated via flow modulation approaches can prevent upregulation of identified biomarkers, we recreated two potential flow modulation protocols (synchronous (SYN) and asynchronous (ASYN) using the ECCM. SYN protocol maintained the same heart rate (80 bpm) as NF while the pulse pressure was maintained at 20 mmHg (intermediate between NF and CF). ASYN protocol maintained heart rate at 40 bpm with a pulse pressure of 45 mmHg. For all conditions, the mean flow rate, mean shear stress and mean arterial pressure were maintained at the same levels. HAECs cultured within the ECCM for 6 days under SYN and ASYN conditions and compared with NF and CF. Our results suggest that ASYN rather than SYN resulted in prevention of upregulation of Nrf-2 and associated antioxidant genes (Nrf-2, Sod1, Sod2, Gclc, G6pd) and proteins similar to NF, whereas, the overall signature following SYN appeared similar to that seen with CF showing statistically significant upregulation in comparison with NF.
Preclinical Surgical Experience With An Intravascular Hemofilter For Organ Replacement Therapy

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Study: Intravascular bioartificial organs depend on high-efficiency hemofiltration for immune-privileged convective mass transfer. We sought to optimize a silicon nanopore membrane (SNM)-based hemofilter (HF) for renal and pancreatic islet replacement therapy.

Methods: We performed a proof-of-concept study to refine HF design and implantation considerations, enabling long-term HF patency. A swine model was chosen to approximate human vascular anatomy and thrombogenesis. HF prototypes housing SNM were implanted in arteriovenous fashion to the vasculature, enabling iterative assessment of HF characteristics: implantation technique, blood flow path, vessel-graft-device interface, and ultrafiltrate (UF) drainage. Patency was assessed by physical exam, Doppler ultrasound, and fluoroscopy.

Results: A HF was designed to eliminate high- and low-shear flow conditions using computational fluid dynamics (CFD) modeling, then constructed from polycarbonate and SNM (total silicon area 24 cm²). The prototype HF was attached via polycarbonate barbed connector to ePTFE vascular grafts anastomosed to swine vasculature. UF was drained into a vein or externalized for collection or renal replacement. Initial patency was 50% (4/8). Subsequent alterations including: tunneled subcutaneous or retroperitoneal implantation, use of a stainless steel barbed graft connector, silicone reinforcement of ePTFE grafts, and application of an antithrombotic UF catheter resulted in improved HF functionality, and 80% patency (8/10) up to 26 days’ duration. In summary, refinement of HF components and surgical technique may improve HF patency and function, establishing a platform for development of hemofiltration-based bioartificial organs.

Platelet Membrane Fluidity: A Mechanistic Component Of Shear-Mediated Platelet Activation

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Study: Shear-mediated platelet activation (SMPA) is a primary driver of thrombosis in mechanical circulatory support (MCS). We previously demonstrated the importance of “mechanotransduction” as a means of transfer of shear force to and within platelets leading to SMPA. The primary interface of platelets to hemodynamic shear is the outer membrane with embedded receptors - acting as signal acceptors/transducers of shear. Membrane fluidity is a primary biophysical property of membranes, determining lateral mobility of receptors in the lipid bilayer, as well as overall membrane integrity. What remains unknown is the impact of MCS shear on platelet membrane fluidity. Here we hypothesize that shear stress exposure will differentially alter platelet membrane fluidity compared to that of biochemical agonists. We explore this parameter as a potentially manipulable target of platelet reactivity.

Methods: Gel filtered platelets (GFP) (20k plts/ul, healthy volunteers) were exposed to 70 dynes/cm² shear, for 2, 5, and 10 min via a hemodynamic shearing device; or to sonication (75W, 10 sec.). Alternatively, GFP were incubated (10 min, 24°C) with thrombin (5uM) or ADP (10uM, in 0.05M Tris buffer). Platelet activation was determined via chromogenic platelet activity state (PAS) assay. Membrane fluidity was assessed via fluorescence polarization (measured variable is anisotropy, an inverse measure of fluidity).

Results: Under conditions tested both shear and biochemical agonists led to similar level of platelet activation. However: 1. Shear exposure lead to an increase in platelet membrane fluidity, which was “dose-dependent” increasing progressively with time of exposure. 2. Sonication, a means of imparting intense instant shear, led to even greater fluidity change. 3. No increase in membrane fluidity was observed with chemical agonist exposure. These finding underscore differences in mechanisms operative in SMPA and suggest membrane fluidity as a novel target for modulating SMPA in MCS.

Figure 1. (left) Fluidity increases with extent of shear activation. (right) Fluidity does not change when biochemical agonists are included.
Packaging Considerations For An Implantable Hemofilter Based On Silicon Nanopore Membranes (SNM)


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Study: Silicon nanopore membranes (SNM) are being utilized to develop an implantable renal replacement device, which will consist of a tandem arrangement of a silicon hemofilter and renal cell bioreactor. Here we report the successful development of an implantable hemofilter using a scalable packaging method.

Methods: To significantly reduce prototyping time and cost, a small-scale version of the full-scale device was developed with 1/5 the number of blood channels. The small-scale hemofilter consists of a filtration cassette sealed into a biocompatible polycarbonate body. The filtration cassette is composed of several SNM plates covalently bonded in parallel fashion with intermediate silicon channel layers. FEA modelling of small and full-scale devices (with >2x physiological blood pressure loads) shows maximum stress and deformation values for the cassette components change by 7.14% and 0.46% respectively for the silicon layers, and 0.90% and 0.17% respectively for the SNM plates. All device components showed sub-critical stress values resulting in no significant difference in structural integrity between the small and full-scale devices. Additionally, in vitro small-scale device testing demonstrated structural integrity at blood pressures exceeding 350 mmHg. Based on comparative FEA results, the full-scale device is expected to successfully operate well above physiological blood pressure loads.

Results: In vitro filtration efficiency studies of the small-scale device showed urea transport of 129 ml/min/m² without the presence of albumin using the filtration cassette. Combined with the structural analysis, these results show that the filtration cassette assembly and packaging method can be used to create a clinically relevant full-scale implantable renal replacement device.

Inventive Knowledge Flow: Tracking The Progress Of Biomedical Innovation

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Study: Advancement of medical technologies is accomplished by iteration and improvement of existing inventive knowledge. Novel results are published in academic journals which is disseminated to inventive researchers. Intellectual property also generates knowledge. The United States Patent and Trademark Office publishes patents which serves as another tool for creation of derivative works. This study dissects the origin and natural progression of the 22 most impactful medical technologies of the 21st century, between and within the patent and academic domains. For each technology we pinpoint the preceding inventive knowledge and track its dissemination and derivations using data-driven algorithms.

Methods: 100 top-cited patents were analyzed and filtered for societal impact using the Derwent Innovation Index, leading to 22 unique medical products. Preceding and derivative patents, dissemination of the technology, identifying keywords, and practical usability were taken into account. The inventor(s), defined product, invention topic, and identifying keywords were used to search science literature for publications related to the technology. The Web of Science was used for academic literature searches. A doc2vec natural language processing algorithm was deployed to compare patented products to our database of 12,000 science papers. Subjective comparison of inventions and papers was completed by an expert panel to validate results.

Results: 8 of the 22 unique patented medical products were associated with preceding science publications as interpreted by the doc2vec algorithm. The remaining 14 technologies were patented before derivative works were observed in the science literature. These findings encourage medical-scientists to utilize both domains of knowledge while designing novel research studies and developing practical solutions.
Using Salt To Treat Driveline Site Hyper-Granulation Tissue In Patients With Left Ventricular Assist Devices

5

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Study: Hyper-granulation tissue can develop around driveline sites of left ventricular assist device (LVAD) patients either due to mechanical irritation of the driveline site or as the result of infection at the site. The hyper-granulation tissue can cause bleeding and pain. Topical applications of silver nitrate have been employed to reduce the tissue. This treatment can be costly, require repeated clinic visits and cause additional burning pain. We used iodized salt at the driveline site, instead of silver nitrate to see if it would be an effective, inexpensive, more efficient and less painful treatment modality.

Methods: LVAD patients who were noted to have hyper-granulation tissue at their driveline sites were selected to participate. The sites were gently cleansed using sterile gauze soaked in a non-alcohol based broad-spectrum antimicrobial cleanser. Approximately 1 to 3 milliliters of iodized salt was dusted over the tissue and then covered by a dressing. The dressings were changed daily, using the same technique until the hyper-granulation tissue had resolved. Photographs of the sites were taken before, during and after the salt treatment.

Results: 9 patients were included in the study. Average age was 72.8. All patients had a history of, or an active driveline site infection as documented by positive wound cultures. The hyper-granulation tissue diminished in size or was completely resolved in all patients within 3 to 8 days. 7 Patients had complete resolution of hyper-granulation tissue, while 2 patients had recurrence. The ones who had recurrence had lesser amounts of regrowth and were able to be successfully retreated with the salt. Patient’s caregivers were able to perform the treatment at home, using inexpensive iodized salt. All, but one, reported less pain with the salt treatment compared to the silver nitrate application. We concluded that using iodized salt is a viable alternative to using silver nitrate for treating hyper-granulation tissue.

A Multimodal Approach To A Partial Outflow Graft Obstruction Diagnosis In LVAD Patients

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Study: Patients supported by LVADs may develop worsening heart failure (HF) and/or pump related issues such as outflow graft (OG) kink, stenosis, and/or occlusion. The common associated symptoms are insufficient for a differential diagnosis. On the contrary, pump thrombus, complete inflow or outflow graft occlusions are more evident due to abnormally high pump power consumption and/or characteristic drastic drops in pump flow. The present study sought to demonstrate the diagnostic power of log file analysis in conjunction with in-vivo OG pressure gradient measurements to discriminate worsening HF from an OG partial occlusion in bridge to transplant patients supported by LVADs.

Methods: Two patients supported by the HVAD system presented with dyspnea, near syncope, and chest pain. A program was used to visualize pump power, flow, pulsatility, and overall waveform morphology. Patients underwent CTA, heart catheterization, and in-vivo OG pressure measurements. A multipurpose fluoroscopy guided catheter measured two data points inside the OG, one proximal and the other distal to the pump.

Results: One graft was 75% occluded as demonstrated by CTA and 52 mmHg pressure differential across the OG (Fig 1), while the other remained circular on all CTA cross-sections and had a 1mmHg differential. The partially occluded graft patient underwent heart TX and histology revealed fibrin to be the occluding material. Furthermore, pump data revealed a sharp decay in flow and pulsatility (~38% decrease in 3 months) that only became apparent when the files were viewed in a 2 year window (Fig 2A). Thus, shorter time windows are less insightful for identifying partial occlusions. In contrast, the log file view of the circular graft revealed slower decaying trends indicative of worsening HF (Fig 2B). Further study is warranted to fully correlate log files with the corresponding clinical data and to develop a robust characterization method to non-invasively gauge the status of an LVAD outflow graft.

Figure 1. A,B Partially occluded OG cross-section. C1 Fibrin, C2 Gore-Tex conduit, C3 LVAD OG.

Table 1. OG Comparison

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<thead>
<tr>
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<th>Partially-Occluded Graft</th>
<th>Non-Occluded Graft</th>
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<tr>
<td>HVAD Pump parameters</td>
<td>Flow</td>
<td>Pulsatility</td>
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<td>30 day log file view</td>
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<td>2 year log file view</td>
<td>decrease</td>
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<tr>
<td>Outflow graft CTA &amp; histology cross section</td>
<td>52 mmHg</td>
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Figure 2. Pulsatility vs. time pump log file plots. A. Partially occluded OG. B. Non-occluded OG, worsening heart failure. Pump speed for both patients was 2800 RPM.
**Progression Of Driveline Failure In A Heartmate II LVAD Patient**

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**Study:** The HeartMate II (HMII) left ventricular assist device (LVAD) is powered by a driveline (DL) of six insulated wires making up three phases, surrounded by a metal shield, polyurethane, and silicone (Figure 1a). If the insulation on these wires wears down, phase-to-phase or phase-to-shield shorts can occur, causing the ventricular assist device (VAD) to stop. DL phase data within some log files stored in VAD controllers can describe signs of DL failure.

**Methods:** A 70-year-old patient underwent destination therapy HMII LVAD implant and aortic valve closure. Patient eventually developed DL failure. Timeline of the case and DL phase data are presented in Figure 1b. X-rays taken before percutaneous lead repair (Figure 1c) showed problem areas near the metal connector (A) and DL exit site (B). Post-explant device evaluation revealed thinning of the shield, a fractured wire, and worn insulation.

**Figure 1a.** Cross-section of HMII LVAD DL. **Figure 1b.** Device implanted (Post-Operative Month (POM) 0). First DL fault alarm logged; found to be an issue with controller (POM 28). Multiple DL fault alarms occurred. Current through wire of phase 2 increased as failure progressed. Unshielded patient cable issued (POM 35–38). One syncopal episode associated with brief VAD stop led to percutaneous lead repair (POM 48). Multiple syncopal episodes associated with brief VAD stops led to VAD exchange (POM 49). **Figure 1c.** X-ray images of presumed deformation near controller (A), deformation near exit site (B), and exit site (C) before percutaneous lead repair.

**Results:** DL fault alarms indicated early signs of DL wear but did not describe severity. Divergence of phase 2 demonstrated severity, indicating that controller circuitry caused the first fault at POM 28, wear of the DL became remarkable around POM 35, and wear progressed to a fractured wire at POM 48 (Figure 1b). This data allowed the patient to stay out of the hospital, avoiding high-risk interventions (POM 48, 49) until they were necessary.

**Pattern Of Preoperative Echocardiographic Findings Determines Outcomes After Left Ventricular Assist Device Implantation**

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**Study:** We use a statistical clustering algorithm to identify preoperative echocardiographic characteristics that predict right ventricular failure (RVF) after continuous flow left ventricular assist device (LVAD) implantation.

**Methods:** Durable continuous flow LVAD implants in 490 patients (2003–2017). Two-step clustering of preoperative echocardiographic findings including left ventricular (LV) ejection fraction, right ventricular (RV) function, aortic insufficiency (AI), mitral regurgitation (MR), tricuspid regurgitation (TR) and heart rate: Group (Grp) 1: LV failure (LVF) with moderate RV dysfunction (RVD), severe MR, and no TR (n=110); Grp 2: LVF with severe RVD, severe MR and TR (n=64); Grp 3: LVF with moderate RVD, and severe AI (n=16); Grp 4: LVF with mild RVD and no valve pathology (n=163); and Grp 5: LVF with severe RVD and no valve pathology (n=137). Silhouette measure of cohesion and separation demonstrated good separation at 0.6.

**Results:** Grp 2 had the highest INTERMACS Level 1 (25%, P<0.001), preoperative right atrial pressure (11 ± 5mmHg, P<0.001), postoperative RVF incidence (20%, P=0.001), postoperative nitric oxide duration (median 3 days, IQR=1, P=0.001), delayed sternal closure (61%, P=0.002), postoperative permanent dialysis (6%, P=0.002), tricuspid valve repair rate (n=52; 81%, P<0.001), and lowest RV stroke work index (489 ± 228cc-mmHg/m²/beat, P=0.002). RVF in Grps 1, 3, 4, and 5 were 6%, 0%, 6%, and 3% respectively. No differences in heart transplantation (P=0.478), or survival (figure, P=0.557) was seen. Severe TR predicted RVF in those with moderate-severe preoperative RVD and no valve pathology (n=163). Clustering demonstrated the importance of preoperative TR plus MR in predicting RVF. Combined severe LV and RV failure with severe MR and TR portends the worse prognosis.
Controlling An LVAD Wireless Power System For Temperature Studies

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Study: Current ventricular assist devices (VADs) require a percutaneous driveline which is susceptible to infections. A wireless transcutaneous energy transmission system (TETS) can replace the driveline. While a TETS reduces risk of infection, power losses can contribute to tissue heating and must be managed. Previous studies correlated power loss, measured as heat flux, to tissue heating with deep tissue implants. A swine model was used to correlate heat flux with tissue heating for TETS coils in a shallow (0.5 cm) subcutaneous location. Delivered power and drive frequencies were also varied to determine if these factors impact tissue heating.

Methods: A TETS was designed to transfer continuous power up to 12W, suitable for current VADs, and to limit implanted coil heat flux by externally controlling the duty cycle and amplitude of circulating currents. Tissue heating was measured by thermistors in vivo with implant coil heat fluxes of 4 to 8.5 mW/cm². Drive frequencies were varied from 200 kHz to 1 MHz. Power transfer ranged from 6 to 12 W. An implanted resistive heater driven by direct current at comparable heat fluxes was used as a control.

Results: A method to control heat flux in a TETS was developed and tested in vivo. Temperature rise from baseline of 1.4°C to 3.2°C was linear with relation to heat flux over 4 to 8.5 mW/cm² as shown. The temperature rise in the subcutaneous location for a particular heat flux is significantly higher than previously published research in deep muscle and lung. Absolute tissue temperature during heating ranged from 37.6 to 39.5°C. Heat flux from resistive heating was the primary contributor to tissue heating, as shown by the similar temperature rise from the direct current resistive heater. This study did not attempt to minimize coil temperature rise, but to design a system that can control and limit heat flux to produce predictable changes in tissue temperatures.

Biochemical Characterization Of Ex Vivo Hemoperfused Hearts

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Study: The PhysioHeart an ex vivo beating heart platform is similar to portable cardiac care systems (CCS) which ensure an ex vivo beating status during cardiac transport. CCS prolong preservation time, avoid reperfusion injury and monitor cardiac function during transport contrary to the current method of cold preservation. Despite perfusion, myocardial edema and dysfunction are described. This study reports biochemical changes during ex vivo cardiac perfusion to create awareness of ex vivo physiology which we think are likewise representative for CCS perfusion and the reasons for the reported limitations.

Methods: Hearts (n=5, 450 ± 30 g) harvested from slaughterhouse pigs were arrested with St Thomas cardioplegia (4°C). After transport, hearts were revived with blood in the PhysioHeart platform to restore physiological cardiac performance in 2 chamber working heart mode for 4 hours maintaining glucose and pH values. Every hour blood was examined with I-STAT (Abbott) and C8000 (Roche) analyser to verify blood gases, electrolytes, nutrients, waste products, vitamins and cell damage.

Results: Normal cardiac performance was attained in terms of mean cardiac output (4.7 ± 0.1 l/min) and pressures (120/80 mmHg) but deteriorated over time. Osmolarity (+13 ± 4%) and electrolytes (chloride, +8 ± 0.1%; phosphate, +43 ± 10%; sodium, +11 ± 2%; potassium +12 ± 2%) increased significantly whereas hearts were edematous and increased in weight (+144 ± 41 g). Increasing troponin (6500-fold) and myoglobin (55-fold) revealed necrotic myocardium. Values of albumin, triglycerides, urea, creatinine, calcitriol and free haemoglobin remained static. Fatty acids (-51 ± 10%) declined significantly while ammonia (+311 ± 62%) increased. Increase of lactate after 3h is conceivably ascribable to ammonia toxicity known to impair anaerobic glycolysis and lead to edema. In conclusion, ammonia toxicity is an expected reason for ex vivo cardiac dysfunction. Dialysis might reduce this toxicity and ensure a constant ex vivo cardiac function.
Patients Of All Body Mass Index Classifications Gain Weight After First LVAD Implant

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Study: To qualify for heart transplant, patients must not be significantly under- or over-weight. LVADs can offer chronic cardiovascular support for patients awaiting transplant or decision on candidacy. For patients who do not qualify for transplant due to body mass index (BMI), LVAD therapy can support survival until sufficient weight is lost or gained to achieve candidacy. The purpose of this study was to understand BMI changes after initial LVAD placement.

Methods: First-time LVAD implants were retrospectively identified from patients with cardiovascular disease within the de-identified Optum EHR database during 2007–2016. The database was queried for demographic, procedural, height, and weight data of each patient with LVAD-related procedure code records. The data set was limited to patients ≥18 years old with weight and height measurements on the date of implant (n=456 patients across 16 centers). BMI was calculated using weight measurements collected up to 12 months post-implant and baseline height measurement. BMI classifications (Underweight, Normal, Overweight, Obese) were according to World Health Organization definitions.

Results: Compared to baseline, 11.3% (18/159) lost weight to change BMI class at 6 months and 2.9% (3/103) at 12 months. Some patients gained weight to change BMI class—23.3% (37/159) at 6 months and 36.9% (38/103) at 12 months. Statistically significant weight gain was evident at 12 months in baseline Normal (p <0.001, n=29), Overweight (p<0.001, n=29), and Obese (p = 0.001, n=43) groups. Statistics at 12 months were not performed on the Underweight group due to sample size (n=2), though both patients increased BMI from baseline. These results suggest it is unlikely obese patients will lose significant weight with LVAD therapy, and additional measures should be taken to achieve body weight necessary for transplant candidacy. Underweight patients may use LVAD therapy to achieve candidacy, but additional analysis is required.
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MELD-Xi Score And Outcomes In Adults Supported With Short Term Continuous Flow Ventricular Assist Devices

Study: Short-term continuous flow VADs (STCF-VAD) are increasingly being utilized to support patients. The model for end-stage liver disease without international normalized ratio (MELD-Xi) is associated with mortality and morbidity in patients requiring ECMO support and undergoing durable VAD implantation. We sought to determine the relationship between MELD-Xi score and outcomes in adults undergoing STCF-VAD implantation.

Methods: All adult patients supported with a STCF-VAD between June 2009 and December 2015 were included in this retrospective single centre study. The associations between MELD-Xi score and major bleeding, neurological dysfunction and death on device were assessed. Parametric variables were compared using a student’s t-test.

Results: A total of 61 patients were identified. In total, 43% of patients died on the device (n=26), 33% experienced a major bleeding event (n=20), and 20% suffered neurological dysfunction (n=12). The average MELD-Xi score of all patients was 22. In patients experiencing a major bleed, we observed a trend towards an increased MELD-Xi score compared to those who did not experience a major bleed (MELD-Xi= 25 vs. 21; p=0.07). In patients that suffered neurological dysfunction, no significant difference in MELD-Xi scores compared to those who did not suffer neurological dysfunction was observed (MELD-Xi= 22 vs. 22; p=0.91). In those patients who died on their device, we observed a significantly higher MELD-Xi score compared to survivors (MELD-Xi= 26 vs. 19; p<0.001). Taken together, we found that the MELD-Xi score was significantly higher in patients that died on their device, with a trend towards a higher MELD-Xi score in those experiencing a major bleed, likely reflecting the severity of illness pre-implant. Further studies are required to determine if the MELD-Xi score is an independent predictor of outcomes in a larger series of STCF-VAD implantation.

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Management Of Cardiac Standstill On Va-Ecmo Using A High Flow Strategy

Study: Cardiac standstill may be observed during veno-arterial extracorporeal membrane oxygenation (VA-ECMO). Management strategies to decompress the heart include left-sided vent (LSV) insertion or high flows without LSV. However, evidence that either method reduces mortality or neurological injury is unknown. In this study, we reviewed the outcomes of patients treated for cardiac standstill during ECMO with high flows instead of LSV placement.

Methods: 189 patients underwent VA-ECMO from 2010 to 2016. Cardiac standstill was defined as non-pulsatile arterial line tracing 6–8 hours after corrections of metabolic abnormalities. Patients who developed cardiac standstill were studied for the duration of cardiac standstill and their clinical outcomes.

Results: 22 patients (12%) developed cardiac standstill during VA-ECMO. 9 (41%) survived ECMO therapy and 6 (27%) survived to discharge with full neurological recovery. Of the ECMO survivors, cardiac standstill was observed over 6.6 ± 4.4 days and ECMO flow was increased by an average of 32%. Causes of death for non-ECMO survivors were anoxic brain injury (3, 23%), ischemic stroke (4, 31%), hemorrhagic stroke (2, 15%), sepsis (1, 7.7%), bleeding/disseminated intravascular coagulation (2, 15%) and malignant arrhythmias (1, 7.7%). Cardiac standstill persisted until death in all non-survivors. Intraventricular thrombi developed during standstill in 6 patients (27%) and resolved in 3 patients after 5.7 ± 3.5 days. Causes of death were related to pre-existing conditions and anticoagulation regimen, not thrombus formation. Survival of patients with and without thrombi were similar (33% vs. 44%, p = 0.999).

Conclusions: High ECMO flow adjustments can be an effective alternative to LSV as a method of decompressing the heart, without increasing neurological complications. With this strategy, patients diagnosed with cardiac arrest during ECMO have reasonable survival outcomes (40%).
Upgrade To Biventricular Support Using Two Separate Heartmate 3 Ventricular Assist Devices - A Proof Of Concept

Study: Right ventricular failure remains one of the major impairments to success of left ventricular assist device (LVAD) implantations. The introduction of HeartMate 3 (HM3) fully magnetically levitated LVAD has generated interest in using it also as a biventricular assist device (BiVAD). The aim of this report is to summarize our experience with a upgrade to BiVAD using two HM3 pumps.

Methods: Three males were implanted each with two HM3 as BiVAD in our center. Their mean age was 56.6 (range 45–64) years. One pt was in INTERMACS level 2 and two pts in level 3. In two pts the HM3 right ventricular assist device (RVAD) was implanted after 22 and 32 days of temporary RVAD support (Levitronix) and in one patient after 56 days of isolated LVAD implantation. In all pts an 8 mm down-sized grafts were used as RVAD outflow graft to pulmonary artery and connected end-to-end to the original HM3 outflow prosthesis. The HM3 RVAD has been implanted into the free wall of the right atrium in the axis of the right upper pulmonary vein towards the tricuspid valve. A spacer consisting of 6 to 8 felt rings were used to achieve a appropriate pump housing and inflow canula alignment.

Results: After RV upgrade, the initial LVAD flows ranged from 3.6 to 5.8 (mean 4.4) l/min, with LVAD pump speeds of 5200–6200 (mean 5400) RPM, and RVAD initial flows were 3.7 to 4.2 (mean 3.8) l/min, with RVAD pump speeds of 4800–6000 (mean 5400) RPM. Two out of three pts are still alive and ongoing on BiVAD support for 60 and 240 days. Our first patient died after 60 days of support due to severe sepsis with multigorgan failure. Two pts are discharged and listed for heart transplantation. Major complications included sepsis in two pts and wound infection in one. Two pts are on intermittent dialysis. The RV upgrade to biventricular support by two HM3 devices can be performed very safely in this highly selected patient cohort. Further clinical experience with this new configuration is needed before a routine application can be recommended.

Comparison Of Hemodynamic And Microcirculatory Assessment In Cardiopulmonary Bypass: Pulsatile- vs Centrifugal-Flow Pumps

Study: The VentriFlo™ True Pulse Pump (Design Mentor, Inc., Pelham, NH, USA) is a novel pulsatile blood pump designed to mimic the human heart-beat. We evaluated hemodynamic performance and microcirculation with this pump during cardiopulmonary bypass (CPB) in pigs and compared results with those of a conventional centrifugal pump (ROTAFLOW, MAQUET Holding B.V. & Co. KG, Rastatt, Germany).

Methods: Piglets (40–45 kg; n=12) were supported by 6-hr CPB with the VentriFlo or ROTAFLOW. In addition to hemodynamics, blood chemistry and gas analysis, microcirculation was evaluated at the groin skin by computer-assisted video microscopy (Optilia, Sollentuna, Sweden) in 8 piglets.

Results: All results shown are from 6-hr CPB. Hemodynamically, VentriFlo showed mean aortic pressure and pump flow rate comparable to ROTA- FLOW (30.5 ± 3.5 vs 29.8 ± 10.2 mm Hg and 2.16 ± 0.25 vs 2.16 ± 0.21 L/min [ns]) but with much higher pulse pressure (30.7 ± 4.1 vs 4.1 ± 7.8 mm Hg [p=0.0002; aortic pressure measured at carotid artery]). Plasma free hemoglobin, hematocrit, and lactate were comparable (32.1 ± 19.0 vs 36.4 ± 25.2 mg/dl, 18.8 ± 2.3 vs 20.7 ± 3.0%, 13.0 ± 8.3 vs 6.2 ± 3.3 mmol/L [ns]). O2 transfer rate of oxygenator was preserved in both pumps (12.4 ± 2.2 vs 12.4 ± 2.0 ml/min [ns]). As for microcirculation, capillary flow regulation was relatively well preserved with the VentriFlo but was dysregulated with the ROTAFLOW, which showed episodes of slower and more rapid flows than optimal. By both gross and histologic analysis, we found no evidence of thrombus, congestion, or ischemic changes in major organs of any animals, and no thrombus or pump deterioration in any pumps. This initial study demonstrated feasibility and safety of the VentriFlo pump in this 6-hr CPB model.
**Leadless Pacemaker Implantation In An LVAD Patient**

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**Study:** Annually, almost 1 million pacemakers are implanted globally. With the potential for fewer complications, leadless pacemakers might be the new alternative to traditional pacemakers requiring leads. Given the relative novelty of these pacemakers, they are still under investigation. There are no data on these devices in patients with left ventricular assist devices (LVAD). We present a case of a patient with an LVAD and underlying complete heart block (CHB) who underwent LVAD exchange and implantable cardioverter defibrillator (ICD) explant due to device endocarditis.

**Methods:** A 56-year-old Caucasian male with a history of CHB and end stage heart failure status post HeartMate 2 implantation, complicated by right ventricular (RV) heart failure, pseudomonas driveline infection, and Staphylococcus epidermidis bacteremia, presented to the hospital with a lactate dehydrogenase (LDH) of 724. His LDH continued to rise suggesting worsening pump hemolysis. Due to the patient’s extensive history of device endocarditis and pump hemolysis, he underwent LVAD exchange to HeartWare (HW) HVAD and laser lead extraction and ICD explantation. Implantation of a leadless single chamber pacemaker device was performed. Postoperatively patient remained in a ventricular paced rhythm with adequate HW HVAD flows. Device interrogation revealed that the pacemaker and LVAD were operating simultaneously without any electronic interference. No pacemaker complications have occurred in the first 60 days.

**Results:** Our case is the first known successful case of leadless pacemaker (MicraTM) implantation in an LVAD patient. The risk of infection in LVAD patients is high and may make a leadless pacemaker system an important consideration. Drawbacks of leadless pacemakers include the inability to have a defibrillator potential and only single chamber pacing ability. Regardless, for our high risk patient with a history of device endocarditis, RV failure, and complete heart block, the leadless system has allowed for substantial clinical improvement.

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**Hemodynamic Speed Optimization In VAD Support**

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**Study:** This study demonstrates the importance of VAD speed optimization and mean arterial pressure (MAP) management to improve outcomes.

**Methods:** A computational hemodynamic lumped parameter model (CHLPM) of the systemic and pulmonary circulation, including all four cardiac chambers, intrinsic baroreflex, blood pressure pharmacotherapy, and LVAD-specific H:Q relationships has been developed. The response of VAD patient’s cardiovascular system to a range of LVAD speeds, blood pressure medications, and baroreflex response was investigated. The correlation between LVAD speed, MAP and CO was analyzed. This model has been validated in patients implanted with the Medtronic HVAD system at our center.

**Results:** A target MAP of 70 mmHg and target CO of 5 L/min was used. Clinical scenarios for LVAD patients were explored with this rapid turnaround model. No single LVAD speed achieved both targets of MAP and CO without pharmacotherapy for MAP control. Maintaining an ideal MAP of 70 mm Hg enabled optimizing perfusion and MAP targets without the need to raise HVAD speeds above 2360 rpm for all patients studied. Hypotension (MAP < 50 mmHg) resulted in supraphysiologic CO (> 6 L/min), whereas uncontrolled hypertension (> 90 mmHg) resulted in markedly decreased CO (< 3.5 L/min). Thus, MAP control is imperative in optimizing long-term outcomes of VAD support.

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**Figure 1:** Effect of varying LVAD speed with MAP control to achieve target MAP of 70 mmHg and target CO of 5 L/min.
Computed Tomographic Imaging Is Comparable To Chest X-Ray In Determining Left Ventricular Assist Device Angulation


Study: Left ventricular assist device (LVAD) inflow cannula angulation has been evaluated as a predictor of pump thrombosis. Prior investigation has predominantly evaluated Heartmate II (HM II) inflow cannula angulation using chest X-ray landmarks and standardized measurements. Cannula angulation has been defined with respect to the body of the HM II device as well as to the spine. We attempted to validate inflow cannula angle on computed tomography (CT) in comparison to chest X-ray.

Methods: All patients who received an HM II at our institution from 2012 to 2016 and had chest X-ray and CT imaging were identified. Chest X-ray measurements including inflow cannula-pump (ICP) angle and pump-spine (PS) angle were completed according to Taghavi, et al. On CT imaging, inflow cannula angulation was defined using the axis from the central mitral annular plane to the apex as 0 degrees. The angle from this 0°-mark to the center of the inflow cannula was defined as the LV inflow angle and measured with image analysis tools (Fig 1).

Results: 81 patients were included. On chest X-ray, median inflow cannula angulation was 62.3° (range, 26.9°-95.8°). Median inflow cannula angulation on CT imaging was 32° (1°-57°). Chest X-ray ICP angle and CT imaging LV inflow angulation were correlated (r=0.46, p=0.002; Fig 2). Interestingly, there was also good linear correlation with the chest X-ray PS angle and CT imaging inflow cannula angle (r=0.45, p=0.0018).

Conclusions: In this direct comparison, HM II inflow cannula angle on CT imaging correlated well with X-ray measures. Thus, chest X-ray may hold promise as a cheaper and easily obtained test.
Simulated Performance Of Cleveland Clinic Continuous-Flow Total Artificial Heart Using The Virtual Mock Loop

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Study: Our new virtual mock loop (VML) is a mathematical model designed to simulate the human cardiovascular system in interaction with mechanical circulatory support devices. Here, we aimed to mimic the hemodynamic performance of Cleveland Clinic’s self-regulating continuous-flow total artificial heart (CFTAH) via VML and evaluate VML’s accuracy vs. bench data from our standard mock circulatory loop.

Methods: The VML reproduced 23 hemodynamic conditions. Systemic/pulmonary vascular resistances and pump rotational speed were set for VML from bench-test data. We compared outputs (pump flow, left/right pump pressure rise, normalized pump performance, and atrial pressure difference) of the two methods.

Results: Data from pump flow and left-pump pressure rise were similar, but right-pump pressure rise slightly differed. Left-pump normalized pump performance curves were similar. Right-pump VML results were within the same performance range indicated by bench tests (Figure). The plot of atrial pressure differences of VML vs. bench-test data were similar, but slightly differed in the mid-range of systemic/pulmonary gradients. VML successfully reproduced results from our mock circulatory loop of CFTAH test conditions. The CFTAH’s self-regulation feature of right-pump performance was also calculated effectively. We foresee using versions of the VML for training, simulating physiological cardiac conditions, and patient monitoring.

Figure: Normalized performance of left/right-pump pressure rise vs. flow, speed. Normalized pressure = ratio of pressure rise ÷ speed2. Normalized flow = ratio of pump flow ÷ pump speed.

Electrocardiogram-Synchronized Rotational Speed Modulation System Can Reduce The Recirculation Due To Aortic Insufficiency In LVAD Support

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Study: Aortic Insufficiency (AI) is one of the worrisome complications in LVAD support. Progressive AI can cause to increase recirculation from LVAD to LV. Our previous study suggested that high rotational speed of LVAD can lead to increasing LVAD-LV recirculation. We have previously developed Electrocardiogram-Synchronized Rotational Speed Modulation System (ESRSM), which can change the rotational speed synchronously to ECG cycle. The aim of this study was to reduce the LVAD-LV recirculation by controlling the rotational speed with ESRSM.

Methods: Eight goats (45 ± 2 kg) underwent LVAD (EVAHEART) implantation. Cardiac dysfunction was induced by continuous infusion of beta-blockade (esmolol). The AI model was established by placing a temporary inferior vena cava filter in the aortic valve. The degree of AI was controlled to three levels (none, mild, severe). Hemodynamics was evaluated in three levels of AI with the three modes of the ESRSM. The Co-pulse mode raises rotational speed in systolic phase, the Counter-pulse mode does in diastolic phase, and the Continuous mode does not change rotational speed (normal control). The rotational speed of each modes was set to maintain the same systemic flow. Recirculation rate which indicates the percentage of LVAD-LV recirculation to LVAD output was calculated as the index of AI.

Results: Continuous mode was driven with 1825 rpm (mean), and mean systemic flow was 2.1 L/min. The rotational speed needed to maintain the same flow was 2113 and 1563 rpm (systolic and diastolic phase) in Co-pulse mode, and 1488 and 1813 rpm in Counter-pulse mode. The mean rotational speed of each modes was set to maintain the same systemic flow. Recirculation rate which indicates the percentage of LVAD-LV recirculation to LVAD output was calculated as the index of AI.
Ambulatory Power-Tracking Algorithm For HVAD May Facilitate Prevention Of Adverse Events

A. Kadrolkar, R. Stadler. Research and Technology, Medtronic, Mounds View, MN.

Study: Although LVAD therapy reduces mortality, avoiding adverse events remains a challenge. Ambulatory monitoring and alerting has potential to facilitate early intervention and prevent adverse events. The Medtronic HeartWare HVAD system provides high resolution waveforms of power consumption and estimated flow, which may be employed during ambulatory monitoring. Non-physiologic increases in power consumption have been associated with abnormal operation, indicative of possible adverse events. This abstract presents an algorithm to detect subtle increases in power consumption over time to provide early warning of adverse events.

Methods: The power waveform from HVAD was processed to estimate short-term and long-term power consumption. An index of power changes over time was created by accumulating the difference between these two estimates. A threshold on this accumulated difference was used to trigger an alarm condition. The algorithm (shown in Fig. 1) was tuned on a development database of 90 HVAD log files with no adverse events (15.0 patient-years of follow-up) and 45 HVAD log files with confirmed thrombus. Because thrombus events are rare occurrences, the threshold (operating point) was chosen to minimize false alarms during normal pump operation. An independent database of 78 HVAD log files with no adverse events (9.6 patient-years of follow-up) and 40 HVAD log files with confirmed thrombus was used for validation.

Results: On the development database, the algorithm detected 84.4% of thrombus cases with an average of 1.9 days of alarm before the patient presented with symptoms. On the validation database, the algorithm detected 97.5% of thrombus cases with an average of 3.2 days of alarm before the patient presented with symptoms (performance shown in Fig. 2). There were no false alarms on either database. Early warning of adverse events in ambulatory HVAD patients is therefore feasible, and may facilitate intervention which could lead to prevention of adverse events.
Results: Overall, MVA donors were the most common DDs (27,650 from 144,237 DDs, 19%) & the most common donors utilized for CT-Tx (19,788 from 73,907 CT-Tx, 27%). Compared to the 1996–2007 era, the proportion of DDs from MVA & the proportion of CT-Tx utilizing MVA donors had a significant drop (20%, 35% & 29% respectively) in the post 2007 era [Figure]. By 2030, the projected 90% drop in MVA deaths would decrease the proportion of DDs from MVA to 1.2% & proportion of CT-Tx utilizing MVA donors to 1.5%.

Conclusion: MVA donors are the most common DDs overall & also the most common donors used for CT-Tx. The decline in MVA deaths post 2007 caused a significant drop in potential MVA donors & CT-Tx using MVA donors. The mass adoption of self-driving cars by 2030 is anticipated to cause a steep decline in MVA donors, causing our largest donor population today to drop to insignificant numbers by the end of the next decade.
Development Of A Foldable, Self-Assembling, Structural Brace For A Soft Robotic Ventricular Assist Device: A Design Strategy For Minimally Invasive Implantation

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Study: Many alternative ventricular assist devices (VAD) are being developed to address the problems with mechanical circular support options. We have developed a soft-robotic VAD-alternative that relies on a solid 11.4 cm diameter semicircular arc as a structural brace to be implanted around the ventricle, requiring a large insertion point and open chest surgery. Using a “beads-on-a-string” design strategy, our alternate brace described here consists of an arc broken into 5 arc segments held together into a rigid semicircular arc (schematic: Fig. A, rendering: Fig. B). We have developed a foldable, piecewise, self-assembly mechanism allowing the brace to be inserted through a much less invasive 5 cm by 4 cm thoracotomy.

Methods: The brace prototype was 3D-printed in an Objet Connex 500 printer. Bench top testing was conducted using a 1L saline bag as a ventricular model. A simulated ejection volume was measured by recording vertical volume displacement. Next, a simulated device deployment was conducted on an adult cardiothoracic surgical simulator (Fig. C) visualized endoscopically.

Results: During benchtop testing, the piecewise brace performed comparably to the solid brace in maintaining structural integrity, with at most 2% dimensional elastic change. We demonstrated on a surgical simulator that the brace can be successfully inserted and assembled within the pericardial space in under 15 minutes through a 5 cm incision with 4 cm rib spreaders (Fig. D). This design strategy can be easily applied to other large, inflexible, structural components of artificial internal organs to reduce the invasiveness of device implantation procedures.

Implementation Of A Physiologic Coronary Circulation In A Mock Circulatory Loop To Evaluate Rotary Blood Pump Support Strategies

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Study: Adequate delivery of coronary artery flow may improve ventricular function with rotary blood pump (RBP) support. However, previous mock circulation loop (MCL) attempts at optimizing RBP support strategies to improve coronary artery flow have been limited by unphysiologic coronary circulation simulations. This is due to inadequate simulation of the coronary autoregulatory response. This study aimed to implement a physiologic coronary circulation into a pre-existing MCL and then to evaluate coronary artery flow with RBP support at full and partial assist using constant and pulsatile speed modes.

Methods: Coronary circulation was implemented into a pre-existing MCL using an additional circuit from the aorta to the right atrium with a control valve used to simulate biphasic flow. Healthy and diseased coronary autoregulation was simulated by two different algorithms which automatically adjusted coronary vascular resistance based on coronary perfusion pressure (CPP) and left ventricular pressure-volume area (PVA). Coronary circulations were simulated with a range of PVAs (0.5 - 1.5 J) and CPPs (30 - 170 mmHg) and compared against theoretical expectations. Full and partial assist RBP support strategies in constant and pulsatile (co- and counter-pulse) speed modes were then compared in the MCL with physiologic coronary circulation.

Results: Measured coronary artery flow showed strong correlation to theoretical values for both healthy and diseased coronary circulations ($R^2$: 0.98). Full assist RBP support reduced PVA and coronary artery flow compared to partial assist, whilst varying pulsatile modes had little effect (Fig. 1). The physiologic coronary circulation may be used to further investigate RBP support strategies which improve coronary artery flow.

Fig.1 Comparison of a) pressure-volume area (PVA) and b) coronary artery flow (QCOR) of rotary blood pump (RBP) support strategies. CS - constant speed, CO - co-pulse, COUNTER - counter-pulse.
**Influence Of VAD Pressure-Flow Characteristics On Exercise Physiology: Hemodynamic And Energetic Evaluation With A Computational Model**


**Study:** Continuous-flow VADs have proven to sustain patients' hemodynamic at rest but their capability to properly sustain patients' hemodynamic during exercise is still an open question. Aim of this work is to investigate which VAD pressure-flow relationship can better support exercise physiology, so to provide some indications for future VAD design strategies.

**Methods:** A cardiorespiratory simulator was used to reproduce heart failure hemodynamic at rest and at exercise. Two VADs were simulated in turn: VAD1 with a steeper characteristic (12.5 mmHg/l/min average gradient up to 10 l/min) and VAD2 with a flatter characteristic (4.8 mmHg/l/min). Each VAD was set to a basal speed in order to assure a full support of 4.5 l/min at rest. Then, an exercise of 80 Watts was simulated and the cardiorespiratory system was left evolve to a steady condition.

**Results:** Both VAD1 and VAD2 increased their flow during exercise, due to a change of the hemodynamic condition across both devices. VAD2 can assure a higher flow than the VAD1 at exercise as it is shown in the figure (6.6 l/min vs. 5.7 l/min). As a consequence, VAD2 can also better unload the left ventricle compared to VAD1 (ventricular flow 1.0 vs 1.8 l/min) and reduce left atrial pressure (20 mmHg vs 21 mmHg). Positive effects of VAD2 were also observed on energetic parameters: left ventricular power increased from rest to exercise of +150% with VAD2 and of +240% with VAD1. To conclude a VAD with a flatter pressure-flow characteristics can assure a better support of hemodynamic during exercise. This is a desirable characteristic especially for patients with a poor residual left ventricular function for whom the increase of cardiac output at exercise mainly depends on the VAD itself.

**Acknowledgement:** This work was supported by the Frans van de Werf scholarship and the Erich and Hanna Klessmann foundation.

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**Improved Nutritional Status In Patients With Advanced Heart Failure Following Left Ventricular Assist Device Implantation**

I. Genev, G. Yost, G. Bhat, M. Gregory, P. Pappas, A. Tatooles. Center for Heart Transplant and Assist Devices, Advocate Christ Medical Center, Oak Lawn, IL.

**Study:** Left ventricular assist device (LVAD) implantation for advanced heart failure is known to improve survival, functional capacity, and quality of life. Most patients implanted with LVADs suffer from moderate/severe malnutrition and deconditioning due to their advanced disease. The Mini Nutritional Assessment (MNA) and the short form of the survey (MNA-SF) are two well-validated clinical tools, previously used to assess patient nutritional status in numerous conditions. Prognostic nutritional index (PNI) is a recognized indicator of nutritional status incorporating serum albumin and total lymphocyte count. Previous work has demonstrated that low nutritional scores can independently predict mortality in the LVAD population. This study explored changes in MNA scores and other clinical markers following LVAD.

**Methods:** This retrospective study included 74 patients implanted with LVADs between 2012 and 2017. MNA or MNA-SF along with other clinical data and nutritional indices were assessed during the preoperative workup and reassessed on average 423.9 days post-LVAD. Paired-samples T-tests were used to evaluate any changes.

**Results:** Despite an average BMI of 30.8, 25.4% of patients were classified by MNA as malnourished and 61.2% were considered at risk prior to LVAD implantation. Post device, MNA scores improved from an average of 19.2 to 23.0 (p<0.001), with now only 3.8% classified as malnourished and 45.3% at risk. MNA-SF, PNI, and mean serum albumin also improved significantly (Table). The improvement in multiple nutritional indicators after LVAD implantation is likely due to enhanced organ perfusion, exercise capacity, and gastrointestinal absorptive functionality.

**MNA scores and clinical data associated with nutritional status**

<table>
<thead>
<tr>
<th></th>
<th>Pre-LVAD</th>
<th>Post-LVAD</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MNA-SF (N=59)</td>
<td>8.7 +/- 2.7</td>
<td>10.8 +/- 2.7</td>
<td>&lt;0.001</td>
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<tr>
<td>MNA (n=53)</td>
<td>19.2 +/- 3.7</td>
<td>23.0 +/- 3.1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>30.8 +/- 7.9</td>
<td>31.7 +/- 7.7</td>
<td>NS</td>
</tr>
<tr>
<td>Serum Albumin (g/dL)</td>
<td>3.0 +/- 0.5</td>
<td>3.4 +/- 0.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Prognostic Nutrition Index (PNI)</td>
<td>29.7 +/- 4.9</td>
<td>33.6 +/- 5.5</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

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**Improved Nutritional Status In Patients With Advanced Heart Failure Following Left Ventricular Assist Device Implantation**

I. Genev, G. Yost, G. Bhat, M. Gregory, P. Pappas, A. Tatooles. Center for Heart Transplant and Assist Devices, Advocate Christ Medical Center, Oak Lawn, IL.

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Corwave Neptune LVAD: Timing Of Synchronized Pulsatility To Create Maximum Pulse Pressure

Study: The current generation of implantable long-term blood pumps employ high speed rotary impellers. The use of these devices is limited to a small portion of the addressable patient population due to high stroke rates, bleeding complications and infection. CorWave is developing a new blood pump inspired by the swimming motion of a fish. Cyclic low amplitude linear actuation creates a wave motion on a polymer membrane, gently pushing the blood through the pump. This approach offers a less damaging method for pumping blood and provides full physiologic pulsatility by cycling the pump between high and low flow rates. CorWave’s unique pumping technology aligns well with the critical requirements for a next generation blood pump and may hold promise for future evolution of the field.

Methods: Design enhancements have significantly increased the hydraulic power of the CorWave LVAD. The pump output is modulated by the frequency and amplitude at which it is operated. The current design, sized and configured for intra-pericardial apical placement was evaluated on a mock circulatory loop. Flow vs. pressure (HQ) curves were generated to establish operating parameters. The pump was evaluated in synchronous pulsatile mode to determine the optimal timing to maximize aortic pulse pressure.

Results: HQ curves for the design operating range of 60 Hz-120 Hz were generated (Figure 1). On a mock circulatory loop, the aortic pulse pressure was measured with the actuation being modulated between 100 Hz and 50 Hz, for 25% and 75%, respectively, of the cardiac cycle. The LVAD and left ventricle were both operated at a rate of 80 bpm and the onset of high flow output of the pump shifted from 0 to 100% of the cycle. Peak pulse pressure of 45mmHg was achieved when the high flow state was triggered at a delay of 13% phase shift from the start of ventricular contraction (Figure 2). Mean aortic flow under these conditions was 5.2 liters per minute.
Chronic In Vivo Test Of A Mechanical Circulatory Assist Device For Failed Fontan Circulation

Study: An implantable rotary blood pump was developed to provide long term mechanical right heart support for patients who have failing Fontan circulation. The objective of this study was to evaluate the pump in vivo in a 30-day animal study.

Methods: The chest of a 93 kg, 3 year old male sheep was exposed via a right thoracotomy. While on cardiopulmonary bypass, the SVC and IVC were completely separated from the RA and anastomosed end-to-end to the pump inlet cannulae. The outlet cannula was anastomosed end-to-side to the PA. Pump flow was initiated and increased as bypass flow was simultaneously weaned and discontinued. Pressure monitoring lines were placed on the SVC, IVC, and PA and brought out separately through the posterior chest wall. Pump speed was set at 3900 rpm for the duration of the study. Heparin was started at 10 U/kg/hr post-operatively and increased to 20 U/kg/hr on Day 15. Coumadin was started on Day 1 at 5 mg and increased to 20 mg on day 11. The animal was euthanized after day 30 and the pump was removed and examined for wear and thrombosis.

Results: Pump power increased from 4.3 W on Day 3 to 4.6 W at Day 30, which corresponds to pump flows of 4 lpm and 5 lpm, respectively. The pump inlet pressures for the SVC and IVC were 14 ± 15 mmHg and 11 ± 15 mmHg, respectively over the duration of the study. Hematocrit remained stable at 30% ± 4%. PTT steadily increased from 30 s pre-operatively to a high of 59 s on Day 20, while PT remained at 20 ± 2 s for the duration of the study. On pump inspection, the IVC and SVC inlets were completely clear of any deposits, there were small thrombi (approximately 0.5 mm diameter) between each of the three rotor blades, and there were deposits on 20% of the parting line of the two volute halves.

Summary: A complete right heart bypass was performed, post-operative recovery was successful, and the pump demonstrated adequate circulatory support and normal physiologic pulmonary and venous pressures. This study was the first successful test of a right heart replacement device in a chronic animal study.

Higher Pulsatility Index At The Time Of Pump Implant Is Associated With Improved Hemodynamics And Reduced Morbidity In 1 Year Follow-Up

Study: HeartMate II (HMII) Left Ventricular Assist Device controllers provide data reflecting the relationship between pump function and hemodynamics. We propose that a higher pulsatility index (PI) at implant may be associated with less vascular congestion and improved clinical outcomes.

Methods: A retrospective analysis of 40 end-stage heart failure patients (age 59.2 +/- 10.1 years) supported with the HM II device was conducted. Pump parameters, data from right heart catheterization performed prior to implant and at a median of 377 days, and all-cause rehospitalizations within 1 year were analyzed. Pearson correlation, Andersen-Gill, and Cox proportional hazard analysis were employed to examine relationships between variables and to calculate hazard ratios.

Results: Data revealed negative correlations between PI at implant and right atrial pressure (RAP), pulmonary artery systolic pressure (PAs), pulmonary artery diastolic pressure (PAd), mean pulmonary arterial pressure (MPAP), and pulmonary capillary wedge pressure (PCWP) at follow-up assessment, respectively (r= -.31, p=.05; r= -.37, p=.02; r =-.40, p <.01; and r= -.35, p=.03, resp.). The EPC controller data sub-analysis (n=28) demonstrated a stronger relationship between PI and RAP, PAs, PAd, MPAP, and PCWP, resp. (r= -.57, p<.01; r= -.38, p<.05; r= -.59, p<.01; r= -.47, p=.01; and r= -.53, p<.01, resp.). Finally, the PI from the EPC controller was associated with the risk of rehospitalization rate within 1-year post-LVAD implant with a HR=.56; 95% confidence interval [.32 to .98]; p=.04 and with the time to first readmission (Figure 1).

Conclusions: A higher PI at the time of implant was associated with greater volume unloading and lower pulmonary pressures at one-year follow-up. Additionally, lower PI was related to a higher risk of all-cause readmission rate within 1-year post-surgery. Pump derived data may be beneficial in predicting hemodynamics and disease risk stratification.
Concentric Heart Retains Natural Atria And Valves
A. J. Lande. Northport Navigable Waters Institution, Northport, MI.

Study: Describe three new innovations, since the previously patented and prototyped Concentric Heart utilizing artificial valves and air drive, was shown pumping 9 L/min attached to a Donovan Mock Circulatory Loop: 1) Replace only the damaged ventricles, while retaining the in-and-outflow enhancing atria and sinoatrial node and embolus avoiding natural valves. 2) Three previously described spherical with ducts balloons are supplemented by a fourth, triple bulb hourglass shape, one end bulb of which functions as the innermost hydraulic fluid and pump-containing additional primary drive balloon. This end bulb is continuous with the doubled-back-over-themselves remaining bulbs composing the all-enveloping compensation chamber. 3) Total intrapericardial placement, with only the battery and skin bridging induction coil located elsewhere. Definitively aid the large proportion of adult and even smallest pediatric patients, for whom there are no available donors.

Methods: We retrospectively analyzed all patients (n=140) between 2012–2016 who received VA-ECMO (n=59) or Impella (n=81) for CS at two institutions. Vasoactive agent use was documented prior to AMCS placement.

Results: The most common first line agents were norepinephrine, dobutamine and milrinone. Compared to VA-ECMO, Impella patients more frequently received dobutamine (70 vs. 31%, all comparisons p<0.05) and less frequently received phenylephrine (23 vs. 50%) or norepinephrine (63 vs. 89%). In-hospital mortality was 49%. Survivors were treated with fewer vasoactive agents (1.3 ± 1.1 vs 2.2 ± 1.3). There was no difference in mortality at low, moderate, and high doses of pressors or inotropes. Compared to 0–1 agents, use of ≥2 agents correlated with a higher Cr (2.1 ± 1.3 vs 1.4 ± 0.6 mg/dl), higher ALT (663 ± 1380 vs. 222 ± 653 IU/L), AST (1265 ± 3185 vs. 331 ± 1034 IU/L), and INR (1.9 ± 1 vs. 1.4 ± 0.4). Use of ≥2 agents correlated with a higher RA/PCWP ratio (0.78 ± 0.25 vs. 0.63 ± 0.23) and lower pulmonary artery pulsatility index (1.23 ± 0.78 vs. 1.89 ± 1.8). ROC analysis revealed an AUC of 0.838 for in-hospital mortality with an optimal cutoff of ≥2 agents. Vasoactive agent usage prior to AMCS for CS is associated with impaired end-organ function, right heart dysfunction and increased mortality. The number of vasoactive agents serves as a simple metric of CS severity and may identify patients at risk of hemo-metabolic shock potentially benefiting from early initiation of AMCS.
Survival And Functional Status After Bridge-To-Transplant With A Left Ventricular Assist Device


Study: The use left ventricular assist devices (LVAD) as a bridge-to-transplant (BTT) has become a common modality to treat end-stage heart failure. We sought to examine the impact of BTT on long-term survival and functional status.

Methods: The present study examined adults undergoing isolated heart transplantation in the United States between 2007 and 2017. We focused on BTT patients with a LVAD (Heartmate II or Heartware HVAD only) and compared these to patients undergoing de novo heart transplantation. Patients with other modalities of circulatory support were excluded. Our primary endpoint was survival at 1-, 2-, and 5-years. Secondary endpoints were hospital readmission, graft rejection requiring treatment, return to work, and functional status. Unconditional and conditional survival was estimated with the Kaplan-Meier method. The independent influence of BTT on risk-adjusted mortality was determined using Cox proportional hazard models.

Results: In this period, 5,584 patients were bridged with a LVAD and 12,295 underwent de novo transplantation. Unconditional survival was 2% higher in de novo patients at 1-, 2-, and 5-years. After risk-adjustment, BTT was associated with increased mortality at each time point. Unadjusted 5-year survival, conditional on 90-day survival, was similar between groups (82.6 vs 83.4%, p=0.15). Functional status, return to work, and unadjusted rates of hospital readmission and graft rejection were similar at 1-, 2-, 5-years. Bridge-to-transplant with LVAD provides excellent survival and similar quality of life to that of patients undergoing de novo heart transplantation. BTT patients experience a slightly higher mortality rate within 90-days of transplantation.
Congestive Profiles Correlate With Clinical Outcomes Among Patients Requiring Acute Mechanical Circulatory Support For Cardiogenic Shock

K. J. Morine,1 M. Esposito,1 S. Annamalai,1 R. Pedicini,1 L. Jorde,1 K. Gobeil,2 J. Hernandez-Montfort,2 N. K. Kapur1. 1Cardiology, Tufts Medical Center, Boston, MA, 2Cardiology, Baystate Medical Center, Springfield, MA.

Study: The impact of congestive profile on clinical outcome in patients with cardiogenic shock (CS) supported by acute mechanical circulatory support (AMCS) is not well understood.

Methods: We retrospectively analyzed all patients (n=140) between 2012–2016 receiving VA-ECMO (n=59) or Impella (n=81) for CS at two institutions. Hemodynamic data were available for 106 patients and were used to categorize CS as euvolemic [right atrial pressure (RAP)<14 and pulmonary capillary wedge pressure (PCWP) <16], LV-dominant (PCWP>16 only), RV-dominant (RAP>14 only) or BiV congestion.

Results: BiV congestion (56%) was more common than LV-dominant (15%), RV-dominant (14%) or euvolemic shock (14%; p<0.01 for comparison). Compared to LV- or RV-dominant congestion, BiV congestion correlated with higher serum creatinine (1.94 ± 1.12, 1.45 ± 0.59, 1.64 ± 1.15 mg/dl, p<0.01 for all comparisons), AST (1178 ± 3281, 588 ± 1774, 299 ± 257 IU/L), ALT (541 ± 1264, 358 ± 1041, 161 ± 196 IU/L) and lactate (5 ± 4.1, 3.8 ± 6.7, 4.3 ± 2.6 mEq/L). Euvolemic shock was associated with similar serum creatinine, AST, ALT and lactate compared to LV- and RV-dominant congestion. Mortality was similar among patients with BiV congestion managed with left or right sided Impella (44%), BiPella (40%), VA-ECMO without (43%) and with a LV venting strategy (60%). Compared to VA-ECMO, in hospital mortality was lower among patients receiving impella with LV-dominant congestion (0 vs 67%; p<0.01). Biventricular congestion is common and associated with worse end organ function compared to univentricular dominant congestion among patients with CS supported by AMCS. Mortality was lower for patients with LV-dominant congestion supported by Impella. Improved understanding of hemodynamics in CS may allow for congestive profile-device matching and potentially improve outcomes.

Clinical Outcomes Among Patients Requiring Acute Mechanical Circulatory Support For Cardiogenic Shock Supported By Impella Or VA-ECMO

K. J. Morine,1 M. Esposito,1 S. Annamalai,1 R. Pedicini,1 L. Jorde,1 K. Gobeil,2 J. Hernandez-Montfort,2 N. K. Kapur1. 1Cardiology, Tufts Medical Center, Boston, MA, 2Cardiology, Baystate Medical Center, Springfield, MA.

Study: Clinical trials for acute mechanical circulatory support (AMCS) for cardiogenic shock (CS) have exclusively focused on patients with acute coronary syndrome (ACS). Outcomes for patients supported with AMCS for other indications have not been well described.

Methods: We retrospectively analyzed all patients (n=140) between 2012–2016 receiving VA-ECMO (n=59) or Impella (n=81) for CS at two institutions.

Results: The indications for AMCS were acute coronary syndrome (46%: STEMI 30% and NSTEMI 70%), acute decompensated heart failure (ADHF) (39%), myocarditis (8%) and post-cardiotomy CS (7%). Compared to VA-ECMO, Impella patients were older (59 ± 14 vs 54 ± 12 years, all comparisons p<0.01) and more likely to have hypertension (57% vs 24%). Impella pts had a lower lactate (3.3 ± 2.7 vs. 7.1 ± 5.8 mEq/L), higher pH (7.33 ± 0.17 vs. 7.24 ± 0.16) and higher MAP (72 ± 15 vs. 61 ± 15 mmHg) compared to VA-ECMO. The median duration of support was longer for VA-ECMO than Impella (7.4 days vs. 5 days, p=0.03). Overall in hospital mortality across indications was lower for Impella than VA-ECMO (40% vs. 59%, p=0.03). Compared to VA-ECMO, mortality was lower with Impella for ADHF (31% vs 57%, p=0.037). For patients with CS supported by AMCS, mortality is lower for patients supported with Impella, particularly for ADHF, although indices of CS severity are worse among VA-ECMO recipients. Investigation of outcome predictors for AMCS recipients is warranted.
**PVAD: A Linear, Pulsatile, Peristaltic Ventricular Assist Device Mechanism**

**Study:** Heart failure remains a major cause of death, and is expanding in prominence in impoverished nations due to rheumatic heart failure. A demand exists for an artificial heart design that may be produced cheaply and used with minimal pharmacological intervention. In this study, our team investigates the potential application of a novel, linear valve-free pumping mechanism inspired by esophageal peristaltic motion for use as an LVAD. Our design in principle allows for much lower shear forces that may reduce or eliminate the need for anticoagulants. Additionally, by eliminating the presence of moving parts in contact with the patient’s blood, the device may drastically lower the material cost of fabrication and open the possibility of 3D printing components from conventional polymers if properly coated by biocompatible polymers. If used as an extracorporeal pump, our device may be invaluable in triage situations where anticoagulants are not always available.

**Methods:** In this study, we characterize the hemodynamic properties of this pump using an artificial vascular system and a doppler flowmeter. We then compare white cell activation after prolonged circulation, and quantify the level of hemolysis using a buffered solution of porcine red blood cells.

**Results:** Our prototype has achieved 100% occlusion and may displace 200mL every 0.5 seconds, making it suitable for use as an LVAD.

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**Evidence For Pulsatile Inertance As A Cause Of Outflow Conduit Pressure Loss In The Heartware HVAD**
P. Jain,1 S. Shehab,1 M. Stevens,1 P. Jansz,2 P. Macdonald,4 C. Hayward1. 1Cardiology, St Vincent’s Hospital, Darlinghurst, AUSTRALIA, 2Biomedical Engineering, University of New South Wales, Kensington, AUSTRALIA, 3Cardiothoracic Surgery, St Vincent’s Hospital, Darlinghurst, AUSTRALIA, 4Victor Chang Cardiac Research Institute, Darlinghurst, AUSTRALIA.

**Study:** Although it is known that cf-LVADs are afterload sensitive, pressure losses across an unobstructed outflow conduit under physiologic conditions have not been quantified. We sought to evaluate mean and peak pressure drop (gradient) across the outflow conduit in a pulsatile mock-loop circulation.

**Methods:** A mock-loop circulation incorporating Heartware HVADs for LV and RV support, with a 40cm polyvinyl chloride LVAD outflow conduit, was assessed at 3 conduit diameters (8, 10 and 12.7mm). Steady-state, continuous 50Hz measurements of LVAD flow and pressures within the LV, proximal and distal conduit and proximal aorta were obtained at varying pump speed, LV contractility (including zero), hematocrit (Hct) and heart rate (HR). Data were analyzed using multiple linear regression (MLR).

**Results:** Conduit cross-sectional area was negatively and non-linearly associated with both mean and peak gradient, consistent with the Hagen-Poiseuille equation (figure 1). Across the 10mm conduit, both mean and peak gradient correlated linearly with mean pump flow, systolic dQdt and Hct (p<0.001 for each, r² = 0.957 (mean), r² = 0.929 (peak)). HR did not correlate significantly with either mean or peak gradient. Mean gradient was most strongly predicted by mean flow, whereas peak gradient was most affected by peak systolic dQdt (figure 2A and 2B). Inclusion of conduit into the mock-loop results in significant hysteresis and leftward shift of the H-Q pump function curve during systole (figure 3).
Comprehensive Shear Stress Analysis In CH-VAD - An Ultra-Compact Fully Magnetically Suspended Implantable LVAD

P. Hsu, 1 F. F. Lin, 1 Y. Ma, 1 C. Chen. 1 Soochow University, Suzhou, CHINA, 2 CH Biomedical Inc., Suzhou, CHINA.

**Study:** Magnetic bearing in blood pumps allows for bigger suspension gap and applies less geometrical constraints as compared to hydrodynamic bearings. Therefore, fully magnetic suspension technology gives the blood pump designers more freedom to manipulate the flow path for optimal hemocompatibility. CH-VAD (CH Biomedical, Suzhou, China) is an ultra-compact (190gram, 49mm diameter, 26mm thickness) centrifugal blood pump with fully magnetic suspension. Several features, such as shroudless impeller and purely radial (inducerless) blades, have been incorporated in the CH-VAD design to minimize shear stress and promote wash out. This study provides a comprehensive analysis of the shear stress in this pump.

**Methods:** Computational fluid dynamic (CFD) simulations were conducted at nominal pump operating speed (3300rpm) at low and nominal flow conditions (2.0 and 5.0 L/min). The k-omega shear-stress-transport (SST) turbulence model was employed. Fluid properties were set to have a density of 1000 kg/m³ with a viscosity of 3.2 cP. Special care was taken for the mesh density at the secondary flow gap to capture shear stress accurately.

**Results:** We verified through the Reynolds number that more than 50% volume of the flow field in the pump is turbulent, which justified our selection of turbulence model over laminar model. The computed pressure heads were 124.4 and 101.9 mmHg at low and nominal flow conditions, respectively. In comparison with the experiments, these results gave a reasonable prediction: 1% and -5% at nominal and low flow conditions, respectively. Greater than 99.6% of flow volume underwent below 150Pa shear stress and 93% below 50Pa in all flow conditions. Shear stress distribution in the CH-VAD was comprehensively studied in silico and majority of blood would be exposed in low shear level, indicating a good hemocompatibility potential.

Cardiohepatic Syndrome Correlates With Mortality Among Patients With Cardiogenic Shock Requiring Acute Mechanical Circulatory Support

K. J. Morine, M. Esposito, S. Annamalai, R. Pedicini, L. Jorde. Cardiology, Tufts Medical Center, Boston, MA.

**Study:** Liver dysfunction attributable to heart failure, or cardiohepatic syndrome (CHS), has been associated with worse prognosis among patients with chronic heart failure. The relationship between CHS and clinical outcomes in cardiogenic shock (CS) is not known.

**Methods:** We retrospectively analyzed all patients (n=140) between 2012–2016 receiving VA-ECMO (n=59) or Impella (n=81) for CS at two institutions. CHS was characterized as hepatocellular [alanine transaminase (ALT) or aspartate transaminase (AST)>upper limit of normal (ULN)], cholestatic [total bilirubrin (TB), direct bilirubin (DB), or alkaline phosphatase (AP)]>ULN], or mixed (criteria for hepatocellular and cholestatic). Mortality was higher for mixed CHS (62%) compared to hepatocellular (41%, p=0.045), cholestatic CHS (33%, p=0.043) or a normal LFT profile (0%; Figure). Elevated right atrial (AST: Pearson r=0.22, p=0.04; ALT: r=0.27, p=0.01) and right atrial/pulmonary capillary wedge pressure (PCWP) ratio (AST: r=0.31, p=0.003; ALT: r=0.32, p=0.003) correlated with markers of hepatocellular, not cholestatic CHS. No correlation was observed between PCWP or cardiac index and markers of hepatocellular or cholestatic CHS. CHS is common among patients with CS requiring AMCS, is associated with right ventricular dysfunction and portends a worse prognosis. Further study of cardio-hepatic interactions in heart failure is required.
Aortic Spiral Flow Dynamics: The Impact Of Mechanical Circulatory Support Devices
P. Huang Zhang, S. Tauscher, J. Y. Kresh.  Cardiothoracic Surgery and Medicine, Drexel University College of Medicine, Philadelphia, PA.

Study: Continuous-flow mechanical circulatory support (MCS) devices are being used increasingly for end-stage heart failure patients as a bridge to transplant. With the advent of improved designs and enhanced flow dynamics, these devices are gaining broader application for destination therapy and bridge to recovery. However, MCS generate flow patterns that are non-physiological and maladapted to the aortic vascular structure. The aim of the study is to demonstrate the disruption of the stable aortic spiral flow patterns by existing MCS devices.

Methods: Computational Fluid Dynamic (CFD) simulations were conducted to study the coupling between aortic root and MCS outflow conditions and the resultant characteristic flow structures. 3D MRI image of the human aorta was rendered with a high mesh resolution (~1.5 million cells). The model boundaries were treated as stiff with no slip and the fluid was considered Newtonian, with the viscosity (4.1cP) and density (1060kg/m^3) of blood. Inlet flow was set with varying degrees of spirality: straight, clockwise, and counterclockwise.

Results: Shown in the figure, straight inlet-flow comparison of localized normalized helicity (LNH) superimposed on velocity streamlines between a normal aorta and one with an MCS cannula. The unassisted aorta shows increased cohesiveness of LNH coloring in the branch-off region, demonstrating normalized rotational order in the fluid (red=counterclockwise, blue=counterclockwise). The higher velocities are differentially distributed in the descending aorta, affecting overall wall shear stress distributions and recirculation regions. In summary, MCS introduce blood flow-regimes that are markedly different in terms of velocity distributions and spirality content, known to cause vascular remodeling and microvascular function implications. Future MCS designs incorporating spiral flow generating features are expected to induce device-to-native flow streamline coherence, impacting long-term recovery.

Modeling Of Virtual Mechanical Circulatory Support Hemodynamics For Biventricular Heart Failure
J. H. Karimov, D. J. Horvath, D. Horvath, T. Miyamoto, N. Byram, B. D. Kuban, R. Dessoffy, K. Fukamachi.  The Cleveland Clinic, Cleveland, OH.

Study: We developed a dynamic system platform, the Virtual Mock Loop (VML), to model the interactions of a mechanical circulatory support (MCS) pump using an extensive combination of patient-specific heart failure conditions. In this study, we analyzed the MCS environment of simulated biventricular assist device (BiVAD) support.

Methods: The VML was used to input blood flows, pressures, and volumes as they surge through the MCS-supported biventricular heart failure cardiovascular system. The developed software (MATLAB; MathWorks®, Natick, MA) simulates the hemodynamics in a novel way: using a lumped-parameter model, with systemic/pulmonary circulation (values for impedance, systolic and diastolic ventricular compliance, beat rate, and blood volume), and characteristics of the cardiac chambers and valves. BiVAD support (run at 4.0 krpm) was simulated by the VML by inputting both a left (LVAD) and right ventricular assist device (RVAD) using bench mock-loop values from the Cleveland Clinic continuous-flow total artificial heart (CFTAH). In BiVAD configuration, the left/right balancing function of the device based on pressures and flows at the four pump ports, was included. Four simulated cases having combinations of left and right systolic heart failure severity were evaluated (Fig.1).

Results: The advantage of this new VML-based approach is that it enables reproducible explorations of the interactions between a variety of heart failure conditions and hemodynamic environments. Fig.1. Simulations from Virtual Mock Loop. Selected biventricular heart failure case scenarios were plotted to compare different simulation cases. The left and right pump dynamic head curves are shown.
The Association Of Peak Lactate Levels With Length Of Stay And In-Hospital Mortality After LVAD Implantation

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Study: Measurement of lactate after LVAD implantation is common but implications are unclear. The primary aim of this study was to evaluate the association of peak lactate levels with length of stay, and in-hospital mortality, after LVAD implantation.

Methods: We retrospectively identified patients from the Advanced Heart Failure database who underwent implantation of a HeartMate II or a HeartWare HVAD LVAD between 1/1/2009 and 10/1/2017 and had peak lactate levels recorded in the immediate postoperative period. We excluded patients who had right heart failure requiring biventricular mechanical support. Baseline subject and perioperative characteristics were obtained. In-hospital mortality was defined as death during index LVAD implant hospitalization. Multivariable linear and logistic regression models were constructed to assess the association between peak lactate (independent variable) and postoperative length of stay and in-hospital mortality (dependent variables), respectively.

Results: A total of 301 subjects constituted our study cohort. Table 1 presents baseline subject characteristics according to three lactate value categories: <2 mmol/L, 2–4 mmol/L and ≥4 mmol/L. After adjusting for age, sex, BMI, race, INTERMACS profile, ischemic etiology, and pump-time, peak lactate was significantly associated with postoperative length of stay (β = 0.05 mmol/L; p = 0.02) and in-hospital mortality (OR: 1.33 (95% CI:1.13- 1.56); p = 0.0006). In patients undergoing LVAD implantation, postoperative peak lactate levels are independently associated with increased post-operative length of stay and with mortality during index hospitalization. Further research is needed to assess the mechanisms responsible for elevated postoperative lactate levels and whether targeted therapy will improve hospital course.

Baseline characteristics

<table>
<thead>
<tr>
<th>Lactate</th>
<th>Lactate</th>
<th>Lactate</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;2 mmol/L</td>
<td>2–4 mmol/L</td>
<td>≥4 mmol/L</td>
</tr>
<tr>
<td>N</td>
<td>94</td>
<td>134</td>
<td>73</td>
</tr>
<tr>
<td>Age (Years)</td>
<td>57 (11)</td>
<td>54 (13)</td>
<td>56 (13)</td>
</tr>
<tr>
<td>Sex (% Men)</td>
<td>78</td>
<td>73</td>
<td>67</td>
</tr>
<tr>
<td>Race (% African American)</td>
<td>68</td>
<td>66</td>
<td>63</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>29.5 (6.5)</td>
<td>28.6 (6.5)</td>
<td>28.2 (5.6)</td>
</tr>
<tr>
<td>Ischemic Cardiomyopathy (%)</td>
<td>36</td>
<td>35</td>
<td>33</td>
</tr>
<tr>
<td>VAD Type (% HM II)</td>
<td>63</td>
<td>58</td>
<td>51</td>
</tr>
<tr>
<td>Pre-Operative Inotropes (%)</td>
<td>89</td>
<td>86</td>
<td>82</td>
</tr>
<tr>
<td>Pump Time (min)</td>
<td>58 (25)</td>
<td>69 (31)</td>
<td>81 (35)</td>
</tr>
</tbody>
</table>
Evaluation Of Gastrointestinal Bleeds In Left Ventricular Assist Device Patients Receiving Phosphodiesterase 5 Inhibitors

Study: LVADs are associated with many adverse effects including right sided heart failure and GI bleeds. PDE-5 inhibitor therapy is often used to treat or prevent right sided heart failure in LVAD supported patients by unloading the right ventricle; however, the use of PDE-5 inhibitors may be associated with increased risk of GI bleeds. The proposed mechanism behind this is the effect of increasing cGMP in the GI tract which leads to increased extracellular signal regulated kinase 1 and 2 as well as p38 phosphorylation causing angiogenesis and increased risk of bleeding.

Methods: This study is a single-center retrospective chart review that included 319 patients implanted between 2012 and 2017 with a HeartMate II, HeartMate 3, or HeartWare LVAD for a minimum of 6 months. Patients taking PDE-5 inhibitors were compared to those not taking a PDE-5 inhibitor. The occurrence of GI bleeding was based on clinic records as well as admitting diagnoses of bleeds meeting INTERMACS criteria. Included patients were also compared for secondary outcomes including epistaxis, intracranial hemorrhage, and all-cause mortality.

Results: Of the 119 patients who received PDE-5 inhibitors, 45.4% experienced a GI bleed compared to 38.7% of the 199 patients who did not receive the medication (p=0.253). Of these patients, 76.5% were implanted with the HeartMate II, 3.8% with the HeartMate 3, and 19.7% with the HeartWare device. The average daily dose of sildenafil and tadalafil in patients who bled was 74.7 mg and 33.3 mg, respectively. In the population examined in this study, the use of PDE-5 inhibitors did not lead to a statistically significant increased risk of GI bleeds; however, the numerically increased risk observed in patients taking a PDE-5 inhibitor warrants further investigation.

Update: Progress In The Development Of An Advanced Ventricular Assist Device With Pulse Augmentation And Regurgitant Flow Shutoff
N. Byram, D. J. Horvath, J. Adams, T. Miyamoto, J. Karimov, B. D. Kuban, R. Dessoffy, K. Fukamachi. Biomedical Engineering, Cleveland Clinic, Cleveland, OH; R1 Engineering, Euclid, OH.

Study: We have developed a ventricular assist device under NHLBI funding (Grant 5R21HL133871) that automatically couples with the ventricle and previously reported that model AV010 improved pulsatility and prevented regurgitant flow during pump stoppage. Further design changes have been made (model AV020). This study evaluated, on a mock loop, the effects of the relative spacing of the magnets and impeller on pulsatility and functionality of the shut-off feature.

Methods: Bench testing of three versions of the AV020 was performed on a pulsatile mock loop with a pneumatic device simulating the native ventricle in heart failure. Each pump was run at 3000 RPM to evaluate pulse augmentation, then was stopped to assess regurgitant flow through the pump. The outflow graft was then clamped to demonstrate the feasibility of a clinical pump-off test. The resulting data, with changes to the primary (models 3S and 6S) and secondary (model RC) impeller spacing, were compared to our previous results.

Results: AV020 RC showed greater pulse pressure than AV010. AV020 3S, while having a slightly higher pulse pressure, had 40% lower mean pressure output than all other models; AV020 6S ran well but did not outperform the RC version. When all versions of the AV020 were stopped, we noted no remarkable regurgitant flow (Figure). No significant changes in the arterial pressure waveform occurred in any pump when the outflow conduit was clamped, indicating that the pump-off test could be done without clamping the outflow conduit. In conclusion, the AV020 RC showed improved pulsatility and functionality of the shut-off feature over the AV010, and is ready to move into in vivo studies.
ASAIO CARDIAC ABSTRACTS

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Asymptomatic Moderate Aortic Insufficiency With A Left Ventricular Assist Device Portends A Worse Long-Term Survival


Study: The development of aortic regurgitation (AR) is known to be associated with prolonged left ventricular assist device (LVAD) support, but its overall significance with regards to long-term outcomes is unclear. This uncertainty translates to a lack of consensus regarding management of AR in this patient population - an increasingly pertinent question as more patients are placed on LVAD support as destination therapy.

Methods: A retrospective review of a single, high volume institution was performed to assess outcomes in patients who received a HeartMate II or HeartWare (LVAD) between 2008–2016. Patients were stratified by AR severity at six months, and those with LVAD support of less than six months were excluded. The primary endpoint was mortality, and secondary endpoints were right heart failure and functional exercise capacity.

Results: At six month follow up 55, 78, and 16 patients had no (0), mild (1) and moderate (2) AR, respectively. Severity of AR was not associated with a change in symptoms as measured by quality-of-life questionnaires (p=0.245). Three-year survival based on Kaplan-Meier analysis was significantly worse in patients with moderate AR (p=0.0003) compared to patients with no AR. Worse AR status at six months trended toward predicting worse functional exercise capacity at one year (measured by six-minute walk test) but was not significant after multivariable analysis (1: p=0.142; 2: p=0.089). The incidence of right heart failure was not significantly different between groups (1: p=0.0796; 2: p=0.140). In conclusion, moderate aortic insufficiency at six months post-LVAD implant is associated with worse long-term mortality. More aggressive management strategies targeting AR development in long-term LVAD patients may be warranted.

<table>
<thead>
<tr>
<th>AR at 6 Months</th>
<th>0 (None)</th>
<th>1 (Mild)</th>
<th>2 (Moderate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n = 55</td>
<td>n = 78</td>
<td>n = 16</td>
<td></td>
</tr>
<tr>
<td>Three-Year Mortality</td>
<td>10.9%</td>
<td>14.1%</td>
<td>20.5%</td>
</tr>
<tr>
<td>Multi-variable p</td>
<td>p=0.588</td>
<td>p=0.849</td>
<td>p=0.0001</td>
</tr>
<tr>
<td>p = 0.006</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Six-Minute Walk Distance at One Year</td>
<td>1443 ft.</td>
<td>1100 ft.</td>
<td>1064 ft.</td>
</tr>
<tr>
<td>Multi-variable p</td>
<td>p=0.0151</td>
<td>p=0.142</td>
<td>p=0.0318</td>
</tr>
<tr>
<td>p = 0.089</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right Heart Failure at One Year</td>
<td>0%</td>
<td>29.6%</td>
<td>25.0%</td>
</tr>
<tr>
<td>Multi-variable p</td>
<td>p=0.0796</td>
<td>p=0.1396</td>
<td></td>
</tr>
</tbody>
</table>

In Vitro Simulation Of Partial Left Ventricular Assist In An Adult

G. M. Pantalos, A. Drummond, E. Boland, J. Tourro, D. Morley, D. Burkhoff. Cardiovascular Innovation Institute, University of Louisville, Louisville, KY, USFDA, Silver Spring, MD, Columbia University, Saddle Brook, NJ.

Study: In Vitro simulation of continuous flow, partial left ventricular (LV) assistance for an adult was conducted with a mock circulation that approximated a contracting LV, left atrial inflow cannulation, and assist pump flow return to a thoracic artery. Left ventricular pressure-volume loops, left atrial pressure, aortic pressure and flow, and assist device outflow were measured.

Methods: Test conditions included normal ventricular function (CO = 5.0 L/min, AoP = 95 mm Hg, LAP = 8 mm Hg), mild, moderate, and severe, dilated left ventricular dysfunction (CO = 3.0 L/min, AoP = 70 mm Hg, LAP = 22 mm Hg), arterial hypertension (AoP = 120 mm Hg), and ventricular fibrillation.

Results: Acceptable partial support response was observed for assist pump flows up to 3.2 L/min. Aortic and left atrial pressures were normalized and total systemic flow was increased with partial LV support during heart failure and ventricular fibrillation conditions. During arterial hypertension, blood pressures and flows were improved with pump speed management. The majority of the aortic pulse pressure (30 mm Hg) remained with partial assistance. A leftward shift of the ventricular pressure-volume loop was observed during partial support conditions. This simulation demonstrates the ability to restore beneficial hemodynamic conditions during partial LV assistance during left ventricular dysfunction while inducing a degree of left ventricular reverse remodeling that may contribute to the myocardial recovery process.
Correlation Of Doppler Opening Blood Pressure To Invasive Mean Arterial Pressure In Continuous Flow VADS

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1Cardiology, University of Washington, Seattle, WA, 2Cardiac Surgery, University of Washington, Seattle, WA, 3Pulmonary and Critical Care Medicine, University of Washington, Seattle, WA, 4Mechanical Engineering, University of Washington, Seattle, WA.

Study: Accurate blood pressure measurement in continuous flow VAD patients is imperative in reducing stroke risk. This study assesses whether noninvasive Doppler opening blood pressure accurately estimates invasive arterial blood pressure in continuous flow VADs.

Methods: In a longitudinal cohort of VAD inpatients with arterial line blood pressure monitoring, recorded Doppler opening pressures were correlated to invasive arterial line blood pressures taken within one minute of each other. The correlation between Doppler opening pressure and invasive mean arterial pressure (MAP) was examined for HeartMate II™ (HM2) and HVAD™ patients.

Results: A total of 1870 pairs of Doppler opening pressure and arterial line pressure readings within one minute of each other were identified in 147 patients. Doppler opening pressure closely approximated invasive MAP in HM2 and HVAD patients with a mean difference of 2.3 mmHg (r = 0.744 and 0.662, respectively). Arterial line pulse pressure did not meaningfully affect the accuracy of Doppler opening pressure. In conclusion, for clinical purposes, measuring Doppler opening blood pressure should be considered the standard for most VAD patients.

Hemodynamic And ECHO Measurements During Weaning Of VA ECMO Suggest Acceptable LV Unloading


Study: One major concern of utilizing VA ECMO in advanced cardiogenic shock (ACS) patients is its inability to completely unload the left ventricle (LV). However, the clinically significant degree of LV unloading required for recovery is not well described. We hypothesized that measuring hemodynamics during VA ECMO weaning trial would help better understand the impact of VA ECMO on LV unloading.

Methods: From January 2017 to October 2017, 22 patients with advanced cardiogenic shock (ACS) required VA ECMO support for longer than 24 hours (acute on chronic heart failure patients were excluded). A weaning protocol utilizing hemodynamic measurements and echocardiogram (ECHO) was applied in 14 patients who showed acceptable end organ recovery (mean age 58 ± 16; male 13). The etiology of ACS included 5 cases of acute MI, 5 cases of post cardiotomy, and 1 case each of myocarditis, metabolic derangement, primary graft failure, and refractory ventricular fibrillation. The mean duration of support before weaning was 10 days (±5). All patients had a Swan-Ganz catheter (SGC). Hemodynamics and ECHO measurements were obtained at full ECMO support (100%), then with support reduced to 75%, 50%, 25%, and off (0%). Hemodynamic stability for more than 2 minutes was required before further reduction of support.

Results: As seen in the table below, mean values of pulmonary capillary wedge pressure (PCWP) were significantly higher with ECMO support off compared to 100% of support (p-value: 0.027). Eleven patients (78.6%) showed an increase in PCWP upon reducing the ECMO support, 2 patients (14.3%) showed slight decrease, and 1 patient (7.1%) remained unchanged. Twelve patients were discharged (85.7%) of which 11 were weaned (78.6%) and 1 was bridged to LVAD. Care was withdrawn on 1 patient. The results show the capability of VA ECMO to unload the LV to a clinically acceptable level. However, LV unloading should be carefully measured via complete hemodynamic assessment utilizing SGC and ECHO.

<table>
<thead>
<tr>
<th>ECMO Support</th>
<th>PCWP [mmHg]</th>
<th>CVP [mmHg]</th>
<th>Mean PA Pressure [mmHg]</th>
<th>Mean Arterial Pressure [mmHg]</th>
<th>Stroke Rate [GPM]</th>
<th>LV Echodensity [1]</th>
<th>Pump Flow [GPM]</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td>8.8±4.6</td>
<td>7.0±4.6</td>
<td>16.7±4.8</td>
<td>8.0±2.5</td>
<td>90.28±17.7</td>
<td>4.90±0.8</td>
<td>4.12±0.59</td>
</tr>
<tr>
<td>75%</td>
<td>10.7±5.25</td>
<td>8.6±6.4</td>
<td>17.4±5.3</td>
<td>8.3±1.5</td>
<td>93±18.7</td>
<td>3.04±0.46</td>
<td></td>
</tr>
<tr>
<td>50%</td>
<td>11.9±6.4</td>
<td>9.0±5.1</td>
<td>18.9±5.3</td>
<td>9.1±1.4</td>
<td>94.29±17.4</td>
<td>2.08±0.32</td>
<td></td>
</tr>
<tr>
<td>25%</td>
<td>14.4±6.9</td>
<td>10.2±5.2</td>
<td>22.0±5.9</td>
<td>7.8±1.2</td>
<td>84.3±18.4</td>
<td>1.08±0.17</td>
<td></td>
</tr>
<tr>
<td>OFF</td>
<td>13.8±5.5</td>
<td>10.0±5.4</td>
<td>22.3±5.7</td>
<td>7.3±1.4</td>
<td>102.46±20.10</td>
<td>4.75±0.64</td>
<td></td>
</tr>
<tr>
<td>P-value (100% vs OFF)</td>
<td>0.027</td>
<td>0.006</td>
<td>0.002</td>
<td>0.002</td>
<td>0.006</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Significant Decrease In HgA1c Levels In Diabetics After Continuous-Flow Left Ventricular Assist Device Implantation


Study: We examined changes in glycosylated hemoglobin (HbA1c) levels as a marker for glycemic control in patients with diabetes mellitus (DM) who underwent continuous flow left ventricular assist device (CF-LVAD) implantation.

Methods: Retrospective review of 700 patients implanted with CF-LVADs at a single center from 1999 to 2017. Demographics, outcomes, and long-term survival were compared between DM and non-DM patients. Baseline HbA1c for all patients and post-operative HbA1c for DM patients at 1 and 2 years post-implant were compared.

Results: Of 700 patients, 304 (42%) had DM. Patients with DM were older (58.0 ± 10.9 vs. 51.2 ± 14.6 years, p<0.001), had higher rates of ischemic cardiomyopathy (57.1% vs 37.8%, p<0.001), higher baseline BMI (29.4 ± 6.4 vs 27.7 ± 14.5 kg/m², p=0.005), and an increased incidence of hypertension (71.9% vs 50.6%, p=0.001), myocardial infarction (27.9% vs 13.3%, p=0.01), chronic kidney disease (57.1% vs 45.3%, p=0.04) previous sternotomy (41% vs 34.4%, p=0.05), and higher baseline HgA1c (7.2 ± 1.6 vs 6.0 ± 0.7%, p<0.001). HgA1c decreased in the DM group at 1 year from 7.3 ± 1.7 to 6.8 ± 1.9 (p=0.02). DM patients had similar long-term survival (Figure 1), a similar incidence of postoperative hemorrhagic neurologic deficits (13.7% vs 14.0%, p=NS), drive line infections (9.8% vs 11.1%, p=NS), pump infections (7.0% vs 5.1%, p=NS), acute kidney injury (4.9% vs 8.8%, p=NS), RVAD insertion (4.3% vs 4.8%, p=NS), gastrointestinal bleeding (30.5% vs 22.4%, p=NS), length of stay (63.7 ± 79.4 vs 57.0 ± 54.1 days, p=NS), early readmission (18.1% vs 21.2%, p=NS), and pump exchanges (14.5% vs 15.6%, p=NS). DM patients had a higher incidence of postoperative ischemic neurological deficits (20.1% vs 12.7%, p=0.01).

Conclusion: DM patients who underwent CF-LVAD implantation had similar long-term survival compared to non-diabetic patients and experienced a significant decrease in their HgA1C at 1-year post-LVAD.

VAD Displayed Flow Frequently Fails To Accurately Predict Cardiac Output Measured By Right Heart Catheterization


Study: Accurate noninvasive assessment of cardiac output could be very useful in the management of VAD patients. This study assesses the correlation between VAD displayed pump flow and invasive cardiac output measurement by right heart catheterization (RHC).

Methods: In a longitudinal cohort of continuous flow VAD patients, invasive cardiac output measurements by RHC were matched with VAD displayed flow rate estimates recorded closest to the time of RHC and within 8 hours of each other. The correlation between VAD displayed flow rate and invasive cardiac output measurements was examined for both HeartMate II (HM2) and HeartWare HVAD and over different blood pressure ranges.

Results: A total of 146 pairs of measurements were identified in 96 unique VAD patients. For HM2 (n = 77), VAD displayed flow rate did not correlate with either Fick or thermodilution (TD) cardiac outputs by RHC (Fick: r 0.16, p-value 0.16; TD: r 0.14, p-value 0.22). For HVAD (n = 69), VAD displayed flow rate had a statistically significant but poor degree of correlation with both Fick and TD CO (Fick: r 0.35, p-value 0.003; TD: r 0.36, p-value 0.002). For subgroups of blood pressure ranges (MAP < 70, 70–80, and >80 mmHg), the correlation between VAD flow rate and Fick cardiac output was only statistically significant in the 70–80 mmHg range (r 0.33, p-value 0.004). In summary, device displayed VAD flow estimates frequently are not sufficiently reliable for patient care decision-making compared to RHC.
Proposed A In-Vitro Test Jig To Improve The Availability Of VADS In Patients Suffering From Severe Heart Failure

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Study: In vitro test platform of DAVs to obtain the variation of their dynamic behavior, over time, because they are a class of systems variant in time. In this context, the objective is to identify the failure modes that occur during its useful life and that affect its functionality. After this, the test platform auto-adjusts the setup of its variables, associated to the control of the behavior of the DAVs, within operating ranges inherent to the needs of a patient with heart failure. Thus, it is being contemplated that VAD is a time-varying device, which allows for greater availability of the device for patient use.

Methods: This research will be based on an experimental test of devices, divided in: (i) programming the initial set up of the variables for surveying the reference curves of the dynamic behavior of the device; (ii) programming a supervisory system capable of identifying deviations in the reference curves resulting from the occurrence of failure modes and reacting by performing a self-tuning to cause a new set-up of the variables mentioned in (i) the needs of a patient; (iii) development of a reliability data acquisition system for describing the time-varying behavior of a VAD; (iv) the dynamic tests are paused when the functionality of the DAV under test no longer addresses the needs of the patient (the variables on the test platform are outside the predefined operating range) or when there are unexpected critical failures that interrupt the functioning of the VAD; (v) after the interruption of the tests, corrective inspection and maintenance procedures must be performed to treat the faults; (vi) the test jig is terminated when all components of each DAV under test are closed.

Results: Obtaining the collection of a set of reference curves capable of representing the dynamic behavior of the device; obtaining a database of reliability of the DAV, contemplating all its components.

Echocardiographic Estimates Of Right Heart Pressures Fail To Approximate Invasive Hemodynamics In Continuous Flow VAD Patients


Study: Accurate monitoring of right heart pressures is essential to VAD patient management. The utility of transthoracic echocardiography in estimating right atrial pressure (RAP) and pulmonary artery systolic pressure (PASP) in continuous flow VAD patients has not been established. This study assesses the accuracy of noninvasive echocardiographic estimates of RAP and PASP versus direct measurements by right heart catheterization (RHC) in continuous flow VAD patients.

Methods: In a longitudinal cohort of VAD patients, echocardiographic estimates of mean RAP and PASP were correlated with direct measurements by RHC performed within 24 hours of each other. The correlation between echocardiographic estimates and direct measurements by RHC was examined before and after VAD implantation in the same cohort of patients.

Results: For RAP, 69 pairs of values were identified before and 72 pairs after VAD implantation in 104 VAD patients. There was modest correlation between echocardiographic and RHC RAP measurements both before and after VAD implantation (r = 0.487 [CI 0.283–0.649] and 0.572 [CI 0.392–0.709], respectively; p < 0.001). Using RAP ranges of 0–5, 5–10, 10–15, and >15 mmHg, the chance of echocardiographic and RHC measurements being concordant was 39.1% before VAD and 36.1% after VAD.

For PASP, 67 pairs of values were identified before and 58 pairs after VAD implantation in 96 VAD patients. There was modest correlation between echocardiographic and RHC PASP measurements before VAD implantation (r = 0.635 [CI 0.466–0.759]; p < 0.001) and poor correlation after VAD implantation (r = 0.246 [CI 0.013–0.474]; p = 0.063). Using PASP ranges of <40, 40–50, 50–60, and >60 mmHg, the chance of echocardiographic and RHC measurements being concordant was 44.8% before VAD and 69.0% after VAD. In conclusion, RHC remains the clinical gold standard of assessing right heart pressures in continuous flow VAD patients.
Should A History Of Illicit Drug Use Be An Absolute Contraindication For LVAD Implantation?


Study: Active substance abuse involving illicit drugs is accepted as a contraindication for continuous flow left ventricular assist device (CF-LVAD) implantation. However, the impact of any history of illicit drug use on outcomes is unclear. We analyzed the effects of previous illicit drug use on LVAD outcomes.

Methods: Retrospective review of 725 patients with CF-LVAD (1999–2017) was conducted. History of substance abuse (excluding alcohol), toxicology reports, demographics, and outcomes were abstracted for 643 of these patients.

Results: Overall, 92 patients (14.3%) had a history of illicit drug use. Of these, 41 (44.6%) underwent bridge therapy and 51 (55.4%) underwent destination therapy. Active use was reported by 13 (14.1%), use within last five years by 24 (26.1%), and use ≥5 years ago by 46 (50%) patients. Median patient age was 48 years (37.3–57.8 years) and 82 (87.2%) patients were male. Use of one illicit drug was reported by 30 (32.6%) patients while 54 (58.7%) reported ≥2 illicit drugs. Common illicit drugs included marijuana (n=68, 73.9%) and cocaine (n=37, 40.2%). Fig. 1 depicts pre-operative toxicology. Compared to patients with no history of drug abuse, those with positive history had similar incidence of neurological deficits (34.8% vs. 23.2%, NS), length of stay (52.3 ± 37.2 vs. 60.1 ± 71.1 days, NS), early readmission (25% vs. 20.9%, NS), and 30-day mortality (7.6% vs. 9.6%, NS). More illicit drug users developed drive line infection requiring surgical intervention when compared to non-users (19.6% vs 8.5%, p=0.001). Patients with positive history had greater number of LVAD exchanges (25.6% vs 14.6%, p=0.012). The 2- and 5- year actuarial survival was 65.2% and 49.4% (NS)(Fig. 2).

Conclusion: CF-LVAD implantation in patients with any history of illicit drug use is associated with higher rates of drive line infection and LVAD exchange. However, there was no effect on early or long-term survival. Further analysis of illicit drug users who undergo LVAD implantation is warranted.
Applicability of Ultrasonic Sensors to Measure Volume on the Ventricular Assist Device Inlet Cannula


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Study: Ventricular volume sensors have the potential to make left-ventricular assist devices (LVADs) smart in terms of their response to the physiologic need of a patient. Complex ultrasonic systems are commonly used to measure left-ventricular (LV) volume in the clinic, but a simplified ultrasonic sensor (US) could be integrated in the LVAD cannula. The proposed dual US measures the inner diameter (D) of the LV with two transducers. Aim of this study was to investigate the quality and robustness of using D to estimate the LV volume and examine its accuracy in-vitro.

Methods: A newly developed in-vitro test-bench was equipped with five talcum-infused silicone heart phantoms with end-diastolic filling volumes ranging from 180─480 mL. The intra-ventricular surface replicated papillary muscles and trabeculae carnae. This reference volume was altered with a syringe pump by ±40 mL in steps of 5 mL. From the position of an LVAD cannula, we measured wall-distances in 84 directions, corresponding to different Ds. The volume was analyzed by 5/6 (D/2)^2L and calibrated over the respective length L corresponding to the axial length of the LV. A Bland-Altman analysis reports the accuracy as bias (µ) and limits of agreement (LOA) between the estimated and the reference volume.

Results: The accuracies are strongly dependent on the choice of diameters' location. The most promising diameters correspond to the location of the LV end-diastolic diameter commonly used in clinical assessment.

Discussion: Considering the simplicity of the ultrasonic sensor, the proposed dual US promises to be a viable approach for an integrated LV volume sensor in an LVAD, bearing in mind its simplicity.

A Shift In Paradigm: Transitioning From Surgical To A Medical Multidisciplinary Approach To Inpatient Management Of Patients With Ventricular Assist Devices


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Study: With an ever-expanding population of ventricular assist device (VAD) patients and extended durations of support, the care of VAD patients has become increasingly complex. As mechanical reliability of VADs has improved, reasons for hospital readmissions have shifted from historically surgical to predominately medical. This paradigm shift has created the need to optimize inpatient VAD management via a progressive multidisciplinary approach.

Methods: We describe the development of a multidisciplinary internal medicine-based team at a large, quaternary academic medical center for management of VAD patients. The team consists of VAD-trained hospitalists, advanced heart failure and transplant cardiologists, advanced practice providers, cardiac surgeons, social workers and pharmacists.

Results: Along with standardized processes for admission, discharge, transitions of care, and follow-up, the multidisciplinary care team developed and implemented protocol-driven pathways for frequent admitting diagnoses such as anticoagulation management, hypertension, gastrointestinal bleeding, diuresis, and right ventricular failure. The medical care of VAD patients is complex and resource intensive which can be optimized in a sustainable manner by providing protocolized inpatient management via a multidisciplinary team approach. With such an approach, we developed strategies to improve quality of care, reduce practice pattern variation, and positively impact outcomes and resource utilization.
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The Incidence, Risk Factors, And Outcome Of Gastrointestinal Bleeding In Patients With Left Ventricular Assist Device: Japanese Single Center Cohort Study
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Study: Continuous flow left ventricular assist devices (CF-LVADs) have become a valuable therapeutic option in the management of advanced heart failure. Several Western country cohort studies demonstrated that patients with CF-LVADs are at an increased risk of gastrointestinal (GI) bleeding. However, few reports have presented the current status of GI bleeding in Asian cohort. This study evaluated GI bleeding in patients receiving CF-LVADs at our institution.

Methods: The records of adult patients who received CF-LVAD between October 2008 and January 2017 were reviewed. GI bleeding was defined as melena, hematochezia, and hematemesis of GI bleeding detected by diagnostic imaging. GI bleeding events recorded until death, time of heart transplantation, or end of observation. All patients were anticoagulated postoperatively with warfarin and also started single anti-platelet therapy (81mg aspirin or 25-75mg clopidogrel).

Results: Fifty four patients underwent CF-LVAD implantation, of which 14.3% presented with overt GI bleeding for a total of 12 presentations. GI bleeding was associated with older age (p=0.033) and higher body surface area (p=0.028). Freedom from GI bleeding was 85.8% at 1 year. Median international normalized ratio at the time of first GI bleeding was 2.6 ± 1.3. The most common bleeding site was small intestine (73%). Most patients required blood transfusion; however, no patients required surgical intervention. Recurrent GI bleeding after the first episode occurred in three patients with four separate GI events. The incidence of GI bleeding in patients with CF-LVAD in our institute was comparable with several Western cohort studies. The main GI bleeding source was small intestine bleeding. We have not used capsule endoscopy for diagnosis. Therefore, it is possible to underestimate the patients with occult GI bleeding. Considering lower pump speed management and smaller amount of anti-platelet therapy, it might be possible Asian patients with CF-LVAD have more GI bleeding complications.

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Excessive LVAD Speed Causes Right Heart Pressure / Volume Overload And Precipitates RV Failure
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Study: This work investigates the mechanics of VAD Speed on right heart hemodynamics, and RV function.

Methods: A computational hemodynamic lumped parameter model (CHLPM) of the systemic and pulmonary circulations including all four cardiac chambers and LVAD specific H:Q relationships has been developed. A range of different variables, including mean arterial pressure (MAP), VAD speed, and right heart pressures were evaluated and the pulmonary system response was analyzed.

Results: Using a target MAP of 70 mmHg, our findings confirm that if MAP is controlled without decreasing centrifugal VAD speed to a commensurate degree, right ventricle end diastolic volume (RVEDV) rises by 61% and right ventricle end systolic pressure (RVESP) increases by 25% above baseline, in addition to increase in pulmonary artery systolic pressure (PASP). This combination of right sided pressure / volume overload contributes to right heart failure. VAD speed needs to be optimized under hemodynamic guidance to reduce risk of RV failure during long-term support.
Abdominal, Not Thoracic, Positioning Of A Novel Intra-Aortic Micro-Axial Fluid Entrainment Pump (Aortix) Provides Superior Hemodynamic Effects In A Swine Model Of Ischemic Heart Failure

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Study: Aortix is a novel intra-aortic micro-axial fluid-entrainment pump that accelerates flow in the descending aorta (Ao). We explored the hemodynamic effects of Aortix positioned in either the thoracic or abdominal segments of the descending Ao in a model of ischemic heart failure.

Methods: Eight adult swine underwent 120 minutes of left anterior descending artery occlusion followed by reperfusion and recovery. After 28 days, Aortix (Procyrion, Houston, TX) was implanted in the descending Ao: thoracic (n=3), abdominal above the renal arteries (n=3), and sequentially in the thoracic then abdominal positions (n=2). Ao pressure, coronary flow, carotid pressure, pulmonary artery catheter, and pressure-volume loop data were obtained at baseline and at incremental ramp speeds: medium (28-30K), high (34-37K) in thoracic position (Thoracic, n=5) and low (22-25K), medium, high in the abdominal position (Abdominal, n=5).

Results: Both Thoracic and Abdominal Aortix activation generated trans-Ao gradients at all measured speeds (p<0.01). Abdominal position increased distal Ao MAP at medium speed (78 ± 5 vs 65 ± 8 mmHg, p<0.05) and generated larger trans-Ao gradients than Thoracic position (medium: 22 ± 11 vs. 6 ± 1 mmHg; high: 37 ± 16 vs. 10 ± 2 mmHg, p<0.05). Ao root pressure, coronary arterial pressure, and coronary flow velocity were unchanged. Abdominal position decreased systemic vascular resistance at all speeds (p<0.05) and arterial elastance at low speed (p<0.01). Abdominal position increased left ventricle volumes at low and medium (p<0.05) speeds, thermodilution cardiac output at low speed (5.3 ± 0.9 to 7.2 ± 1.4 L/min, p<0.046) and the transpulmonary gradient at medium and high speeds (p<0.05). Aortix activation in the abdominal position generates a greater hemodynamic effect compared to thoracic positioning, which may be due to more efficient entrainment of a larger column of Ao blood.
Management And Outcomes Of Left Ventricular Assist Device Related Endocarditis: A Systematic Review And Meta-Analysis

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Study: Left ventricular assist device (LVAD) related endocarditis remains poorly studied. The aim of this systemic review was to assess the outcomes of LVAD related endocarditis.

Methods: Electronic search was performed to identify all studies in the English literature on endocarditis in patients with LVADs. Identified articles were systematically assessed for inclusion and exclusion criteria.

Results: 16 studies were included for analysis, with a total of 26 patients of which 7 had a continuous-flow (CF-LVAD) and 19 had a pulsatile-flow device (p-LVAD). Time to development of endocarditis following LVAD implantation was 91 days (CF-LVAD 152 [IQR 91–1422] days; p-LVAD 65 [IQR 55–153] days, p=0.05). 11/25 (44%) patients were treated with antibiotics only with the remainder undergoing additional surgical intervention including heart transplantation (n=6), LVAD exchange (n=5), LVAD explantation (n=3), inflow-outflow valve exchange (n=1), and outflow graft repair (n=1). At a follow up time of 344 days [CF-LVAD 395 [IQR 350–1551] days; p-LVAD 266 [IQR 103–859] days, p=0.10], there was no difference in mortality between CF-LVAD and p-LVAD related endocarditis (57% vs. 42%, p=0.81). Patients who underwent surgical intervention had superior survival (71%) as compared to those treated with antimicrobials only (27%); however the Kaplan-Meier analysis was underpowered to detect statistical significance (p=0.17) (Figure). Compared to p-LVAD, CF-LVADs appeared to be resistant to early development of LVAD related endocarditis. A possible survival advantage of surgical intervention vs medical therapy alone deserves further exploration to determine its applicability in the CF-LVAD cohort.

Percutaneous Right Ventricular Support: Initial Experience From The TandemHeart Experiences And Methods (Theme) Registry

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Study: Right ventricular (RV) failure after open cardiac operations increases morbidity, and mortality can be as high as 50%. Until recently, mechanical RV support required open chest implantation and removal. We present the initial outcomes of percutaneous RV support using the TandemHeart pump (THP) and PROTEK Duo cannula (PDC). The dual-lumen PDC allows both drainage and reinfusion of blood and can provide RV support when placed with the inflow in the right atrium and outflow in the pulmonary artery. With the THP, the PDC can provide up to 5 L/min continuous flow.

Methods: We identified patients supported for RV failure after cardiac surgery using the TandemHeart Experiences And Methods (THEME) Registry.

Results: Twenty patients received support with a THP and PDC as a percutaneous right ventricular-assist device (pRVAD). Their mean age was 53 ± 17 years; 14 were male. RV support was needed after left ventricular-assist device (LVAD) implantation in 80% (81.3% early; 18.8% late), post-cardiomyotomy shock (PCS) in 10%, and post-heart-transplant failure (PHTF) in 10%. The PDC was successfully placed all patients, and there were no major complications associated with pRVAD implementation including no cardiac ruptures or severe ventricular arrhythmias. Mean support was 10.3 ± 6.7 days with a mean flow of 3.9 ± 0.8 L/min. Complications included bleeding (25%), infections (10%), and hemolysis (5%). There was 1 cardiac arrhythmia 2 days post-insertion requiring amiodarone and cardioversion. Cannula thrombosis occurred after 26 days of support in 1 patient. The need for inotropes and vasoconstrictors rapidly decreased with pRVAD support. Using the THP with a PDC as a pRVAD is a safe and effective way to manage RV failure after cardiac operations and is an alternative to surgically implanted devices.

Fig. 1. Inotropes and pressures during pRVAD support
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Acute Mechanical Unloading Prior To Reperfusion Is Cardioprotective And Limits The Development Of Heart Failure After Myocardial Infarction


Study: Ischemic heart failure after acute myocardial infarction (AMI) is a major cause of morbidity and mortality worldwide. We recently reported that activation of a trans-valvular axial-flow pump in the LV and delaying myocardial reperfusion, known as Primary Unloading (PU), limits infarct size in association with decreased LV wall stress. The mechanisms underlying the cardioprotective benefit of PU and whether the acute decrease in infarct size results in a sustained improvement in cardiac function remain unknown. We tested the importance of delayed myocardial reperfusion, the functional significance of cardioprotective signaling and the late-term impact on myocardial function associated with PU.

Methods: Adult male swine were subjected to Primary Reperfusion (PR) or PU after 90 minutes of left anterior descending artery occlusion.

Results: Compared to PR, 30 minutes of PU was necessary and sufficient prior to reperfusion to limit infarct size 28 days after AMI. PU was associated with a global shift in gene expression within the infarct zone favoring cardioprotection. Compared to PR, PU for 30 minutes preserved myocardial expression of the cardioprotective cytokine, stromal derived factor 1 alpha (SDF1a) protein levels within the infarct zone and promoted a shift towards anti-apoptotic signaling within the infarct zone. PU reduced activity levels of proteases known to degrade SDF1a. Blocking the cognate SDF1a receptor, CXCR4, attenuated the cardioprotective effect of PU by supporting a role for SDF1a in the mechanism of cardioprotection. Finally, PU reduced LV scar size, improved cardiac function, and limited cardiac expression of markers associated with heart failure and maladaptive remodeling 28 days after acute myocardial infarction. These findings identify a novel approach to limit the onset of ischemic HF after AMI.

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Real-Time, Continuous Measurement Of Right Ventricular Free Wall Strain Using An Implantable, Stretchable Sensor

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Study: Right ventricular (RV) wall strain is a fundamental assessment of RV mechanics during progression of right heart failure (RHF). Clinically, RV strain is measured by echocardiography or cardiovascular magnetic resonance imaging at discrete time points, often days or weeks apart. The objective of this study was to evaluate the accuracy of an implantable, stretchable Eutectic Gallium-Indium (EGaIn) sensor at continuously measuring RV free wall strain.

Methods: The 40mm EGaIn sensor was made of a silicone elastomer embedded with microchannels filled with conductive liquid. After the sensor performance was characterized on a bench-top tester and on ex vivo isolated porcine hearts (n=3), it was implanted in Yorkshire swine (n=4) for up to 3 hours. The sensor was prestretched and sutured from the RV apex to the RV outflow tract. Sonomicrometry crystals were sutured adjacent to the sensor as a strain comparison tool. RV hemodynamics were measured using a pressure-volume loop catheter. RHF was simulated by banding the main pulmonary artery.

Results: Benchtop results demonstrated no EGaIn signal drift over 5 hrs, and a low force (1N) required to stretch the sensor 100% of its original length. In vivo, EGaIn strain measurement was highly correlated with RV pressure (r = 0.88). EGaIn and Sonomicrometry measurements were highly correlated (r = 0.89). Comparing the strain, the two measurements disagreed with a systematic bias, depending on the proximity of the sensor or crystals to the interventricular septum (IVS). When attached further from the IVS than crystals, EGaIn showed a mean positive bias of 4.0% (2.6–5.5%), and when closer to the IVS than crystals, EGaIn showed a mean negative bias of 4.5% (3.1%-5.9%). In conclusion, the EGaIn sensor provides real-time accurate measurement of the RV free wall strain, which can be used in continuous monitoring of RHF.
**Case Report First-In-Human (FIH) Studies Of CH-VAD In China**
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**Study:** CH-VAD is an ultra-compact, centrifugal-flow, magnetically-levitated, implantable blood pump developed by CH Biomedical, Inc. to treat the patients with advanced heart failure (AHF). Over the past 10 years, great efforts have been spent on the flow path optimization, the magnetic bearing design and the system integration to aim to reduce adverse events (stroke, infection, bleeding, etc.) and enhance device safety and functionality. From June to October 2017, three male AHF patients age 46, 44, and 24 were implanted with CH-VAD in China to evaluate the device safety and efficacy.

**Methods:** All three patients were diagnosed with dilated cardiomyopathy and worsening heart failure symptoms with NYHA Class IV and INTERMACS Profile 1 and had been sustained with ECMO and/or IABP for 14 days prior to LVAD implantation. Through median sternotomy the pump was placed in the pericardial space with its inlet inserted into the left ventricle and the outlet graft anastomosed to the ascending aorta while the patient was put on the full pulmonary bypass. Heparin-bridged anticoagulation scheme with warfarin and aspirin was used throughout the post-op care with INR set at 2.0–3.0.

**Results:** The health condition of the patients improved significantly with the support of CH-VAD. Within 4 weeks after implantation, all three patients’ activities increased substantially and their NYHA classification was recovered to I or II. One of the patients was successfully bridged to heart transplant on POD 153 while the other two were released to home with the device running on POD 112 and 225 respectively. The pump performed as intended at a speed range of 2800–3400 RPM and showed no mechanical failure, no thrombosis, no stroke, no infection, no GI bleeding, no hemolysis or other adverse events.

**Simulation Study Exploring The Potential Of Acoustic Resonance To Measure Left Ventricular Volume**
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**Study:** Left-ventricular (LV) volume is an essential parameter to assess cardiac health. Currently, continuous measurement of LV volume is achieved using cardiac impedance measurement. Yet, cardiac impedance is used in short-term applications only and is affected by its sensitivity to the measurement position. As an alternative method, the acoustic resonance frequency of a fluid-filled body in air is theoretically highly sensitive to volume. As a potential advantage, acoustic waves in the audible range have long wavelengths, and thus are expected to be insensitive to the measurement position. Aim of this study was to explore the potential of using acoustic resonance for LV volume measurements.

**Methods:** The simulation was performed with the pressure-acoustic module of COMSOL. The validation of the simulation was ensured with a comparison to analytical results and a reference experiment. In two separate simulations, the heart was (1) surrounded by air and (2) surrounded by an idealized thorax (myocardium, pericardial fluid and muscle). The heart was simulated as a blood-filled sphere. Located inside the LV, a pressure source excited the system at filling volumes of 195 mL ± 25% and ± 50%. The measurement and pressure source position was altered along the entire range of the radial direction.

**Results:** A comparison of the two simulations showed that the resonance frequency was three orders of magnitude more sensitive in the air (31 Hz/mL) than in the thorax environment (0.055 Hz/mL). The resonance remains constrained by the air boundary, but it is delocalized once surrounded by the thorax. Encouragingly, effects on the resonance frequency from changing the pressure source position or the measurement position remained below 1% of the resonance frequency. If the remaining sensitivity is found to be detectable in experiments, acoustic resonance has the potential to be used for LV volume measurements.
LVAD Patients With Chronic Kidney Disease: Are Two Organs Better Than One?
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Study: Limited data guides dual organ allocation in patients implanted with a mechanical circulatory support device with bridge to transplant intention who also have chronic kidney disease. The goal of our study was to determine survival outcomes post transplant in LVAD patients with chronic kidney disease who either received heart transplant alone(HTA) or heart kidney transplant(HKTx).

Methods: 11910 HTA and 295 HKTx recipients were identified from UNOS (1987–2015) and grouped based on the glomerular filtration rate(GFR) < 45 or >45. Patients were excluded if they were less than 18 years old, lost to followup or data regarding renal function was not available. Survival was censored at 12y. Multivariate Cox proportional hazard regression analysis was adjusted for age, sex, DM, race, ischemic time, dialysis, life support, wait status & HLA mismatch.

Results: We identified 295 patients who received HKTx during the study period, 261 with GFR<45 and 34 with GFR>45. These patients were more likely to be male (p<0.001), diabetic (p=0.002), have a higher serum creatinine and lower GFR(p<0.001) and on dialysis (p<0.001). Survival was significantly higher in those patients who underwent HKTx with a GFR <45. Survival benefit was clearly demonstrated in the subset of the cohort with GFR<30 and GFR>30, log rank p<0.001 and p<0.03, respectively. Patients who received dual organ transplant with GFR <45 was also significant, log rank p<0.002. Survival outcomes are significantly improved with dual organ transplantation in LVAD patients with chronic kidney disease. Benefit of dual organ transplantation noted both at GFR<30 and GFR>45. Further study is necessary to determine standardized allocation criteria in this unique and growing population.

New Tool For Left Intraventricular Visualization And Bloodless LVAD Insertion
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Study: We are developing a tool for intraventricular visualization during connection of a left ventricular assist device (LVAD) for a beating heart insertion with minimal blood loss.

Methods: A prototype was tested ex vivo in adult bovine hearts (n = 4; weight, ~2.20 kg). The device consists of an occlusion system attached to a catheter with a Luer-lock connected at the end; the occluder comprises a single-lumen rubber balloon (12.7 mm I.D. Penrose Drain; Bard) and a membrane attached to the distal part of the balloon, suitable for transapical placement (Fig. 1). The device was inserted through a round (cored) incision in the cardiac apex and visualized with an endoscope (Storz camera, 30°-angle view) placed transapically. The anterolateral wall of the left ventricle (LV) was cut for direct visualization of the device in place.

Results: This method of device insertion proved feasible. The balloon portion of the occluder was properly inflated inside the LV and closed the cross-sectional plane of the ventricle. The device design was successfully tested in a large bovine heart model. The study is ongoing. Future pre-clinical studies will focus on a miniaturization of the device prototype and feasibility evaluation of this device concept in vivo with a beating heart. Fig 1. Prototype testing. A, LV coring; B, apical opening; C, endoscopic view of LV occlusion; D, direct view of prototype orientation.
Accuracy Of Postoperative Risk Scores On Survival Prediction In CF-LVAD Recipients

Study: At many centers, continuous flow left ventricular (CF-LVAD) implantation in INTERMACS Profile 1 patients is a relative contraindication due to high morbidity and mortality. We analyzed the ability to post-operatively apply various risk scores after CF-LVAD to predict survival in this cohort.

Methods: Retrospective review of 605 patients from 11/2003 to 03/2016 with primary CF-LVAD implantation at a single center. For 88 (14.5%) of these patients who were INTERMACS Profile 1 we calculated HeartMate II Risk Score (HMRS), Right Ventricular Failure Risk Score (RVFRS), Model for End-Stage Liver Disease (MELD), MELD-excluding INR (MELD-XI), Post Cardiac Surgery Risk Score (POCAS), and Sequential Organ Failure Risk Score (SOFA) for postoperative days (POD) 1–5. Receiver operator Curve (ROC) analysis for mean, maximum, and POD5 scores for 30-day, 90-day, and 1-year survival was performed.

Results: Profile 1 patients had higher rates of co-morbidities and pre-operative risk factors; smoking history (94.3% vs. 38.7%, p<0.001), mechanical circulatory support (93.2% vs. 45.6%, p<0.01), and inotropic support (100.0% vs. 83.9%, p<0.001). Postoperatively, Profile 1 patients had higher rates of right heart failure (21.6% vs. 9.7%, p<0.01), but lower incidence of GI bleeding events (15.9% vs. 28.6%, p=0.10). Although survival was lower in Profile 1 patients, this difference did not reach statistical significance (p=0.10)(Figure 1). In Profile 1 patients, ROC curve analysis demonstrated mean POCAS to be the best predictor of 30-day, 90-day, and 1-year survival, with area under the curve of 0.87, 0.82, and 0.79, p<0.001, respectively (Table 1).

Effects Of Continuous Flow Left Ventricular Assist Devices On Long-Term Kidney Function

Study: Continuous flow left ventricular assist devices (CF-LVADs) have improved outcomes of end-stage heart failure patients. The effect of continuous-flow devices on long-term kidney function has not been well studied. Here we analyze long-term kidney function of patients with these devices.

Methods: We performed a retrospective review of 523 patients who underwent primary implantation of CF-LVADs (HMII or HVAD) from November 2003 through March 2016 at our center. Estimated glomerular filtration rates (eGFRs) were calculated using the Cockcroft Gault equation. Values for eGFR were calculated preoperatively, and at 1, 3, 12, 24, 36 and 48 months.

Results: Preoperative eGFR values were calculated for 508 patients at 1 month N=474, 3 month N=386, 6 month N=344, 12 month N=288, 24 month N=215, 36 month N=102 month N=78 (Figure 1a). Within the first 3 months of implantation, average eGFR increased in patients with low eGFR (<60mL/min/1.73m^2) (Figure 1b). Younger patients had higher preoperative and postoperative eGFRs compared to older patients (Figure 1c). Patients >60 saw a downward trend of eGFR during the study period, those in their 50s remained stable, and those <50 saw a positive trend (Figure 1c). There was no difference in eGFRs between males and females (Figure 1d). Patients with ischemic cardiomyopathy had lower preoperative eGFRs, and saw a negative trend postoperatively, while patients with non-ischemic cardiomyopathy had a positive trend (Figure 1e). Patients with a smoking history had lower eGFRs compared to their non-smoking counterparts immediately following implantation (Figure 1f). Diabetic patients had lower eGFRs compared to their non-diabetic counterparts throughout the duration of the study (Figure 1g). Patients without a history of hypertension saw an increase in eGFR starting at 36 months, while the eGFR of their hypertensive counterparts remained stable (Figure 1h). Compared to HMII recipients, HVAD recipients developed significantly lower eGFRs at 12 months and beyond (Figure 1i).
Hospital Readmissions For Patients With Left Ventricular Assist Devices (LVAD)

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Study: Left ventricular assist devices (LVAD) have improved the outcomes and quality of life for patients with advanced heart failure. However, previous studies have shown that readmission rates for patients with LVADs are high. We report overall hospital readmission data at a single site over 4 years for patients with LVADs.

Methods: The readmission data at our institution for 193 patients with LVADs between 2013 and 2016 were retrospectively analyzed. Data including number of readmissions, planned versus unplanned readmissions, and most common causes for readmission were collected from the electronic medical record (EMR).

Results: This cohort of 193 patients had a total of 895 readmissions in the course of follow up. The range was 0 to 19 readmissions per patient. Out of the 895 readmissions, 74 were planned and 821 were unplanned. The most common reasons for unplanned readmission were infection (24%), cardiac pathology (20.4%), and bleeding (16.8%). Infectious etiologies were further subdivided into LVAD-related (38.6%), non-LVAD related (25.6%), all-cause bacteremia (27.4%) and all-cause sepsis (8.4%). Other diagnoses for readmissions included neurological problems (8%) including cerebrovascular accidents, transient ischemic attacks, and syncope. LVAD thromboses accounted for 3.6% of readmissions with 40.6% of all admissions for LVAD thromboses requiring LVAD exchange.

Conclusion: Infection is the most common cause of readmission for patients with LVADs, followed by cardiac pathology and bleeding related complications. Further studies are required to minimize unplanned readmissions in patients with LVADs.

Changes In Functional Status And Quality Of Life Measures In Ventricular Assist Device Patients Implanted With A Cardiomems™ Device

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Study: Use of CardioMEMS™ devices for hemodynamic monitoring in New York Heart Association (NYHA) Class III heart failure (HF) patients has been shown to reduce HF hospitalizations, increase functional status and improve quality of life. Patients with a ventricular assist device (VAD) can have refractory HF symptoms despite VAD therapy. We investigated changes in functional status and quality of life (QOL) in VAD patients who received a CardioMEMS™ monitoring device.

Methods: A retrospective, observational chart review was performed on VAD patients who subsequently had a CardioMEMS™ implanted. Patients with a CardioMEMS™ implanted prior to VAD implant were excluded. Data for each patient was assessed immediately prior to CardioMEMS™ implant and compared to the most recent clinical data. Changes in NYHA Class, Kansas City Cardiomyopathy Questionnaire (KCCQ-12) and Visual Analog Scale (VAS) were assessed. Wilcoxon signed rank test was used to assess statistical significance. The study was approved by the institutional review board.

Results: A total of 63 patients with VADs were screened and 9 patients were identified who received a CardioMEMS™ after VAD implant. Patients were implanted with CardioMEMS™ an average 606 days post VAD implant. Follow up QOL scores and NYHA Class were measured an average of 221 and 348 days post CardioMEMS™ implant, respectively. There was a significant decrease in NYHA Class from a median of 4 to 1 (mean of 3.6 to 1.6) (p< 0.005). There was no significant change in KCCQ-12 or VAS scores. In this small, retrospective study VAD patients who later received a CardioMEMS™ device showed a significant improvement in functional status, as shown by decrease in NYHA Class. No change was seen in QOL scores. Further larger studies are warranted.
Comparison Of HMII And HVAD Outcomes In Patients Supported For Over Two Years

Study: Continuous-flow left ventricular assist devices (CF-LVADs) have improved long-term outcomes in patients with end-stage heart failure. However, few studies have compared outcomes between HMII and HeartWare HVAD recipients in patients supported for greater than 2 years, which was the focus of our study.

Methods: We retrospectively reviewed records of 740 patients who underwent primary CF-LVAD implantation at our center between March 2003 and January 2016 and identified patients who were on either HMII or HVAD support for greater than 2 years. Preoperative characteristics and postoperative complications were compared between recipients of the two devices.

Results: There were 50 HVAD and 191 HMII patients supported for over 2 years. HVAD recipients were more likely to be female (40.0% vs. 20.9%, p=0.006), implanted for BTT (86.0% vs. 46.6%, p<0.001), and on preoperative inotropic support (94.0% vs. 72.8%, p=0.001). HVAD patients also had lower BMI’s (25.4 vs. 29.6kg/m², p<0.001), lower AST and ALT levels (44.2 vs. 81.7; 46.1 vs. 103.9, p<0.01 for both), higher serum albumin (3.7 vs. 3.5, p=0.01), and lower central venous pressures (9.3 vs. 11.7 mmHg, p=0.04). They were also more likely to have severe mitral regurgitation (34.0% vs. 13.1%, p<0.001). Although long-term survival was similar for patients supported with HMII and HVAD (p=0.26; Figure 1), HVAD recipients experienced a lower incidence of GI bleeding (EPPY 0.12 vs. 0.24, p=0.004), infections (EPPY 0.21 vs. 0.43, p<0.001) and neurological dysfunction (EPPY 0.09 vs. 0.12, p=0.048) (Table 1).

Conclusions: In patients on LVAD support for 2 years or greater, HVAD recipients had a lower incidence of GI bleeding, infections, and neurological dysfunction compared to patients supported with HMII. These complication profiles may aid in device selection for patients presenting for destination therapy.

<table>
<thead>
<tr>
<th>Incidence of Postoperative Complications after 2 years of Support</th>
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<tr>
<td>GI Bleeding</td>
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<tr>
<td>Infection</td>
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<tr>
<td>Neurologic Dysfunction</td>
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<tr>
<td>Pump Failure</td>
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<td>Respiratory Failure</td>
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EPPY, events per patient-year; GI Bleeding, gastrointestinal bleeding
HMII - Total Support Time = 765.6 years, Support Time Beyond 2 years = 399.6 years
HVAD - Total Support Time = 165.6 years, Support Time Beyond 2 years = 65.6 years

Kaplan–Meier Survival Analysis

Incidence of Postoperative Complications after 2 years of Support
Continuous-Flow Left Ventricular Assist Device Decommissioning As Compared To Explantation For Ventricular Recovery: A Systematic Review And Meta-Analysis

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Study: Recovery of heart function with continuous flow left ventricular devices (CF-LVADs) has allowed for device withdrawal. The aim of this systematic review was to examine the outcomes of device withdrawal via minimally invasive pump decommissioning as compared to reoperation for pump explantation.

Methods: Electronic search was performed to identify all studies in the English literature assessing CF-LVAD withdrawal. All identified articles were systematically assessed for inclusion and exclusion criteria.

Results: 44 studies were included in the analysis with a total 85 patients, of which 17/85 (20%) underwent pump decommissioning and 68/85 (80%) underwent pump explantation. CF-LVAD type was HeartMate II [decommissioning 4/17 (23.5%) vs. explantation 41/68 (60.3%), p=0.01] and HeartWare HVAD [decommissioning 13/17 (76.5%) vs. explantation 12/68 (17.6%), p<0.001]. During follow-up [decommissioning 413 (IQR 168–593) days vs. explantation 365 (IQR 92–710) days, p=0.85], there were no significant differences in cerebrovascular accidents [decommissioning 0/13 (0.0%) vs. explantation 3/52 (6.0%), p=0.88]. Kaplan-Meier analysis of estimated survival and freedom from infection were similar with a trend towards greater freedom from heart failure for patients who underwent decommissioning (p=0.06, Figure). Decommissioning appears to be a viable alternative to CF-LVAD explantation and was utilized more in patients with intrapericardial apical centrifugal pumps as opposed to preperitoneally placed axial devices. The trend towards higher rates of freedom from heart failure in those who underwent CF-LVAD decommissioning warrants further investigation.
An Exploratory Study Of Adhesion Strategies For Epicardial Cardiac Assist Devices


Study: To avoid thromboembolic complications associated with blood-contacting blood pumps, alternative cardiac assist devices can be designed to wrap around the epicardium for direct compression and/or applied torsion to improve cardiac function. One key design consideration is the means of device attachment. This project aims to identify suitable bioadhesives to bond alternative ventricular assist devices (VADs) to the epicardial surface by comparing adhesive energies to the minimum energy required to secure the device as it twists the heart.

Methods: Quantitative testing of butyl and octyl/butyl cyanoacrylate adhesives (Vetbond™ and GLUture™, respectively) were performed using lap-shear protocols outlined in ASTM-F2255. Rectangular slips of 316 stainless steel sheets (316S), 18 (18M) and 14 (14M) wires/inch stainless steel mesh, and P70 and P592 silicone were adhered to ovine epicardial tissue and cured for 5 and 60 minutes at room temperature. Using an Instron 4400 Universal Testing Machine with a 30 kN load cell, the samples were pulled apart at a rate of 1.0 mm/s to mechanical failure.

Results: Based on previous studies measuring the torque required to apply varying levels of torsion in excised porcine hearts and silicone heart models, adhesion energy requirements for a torsion-based VAD were estimated to be between 53.90 and 98.04 J/m². Most of the samples tested (80%) exceeded these energy requirements, confirming that the steel and P592 silicone surface materials combined with either adhesive could potentially secure the device to the heart during actuation.

<table>
<thead>
<tr>
<th>Model</th>
<th>Applied Torque (N-m)</th>
<th>Adhesion Energy (J/m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isolated Porcine Heart</td>
<td>11.00</td>
<td>53.92</td>
</tr>
<tr>
<td>Silicone Heart Model</td>
<td>20.00</td>
<td>98.04</td>
</tr>
</tbody>
</table>

Table 1: Adhesive energy requirements based on an effective contact area of 20.4 cm² with an applied torsion angle of 90 degrees.

<table>
<thead>
<tr>
<th>Adhesives</th>
<th>Cure time (min)</th>
<th>Average Adhesion Energies (J/m²)</th>
<th>n=5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>316S</td>
<td>18M</td>
</tr>
<tr>
<td>Vetbond™</td>
<td>5</td>
<td>293.60</td>
<td>226.37</td>
</tr>
<tr>
<td>GLUture™</td>
<td>60</td>
<td>270.07</td>
<td>343.27</td>
</tr>
<tr>
<td>GLUture™</td>
<td>60</td>
<td>270.07</td>
<td>332.50</td>
</tr>
<tr>
<td>GLUture™</td>
<td>60</td>
<td>293.60</td>
<td>379.96</td>
</tr>
</tbody>
</table>

Table 2: Adhesive energy values based on recorded tensile loads integrated over the crosshead displacement and divided by the initial adhesive cross-sectional area for each material-adhesive combination.
“Temporary” VAD Anticoagulation Management And Positive Outcomes

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Study: Temporary or paracorporeal continuous-flow ventricular assist devices (pcfVADs) are increasingly being used not only for short term support but also for medium to long term support. Hemocompatibility outcomes and the optimal anticoagulation strategy have not been defined when using these devices as VADs. We sought to define single center anticoagulation strategy and outcomes with the use of “temporary” VADs.

Methods: We reviewed the charts of all patients supported with pcfVADs from 2012–2017 at a single center for relevant clinical outcomes. Anti-coagulation values and therapy were assessed beginning post-operative day 1.

Results: A total of 19 patients (22 devices) were supported for a median of 5.5 days, with 3 patients supported more than 20 days and one patient supported for 57 days (Table 1). Two patients (9%) died while on pcfVAD support, 7 (32%) patients were bridged to durable device, 2 (9%) bridged to transplant, and 11 (50%) were explanted. Bleeding requiring chest exploration was the most common complication occurring in 11 (50%) of implants. Only 5% (1/19) of patients had a stroke, which was minor and did not result in death. Heparin was the anticoagulant used in 19, bivalirudin in 2, and argatroban in 1 of VAD runs (Table 2). For Heparin patients, aPTT times ranged from 43.4–84.4 seconds (median 62.3), unfractioned Heparin levels ranged from 0.21–0.44 units/mL (median 0.28) and only 1 patient was on aspirin. The two bivalirudin patients had a heparin aPTT range of 70.4–72.1 seconds (median 71.2) and both were on aspirin. Sixteen patients (73%) received packed red blood cells (PRBCs), 11 (50%) received platelets, 8 (36%) received fresh frozen plasma (FFP) and 3 (14%) received cryoprecipitate (CRYO). Our “temporary” VAD patient population had high survival and low complication rates despite relatively low levels of anticoagulation. The results from this study demonstrate the use of pcfVADs for a wide spectrum of support durations and that the anticoagulation required is relatively minimal.
Development Of Mock Circulatory Loops To Assess VAD Performance
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Department of Mechanical Engineering, University of Maryland, College Park, MD.

Study: Predicting the complex interactions between VADs and patients during clinical use can be difficult. There is a need to bridge the gap between pre-clinical bench testing and real-world clinical outcomes by developing more meaningful test methods for evaluating VADs with emerging technologies. Currently, no standard in vitro test methods to assess the advanced functionality of VADs exist. Thus, we aim to evaluate the usefulness of robust mock circulatory systems in characterizing VADs under variable physiologic and pathophysiologic conditions.

Methods: A mock circulatory loop has been constructed to allow for simple tunability, reproducibility, and automation during pre-clinical bench testing of VADs. Multiple parameters can be acquired simultaneously, including ventricular and VAD flows, ventricular pressure, VAD inlet and outlet pressures, and VAD pump speed and power. Representative cardiac pressure and flow waveforms are proposed to simulate a range of heart failure conditions (50 mmHg < MAP < 115 mmHg) with and without VAD support, disease states, and patient populations (e.g. pediatric and geriatric) on the bench. Pre-clinical test methods for characterizing variable pulsatile flow modes, suction detection, closed-loop feedback control, retrograde flow monitoring, VAD weaning and the impact of adverse events are under development to optimize the utility of this evaluative tool.

Results: FDA has developed a versatile, automated, and reproducible in vitro mock circulatory test system and identified key components necessary for characterizing the complex capabilities of high-risk cardiovascular devices. Using in vitro test methods to evaluate hydrodynamic performance of emerging VAD technologies will strengthen current regulatory practices, ultimately leading to safer, high-quality devices when introduced into clinical trials.

Rejection In Heart Transplant Patients Is Correlated With HLA Epitope Matching And Not With LVAD-Bridging
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Study: The priming of the immune system due to various components of a left ventricular assist device (LVAD) may lead to antibody development to donor human leukocyte antigen (HLA). This study focused on patients bridged to heart transplant with an LVAD (HTxR) to explore if they had a higher incidence of antibody mediated rejection (AMR) independent of HLA matching. It then examined whether HLA-matching, in combination with detection of de novo donor specific antibody (dnDSA), correlated with AMR.

Methods: This retrospective study consisted of 123 patients receiving a heart transplant (2013 - 2017) at our center. Patients were tested for HLA Abs pre-Tx. Biopsies (n=119, 4 were excluded for no biopsy > day 0) were evaluated using Banff criteria. HLA typing for HLA-A, B, C, DRB1/3/4/5, DQA1, DQB1 was performed for donors/recipients. Ab assessment was done using flow panel reactive panel (fPRA) and single antigen bead assays. PIRCHE and HLA Matchmaker programs were used to quantify T and B cell epitopes, respectively.

Results: Patients were either LVAD-bridged (n=53) or not LVAD-bridged (n=66) to heart transplant. There was no correlation with severe cellular rejection (biopsy ≥2R), AMR, survival (Figure 1), freedom from rejection (Figure 2), # of HLA mismatches (0, 1, 2, fPRA class I and II (>4%) and C4d positivity. A small subset of HTxR with dnDSA (n=6) had a significant difference in the number of HLA-DQB1 T-cell epitopes (18.9 vs. 31.7, p=0.04) and %C4d+ (33 vs. 67, p< 0.001) compared to HTxR (n=74) without DSA.

Conclusions: Sensitized LVAD patients bridged to heart transplant could be at a higher risk for rejection due to the priming of the immune system against donor HLA. Accounting for the immune response against HLA is critical in determining alloimmune risk. However, additional investigation is required using a larger cohort to assess the potential impact of HLA epitope matching, type of LVAD, and duration of LVAD support as risk factors for rejection after heart transplant.
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Inter-Laboratory Particle Image Velocity (PIV) Measurements In The FDA Blood Pump Model

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Study: An important consideration in the continued development of computational fluid dynamics (CFD) as a tool for the assessment of medical device safety (e.g. blood damage) is the reliance on credible experimental data. As part of an FDA sponsored interlaboratory study, fluid velocities and pressures were measured in a benchmark centrifugal pump geometry to provide experimental data for validating CFD simulations.

Methods: The centrifugal blood pump model was made from clear acrylic and included an impeller, with four equally spaced blades, and was supported by mechanical bearings. PIV measurements were performed at several locations throughout the pump by three independent laboratories. The velocity field was obtained at the pump entrance, mid-blade area, front and back rotor gap regions, near the blade tips, and at the exit cut-water and flow outlet diffuser regions. A blood-analog fluid composed of sodium iodide, glycerin, and water was used as the working fluid for the experiments. The velocity measurements were made for five different pump flow conditions with the flow rate ranging between 2.5 and 7 lpm for the pump speeds of 2500 and 3500 rpm.

Results: For test condition 5 (6 L/min, 3500 rpm), the velocity data were reproducible among the three laboratories. Peak velocities of 8.7 ± 0.5 m/s and 7.3 ± 0.7 m/s were measured near the blade tip and at the entrance to the exit-diffuser region. Similar analyses are being done for all of the flow conditions and the inter-laboratory mean and variance of the velocity and pressure data will be posted on a publicly available website. Experimental data sets from the inter-laboratory characterization of benchmark flow models (i.e. the blood pump model and our previous nozzle model) are being used to collaboratively develop guidelines on proper verification, validation, uncertainty quantification (VVUQ), and the credibility assessment of CFD simulations in the evaluation of medical devices (e.g. ASME V&V 40 standards working group).

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Implantation Of Left Ventricular Assist Device After Descending Aortic Stent Graft For Mural Thrombus

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Study: The presence of aortic mural thrombus is considered a contraindication to intra-aortic balloon pump (IABP) placement and a relative contraindication to left ventricular assist device implantation (LVAD) due to the risk of emboli. Here we report our treatment strategy for a 66 year old man with ischemic cardiomyopathy in cardiogenic shock and mural thrombus in the descending thoracic aorta (Figure 1). An endovascular stent graft was placed over the area with mural thrombus. This allowed for the placement of an intra-aortic balloon pump for pre-operative optimization (Figure 2). After 3 days, a LVAD was implanted via left anterolateral thoracotomy with hemi-sternotomy, and the IABP was removed. Post-operatively he had a relatively uncomplicated course without signs of embolic phenomena and was ultimately discharged home. Surveillance computed tomography imaging at 6 months showed no endovascular leak or migration of the stent (Figure 3). This case demonstrates a strategy for IABP placement after aortic stent graft placement for aortic mural thrombus. Furthermore, it demonstrated the safety and feasibility of LVAD implantation after recent aortic stent graft placement.
Predictors Of Long-Term Survival Of Patients On Left Ventricular Assist Device Support

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Study: Identify predictive factors of long-term survival in patients on left ventricular assist device support (LVAD).

Methods: We compared patients who received LVADs at our institution from May 2012 to February 2015 and survived >3 years to those patients who died on LVAD support from May 2012 to the end of 2015. Patients who died in the postoperative period <30 days or who underwent heart transplantation within 3 years were excluded.

Results: Forty-one patients (37 men, 4 women) survived >3 years (survival group) and 37 patients (32 men and 5 women) died within 3 years while on LVAD support (non-survival group). The two groups had similar demographic and preoperative characteristics including age (53 ± 12 vs 57 ± 10 years, p=0.062), INTERMACS profile, underlying cardiomyopathy, and type of LVAD device. In the survival group, 3 patients had the pump exchanged twice; 3 patients experienced pump thrombosis once. In the non-survival group, 4 patients had the pump exchanged once, and 2 patients had the pump exchanged twice. Factors that were significantly different between patient groups included body weight (96 ± 18 vs 85 ± 21 kg, p=0.011); body mass index (30.9 ± 6.2 vs. 27.2 ± 5.8 kg/m², p=0.0096), total cholesterol (145 ± 45 vs 116 ± 45 mg/dL, p=0.014); and LDL concentration (79 ± 35 vs 53 ± 29 mg/dL, p=0.021). Albumin levels and statin therapy were not significantly different between the 2 groups. Intensive care unit stay (11 ± 8 vs 25 ± 25 days, p=0.0017) and length of hospital stay (26 ± 13 vs 46 ± 33 days, p=0.001) were significantly shorter in the survival group.

Conclusion: Based on these data, cholesterol and LDL concentrations correlate, and could predict long-term LVAD patient survival. Further evaluation is warranted.

Successful Treatment Of RVAD Thrombosis With TPA In A BIVAD Supported Patient After Heparin And Tirofiban Failure


Study: The incidence of pump thrombosis in the setting of BiVAD support is not well documented. Guidelines recommend the use of intravenous (IV) anticoagulation, thrombolitics, antiplatelet therapy, or pump exchange as treatment for pump thrombosis, the incidence of which has been estimated up to 13%.

Methods: A 39 year old Caucasian female supported by BiVAD Heartware® devices presented to the Emergency Department with a two day history of shortness of breath, dark urine, and high watt alarms. VAD interrogation revealed elevated flow and power affecting the right ventricular assist device (RVAD) with normal left ventricular assist device (LVAD) parameters. Pertinent admission labs include International Normalized Ratio (INR): 2.1, Serum Creatinine (Scr): 1.08 mg/dL, and lactate dehydrogenase (LDH): 1285 units/L. Initial treatment included heparin, titrated to institutional goal using a weight-based nomogram, tirofiban, initiated at 0.075 mcg/kg/min, and a sodium bicarbonate drip, titrated to maintain a urine pH >7. After 2 days of therapy, LDH peaked at 3435 units/L with no improvement of RVAD parameters. Heparin and tirofiban were stopped, a baseline CT head was obtained, and the following tPA regimen was initiated: 5mg IV over 10 minutes, then 5mg IV over 30 minutes, then 4mg/hr IV continuously for 46 hours. RVAD parameters normalized, and heparin was restarted as a bridge to therapeutic INR. Aspirin 81mg by mouth daily and dipyridamole 50mg by mouth three times daily were also started. No neurological or bleeding complications were observed.

Results: tPA therapy resulted in normalization of RVAD parameters, Scr, and LDH with no observed neurological or bleeding complications. This case demonstrates safe and successful treatment of RVAD thrombosis with tPA after heparin and tirofiban treatment failure.
Comparison Of Device Exchange And Non-Exchange Management Of Continuous-Flow Left Ventricular Assist Device-Specific Infections: A Systematic Review And Meta-Analysis

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Study: No standardized treatment algorithm exists for the management of continuous-flow left ventricular assist device (CF-LVAD) specific infections. The aim of this systematic review was to compare the outcomes of CF-LVAD specific infections as managed by device exchange and other treatment modalities not involving device exchange.

Methods: Electronic search was performed to identify all studies in the English literature. All identified articles were systematically assessed for inclusion and exclusion criteria.

Results: 13 studies with 158 cases of CF-LVAD infection were pooled for analysis. 18/158 (11.4%) patients had CF-LVAD exchange (exchange group), and 140/158 (88.6%) patients were treated with other interventions including antibiotics alone (n=79), debridement (n=34), muscle flap (n=31), driveline relocation (n=14) and incision and drainage (n=8) (non-exchange group). Proportion of isolated driveline infection [exchange 64.7% (95%CI 34.6–86.4) vs non-exchange 87.8% (95%CI 70.5–95.6), p=0.11] and pump or pocket infection [exchange 31.1% (95%CI 10.1–64.3) vs non-exchange 22.0% (95%CI 9.3–43.9), p=0.60] did not differ significantly. During a mean follow-up of 290 days [exchange 351 days (95%CI 0–740) vs non-exchange 268 days (95%CI 36–499), P=0.72], there were no significant differences in overall mortality [exchange 17.6% (95%CI 4.3–50.6) vs non-exchange 23.3% (95% CI 15.8–32.9), p=0.67] and infection recurrence rate [exchange 26.7% (95%CI 8.7–58.0) vs non-exchange 38.6% (95%CI 15.4–68.5), p=0.56]. In the setting of CF-LVAD specific infection, device exchange does not appear to confer an advantage in overall mortality and recurrence of infection as compared to non-exchange modalities.

A Mechanized Valve Sparing Aortic Root Remodeling With Annular Stabilization

P. Bonde, A. Geirsson, J. Park. Yale School of Medicine, New Haven, CT.

Study: Preservation of the aortic valve in a dilated aortic root has several advantages, however, techniques for valve sparing root replacement (VSRR) remain complex & technically demanding, thus many aortic valves are replaced instead of being preserved. A simplified, mechanized valve sparing root remodeling (NVSRR) with annular stabilization is presented that is reproducible and customizable as per patient need.

Methods: A mechanized construct with two telescoping barrels were constructed using CAD with the inside constituting an anvil for accurately sizing the aortic annulus. The outside construct is able to staple a correctly sized double woven dacron graft with three slits and corresponding flares to accommodate excess sinus tissue and coronary origins. A lever mechanism is used to accurately fasten specialized surgical staples for the annular attachment.

Results: After thoroughly mobilizing the aortic root with intact coronary arteries, the mechanized construct is lowered with the anvil positioned under vision at the annular plane, the outer barrel is then telescoped till the slit dacron tube accommodates the coronary ostia and overlaps the external annular landmark by 3 mm. A specialized lever and gear system is now activated which fires nine staples from inside of the annulus to exterior, via graft and fixing a felt pledget on either side against the annul. Next the three cusps are pressurized with three balloons to snugly position and coapt the valve while the excess sinus wall above the level of coronary ostia is extruded (see figure) via slits in the graft. The three slits are then clamped on either side with the flared portion of the graft, height of the commissures is adjusted to obtain a competent valve. Finally, three flared slits with excess sinus tissue is excluded using three single staple fires. A mechanized, reproducible VSRR is likely to reduce operative complexity, complications and failure of attaining a competent valve with reduced operative time.
Major Orthopedic Surgical Intervention Post Left Ventricular Assist Device (LVAD) Implantation: A 10 Year Single Center Review

Study: Orthopedic injuries and surgical interventions post VAD implantation are not well described in the literature. We sought to identify frequency of major orthopedic surgical interventions (MOS) in the VAD population in addition to post-procedural morbidity and mortality, admissions for post-procedural bleeding, thrombosis, and death.

Methods: We retrospectively reviewed all patients who underwent VAD implantation from 01/2007 to 07/2017 at our institution. Total hip, knee, and shoulder arthroplasty were defined as MOS for purposes of the study. Of 358 LVAD implants, 18 patients met criteria, having undergone one or more of the described MOS. Patients were predominately male (84%), destination therapy (73%), and dilated (56%), ischemic (33%), or other (11%) cardiomyopathy with a mean age of 63 yrs at VAD implantation. The primary outcome was defined as patients who underwent MOS post-VAD.

Results: VAD patients with osteoarthritis or bony injury post-VAD may require MOS. Of 358 patients implanted with VADs, 18 underwent total shoulder, hip, or knee arthroplasty. Of these, 14 had orthopedic interventions pre-VAD, 3 post-VAD, and 1 post-VAD and transplant. After orthopedic procedures in these 4 patients, 2 are alive (5.9, 1.1 yrs later) and 2 have died (2.8, 4.1 yrs later). None of the 4 patients experienced thrombotic complications or post-procedure bleeding issues. Heparin and/or warfarin was resumed the evening of the orthopedic intervention in all patients. More MOS were undertaken pre-VAD than post-VAD in our cohort. Much hesitation exists regarding anticoagulation requirements, surgical risk, and possible thrombotic complications in the context of such interventions. There was no morbidity or mortality association with MOS post-VAD in our cohort; however, due to small sample size, statistically significant conclusions could not be made. Based on our small series, undertaking MOS post-VAD could be considered in a carefully selected cohort.

A Novel Self-Sealing, Fixation Enabled, Endovascular Stent Delivery Design For Type A Aortic Dissection
P. Bonde, A. Geirsson, J. Park. Yale School of Medicine, New Haven, CT.

Study: Acute type A dissection is a catastrophic disease with high mortality. Contemporary registry data (IRAD) reports operative mortality of up to 20% which has remained unchanged in the last few decades. Surgical techniques are highly complicated with prolonged bypass and circulatory arrest times, with morbidity primarily due to CPB and malperfusion related phenomenon. Current endovascular stents lack ability for proximal/distal graft fixation and sealing due to migratory forces. We present uniquely designed system to percutaneously treat type A dissection.

Methods: A series of CT angiograms from 120 Type A dissection patients (80 male, 40 female) were analyzed by 3D reconstruction techniques for relationships of cardiac structures at the sinotubular junction (STJ), point of distal ascending to arch of the aorta and angulation. Design specifications were considered in terms of diameter, height and sealing areas critical to success of a stent graft.

Results: The STJ lies at 11 degrees horizontal angle to the annular plane, while the angulation between ascending and descending is 60 degrees to 80 degrees. Maximum areas of leak were suspected at origin of innominate and floor of the arch of the aorta. Using CAD, we designed a prototype of the ascending aortic stent graft delivery with magnetic external fixation. The proximal part of the stent was fixed by magnetic arrays placed within the right atrial appendage, main pulmonary artery extending to right pulmonary artery achieving over 90% circumferential seal. Distal stent was designed with two flared components each extending into the innominate and descending aorta (50 degrees angulation) for preventing migration with fibrillary dacron externally to promote adhesion and sealing (figure). This uniquely designed system exploiting critical anatomical relationships may present a less invasive option for critically unstable and sick patients with Type A dissection.
Psychosocial Characteristics Of Patients Selected For Left Ventricular Assist Device Implantation

Study: Psychosocial characteristics of patients who receive LVADs are poorly characterized despite their purported importance in patient selection. We describe the psychosocial profiles of patients undergoing LVAD implantation, including as stratified by a bridge to transplant (BTT) and destination therapy (DT) strategy.

Methods: We included all patients implanted with an LVAD at our institution from 2008–2018, each of whom underwent a highly detailed psychosocial assessment by our clinical psychology team as part of each patient's comprehensive pre-implant evaluation.

Results: A total of 365 patients received an LVAD, 207 as BTT and 158 as DT. Select psychosocial characteristics of the entire LVAD cohort are shown in the Table. Comparisons according to DT vs. BTT implant strategy revealed that DT patients were older 58.8 (14.3) vs 51.3 (12.3), less likely to be currently working 22% vs 41%, yet were more likely to have a 24/7 home caregiver 33% vs 16% (p<.001 for all). Interestingly, DT patients were more likely to have poor coping mechanisms 20% vs 9%, poor medication adherence 17% vs 8%, poor diet adherence 34% vs 26%, and poor appointment adherence 20% vs 6% (p<.001 for all). However, no significant differences were noted in education level achieved, health literacy, or depressive symptoms between DT and BTT patients. Finally, the clinical psychologists were more likely to have significant overall concerns for VAD implant in DT patients compared to BTT patients (22% vs 7%; p<.001). These findings highlight the significant differences that exist in the psychosocial profiles of VAD patients, which likely contribute to the designated VAD implant strategy of DT vs BTT. Whether these psychosocial variables are independently predictive of adverse clinical outcomes remains to be determined.

Table. Psychosocial Characteristics of Patients Undergoing LVAD Implantation (N=365)

<table>
<thead>
<tr>
<th>Variable</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at time of implant</td>
<td>54.7±13.7</td>
</tr>
<tr>
<td>Gender: Male</td>
<td>282 (77)</td>
</tr>
<tr>
<td>Race: White</td>
<td>205 (56)</td>
</tr>
<tr>
<td>≤ High School Education Achieved</td>
<td>128 (43)</td>
</tr>
<tr>
<td>Difficulty in Reading/Writing</td>
<td>30 (10)</td>
</tr>
<tr>
<td>Married or Partnered</td>
<td>196 (61)</td>
</tr>
<tr>
<td>Living Alone</td>
<td>47 (13)</td>
</tr>
<tr>
<td>Poor or Intermediate Social Support</td>
<td>69 (21)</td>
</tr>
<tr>
<td>24/7 Home Caregiver Available</td>
<td>72 (23)</td>
</tr>
<tr>
<td>Currently Working</td>
<td>101 (33)</td>
</tr>
<tr>
<td>Significant Non-Medical Life Stressors Present</td>
<td>92 (31)</td>
</tr>
<tr>
<td>Poor Coping Mechanisms</td>
<td>41 (14)</td>
</tr>
<tr>
<td>Criminal History</td>
<td>48 (16)</td>
</tr>
<tr>
<td>History of Incarceration</td>
<td>23 (8)</td>
</tr>
<tr>
<td>Past Tobacco Use</td>
<td>164 (52)</td>
</tr>
<tr>
<td>Current Tobacco Use</td>
<td>19 (6)</td>
</tr>
<tr>
<td>Current Alcohol Use</td>
<td>69 (22)</td>
</tr>
<tr>
<td>History of Alcohol Abuse</td>
<td>56 (18)</td>
</tr>
<tr>
<td>Past or Current Marijuana Use</td>
<td>63 (21)</td>
</tr>
<tr>
<td>History of Illicit Drug Use</td>
<td>27 (8)</td>
</tr>
<tr>
<td>Poor Medication Adherence</td>
<td>36 (12)</td>
</tr>
<tr>
<td>Poor Diet Adherence</td>
<td>91 (29)</td>
</tr>
<tr>
<td>Poor Appointment Adherence</td>
<td>37 (12)</td>
</tr>
<tr>
<td>Presence of Depressive Symptoms</td>
<td>179 (58)</td>
</tr>
<tr>
<td>Presence of Anxiety Symptoms</td>
<td>141 (46)</td>
</tr>
<tr>
<td>Positive Outlook Towards VAD Implant</td>
<td>206 (71)</td>
</tr>
<tr>
<td>Inadequate Health Literacy</td>
<td>85 (31)</td>
</tr>
<tr>
<td>Moderate/Significant Concerns for VAD Implantation*</td>
<td>149 (48)</td>
</tr>
<tr>
<td>Medicaid Insured</td>
<td>40 (12)</td>
</tr>
<tr>
<td>Medicare Insured</td>
<td>134 (41)</td>
</tr>
<tr>
<td>Private Insurance</td>
<td>116 (36)</td>
</tr>
</tbody>
</table>

*as determined by clinical psychologist

Fig 1. Example of mapping patient data record to AE sequence.

Fig 2. Markov chain of sequential adverse events involving neurological dysfunction. Size of node indicates probability of initiating sequence; thickness of arrow (and label) indicates transition probability.

Sequences Of Adverse Events In Left Ventricular Assist Device (LVAD) Patients Experiencing Episodes Of Neurological Dysfunction
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Study: Neurological dysfunction is one of the main adverse events (AEs) in patients receiving an LVAD. The aim of this study was to apply Markov Modeling (MM) to identify common temporal transitions of AEs in patients who experienced at least one reported episode of neurological dysfunction after LVAD implant.

Methods: This observational study included 4,735 recorded AEs of 1,123 patients (median age of 50–59) abstracted from the INTERMACS registry who had a minimum one neurological dysfunction after a continuous flow LVAD implantation between 2006 to 2015. First, the AEs for each patient were chronologically sorted and then codified into a sequence reflecting a unified single record (Fig 1). A transition matrix was then formed by computing transitions probabilities between each existing pair of AEs in the patients’ sequences. Then, chains of transitions were extracted from the transition matrix by connecting transitions that had transitive relations. Finally, thresholding was performed on the extracted chains based on the transition probabilities and transition frequencies, to emphasize on the most important sequential patterns.

Results: Fig 2 shows the extracted patterns of sequential AEs from the aggregate data record. The color-coded nodes represented one of 14 analyzed AEs. The size of the node reflects its probability of initiating a sequence. The transitions between AEs are represented by arrows, labeled according to their transition probabilities. For instance, it can be inferred from the figure that the probability that a patient who has a current infection will have neurological dysfunction is 32%, and the probability of bleeding leading to infection is 20%. Knowing the probability of transitioning from one AE to any other AE could be helpful for clinicians to make more informed medical decision to anticipate future AEs. In conclusion, MM is a useful tool to model temporal transitions, where the order of events is important.
Title: Novel Vascular Access Device For Minimally Invasive Delivery Of A Counterpulsation Device Through Subclavian Artery

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Study: Introduction: The surgical complexity and invasiveness limits the application of mechanical circulatory support to end-stage heart failure patients. Minimizing the invasiveness of device implant and surgical risk will expand the applicability of mechanical circulatory support to earlier stage heart failure patients.

Methods: A novel arterial interface device (AID) was developed to deliver a long-term, ambulatory intravascular ventricular assist system (iVAS) pump without the need to enter the chest. The AID consists of: a) suture ring - a polyester velour patch sutured to the subclavian artery to provide mechanical support to the artery, b) graft - single lumen textile sutured to the suture ring and artery to provide arterial access, and c) stopper - silicone plug inserted into the graft to prevent clot formation and permit device exchange/explant. A custom access port used in conjunction with the AID minimizes blood loss during pump insertion. The effectiveness and ease of iVAS pump implantation using the AID was evaluated in a US First-In-Human (FIH) study (n=13).

Results: The iVAS pump was successfully implanted in all patients using the AID. The arterial anastomoses were hemostatic and remained secure. There was no complications at the AID access site related to bleeding, infection, or device migration.

Conclusions: Minimally invasive implantation of the iVAS using the AID was successfully demonstrated. The AID minimized surgical risks and complications commonly encountered with traditional subclavian access techniques.

Neutrophil To Lymphocyte Ratio As A Predictor Of Mortality After Continuous Flow Left Ventricular Assist Device Implantation


Study: Elevated neutrophil-to-lymphocyte ratio (NLR) is associated with mortality in a wide range of cardiovascular diseases including heart failure. We examined the prognostic utility of NLR in patients undergoing continuous flow left ventricular assist device (CF-LVAD) implantation.

Methods: Retrospective review of 725 patients undergoing CF-LVAD implantation from 2000 to 2017 at our center, for whom preoperative baseline NLR (N=687) and post-operative 30-Day NLR (N=646) data were recorded. Patients were divided into low, intermediate, and high tertiles based on preoperative NLR values of ≤ 3.13 (n=228), 3.13–5.83 (n=230), and ≥5.83 (n=229). Survival, length of stay (LOS), 30-day readmission, and adverse events were compared among the tertiles.

Results: Of the 687 patients with baseline NLR, mean age was 54.3 ± 0.5 years, 79.3% were male, 45.5% had ischemic etiology, and mean BMI was 28.6 ± 0.5 kg/m². Mean baseline NLR was 6.2 ± 6.0 and mean 30-Day NLR was 7.44 ± 8.92 (p<0.001). Baseline NLR was not associated with ischemic (p=0.23) or hemorrhagic neurologic deficit (p=0.67), GI bleeding (p=0.46), LVAD infections (p=0.23), RVAD implantation (p=0.83), pump exchange (p=0.05) or early readmission (p=0.18). Postoperative acute kidney injury increased in direct proportion to low, intermediate, and high tertiles based on preoperative NLR values of ≤ 3.13 (n=228), 3.13–5.83 (n=230), and ≥5.83 (n=229). Survival, length of stay (LOS), 30-day readmission, and adverse events were compared among the tertiles.

Results: Of the 687 patients with baseline NLR, mean age was 54.3 ± 0.5 years, 79.3% were male, 45.5% had ischemic etiology, and mean BMI was 28.6 ± 0.5 kg/m². Mean baseline NLR was 6.2 ± 6.0 and mean 30-Day NLR was 7.44 ± 8.92 (p<0.001). Baseline NLR was not associated with ischemic (p=0.23) or hemorrhagic neurologic deficit (p=0.67), GI bleeding (p=0.46), LVAD infections (p=0.23), RVAD implantation (p=0.83), pump exchange (p=0.05) or early readmission (p=0.18). Postoperative acute kidney injury increased in direct proportion to low, intermediate, and high baseline NLR tertiles (2.4% vs 6.6% vs 10.2%, p=0.013) as did LOS (47 vs 56 vs 71 days, p=0.001). Overall 30-day mortality was 9.8% with a difference amongst low, intermediate, and high baseline NLR tertiles (3.5% vs 8.7% vs 17.0%, p<0.001). Long term survival was also significantly different, with lowest long-term survival in the high baseline NLR tertile (p<0.001) (Figure 1a). Elevated NLR at 30-Days also demonstrated a similar difference in survival (Figure 1b).

Conclusion: Neutrophile to lymphocyte ratio may serve as a simple and practical biomarker for predicting mortality in CF-LVAD patients indicating a possible role for anti-inflammatory mediators.
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Intraventricular LVAD Pump Position And Pump Thrombosis

Study: An important risk factor for pump thrombosis is malpositioning of Left Ventricular Assist Devices (LVADs) because of disturbed intraventricular flow patterns and inflow conditions. Based on routinely acquired computer tomography (CT) and X-Ray data parameters describing the intraventricular LVAD position were defined and correlations to pump thrombosis calculated.

Methods: X-Rays and CTs of 115 patients implanted with a Heartmate II or HVAD were retrospectively analyzed. Pump thrombosis patients (PT) were identified and a non-thrombotic control group (NT) assigned by propensity score matching. Several parameters describing the position of the pump inflow cannula (IC) and the pump body in relation to natural landmarks were analyzed. A short axis and three-chamber view was reconstructed from CT data and the inflow cannula direction compared to an apex-to-mitral axis.

Results: Pump thrombosis was observed in 15 patients (Age: 60.3 ± 8.1 y, Male n=13, HMII/HVAD n=7/8, BMI: 26.6 kg/m²). A closer position of the IC to the ventricular wall in the CT short-axis view was measured in the PT-group for both pump types. (0.8 ± 0.8 vs. 1.2 ± 0.5cm; p=0.03). A larger deviation of the inflow orientation from the mitral valve was found in the PT group compared to NT patients (angle α: PT -22.0 ± 4.7° vs. NT -1.2 ± 7.5°; p= 0.006). The projected pump area in frontal X-Rays correlated well with this angle (ρ =-0.922; p=0.003). Further significant difference for the short pump diameter between the PT and NT group was found (PT 41.3 ± 4.8 mm vs NT 34.9 ± 6.0 mm, p=0.026) in the frontal X-rays. Additionally for the PT group the areas of the pump body were smaller in the lateral view (PT 2006 ± 77 mm² vs NT 2138 ± 132 mm², p=0.042). From both X-Rays and CT data risk parameters were identified that contain information about a possible malposition of the pump that could lead to pump thrombosis. The risk of pump thrombosis might increases with a more frontal posterior inclination of the pump.

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A Co-Rhythmic, Isolable, Self-Maintenance, Assist (Corisma) Device: An Innovative Option For Class III Heart Failure Patients
P. Bonde, A. Geirsson, J. Park. Yale School of Medicine, New Haven, CT.

Study: Adverse events especially stroke and pump thrombosis related to current tethered LVADs is an obvious impediment to wider application to class III heart failure. These are due to inability to clean and maintain the LVAD in-vivo; a practice ubiquitous to all motors as industry standard. A novel device with a self-maintenance mechanism to clear debris, prevent thrombotic nidi formation & powered wirelessly is presented.

Methods: A trans venous, trans septal insertion with inflow from left atrium to ascending aorta & powered wirelessly while residing within the right atrial appendage was designed and tested. A compact integrated maintenance system has two electronically controllable, external valves located at the inflow and outflow in a pericardium covered stent graft containing axial pump. Integrated maintenance system to clean the intra-pump volume (~5 cc) was designed which can be transcatheterly accessed. Rapid prototyping technique using 3D printer was utilized to create both pump and valve prototypes.

Results: A 31 Fr introducer sheath allowed the pericardium covered stent (with the pump) to be appropriately delivered via human sized internal jugular vein/femoral vein mannequin. Pump performance was optimized for 2 Lt/min - 4 Lt/min. A gear-driven valve showed better performance by properly closing the graft and making the flow near zero, showing promising potentials to minimize the size with compactly arranged gear design. A 0.1mg/ml tPA solution with total volume of 15 cc was adequate to clean all the debris within the pump interior microscopically. An integrated maintenance system with controller, backup battery (two hours) and receive coil for TETS transmission worked without issues in-vitro. A stent delivered miniaturized axial pump with gear driven inflow/outflow valve were successfully tested in-vitro with ability to maintain the pump without thrombotic nidi formation.
Analyzing The Value Of The Pulmonary Artery Pulsatility Index Beyond Predicting Right Heart Failure

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Study: Pulmonary Artery Pulsatility index (PAPi) is an emerging variable that shows value in predicting Right Ventricular Failure (RVF) in patients undergoing LVAD implantation, but its value in predicting other major adverse events is not well known. We evaluated the utility of PAPi in predicting early outcomes in LVAD patients.

Methods: Between February 2007 and December 2017, 389 patients (313 male) underwent primary LVAD implantation at our Clinic. Median age at implant was 62 years (range, 18–82) and 251 patients (65%) were implanted as destination therapy. Preoperative PAPi and central venous pressure to post-capillary wedge pressure ratio (CVP/PCWP) was calculated for all patients. Scatter plots were created to evaluate the relationship of these two markers and comparisons were made in absence and presence of early RVF, renal failure (AKI), hepatic failure (HF), mortality.

Results: Median preop PAPi for all patients was 1.9 (range, 0.3–16) and CVP/PCWP ratio was 0.6 (range 0.1–2.1). PAPi was significantly lower (p<0.001, p=0.01, p=0.02) and CVP/PCWP was significantly higher (p<0.001, p=0.001, p=0.008) for patients who had early RVF, AKI and HF; however, there were no significant differences in PAPi or CVP/PCWP for patients who had early mortality and those who did not (p=0.9, p=0.2, respectively). Two-dimensional scatter plot demonstrates that most patients with early RVF and AKI had PAPi <2.5 and CVP/PCWP >0.5 (Figure 1). PAPi was significantly lower in patients who had RVF, AKI and HF early after LVAD implant, but this did not translate into differences of early mortality. The relationship between PAPi and CVP/PCWP demonstrates good correlation; combining these two variables is useful to identify subjects at high risk for early adverse events.

Figure 1 (CVP/PCWP ratio on Y, and PAPi on X).

Enrich To Recovery: Use Of Sacubitril/Valsartan In Patients With Left Ventricular Assist Devices


Study: Mechanical unloading by a left ventricular assist device (LVAD) in combination with neurohormonal blocking drugs is an established strategy for myocardial recovery. Angiotensin receptor-neprilysin inhibitors (ARNI) are the latest of these drugs recommended by the 2016 ACC/AHA/HFSA guidelines update in heart failure therapies. Following this endorsement, the use of ARNI amongst LVAD patients (pt) has grown. Our aim is to explore outcomes of pts who underwent substitution of Sacubitril/Valsartan for Losartan while on LVAD therapy.

Methods: A retrospective review of CF-LVADs (2003–16; n=526) identified pts who received ARNI therapy during their CF-LVAD support. Preoperative demographics, incidence of post-operative complications, and long-term survival were evaluated.

Results: Three African-American men (age, 37 ± 9 years) with end-stage heart failure (NICM) underwent HeartMate II implantation were identified to receive Sacubitril/Valsartan. Median duration of LVAD support was 540 ± 251 days, of which 76.5 ± 21.6% of days were spent on Sacubitril/Valsartan. All pts were actively weaned by our institution’s protocol. At time of explant, all pts were taking maximum tolerable doses of Carvedilol and Sacubitril/Valsartan. At explanation, LVEDD decreased by 30 ± 16 mm, sys PA pressure had decreased by 29 ± 8 mmHg, and LVEF had increased by 23 ± 9%. One pt underwent explant electively, while the other two pts had LVAD-related complications (LVAD thromboses and a drive line infection). On follow-up (mean survival post-LVAD explant, 153 ± 61 days), all pts are in NYHA Class-I on medical management alone. For selected pts, LVAD explant is possible. Exploration should be considered and pursued in younger pts with NICM, where transplantation would be associated with lifelong immunosuppression and relatively modest survival benefit. Our study recognizes the promising value of Sacubitril/Valsartan in myocardial recovery with simultaneous mechanical unloading.
End Organ Recovery And Survival In Adults On Veno-Arterial Extracorporeal Membrane Oxygenation

Study: Extracorporeal Membrane Oxygenation (ECMO) is a temporary circulatory support system used in certain patients with cardiogenic and/or respiratory shock. Our study reports end organ recovery and survival of patients on Veno-Arterial (VA) ECMO with standardized management protocols at our institution.

Methods: This is an Internal Review Board (IRB) approved, single institution retrospective study of 129 patients placed on VA ECMO between July 2010 and June 2017. Their pre-ECMO end-organ functions were compared to pre-decannulation functions (post-ECMO).

Results: A total of 129 patients (male 87 [67%], female 42 [33%], mean age 50 ± 14 years) were placed on VA ECMO. Out of 129 patients on VA ECMO, 50 patients (39%) died on ECMO, 57 patients (44%) were weaned to medical management, 20 patients (15%) were weaned to mechanical circulatory support, and 2 patients (2%) were weaned to surgical management. The 30-day survival was 46% and 57 patients (44%) were alive at discharge. Significantly lower requirements for vasopressors and inotropes were noted in post-ECMO period. Patients in post-ECMO period had significantly improved blood pH (pre-ECMO mean 7.23 ± 0.17 vs. post-ECMO mean 7.40 ± 0.10, p<0.0001) and lactate levels (pre-ECMO mean 6.6 ± 5.6 mmol/L vs. post-ECMO 3.5 ± 5.7 mmol/L, p<0.0001). In terms of liver function, significantly higher alkaline phosphatase (ALP) levels (pre-ECMO mean 99 ± 85 IU/L vs. post-ECMO mean 126 ± 114 IU/L, p=0.032) were noted in post-ECMO period with no differences in AST and ALT. Out of 129 patients, 36 patients (28%) had improved kidney function, 60 patients (47%) had no change in kidney function, and 33 patients (25%) had worsening kidney function. Chest X-rays improved in 85 patients (67%), while 67% of patients and 70% of patients exhibited improvement in ARDS and pulmonary edema, respectively. Use of VA ECMO in select group of patients with standardized management protocols is beneficial and could lead to improvement and recovery in multiple organ systems.

In-Vivo Validation Of Totally Implantable Ventricular Assist Device Support Using Contactless Wireless Power
J. Park, A. Geirsson, P. Bonde. Yale School of Medicine, New Haven, CT.

Study: Models of power delivery within an intact organism have been limited to ionizing radiation, sound & magnetic waves. We present experimental validation of remote electrical power delivery to an intact biological system using magnetic resonant coupling technology, allowing continuous operation of LVAD, without being dependent on implanted batteries alone at an unprecedented distance of one meter.

Methods: Four Yorkshire pigs were implanted with HVAD device powered and controlled by a wireless power delivery. The implanted coil was separated from transmitting coil within a 3 dimensional space of one meter diameter.

Results: All experiments were successfully concluded without any power drop or interruption. Electrical power was delivered to the implanted coil within a one meter diameter circle. Temperature rose to one degree celsius at the receiving coil. HVAD device could be run either in continuous or pulsed mode. The experiment used an implanted coil, a coil worn in a vest and a coil placed at distance within one meter circle to power the HVAD device using 13.56 MHz frequency. Auto-tuning and frequency modulation allowed power delivery with any angular or radial misalignment of the coils with respect to each other. The system was run for 90 day in vitro continuously without any interruptions or faults. We have demonstrated an uninterrupted power delivery at a substantial distance to an implanted LVAD with flexibility, durability and robustness. This will allow LVAD patients to have unprecedented mobility within a large space covered by wireless power delivery. <!--EndFragment-->
Model Of End-Stage Liver Disease Score As A Predictor For Outcomes Following Left Ventricular Assist Device Implantation


Study: There is little data regarding reliable scores for identifying high risk patients after major surgeries. We seek to evaluate the prognostic role of the Model of End-Stage Liver Disease (MELD) score as a predictor for adverse outcomes in patients’ post-operative left ventricular assist device (LVAD) implantation.

Methods: We conducted a retrospective analysis of 655 patients who received LVADs between the years 1999 and 2017 at a single institution. Patients were divided into two groups, “high risk” with MELD of greater than 17 and “low risk” with MELD of 17 or less. A survival analysis was completed and post-operative events analyzed.

Results: The Mean MELD of all 655 patients was 13.51 ± 5.6. Patients were divided into a “low risk” patients (n=486) with average MELD score of 10.86 ± 2.92 vs. “high risk” patients (n=169) with average MELD score of 21.1 ± 4.1 [p<0.001]. Comparing “low risk” patients to “high risk”, BMI was 27.9 ± 6.3 vs 29.1 ± 7.2 [p=0.03], male gender 373/486 (76.7%) vs. 145/169 (85.8%) [p=0.012], and CKD 100/205 (48.9%) vs. 51/85 (60%) [p=0.036]. No statistical significance was observed for etiology of heart failure, hypertension, diabetes, COPD, PVD, history of CVA, previous sternotomy, previous mechanical circulatory support, or median household income. When post-operative outcomes were measured, neurological deficits 131/486 (26.9%) vs. 33/169 (19.5%) [p=0.06] and 30-day mortality 28/169 (16.5%) vs. 38/486 (7.8%) [p=0.002] were higher. No significance was noted for AKI, GI bleed, LVAD infection, need for LVAD exchange, right heart failure, or re-admission. The long-term survival was significantly higher in favor of the “low risk” group (p=0.016). This retrospective analysis indicates patients with higher MELD scores are at significantly higher risk for more adverse outcomes of 30-day mortality after LVAD implantations. Thus, MELD scores may be considered a reliable tool to predict adverse post-operative events for major surgeries.

Ischemic Mitral Regurgitation: Insights From Robotic Papillary Muscle Construct Using Computational Mechanics

R. Bonde, A. Geirsson, J. Park. Yale School of Medicine, New Haven, CT.

Study: Ischemic mitral regurgitation carries higher morbidity and mortality. Papillary muscle orientation plays an important role in causation. Using complex mechanics, we built a structural robotic papillary muscle construct with high precision, accuracy, and multiple degrees of motion.

Methods: Diastole was the baseline for the robotic papillary muscles. Forward kinematics were modeled in Cartesian coordinates with respect to the midpoint of the bases of the papillary muscles. Source code written in C++ ran twelve stepper motors simultaneously to convert the heart rate to angular velocity by equating one beat to the total distance traveled by the fastest motor shaft during one cardiac cycle. To validate the model, the two parallel manipulators were tested to demonstrate translational and rotational motion about each conventional Cartesian axis based on the commands that were sent to the microprocessor.

Results: The robotic manipulators were able to divide the cardiac cycle into millisecond intervals. The parallel manipulators have twelve degrees of freedom with 4-micron resolution. Cases I & II refer to diastole and systole (Fig. 1). With symmetrical coordinates about Y and Z axes, and asymmetrical about Y and Z axes. Translating the rotational motion of the motor shafts into the motion of the papillary muscles in three-dimensional space allowed to study the effect on leaflet closure. With good coaptation in Case II, and malcoaptation in III & IV. The robotic construct demonstrated a high degree of fidelity with regards to normal physiological motion and pathological conditions. We have constructed and demonstrated a high fidelity robotic manipulator capable of providing fundamental insights into the motion of the papillary muscles relative to each other and other surrounding structures. These insights will help in designing and inventing subvalvular therapeutic options and provide means for tailored therapy for individual patients.
"In The Field" Resuscitative Circulatory Device For First Responders For Out Of Hospital Cardiac Arrest: Strategies For Rapid Hypothermia Induction

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Study: Out of hospital cardiac arrest carries a dismal outcome with less than 10% surviving to discharge in spite of best CPR. ECMO has shown improvement of survival in EPCR cases. We have developed a compact, resuscitative unit capable of allowing patient transport with maintenance of partial cardiac output and achieving simultaneous cooling that can be used by first responders.

Methods: Design and characterization was performed using standard engineering methods. An integrated pump, oxygenator, battery and cooling elements were incorporated with a foot print equal to “Grande” sized device (16 Oz) that can be strapped to the thigh and provide output up to 3 liters/minute. Hypothermia remains an important element of such a system to prevent neurological damage in the early stage of cardiac arrest.

Results: The device is designed to be deployed via groin vessels by first responders such as EMT/Paramedics. The focus of this investigation was to achieve rapid cooling utilizing ammonium chloride. The prototype and experimental steps are shown in the figure. A 10:10 W/V concentration was able to reduce the temperature by 5 degrees celsius and maintain it for 20 minutes. An endothermic reaction can be accelerated further by agitation, keeping in mind not to allow temperature to drift below zero degree celsius to avoid cell damage. It is possible to achieve reasonable hypothermic response in a resuscitative device utilizing ammonium chloride by allowing easy portability.

Delayed Sternal Closure In Heart Transplant Patients Bridged With Continuous Flow Left Ventricular Assist Devices

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Study: Delayed sternal closure (DSC) is common practice for complex cardiac surgeries. We evaluated the incidence and outcomes of DSC in patients who underwent an orthotopic heart transplant (OHT) after previous centrifugal-flow left ventricular assist device (CF-LVAD) support.

Methods: Between 01/09 and 02/17, 116 patients on CF-LVAD support underwent OHT at our center. The incision was classified as delayed sternal closure (DSC) or primary sternal closure (PSC) at time of OHT. Perioperative variables, adverse outcomes including sternal wound infections (SWI), and mortality were compared.

Results: Of 116 patients in our study, 78 underwent DSC. Patients with DSC were more likely to be bridged with HeartMate-II compared to patients with PSC (69.2 vs 7.9%, p<0.01). SWI rates were higher in DSC patients than in PSC patients (12.8 vs 5.3%, p=NS) although this did not reach statistical significance. Number of hours of open sternum was not associated with increased rates of SWI. Mortality and LOS were significantly increased in patients with DSC (32.0 vs 7.9%, p=0.01 and 40 vs. 27 days, p=0.03) (Figure 1 and Table 1). DSC survivors were less likely to have a smoking history compared to DSC non-survivors (33.9 vs 60%, p=0.03) and had higher preoperative hemoglobin (11.6 ± 2.2 vs 10.5 ± 2.2, p=0.04), pulmonary arterial pressure (30.2 ± 10.8 vs 22.4 ± 9.5 mmHg, p<0.01), and pulmonary capillary wedge pressure (20.7 ± 12.0 vs 11.5 ± 6.8 mmHg, p<0.01). There were no differences between DSC survivors and non-survivors in preoperative drive line infections, pump infections, sepsis, or duration of LVAD support. DSC due to graft dysfunction was more likely in non-survivors (32 vs 3.8%, p<0.01) (Table 2).

Conclusion: DSC was not associated with an increased incidence of SWI following OHT in patients with prior LVAD support, but overall mortality and length of stay were significantly increased. Smoking history and DSC due to graft dysfunction were associated with higher mortality following DSC.

| Table 1: Perioperative Complications in Patients with DSC vs. PSC |
|------------------|----------------|----------------|---------------|
|                   | DSC (n = 78)   | PSC (n = 38)   | p value       |
| Mortality within 30 days | 8 (10.3)       | 1 (2.6)       | 0.11          |
| Cause of death     |                |               |               |
| Sepsis             | 5 (6.4)        | 1 (2.6)       | 0.29          |
| Septic shock       | 2 (2.6)        | 2 (5.3)       | 0.15          |
| Nonsurgical        | 1 (1.3)        | 2 (5.3)       | 0.51          |
| Wound infection    | 2 (2.6)        | 0 (0.0)       |               |
| Urosepsis          | 1 (1.3)        | 0 (0.0)       |               |
| Other              | 8 (10.3)       | 1 (2.6)       | 0.96          |
| Length of stay     | 46 ± 34 days   | 37 ± 18 days  | 0.40          |
| 30 day readmission | 27 (34.6)      | 14 (36.8)     | 0.81          |
| Rejection*         | 26 (33.3)      | 15 (40.5)     | 0.40          |
| ASR*              | (40.3)         | (12.6)        | 0.21          |
| Neurological problems | 29 (37.2)     | 13 (34.2)     | 0.82          |
| Sternal wound infection | 10 (12.9)     | 2 (5.3)       | 0.21          |
| Survival (%)       | 72.8%          | 33.3%         | 0.01          |

Table 2: Prognostic Variables in Patients with DSC

<table>
<thead>
<tr>
<th>Variable</th>
<th>Survivors (n=78)</th>
<th>Non-survivors (n=38)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reason for DSC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bladder</td>
<td>12 (15.6)</td>
<td>11 (28.9)</td>
<td>0.13</td>
</tr>
<tr>
<td>Graft Dysfunction</td>
<td>2 (2.6)</td>
<td>8 (21.1)</td>
<td>&lt;0.01</td>
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<tr>
<td>LVAD interval</td>
<td>3 (3.9)</td>
<td>2 (5.3)</td>
<td>0.80</td>
</tr>
<tr>
<td>Other</td>
<td>3 (3.9)</td>
<td>4 (10.5)</td>
<td>0.31</td>
</tr>
<tr>
<td>Hours with open sternal wound</td>
<td>42.8 ± 57.5</td>
<td>60.3 ± 65.8</td>
<td>0.24</td>
</tr>
</tbody>
</table>
Unexplained Syncope In Patients With Left Ventricular Assist Devices (LVAD)


Study: Syncope is defined as loss of consciousness triggered by inadequate transient delivery of oxygen to the brain. The causes of syncope generally include vasovagal syncope (60%), orthostatic hypotension (15%), cardiac arrhythmia (10%), and structural etiologies (5%). 10% of syncope cases have no clear etiology and are defined as cases of unexplained syncope (uSync). We attempt to describe the overall readmission data for unexplained syncope for LVAD patients at a single site over 5 years.

Methods: 895 readmissions for 195 LVAD patients at our institute between 2013 and 2017 were retrospectively analyzed. 43 patients were admitted to the hospital 56 times for a chief complaint of syncope. 23 patients did not meet criteria for uSync (pre-syncope (52.2%), symptomatic arrhythmia (21.7%), infection (13%), neurological disorders (4.3%), orthostatic dysfunction (4.3%), and acute ischemic events (4.3%)) (Figure 1). Parameters including gender, atrial size and function, ventricular size and function, valvular competency, and hemoglobin levels were obtained.

Results: Ten% of LVAD patients were admitted for uSync, accounting for 3% of all the hospital readmissions. Seventy five % of patients with uSync were males. Thirty two % of all patients had normal right atrial (RA) size and function whereas 63% of patients had dilated RA with signs of dysfunction. Twenty % of patients had normal right ventricular (RV) size and function whereas 80% of patients had signs of RV dysfunction. Sixty % of patients had normal opening of the aortic valve but 68.4% of patients had some degree of aortic regurgitation. Eighty percent of patients were anemic with an average hemoglobin level of 10.25 ± 2.27 g/dL.

Conclusion: Most patients readmitted for unexplained syncope were anemic and had signs of right ventricular dysfunction. The aortic valve opened frequently in 60% of patients with LVADS. Future studies are required to determine risk factors for unexplained syncope in patients with LVADS.
Hydraulic Pressure Analysis For Soft Robotic Bi-Ventricular Copulsation Sleeve

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Study: While current ventricular assist devices continue to be problematic due to thrombotic events associated with blood-contacting surfaces, we propose a non-blood-contacting soft-robotic biventricular sleeve that boosts ejection fraction (EF) by applying hydraulic pressure to the ventricular epicardium. The range and relationship between the external hydraulic pressure (EHP) and EF in end-diastolic passive biventricular models - both healthy and diseased (i.e., dilated cardiomyopathy) - were examined in this study.

Methods: A biventricular model with a prolate LV and crescent-shaped RV with wall thicknesses of 10mm and 5mm, respectively, were drawn on SolidWorks (Fig 1A). The Young’s moduli (E), Poisson’s Ratios (ν), and end-diastolic pressures of healthy and diseased ventricles were applied as material properties and boundary conditions prior to running static-structural finite element analysis using ANSYS Workbench (Table 1). The top surface of the model was set as a fixed support to imitate the natural constricted movement of the base of the ventricles. A range of EHP were applied to the epicardial surface of the model (Fig 1B-D) to examine the stroke volume (SV), which was computed by comparing the initial and final cavity volumes, per pressure. The SV was then used to calculate EF of each model.

Results: When an EHP lower than 7.24 mmHg or greater than 37.75 mmHg was applied to a healthy heart model, drastic distortion occurred due to a large inner and outer pressure difference. The EHP within the range resulted in a linear increase in EF, ranging from 10.7% to 80.5% (Fig 2A). For the diseased model, the EHP between 22.49 mmHg and 187.51 mmHg induced EF ranging from 2.4% to 78.7% with a linear relationship (Fig 2B). If we aim to generate an EF of 65% for a diseased heart model, a soft robotic biventricular sleeve would need to evenly apply 155 mmHg of EHP around the ventricles, which compares favorably to the theoretical maximum pressure output of 1,875 mmHg for the device currently under development in our lab.
Predictors And Outcomes Of Renal Replacement Therapy After Left Ventricular Assist Device Implantation


Study: Although renal function may improve after left ventricular assist device (LVAD) implantation, renal failure requiring renal replacement therapy (RRT) can occur post-operatively. We sought to examine the frequency and outcomes of patients requiring RRT early after LVAD.

Methods: The use of in-hospital RRT and outcomes were examined in consecutive adults who underwent continuous flow LVAD implantation between 2007 and 2017 at a large institution. Logistic regression was used to examine predictors of RRT. The associations of RRT with outcomes were examined using Cox proportional hazard regression.

Results: Of 359 patients that underwent LVAD, 54 (15%) required in-hospital RRT. Patients receiving RRT had higher pre-operative Charlson comorbidity index (p<0.014), MELD score (p<0.0001), right atrial pressure (RAP) (p<0.001), estimated 24-hour urine protein (p<0.0001), and lower pre-operative estimated glomerular filtration rate (eGFR) (p<0.0001) than those who did not require RRT. Approximately, 40% of patients with eGFR<45 ml/min/1.73 m² and 24-hour protein of >400 mg required RRT compared with 6% of those with higher eGFR and without significant proteinuria. Younger age, lower pre-operative eGFR, higher 24-hour urine protein, higher RAP and longer cardiopulmonary bypass time were independent predictors of RRT after LVAD. Of those requiring in-hospital RRT, 18 (33.3%) had renal recovery, 33.3% required outpatient hemodialysis, and 33.3% died prior to hospital discharge. After a median follow-up of 25 months, RRT was associated with increased risk of death (hazard ratio [HR] 2.8, 95% confidence interval [CI] 1.7–4.3; p<0.001), gastrointestinal bleeding (HR 2.6, 95% CI: 1.4–2.6; p=0.003) and right ventricular failure (HR 3.2, 95% CI: 1.1–8.1; p=0.038).

Conclusions: In-hospital RRT is associated with poor prognosis after LVAD. A detailed pre-operative assessment of renal function prior to LVAD may be helpful in risk stratification and patient selection.
Respiratory Failure Requiring Tracheostomy After Continuous Flow Left Ventricular Assist Device Implantation

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Study: Respiratory failure requiring tracheostomy is associated with decreased survival after cardiac surgery. We studied the impact of tracheostomy on survival in patients who underwent continuous flow left ventricular assist device (CF-LVAD) implantation.

Methods: From 01/2007 to 08/2017, 93 (16.1%) of 596 patients who underwent primary CF-LVAD implantation at our center required tracheostomy at median duration of 16 days (6–88 days) post-LVAD. The effect of tracheostomy on survival was evaluated. Patients with early tracheostomy (0–14 days, n=36) were compared to patients with late tracheostomy (>15 days, n=57).

Results: Patients requiring tracheostomy were older (58.1 ± 11.5 vs 54.6 ± 13.1 years, p=0.01), implanted more often for destination therapy (55.4% vs 41.9%, p=0.05), had more pre-operative mechanical circulatory support (64% vs 45.9%, p=0.01), more previous sternotomies (51.1% vs 33.7%, p=0.01), lower hemoglobins (10.7 ± 2.1 vs. 11.7 ± 2.2, p<0.001), lower albumins (3.7 ± 2.9 vs 5.1 ± 6.3, p=0.001), higher creatinines (1.8 ± 1.0 vs 1.4 ± 0.7, p<0.001), and longer cardiopulmonary bypass times (101 ± 62 vs 82 ± 49 minutes, p=0.001). Patients requiring tracheostomy had significantly reduced survival at 1 and 2 years (Figure 1) and higher incidence of renal failure (10.7% vs. 4.0%, p=0.04). There was no difference in incidence of postoperative strokes, GI bleeding, RVAD implantation, or drive-line infection (p=NS). Timing of tracheostomy did not affect survival (Figure 2). Tracheostomy patients who died within 1 year had worse preoperative liver function, higher bilirubins (3.9 ± 5.9 vs 1.4 ± 1.9, p=0.004), and higher INRs (1.5 ± 0.79 vs 1.2 ± 0.24, p=0.02).

Conclusions: Risk factors for tracheostomy included advanced age, destination therapy, redo, preoperative mechanical support, poor nutritional status, and renal insufficiency. These data emphasize importance of patient selection to reduce incidence of tracheostomy after CF-LVAD implantation.
Effectiveness Of Time In Therapeutic Range (TTR) In Predicting Adverse Outcomes In Left Ventricular Assist Device (LVAD) Patients


Study: TTR over a 30-day period is routinely used as a quality indicator of anticoagulation in LVAD patients receiving anticoagulation therapies. While individual international normalized ratio (INR) values outside of therapeutic range are associated with adverse events, data on 30-day TTR as a predictor of adverse outcomes are lacking.

Methods: The Intermountain Artificial Heart Program’s databases were queried for continuous-flow LVAD patients implanted from January 2013 to September 2017. Outpatient INR values, all-cause readmissions, and emergency department (ED) visits were collected. TTR, time above (TATR), and below (TBTR) therapeutic range over LVAD support duration and 30 days before a readmission and/or ED visit were calculated by the Rosendal linear interpolation method. Unpaired t-tests were used to determine significance.

Results: 67 patients were included in the study. Median support duration was 282 days. There were 141 readmissions and 82 ED visits in 59 patients over the study period. INR goals ranged from 1.8–2.2 to 3–3.5. Median TTR, TATR, and TBTR for all patients during the study period were 53.5%, 15.1%, and 25.6%, respectively. TTR was lower in patients 30 days before a readmission (36.8%, p=0.001) but not significantly different 30 days before an ED visit (46.8%, p = 0.09). Patients spent significantly more time below (27.4%) than above (16.0%) therapeutic range before a readmission (p=0.0004). Our observations suggest that a low TTR is associated with higher all-cause readmission in LVAD patients on anticoagulation therapy to equally avoid periods of sub- and supratherapeutic anticoagulation.

Functional Prototype For Pulsed Rotary Displacement Pump: Thetaeuguk Pump

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Study: Non pulsatile flow is implicated in GI bleeding, neurological events and diastolic hypertension. However, rotary design is attractive from minimal moving parts with high efficiency and small foot print. We aimed to design a rotary displacement pump with a pulsed operation.

Methods: Rim-driven rotary displacement pump is composed of a fixed stator and Taegeuk patterned rotor. In-runner brushless DC (BLDC) motor design with 12 stators was investigated with different types/numbers of magnets and different turns/size of stator coils to create a functional prototype. Frame of the stator and rotor prototypes were made with polylactic acid (PLA) using a 3D printer. In stator design, 12 metal screws were circularly inserted into the PLA frame and coils were manually wound following dLRK winding scheme. Rotor was designed to have diameter of 62 mm and height of 16 mm to provide priming volume of 24 mL. Electric speed controller was used to run the motor prototype.

Results: Functional prototype was successfully built with the combination of 12 stators and 14 magnets. Each stator coil has 25 turns of 24 gauge wire with total power consumption of 10 W. As number of coil turn increases at the same voltage input, current decreases while magnetic force increases. Power consumptions resulted from 100 turns of 30 gauge wire were similar to that with 25 turns of 24 gauge wire, while magnetic force was greater with the former case. Square magnets had stronger magnetic force compared to circular ones and neodymium was more appropriate than ceramic magnets. Very strong magnets disrupted stability of the rotor supported by a single bearing. With current prototype, proper balance between electromagnetic force and permanent magnetic force allowed successful operation with phasic output simulating a pulsed operation.
Atrial Fibrillation Increases Thrombogenicity Of LVAD Support via Increased Platelet Shear Exposure And Residence Time

J. Beckman,1 V. Chivukula,2 S. Li,1 N. Mokadam,1 K. Koomalsingh,1 J. Smith,1 C. Masri,1 T. Dardas,1 R. Cheng,1 A. Stempien-Otero,1 S. Lin,1 E. Minami,1 G. Wood,1 S. Farris,1 J. Kirkpatrick,1 F. Sheehan,1 S. Rockom,2 A. Aliseda,1 C. Mahr1. 1Division of Cardiology, University of Washington, Seattle, WA, 2Mechanical Engineering, University of Washington, Seattle, WA. Study: This work investigates intraventricular hemodynamics of LVAD therapy in atrial fibrillation. Methods: A 3D time-resolved computational fluid dynamics simulation of a standard surgical LVAD configuration is used to investigate intraventricular hemodynamics. Atrial fibrillation is modeled by chaotic mitral inflow obtained from Echo-Doppler. An average flow rate of 5 LPM over the course of 15 irregular cardiac cycles was maintained, with a temporal correlation representing atrial fibrillation applied. The risk of intraventricular platelet activation and thrombogenesis was evaluated by Lagrangian tracking of O (106) platelets in the left ventricle, from MV to entering the inflow cannula. Platelet Shear Stress History (SSH) and intraventricular Residence Times (RT) were measured, as well as endocardial Wall Shear Stress. Results: Compared to sinus rhythm, we demonstrate that in atrial fibrillation, there is a marked increase in the distribution tails for both SSH and RT. Cross-correlation of these two metrics identifies a larger probability of platelets in atrial fibrillation to have long residence times and being subjected to a high shear stress, increasing the probability of platelet aggregation. This may explain the increased risk of VAD thrombosis observed in patients with atrial fibrillation. Figure 1: (a) Intraventricular 3D flow model of an LVAD-implanted Left Ventricle (b) mitral valve inlet waveform comparing sinus rhythm inlet condition(dotted line) and atrial fibrillation inlet condition (solid line) used in the computational simulations.

Table 1. CFD Predicted pump performance

<table>
<thead>
<tr>
<th>GEOMETRY</th>
<th>Speed (rpm)</th>
<th>Q (LPM)</th>
<th>Head (mmHg)</th>
<th>Efficiency (%)</th>
<th>NIH (g/100L)</th>
<th>Volume of Thromobosis (mm$^3$)</th>
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<td>Baseline</td>
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In Vivo Evaluation Of A Novel Centrifugal LVAD In A Bovine Model Of Short-Term Duration


1Texas Heart Institute, Houston, TX, 2Baylor College of Medicine, Houston, TX, 3CH Biomedical (USA), Inc, Torrance, CA, 4CH Biomedical, Inc., Suzhou, CHINA.

Study: The CH-VAD is a newly developed centrifugal-flow, totally magnetically levitated left ventricular assist device (LVAD). It is implanted in the current clinically standard method, where the pump inflow cannula is inserted into the apex of the left ventricle, and the outflow graft is anastomosed to the ascending (descending in the animal model) aorta. Several key VAD system improvements are: a smaller pump size; a maglev system with a large-gap design that makes it superior in terms of hemocompatibility, demonstrated in previous in vitro hemolysis testing, very importantly, a significantly decreased driveline external diameter.

Methods: In this study, we implanted the CH-VAD in a calf model and evaluated the hemodynamic and hemocompatibility characteristics over a 14-day period. The hemodynamic parameters, the pump data, and blood test results were recorded throughout the study.

Results: The LVAD functioned as designed, with clinically relevant hemodynamics and good hemocompatibility demonstrated by negligible hemolysis as determined by PFHb levels measured throughout the study, with no signs of infection. Necropsy showed expected focal mild-to-moderate adhesions between the pericardial sac (along the pump) and the adjacent rib cage, and between the pericardial sac and the heart. Gross examination of internal organs was unremarkable. Examination of the pump revealed no evidence of thrombus formation internally or around the inflow or outflow cannulas. The CH-VAD system operated as expected for the 14-day period. Future in vivo study plans include increasing study size, the duration to 60days and to add the additional hematology testing for vWF and platelet activation, in order more carefully assess hemocompatibility.
Implantable Cardioverter Defibrillators In Patients With Continuous Flow Left Ventricular Assist Devices: Use, Procedures And Outcomes

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Study: The use of implantable cardioverter defibrillators (ICD) in patients with continuous flow left ventricular assist devices (CFLVADs) has not been evaluated in randomized clinical trials and the observational data published so far is controversial. To our knowledge the burden of ICD related procedures and post left ventricular assist device ICD implantation have not been previously described.

Methods: This is a retrospective single center study that included patients who underwent CFLVAD implantation at the Cleveland Clinic between October 2004 and March 2017. Patients were grouped according to the presence or absence of ICD at the time of LVAD insertion. Outcomes after LVAD insertion were assessed including revisions of existing ICDs and subsequent implantation of ICDs.

Results: There were 486 patients analyzed; of those, 387 (79.6%) had an ICD prior to LVAD insertion. Of the 99 patients without ICD, 52 (52%) underwent ICD implantation after LVAD insertion: 38 for primary prevention and 14 for secondary prevention. There were 4 patients with leads cut during tricuspid valve repair, and 12 that had a post-operative lead dysfunction due to dislodgment. Revision or lead re-insertion occurred in the early postoperative period in 11 (2.9%) of those patients. There were 80 patients with ICD at the time of LVAD implantation (21%) who required 96 procedures after LVAD: 74 generator exchanges because of end of life or technical failure, 15 lead revisions, and 7 complete system removals because of infection. In patients with post-LVAD ICD insertion 4 patients had additional procedures: 2 generator changes due to end of life, 1 lead revision, and 1 system extraction due to pseudomonas endocarditis. The 30-day mortality was 5.2% and 10.1% in patients with and without ICD respectively (p=0.097).

Morphologic Patterns Of Aortic Valve Regurgitation Following Continuous-Flow Left Ventricular Assist Device Implantation


Study: The physiological and clinical importance of aortic valve (AV) regurgitation (AR) following continuous-flow (CF) left ventricular assist device implantation are unclear. In addition, the clinical impact of type of AR morphology in the LVAD recipient population is unknown. We sought to examine the morphology of AR in an institutional cohort of patients who underwent CF LVAD implantation.

Methods: The records of patients undergoing CF LVAD implantation at our institution between 6/1/2012 and 10/31/2017 (n = 263) were reviewed. All transthoracic and transesophageal echocardiograms were reviewed. Patients undergoing concomitant CF LVAD implantation plus AV repair or replacement were excluded (n = 19), yielding 244 patients for study.

Results: Eighteen patients (18/244 = 7.4%) had either moderate (11/244 = 4.5%) or severe (7/244 = 2.9%) AR. All 7 patients with severe AR had clinically relevant heart failure or overt cardiogenic shock, as did 1 patient with moderate AR. Of these 8 patients, 7 underwent an AV procedure, while 1 died prior to being able to receive a procedure. Of the 7 patients who underwent an AV procedure, 4 underwent transcatheter aortic valve implantation (TAVI), while 3 underwent surgical aortic valve replacement (SAVR). Six of 7 patients are alive and well, one of whom underwent heart transplantation. One patient died following TAVI. With respect to AR morphology, 13 patient had central AR morphology, while 5 had eccentric AR morphology. However, within the severe AR group, 4 patients had central AR, while 3 had eccentric AR. In contrast, in the moderate AR group, 11 had central AR, while 2 had eccentric AR. Of the 7 patients who required TAVI or SAVR, 4 had eccentric AR, while 3 had central AR.

Conclusion: Both central and eccentric patterns of AR may develop and progress following CF LVAD implantation. However, eccentric AR may correlate with a higher incidence of clinical heart failure, and need for TAVI or SAVR.
In Vivo Evaluation Of A Novel Intra-Atrial Blood Pump For Partial Support Of The Left Ventricle

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Study: A newly designed miniature axial-flow pump system is under development in our laboratory. It is currently designed to be affixed to the atrial septum and support the compromised left ventricle (LV) in early-stage heart failure with no harm to the ventricular tissue. The device, currently referred to as the intra-atrial pump (IAP), will operate in parallel with the LV, drawing blood from the left atrium and unloading the LV.

Methods: Different blade geometries were tested for the IAP in previous in vitro hydraulic and hemodynamic studies. In addition, two acute in vivo studies were conducted: one in a pig and the other in a calf model. Fluoroscopy with contrast agent was used to evaluate pump position and flow, as well as the outflow graft anastomosis.

Results: Hemodynamics parameters measured on a mock circulatory loop showed that the IAP can potentially reduce end diastolic volume and increase cardiac output when operating in heart failure conditions, and pump geometries that create a steep pressure/flow relationship performed better with atrial cannulation. We conducted the two in vivo studies to test the complete system in a live animal to validate our current manufacturing techniques and determine ideal sensor placements. The IAP was successfully implanted across the atrial septum in a porcine and bovine model with the outflow graft connected to the carotid artery. This study demonstrated that the IAP can provide partial support (1–3 L/min) in vivo, thus showing feasibility of intra-atrial cannulation and the potential to partially unload the heart by providing low-flow support.
22 Work Related Burnout Is A Predictor Of The Quality Of Work Life Among Nurse Practitioners In Mechanical Circulatory Support Programs J. Casida, 1 P. Combs, 2 S. Schroeder, 1 C. Johnson, 1 1University of Michigan, Ann Arbor Michigan, MI, 2University of Chicago, Chicago, IL, Bryant Heart, Lincoln, NE. 

Study: Emerging data shows that nurse practitioners (NPs) in mechanical circulatory support (MCS) programs have high levels of work intensity, role stress, and burnout. The purpose of this study was to explore the relationship between burnout and quality of work life (QOWL) and to examine the degree to which burnout predicts QOWL.

Methods: We employed an observational research involving 47 MCS-NPs from various regions of the US. In addition to demographics, each participant completed the Copenhagen Burnout Inventory (19 items) and Work-related Quality of Life Scale (23 items). Data were analyzed with Pearson’s correlation coefficient (p) and linear regression modeling.

Results: The majority of the participants were female (83%), white (72%), master’s-prepared (89%), with a title of MCS/VAD-NP (45%) from the Northeast (40%). All three domains of burnout (personal, work-related, and client-related) were significantly correlated with QOWL (p = .52 to -.64, p <.001). However, multiple linear regression modeling showed that only work-related burnout was a significant predictor of QOWL (p = .01). The regression coefficient for work-related burnout was .42. Using three domains of burnout as explanatory variables, the general linear model showed that after adjusting for personal and client-related burnout, a 1 point increase in work-related burnout will result to a decrease in an average QOWL score by .64. This study uncovered the significant association between burnout and QOWL in NPs working in MCS programs. Our results inferred that an increase in work-related burnout results to a decrease in overall QOWL. Further studies using large sample case-control design are warranted to confirm our findings. Another aspect is to understand the mechanism of the impact of the NPs QOWL on MCS outcomes.

25 Standardized Mechanical Circulatory Support Guidelines: The Perspective From Coordinators A. T. Lundsstrom, 1 P. Combs, 2 S. E. Schroeder 1 1Mechanical Circulatory Support, Bryan Heart, Lincoln, NE, 2Cardiothoracic Surgery and Vascular Surgery, The University of Chicago Biological Sciences, Chicago, IL.

Study: Mechanical Circulatory Support (MCS) therapy's success has given rise to an increase in number of MCS Programs; thus variation in the care of MCS patients exists. While consensus statements on the delivery of care exist, few resources are available in discussing widely accepted guidelines. This study attempted to gauge the interest of MCS Coordinators in the US regarding the development of standardized guidelines for clinical decision making and therapy advancement.

Methods: A 10-question survey was created to establish interest in the development of standardized guidelines for two separate series of topics, clinical practice and job responsibilities. Participants consisted of members of a VAD Coordinator profession online discussion board.

Results: 54 MCS Coordinators submitted responses with 94.44% (51) respondents favorable to the development of standardized guidelines in that it would be beneficial to their practice. 38.89% (21) said they would adapt them to their current practice and another 53.70% (29) said they would use the guidelines to develop their programs' policies and procedures. Topics of most interest by participants were related to driveline management 81.13% (43), patient selection 73.58% (39), community education 75% (39), MCS staffing ratios, and Job responsibilities each with 65.38% (39) and deliverance of patient education 65.38% (34). MCS therapy has rapidly grown in popularity, thus, standardized guidelines are necessary to mainstream uniformity while allowing for individual selection factors for MCS implanting centers. This study demonstrated that MCS Coordinators would favor standardized guidelines to assist in the management of common issues that are faced. Professional organizations can act as a catalyst for this development by connecting clinicians, engineers, and industry members together for the advancement of MCS therapy.

26 Sleep Quality And Daytime Function Among Adults Implanted With Long-Term Left-Ventricular Assist Devices (LVADS) Z. Chornoby, J. Kazmierski, J. Casida. University of Michigan, Ann Arbor, MI.

Study: Despite the high prevalence of sleep disturbances in heart failure, little is known about the sleep quality (SQ) and daytime function (eg, daytime sleepiness (DS)) of adults with long-term LVADs. This study aimed at characterizing the patterns and examining the changes in the SQ and DS of heart failure patients before and after implantation of an LVAD.

Methods: We employed an observational research design in this study involving 32 subjects with continuous flow LVADs. Their demographics and clinical profiles were extracted from the medical records. Subjective (questionnaires) and objective (wrist actigraph) measures of SQ and DS were used during data collection, which occurred at 1 month before (baseline) and 1, 3 and 6 months after implant. We analyzed the data with descriptive statistics and repeated measures ANOVA.

Results: Subjects were predominantly white (81%), male (59%), aged 30 to 70 years, with HeartWare LVADs (59%). Baseline SQ was poor [eg, low sleep efficiency (SE), total sleep time (TST), and long wake after sleep onset (WASO)], which slightly improved at 3 and 6 months after LVAD implant. However, these changes/improvements were not statistically significant. Similarly, the DS and durations of naps at baseline were abnormal, and did not change significantly at 1, 3, and 6 months after LVAD. Further analyses showed the following correlations: TST and DSS (r=−.40) and TST, SE, and WASO (r=−.56 to .61). All p-values were at <.05. In conclusion, poor SQ and daytime function are common before and up to 6 months after LVAD. Also, poor SQ may be associated with excessive DS. Large-scale research is warranted to support this finding, particularly the effect of poor SQ on daytime function/excessive DS, health, and quality of life of adults with long-term LVADs.

28 A National Study Of Bedside Nurse VAD Competencies J. Casida, 1 P. Combs, 2 M. Abshire, 2 B. Widmar, 2 R. Freeman, 1 L. Baas 1 1University of Michigan, Ann Arbor Michigan, MI, 2University of Chicago, Chicago, IL, 3John Hopkins, Baltimore, MD, 4Vanderbilt University, Nashville, TN, 5University of Cincinnati, Cincinnati, OH. 

Study: This study was framed by the Diffusion of Innovation Theory to investigate VAD nursing competencies.

Methods: We used two subscales (23 items) of the VAD Innovation in Nursing Appraisal Scale, Innovation and Adoption. This newly-adapted self-report scale uses a 5-point Likert scale, where higher scores indicated favorable results. We also used a 4-item visual analog scale (0 to 10) to evaluate nurse perceived knowledge, competence, and confidence in VAD care. Descriptive and inferential statistics were used.

Results: Participants (n=237) were predominantly white (88%) female (85%) and worked in a step-down unit (52%). Innovation and adoption mean scores were 3.90 ± 6 and 3.90 ± 8, respectively, indicating moderate/high levels. Compared to stepdown unit nurses, intensive care nurses reported higher levels of knowledge (7.4 vs. 7.9), competence (6.1 vs. 7.8), and confidence (6.1 vs. 7.7), p<.05. Nurses in intensive care were more likely to seek education from VAD surgeons (79% vs. 30%, p<.01) and clinical nurse specialists (57% vs. 44%, p<.05) than stepdown nurses. Years of nursing experience was associated with innovation scores (r=.30, p<.01). Higher innovation and adoption were positively associated with years of experience caring for VADs (r=.33, p<.01), role in patient/caregiver education (X²=71.5, p<.05), membership in professional organization (X²=50.4, p<.01) and types of VAD programs (X²=45.4, p<.01). Nurses with more years of nursing experience, more years of VAD experience and who work in intensive care have higher levels of innovation and adoption. Further research is needed to examine VAD competency resources available for stepdown nurses and to link nurse competencies with patient outcomes.
The Lived Experiences Of Caregivers Transitioning Home With Persons With A Ventricular Assist Device

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Study: With VADs now utilized to sustain the life of patients, the impact of the device on the caregiver must be evaluated if holistic nursing care is to be provided. Exactly what the caregivers of VAD patients perceive of the transitioning experience from hospital-to-home is unknown. Therefore, the researcher desired to gain an understanding of the meaning of the lived experience for caregivers of VAD patients during their transition from hospital-to-home.

Methods: Using Colaizzi’s method of analysis, caregivers’ experiences regarding their hospital-to-home transition with PsWVAD, were explored using phenomenology. The purposive sample consisted of seven caregivers in the community of a Southern border state. Semi-structured interviews were conducted with each caregiver, and data were analyzed concerning their perspectives. Procedures recommended by Lincoln and Guba (1985) were utilized to confirm trustworthiness. As an authenticity method, participants were given the opportunity to review and confirm the accrued descriptions to validate their experiences.

Results: The concept of “Power” permeated the experience of the hospital-to-home transition and was determined to be the essence of the experience. The resulting six themes are described in terms of power: 1) power of electricity, 2) power of life, 3) power of control, 4) power of super-being, 5) power of change, and 6) power of known and unknown. The overall research goal was to develop an understanding of the experience of the caregiver of a VAD patient regarding the hospital-to-home experience in order to enable nurses to improve care and enhance quality of life.

Changes In The Clinical Characteristics Of LVAD Patients


Study: Left ventricular assist devices (LVADs) are pivotal treatments for end-stage heart failure (HF) and a critical bridge-to-transplantation (BTT) or as destination therapy (DT). While implantation of LVADs has become routine over the last decade, little is known regarding changes in clinical characteristics and treatment regimens over that time period. This study examined medical records of consecutive patients who received an LVAD at Columbia University Medical Center from November 2006 to January 2015.

Methods: We retrospectively analyzed the medical records of 280 consecutive patients who underwent LVAD implant as BTT or as DT. Patient demographics, laboratory values, clinical variables, and medications were examined. Next, we divided the cohort into 2 groups: Those who received an LVAD prior to January 1, 2012 (n=150) and those whose LVAD was implanted after January 1, 2012 (n=130). The clinical characteristics and treatment regimens in the two groups were compared by unpaired t-test and Fisher’s exact test.

Results: The two groups did not differ significantly with respect to age, gender, or etiology of HF. However, those implanted since 2012 were more likely to be hypertensive (88% vs. 63%, p < 0.0001), have dyslipidemia (78% vs. 62%, p=0.004), have a history of smoking (55% vs. 28%, p < 0.0001), and have a history of atrial arrhythmias (42% vs. 19%, p < 0.0001) and/or ventricular arrhythmias (35% vs. 11%, p < 0.0001). Prior to LVAD implantation, the latter group was also more likely to have had an ICD implanted (88% vs. 63%, p < 0.0001) and to be treated with beta blockers (65% vs. 33%), p < 0.0001). Patients undergoing LVAD implantation since 2012 have a greater incidence of cardiovascular risk factors and cardiac rhythm disturbances. They are also more likely to be have been treated with beta blockers and have had an ICD implanted. Nurses caring for those with LVADs need to recognize the interrelated relationship of clinical characteristics and treatments.
LVAD Self-Efficacy And Caregiver Dependency Do Not Mediate The Relationship Between Anxiety, Depression, And Quality Of Life
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Study: Self-efficacy (SE) and caregiver dependency (CD) are important factors affecting the process of LVAD self-management. Emerging data showed the relationship among SE, CD, anxiety, depression, and quality of life (QOL). This study examined whether SE or CD mediates the effect of anxiety or depression on QOL in patients with continuous flow LVADs.

Methods: We analyzed an existing data provided by 100 patients (mean age, 52.0 ± 13.4) who participated in an observational study. Patients mostly were white (78%), male (69%), married (72%), educated beyond high school (72%), and with family caregivers (88%). Nearly 90% of patients had HeartMate II LVADs as a bridge-to-transplant (67%) with mean implant durations of 20.1 ± 16.0 months. A demographic questionnaire and 5 psychometrically sound measures of LVAD care SE, LVAD CD, anxiety, depression, and QOL were completed by patients. We used descriptive statistics and causal mediation analytics for data analyses.

Results: Neither LVAD care SE nor CD showed a significant mediation effect on the relationship between anxiety and QOL or depression and QOL (both p > .05). However, the total effect of anxiety or depression on QOL was significant (p<.05). Also, decreasing anxiety or depression mean scores resulted in an increase in QOL score (both p<.05).

Conclusion: Our analysis indicates that the patient’s SE and CD in LVAD do not mediate the causal relationship between anxiety or depression and QOL. Studies with large random sample are warranted to confirm our findings. Interventions aimed at increasing SE or decreasing CD (eg, adequate LVAD care competency education/training), which may potentially decrease anxiety or depression and increase QOL, are needed for optimizing health and well-being of patients with long-term LVADs.

The Safety And Efficacy Of Vitamin K Administration In Left Ventricular Assist Device Supported Patients With Elevated INR Levels
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Study: Bleeding is a common adverse event in left ventricular assist device (LVAD) supported patients. At the University of Utah, we developed a protocol to standardize Vitamin K administration (VKA) in the setting of INR’s >4. Before this protocol, there was no standard of care for lowering INR levels. Prior therapies used at our hospital included blood product infusions, Vitamin K (VK), and holding warfarin doses. The aim of this study is to evaluate the safety and efficacy of VKA for supratherapeutic INRs in LVAD patients.

Methods: We included all LVAD supported patients in our program from May 1, 2017 - Feb 1, 2018. Patients who had an elevated INR >4 were treated with VK (VK cohort) according to our protocol guidelines. After VKA we evaluated the following: INR and LDH trends, time to therapeutic INR post VKA, incidence of ischemic (ICVA) and hemorrhagic (HCVA) cerebral vascular accidents, and pump thrombosis. We compared the VK Cohort with Non-VK Cohort and historical trial data.

Results: During the study period, 129 patients (mean age 59 +/- 13, 12% female) were included in our study. There were 24 instances of elevated INR in 17 patients (VK Cohort). The mean patient age was 54 years, and 24% were female. The average pre-INR was 5.8 and the average INR after VKA was 2.9 which was reached after a mean of 27 hours. There was no significant difference in LDH between the pre and post VKA values that were monitored up to 2 months after administration (353±124 vs. 316±146, p=0.82). No incidences of pump thrombosis, ICVAs or HCVAs in the VK Cohort which is lower than the non-VK Cohort (table).

Conclusions: The VK protocol seems to be a safe and effective strategy to manage LVAD patients with elevated INRs. This protocol gives a standardized approach to lowering INR levels within approximately 1 day, and does not increase the risk of pump thrombosis or strokes when compared to a baseline LVAD population. Larger-scale studies are needed to confirm our findings.

<table>
<thead>
<tr>
<th>VK Cohort (n=17)</th>
<th>Non-VK Cohort (n=112)</th>
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<tbody>
<tr>
<td>ICVA (%)</td>
<td>0*</td>
</tr>
<tr>
<td>HCVA (%)</td>
<td>2.7</td>
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<tr>
<td>PT (%)</td>
<td>1.8</td>
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*indicates p<.05 for comparison with the Non-VK Cohort
Depression Is Associated With Poor Sleep Quality And Daytime Sleepiness In Advanced Heart Failure Patients Implanted With Left Ventricular Assist Devices (LVADS)

J. Kazmierski, Z. Chornoby, J. Casida. University of Michigan, Ann Arbor, MI.

**Study:** Depression is highly prevalent in heart failure (HF), but its impact on sleep and daytime function (i.e. daytime sleepiness) in LVAD patients is relatively unknown. The purpose of this study was to examine the (1) degree of depression, sleep quality (SQ), and daytime sleepiness (DS) of advanced HF patients before and 6 months after implantation of an LVAD, and (2) relationship among depression, SQ, and DS variables.

**Methods:** We implemented an observational study involving 24 patients with non-pulsatile flow LVADs recruited from 2 centers in Michigan. Data were collected within 1 month before and 6 months after LVAD implant. In addition to demographics and clinical profile, subjects completed psychometrically robust measures of depression, SQ, and DS. Data were analyzed with descriptive and inferential statistics.

**Results:** Subjects’ mean age was 57.0 ± 10.9 years. They mostly were white (76%), male (64%), married (56%) and with Heartmate II LVADs (80%) as bridge-to-heart transplant (48%). During the study, subjects were on antidepressants (20%) and sleep medications (30%). Before implant, subjects’ depression level was minimal, SQ was poor, and DS was high normal DS. Despite the significant decrease in scores at 6 months after LVAD implant, the subjects’ depression remained minimal and SQ still poor. DS score significantly decreased to an “average normal level” at 6 months. Correlational analyses showed significant relationships among depression, SQ, and DS: r=.39 to r=.52, p-values <.05.

**Conclusion:** Although minimal, depression is prevalent before and 6 months after LVAD, which appeared to be associated with poor SQ and some degree of DS. Further research with large random sample is needed to confirm our findings. Depressive symptoms among LVAD patients should be treated to optimize sleep, daytime function, and overall health.

Bedside Nurses Perceived Challenges Of VAD Patient Care: A Qualitative Analysis

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**Study:** The ventricular assist device (VAD) is frequently employed as a bridge to heart transplantation, destination therapy, or myocardial recovery. Hence, Bedside Nurses are more likely to encounter the utilization of the device in current clinical practice. This study examined the Bedside Nurse’s challenges in caring for VAD patients/families.

**Methods:** A qualitative descriptive study was employed on the data provided by ICU (n=36) and stepdown unit (n=35) nurses who participated in a national survey. At the end of the survey, we asked participants to reply to this one open-ended question, “What information should we know about in terms of challenges you encounter when caring for VAD patients and their families?” Responses were transcribed verbatim and content analytic procedures were applied. We used Nvivo 10 software in summarizing sentences, phrases, and words, which were clustered into themes.

**Results:** Four themes emerged from content analyses, descriptive of the Bedside Nurses account on their challenges working with hospitalized VAD patients: 1) the need for education of the bedside nurse, 2) the focus of patient outcomes 3) the preparation of the VAD patient/family regarding life with a VAD, and 4) the need of support to the RNs to care for the hospitalized VAD patient. Notably, the stepdown unit nurses voiced more concern and focus over the possibility of complications with a VAD, while the ICU nurses voiced concern over the VAD patient selection process. The care of VAD patients is a collaborative effort by many healthcare members. Understanding what VAD Bedside Nurses perceive as challenges to care may aid in the development of VAD team strategies that could improve education and increase empowerment and engagement of this essential group of care providers, ultimately reducing barriers to care and improving VAD patient outcomes.
Maintaining VAD Competency For A Growing Program: One Centers Experience
A. T. Lundststrom. Mechanical Circulatory Support, Bryan Heart, Lincoln, NE.

Study: The maintenance of competent nursing staff to care for Ventricular Assist Device (VAD) patients is a difficult task many Mechanical Circulatory Support (MCS) programs face. Education is an essential part of the VAD Coordinator role. It can be time-consuming and challenging to audit when and by whom education was completed. The aim of this abstract is to outline one centers ability to streamline education and quadruple the amount of VAD trained nursing staff within a 1 year period.

Methods: In order to maintain compliance of nursing staff, an Online Educational Tracking System (OETS) was used to identify staff deficient in VAD training. Staff lacking training were notified of the requirement and given 12 months to complete their training. Staff members were able to use the OETS to sign up for a 2-hour monthly in-person VAD training class lead by one of the VAD Coordinators. The class covered information outlined in the facility policies and procedures to assure VAD competency. A written exam was completed, as well as hands-on experience with the equipment to verify learning strategies were met. The VAD coordinator then entered the completed attendance roster into the OETS and verified training for the individual staff members, thus allowing ease of tracking within the OETS.

Results: Within a 9-month time frame, our center was able to increase our number of VAD Trained nursing staff from 45 nurses to 187. Staff reviews of the experience have been positive and patient safety throughout the medical center has improved. Moving forward staff will be notified within 3 months of their VAD Competency expiring and will be able to sign up for the training and complete the class again. This will maintain competency and provide annual best practice updates and training.

How To Improve Homecare After VAD Implantation: A Patients' Perspective
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Study: For patients diagnosed with conservatively exhausted terminal heart failure, the implantation of a ventricular assist device (VAD) has developed into a well-recognized therapy option. Meanwhile, the survival times with a VAD are approaching the survival times after heart transplantation. This leads to a life-long dependency on the proximity to specialists for VAD patients. So far, the requirements for homecare have not been systematically evaluated from the perspective of VAD patients and their relatives. Our aim is to close this gap for homecare after VAD Implantation.

Methods: In September 2016, VAD patients (n = 30) and their relatives (n = 25) were surveyed anonymously on their views on homecare after VAD implantation. For this purpose, the VAD Patient Satisfaction Survey was adapted to the needs of this study.

Results: VAD patients and their relatives experience their daily life with a VAD positive. Information, training, accessibility and regular contacts with the implanting clinic and the VAD Coordinator are central pillars of homecare after VAD implantation. Almost 95% of surveyed patients regard good home support as an important factor that makes life with a VAD easier. The need for long-distance-solutions by using telemedicine-elements became evident. A standardized, patient-centered approach in the care of VAD patients is needed. The care after VAD implantation is very multifarious and goes far beyond simple medical care.
Bridging VA ECMO to Durable LVAD: Keys to Success

Study: There is paucity of data defining criteria for bridging patients supported by venoarterial extracorporeal membrane oxygenation (VA ECMO) for advanced cardiogenic shock to durable left ventricular assist device (LVAD). We evaluated our center’s selection protocol on outcomes for patients bridged from VA ECMO to LVAD.

Methods: From September 2014 to October 2017, a retrospective chart review was performed on all patients that were bridged from VA ECMO to durable LVAD at our center. Patients on VA ECMO accepted for LVAD implantation underwent a thorough, multidisciplinary screening process. Specific criteria for candidacy included 1) end organ recovery, 2) extubation, 3) absence of infection, 4) neurologically intact, and 5) adequate psychosocial support. To compare clinical status and end organ function pre VA ECMO and pre LVAD, Sequential Organ Failure Assessment (SOFA) score and lab data were collected and analyzed (see table). Post LVAD implant outcomes assessed include survival, post LVAD hospital length of stay (HLOS), and readmissions.

Results: Seven patients (age 49 years ±19, 21–72) were bridged from VA ECMO to LVAD at our center. Mean VA ECMO support duration was 9 days ± 4 (6–15). Six of 7 patients underwent uneventful LVAD implantation; however, 1 patient required temporary RVAD support post LVAD. Mean post LVAD HLOS was 22 days ±8. One patient was explanted due to cardiac recovery (481 days post LVAD), and 1 patient received a heart transplant (325 days post LVAD). The final 5 of 7 patients are stable on LVAD support with a mean of 555 days ± 309 (161–1041). As of October 2017, all patients (7) are alive and out of the hospital. We had 6 readmissions in 3 patients, and only 1 was LVAD related.

Conclusion: Applying a thorough selection protocol to INTERMACS level 1 patients bridged with VA ECMO to durable LVAD is a highly successful strategy and yields excellent long term survival.

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<thead>
<tr>
<th></th>
<th>Pre VAE</th>
<th>Pre-LVAD</th>
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<tbody>
<tr>
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<td>1.6±0.8</td>
<td>0.96±0.26</td>
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<td>Blood Urea</td>
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<td>Nitrogen</td>
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<tr>
<td>Lactic acid</td>
<td>5±4</td>
<td>32±16</td>
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<tr>
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<tr>
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<tr>
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<tr>
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<td>160±83</td>
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<tr>
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<td>10±1</td>
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</table>

Women And Mechanical Circulatory Support: A Large Volume, Single Center Experience
K. Meehan, N. Graney, P. Combs, G. Macaluso, S. Pauwaa, G. Bhat, W. Cotts, A. Tatooles, P. Pappas, A. Andrade. Advocate Christ Medical Center, Oak Lawn, IL; University of Chicago, Chicago, IL.

Study: Half of the 6 million adults living with heart failure (HF) in the United States are women, yet they are less often referred for advanced therapies, less likely to be listed for heart transplant, and less likely to be implanted with durable left ventricular assist devices (LVAD) compared to men. These disparities persist despite studies demonstrating equivalent survival after LVAD implantation. We studied outcomes in women with end stage heart failure at a large tertiary care center after durable LVAD implantation to determine if outcomes are comparable to a contemporary cohort.

Methods: We retrospectively investigated all patients who received a durable VAD for destination therapy (DT) or bridge to transplant (BTT) at our institution from 1/2014 until 12/2016. Women who were lost to follow up, underwent VAD exchange, or underwent investigational device implantation were excluded from analysis.

Results: 299 durable VADs were implanted and 71% of all implants were male. After exclusions, 67 women were analyzed. Average age at implant was 56.5 years. Devices included 26 HVADs (Medtronic), 3 BiVADs (Medtronic), and 38 HMII (Abbott). 22 women were BTT and 45 were DT. Average length of support was 589 days. One-year survival was 87% for all women and 66% for women on BiVADs. Two-year survival was 70% for all women. Cause of death at one year: 4/9 right ventricular failure (RVF), 4/9 multisystem organ failure (MOSF), and 1/9 acute leukemia. At one year, 34% of patients had a driveline infection, 16% had bacteremia, 15% had a stroke, 19% had gastrointestinal bleed, and 15% had hemolysis. Seven patients (32% of the BTT) underwent heart transplantation. Our large single center experience compared to the 8th Interagency registry for mechanically assisted circulatory support (INTERMACs) report demonstrates equivalent survival and outcomes for women compared to an entire cohort implanted with a durable VAD. We recognize the importance of analyzing gender differences in order to modify care as deemed appropriate.
Correlates Of Caregiving Characteristics In Left Ventricular Assist Devices
J. A. Xu, 1 M. Abshire, 1 J. Casida 2. School of Nursing, Johns Hopkins University, Baltimore, MD, 2 School of Nursing, University of Michigan, Ann Arbor, MI.

Study: LVAD caregivers manage unique stressors due to the complexity of caregiving for persons living with the device, however little is known about LVAD caregiving characteristics and outcomes. This study examined LVAD caregiver characteristics and the relationships with caregiver self-efficacy and adherence.

Methods: We examined data from the parent study that included LVAD caregivers. Participants completed a questionnaire with demographic and caregiving characteristics (eg, LVAD care knowledge, training hours, direct caregiving hours/week), LVAD Caregiver Self-Efficacy Scale, LVAD Caregiver Adherence Scale, General Self-Efficacy Scale, and General Adherence Scale. Data were analyzed using descriptive and inferential statistics.

Results: LVAD caregivers (n = 98) were mean age, 49.8 ± 12.9 years, mostly female (79%), married (80%), Caucasian (83%), educated beyond high school (89%) and employed (65%). The majority were dedicated caregivers (93%) who completed LVAD care training prior to hospital discharge. We found significant correlations among caregiving training, caregiving hours/week, LVAD caregiver self-efficacy and general adherence, (r=0.25 to 0.45, p<0.05). In addition, LVAD care knowledge was associated with caregiving hours/week (r=0.31, p=0.01). Regression analyses demonstrated that an one point increase in LVAD caregiver self-efficacy mean score would result in an 1/10 increase in general adherence score (p=0.03). Our data suggested that caregiving training, caregiving hours/week and self-efficacy may have an influence on the degree to which caregivers adhere to LVAD care regimens. Further research is needed to confirm our findings and understand the effect of caregiving on LVAD patient outcomes.

When Indecision Is The Decision
J. I. Giordano, 1 T. Martin, 2 B. Dinicola, 2 K. B. Schmidt 2. 1 Heart Failure Treatment and Transplant Program, Newark Beth Israel Medical Center, Newark, NJ, 2 Mechanical Circulatory Support Program, Newark Beth Israel Medical Center, Newark, NJ.

Study: A 28-year-old patient presented to the VAD team 48 hours after a normal vaginal delivery with shortness of breath and an ejection fraction of 20%. She was implanted with a durable left ventricular assist device as a bridge to decision and was discharged from the hospital after an uncomplicated recovery; evaluation for heart transplantation was initiated. The following is a case study describing the dynamic path a VAD/Transplant patient followed during our care.

Methods: The patient underwent a full psychosocial assessment by a Licensed Clinical Social Worker, according to the program’s protocol. The assessment included participation from the patient as well as the patient’s primary caregiver. At the conclusion of the assessment there were concerns raised as to the patient’s insight of her disease process and the expectations both before and after transplantation. Due to an improvement in her cardiac function, the evaluation was closed; however, 3 months later the echocardiogram showed deterioration. The patient was then re-consented for transplant evaluation with the understanding that adherence, including lab work and follow-up visits would be closely monitored. It was decided this patient would be listed for transplantation. Over the next 6 months the patient attended her health appointments and attended all laboratory appointments. She subsequently became pregnant, miscarried and was de-listed. The patient’s Hospitalization, before death, was due to a driveline infection. During hospitalization she suffered a brain bleed and was discharged on IV antibiotics. One week later she suffered a fatal stroke and passed away.

Results: We endeavored to identify the often present difference in paradigms between potential heart transplant candidates; their caregivers and members of the multidisciplinary transplant team. Illustrating within this case study the dynamic form of status within the VAD/transplant paradigm is just one example of the complex care of the patient population we offer care.
ASAIO NURSING CIRC-SUPPORT ABSTRACTS

Language Of The Heart: Revising Consent For Improved LVAD Outcomes
A. Edlund,1 M. Carey,1 R. Adams-Goertel,1 J. Edlund1. 1University of Rochester Medical Center, Rochester, NY; 2Roberts Wesleyan College, Rochester, NY; 3Rochester Institute of Technology, Rochester, NY.

Study: Patients with advanced heart failure may be presented with left ventricular assist device (LVAD) as a potential option in the management of their disease process. There is data that suggests patients do not fully understand the implications of consenting to LVAD. Despite improvements in preoperative teaching and methods of obtaining informed consent, up to 60% of patients are unable to recall the major risks of surgery and cannot answer basic questions about the procedures that they have agreed to. This suggests that existing protocols have not proven effective in improving the health literacy of patients considering this device.

Methods: The purpose of this study was to compare a previous established consent protocol and a new protocol (a revised consent form, an FAQ sheet to use with the established consent form, and a combination of the revised consent form and the FAQ) for understanding. Participants were provided with one of the consent protocols (2 [consent: established, improved] x 2 (FAQ: present, absent). After reading the consent, the participants completed a measure of verbal and analytical abilities. Next, participants completed a 15-item questionnaire based off of information found within the LVAD consent form.

Results: In this study, we found that the inclusion of the FAQ sheet significantly improved participants understanding of the device (M = 6.98, SD = 2.47) compared to conditions where no FAQ was included (M = 5.00, SD = 1.81), F (1, 139) = 29.07, p < .001. Surprisingly, the revised consent form did not improve understanding, nor did it interact with the FAQ condition (p’s > .1). Additionally, verbal aptitude predicted scores on the questionnaire, b = .181, SE.B. = .046, such that higher verbal aptitude lead to higher scores on the questionnaire. This study provides preliminary evidence that an FAQ supplement as part of a consent process can improve understanding of the device. Further research should explore whether the inclusion of FAQ’s will improve health literacy with respect to patients’ devices.

The Inner Workings Of Femoral VA ECMO
M. Tukacs. Columbia University Medical Center- NYP, New York, NY.

Study: Over time, extracorporeal membrane oxygenation (ECMO) evolved into an essential life support tool in adult critical care. While advances in technology and surgical technique allow for variety of ECMO configurations, the femoral vein-femoral artery approach remains most frequently used. Despite its ease of application, it requires expertise in management. The objective of this review is to analyze clinical challenges related to the most commonly used veno-arterial (VA) ECMO configuration at a high volume ECMO center with an ELSO Award for Excellence in Life Support, thereby help clinicians perfect in management of patients on ECMO.

Methods: A retrospective medical review was completed to obtain quantitative and qualitative data regarding ECMO configurations at Columbia University Medical Center, an academic medical center between January 2017 and January 2018. Inclusion criteria included: adult patient, VA ECMO mode, femoro-femoral ECMO configuration. Content analysis was performed.

Results: The review revealed 192 ECMO cases, 2 ECMO modes and 10 different ECMO configurations. Among configurations, the femoral vein-femoral artery approach predominated (n=78) with 41%. Notable challenges related to this ECMO configuration were: differential hypoxemia, left ventricular (LV) distention and ischemia of the cannulated limb. Differential hypoxemia is an upper body hypoxemia developed in peripheral ECMO configuration and caused by respiratory failure that is combined with preserved LV function. Besides traditional medical therapy, reconfiguration of ECMO to either hybrid or central VA ECMO is needed. Distention of the LV develops as a consequence of worsening LV function, necessitating emergent mechanical decompression. Ischemia of the cannulated limb develops mainly due to disproportion in size between the ECMO cannula and the blood vessel it is in. Treatment includes placement of a limb reperfusion cannula. Early recognition of identified challenges is significant for effectiveness of ECMO therapy and improved outcomes.
Survival Post Heart Transplant By Era In Recipients ≥ 65y Bridged With Mechanical Circulatory Support

A. Salimbangon, E. DePasquale, A. Chang, M. Kamath, D. Vucicevic. Ronald Reagan UCLA Medical Center, Los Angeles, CA.

Study: Due to the limited availability of donor organs, appropriate selection of candidates for heart transplantation (HT) is essential. The goal of our study is to compare survival outcomes by era for HT recipients bridged with Mechanical Circulatory Support.

Methods: 1601 HT recipients, that were bridged with MCS, were identified from the UNOS registry from 2000–2017. Recipients were grouped based by Heart Transplant Era. Patients were excluded if they were less than 18 years old, lost to follow up. Survival was censored at 12 years old. Multivariate Cox proportional hazard regression analysis was adjusted for age, sex, DM, race, ischemic time, dialysis, life support, wait status & HLA mismatch.

Results: There was no statistical significance with the demographics (age, gender or ethnic category) of the recipients between the different eras. Patients in Era 3 had a higher incidence rate of diabetes mellitus compared to the other eras (p<0.001). There were less patients in Era 1 who had no prior cardiac surgery (70.1%) before undergoing a Heart Transplant in comparison to Era 2 & 3 (p<0.001). The median number of total days on the waiting list showed that Era 3 had the most at 219.5 days (p<0.001).

Conclusion: Survival outcomes by era are similar between Era 2 & 3. Survival in older recipients has improved in patients with BTT Mechanical Circulatory Support. Further study is necessary to compare the survival outcomes between those patients who were bridged with MCS and those who were not.

Ecmo Transport In Rural Appalachia: Improving Access Through A Nurse-Led Transport Team

S. Griggs, J. Harman, J. Jones, J. Coles, A. Harris, R. Coghill. University of Kentucky, Lexington, KY.

Study: Collaboration is fundamental to meet the growing need to provide complex care for underserved populations. Patients achieve optimal outcomes when nurses and physicians collaborate, and this partnership allows nurses to feel empowered to meet gaps they may see in practice. Cultivating nurse-physician protocols to improve access to safe, high-quality care is essential. An inter-professional group of physicians, nurses, paramedics, and perfusionists was created -- an extracorporeal membrane oxygenation (ECMO) transport team -- to meet the needs of a critically underserved population in rural Appalachia. The purpose of this study was to describe the characteristics of the types of ECMO transport completed by the team, adverse event rates, and survival rates.

Methods: All adult ECMO transport patients in the previous 13 months were identified using a retrospective chart review.

Results: There were a total of 19 patients from primarily rural Appalachia, demonstrating that the transport team and its services were highly used. Of the nineteen transports, 10 were supported through venous-arterial (VA) cannulation, and 9 were supported through veno-venous (VV) cannulation. Average transport time was 146.3 minutes with a range from 15 to 280 minutes. All transports were conducted using a ground, ambulance transport system. No adverse events were reported in any transports. The average survival of VA ECLS in this sample was 50%, and average survival of VV ECLS was 66%, which is in concordance with national averages. A collaborative, inter-professional, nurse-led ECMO transport team, provides safe, effective care to areas of rural Appalachia that would otherwise be without access to this type of advanced medicine. Future research should focus on ways to increase access to this type of service, as well as decreasing transport times.
Reduction Of VAD Coordinator Time Burden And Empowerment Of HVAD Patients Without Compromising Care

T. Schlöglhofer,1 M. Blood,2 J. Pietropaolo,1 J. Lantz4. 1Center for Medical Physics and Biomedical Engineering, Department of Cardiac Surgery, Medical University of Vienna, Vienna, AUSTRIA, 2Department of Mechanical Circulatory Support, University of Alabama at Birmingham Hospital, Birmingham, AL, 3Medtronic Inc., Minnesota, MN, 4Children’s Health, Dallas, TX.

Study: With the increasing demand of LVADs as therapy for end-stage heart failure, the role of VAD Coordinators has become more complex and time demanding. The aim of this International Consortium of Circulatory Assist Clinicians (ICCAC) and Medtronic survey is to understand the time burden of VAD Coordinators and how industry can address these challenges through partnerships.

Methods: The survey was conducted as a web-based questionnaire (14 questions) and was sent to all ICCAC members and a Medtronic list. 51 international VAD Coordinators responded, the majority came from adult only (77%), combined (13%) and pediatric only (10%) centers.

Results: 60% responded that their center has over 50 patients on long-term LVAD support, where 48% were implanted as bridge to transplant and 46% as destination therapy. 78% of VAD patients live with, or have access (12%) to a caregiver, 10% are living alone. Nearly 92% of the participants indicated that their center assumes primary responsibility of day to day care of VAD patients. 71% receive calls multiple times daily from VAD patients outside of planned office visits, 16% report at least one call daily or 3-times a week (8%). Of those calls, 73% last less than 30min and 15% even 30-60min. Pre-discharge, the majority of training time is spent for the VAD system (52%), driveline care (20%) and general care/when to call (11%). Post-discharge, less time is spent for VAD system training (35%), but driveline care (19%), home INR (13%) and blood pressure (BP) management (12%) require more training. Most VAD Coordinators believe that monitoring patient compliance of driveline care (98%), BP management (88%) or home INR (86%) can reduce unplanned patient office visits. Home INR machines, BP cuffs and cardiac rehab were the 3 most common used tools to drive patient independence. The results of this Medtronic/ICCAC survey help to understand what tasks might be addressed to reduce time burden on VAD Coordinators and empower patients without compromising care.

Driveline Infections Following Left Ventricular Assist Device Implantation: Differences Between Three Contemporary Device Types

T. Schlöglhofer,1 P. S. Michalovics,2 C. Gross,3 K. Dimitrov,1 J. Riebandt,1 H. Schima,1 D. Wiedemann,2 D. Zimpfer,2 F. Moscato3. 1Center for Medical Physics and Biomedical Engineering, Department of Cardiac Surgery, Medical University of Vienna, Vienna, AUSTRIA, 2Center for Medical Physics and Biomedical Engineering, Medical University of Vienna, Vienna, AUSTRIA, 3Department of Cardiac Surgery, Medical University of Vienna, Vienna, AUSTRIA.

Study: Driveline infections (DLI) are common adverse events in left ventricular assist devices (LVAD) patients, leading to severe complications and hospital readmission. The study aims at characterizing differences in demographics, and clinical parameters as predictors for DLI in the first 2 years post implant.

Methods: This single-center study included 183 patients on LVAD support (n=43 HMII, n=29 HM3 and n=111 HVAD) between January 2013 and July 2017. Age, gender, BMI, CRP, leukocytes, INR, fibrinogen as well as rates of readmission, infection and survival were retrospectively analyzed.

Results: 12.5% of patients were readmitted for DLI (RDLI), 12.5% experienced DLI but were treated in the outpatient setting (NRDLI) and 75% were free from DLI (NoDLI). Age, gender, BMI, INR were comparable between groups. Median CRP were higher in RDLI group than in NRDLI and NoDLI (2.93 vs 0.79 and vs 0.62 mg/dl, p<0.001). Similar results were found for Leukocytes (10.41 vs 8.17 and vs 7.39 G/l, p<0.02) and Fibrinogen (592 vs 387 and vs 432 mg/dl, p<0.001). Elevated values were detected already up to 90 days before readmission. Staph. aureus was the most common bacterium in RDLI (54.2%) and NRDLI (59.1%). Freedom from any DLI readmission was comparable between HMII and HVAD but significantly lower in HM3 patients (Figure 1). 2-year survival of RDLI, NRDLI and NoDLI patients were similar (79%, 80% and 83%, p>0.13), without significant difference between the LVAD systems. Possible predictors of DLI are elevated values of CRP, Leukocytes and Fibrinogen. DLI related readmissions were more common in HM3 compared to HVAD or HMII possibly because of device specific differences in driveline diameter or surgical differences.
Improving Ventricular Assist Device VAD Patient Education Through Teach Back
E. J. Larsen, MS, RN, P. K. Messner, APRN, CNS, DNP, A. J. Narr, DNP, RN, K. K. Seelandt, MSN, RN. Nursing, Mayo Clinic, Rochester, MN.

Study: Providing meaningful and timely patient education is a key priority for patient care. A multi-disciplinary collaborative quality improvement project was proposed and carried out across a large multi-state healthcare organization to promote efficient, standardized VAD education and training to patients implanted with a VAD and their caregivers. Aims include: Improve the patient and caregiver experience with VAD education by providing timely, clear, consistent, and concise education. Improve RN staff knowledge and comfort level with providing VAD patient education. Enhance multidisciplinary team awareness of individual patient progress toward dismissal. Engage RN staff across the continuum of care in providing VAD patient education.

Methods: A retrospective chart review was conducted on a random sample of newly implanted VAD patients. Review included education documentation related to post-operative date and length of stay following VAD implantation. A subjective review of RN comfort level in providing VAD patient education was completed. A VAD care map and patient education teach back tool kit were developed and vetted through unit councils and state specific multi-disciplinary teams.

Results: A VAD teach back toolkit has been implemented across the organization. Data continues to be collected and reviewed. The RN as a teacher is exemplified through the delivery of high-quality patient education. Providing a VAD teach back toolkit supports the bedside RN in assisting patients with a VAD in self-management and preparation for discharge while improving the patient experience.

Impact Of Substance Abuse On Left Ventricular Assist Device Outcomes
H. Moody, J. Trivedi, M. Slaughter. Cardiothoracic Surgery, University of Louisville, Louisville, KY.

Study: Background Opioid epidemic due to prescription drug abuse for chronic pain and recreational drug use has become a significant public health problem in recent years. There are few studies reporting on impact of chronic substance abuse due to either prescription pain medication use or recreational drug use in left ventricular assist device (LVAD) outcomes. Aim of the study is to evaluate outcomes of chronic substance abuse patients undergoing LVAD implantation.

Methods: Methods A single center mechanical circulatory database was queried between years 2015 and 2017 to identify patients undergoing primary durable continuous flow LVAD implantation. Patients were divided in 3 groups based on their history of substance abuse; group 1 had patients with prescription drug abuse due to chronic pain, group 2 had patients with recreational drug use and group 3 had patients with no history of substance abuse. Baseline characteristics between the groups were studied. Mortality, stroke, driveline infection and GI bleeding at 1 year were evaluated as outcomes metrics.

Results: Results There were 94 patients included in the study group of whom 18% (n=17, 12 had prescription drug abuse and 5 had recreational drug abuse). Patients with no history of drug abuse were older, more likely to be married and had chronic kidney disease. More patients in the prescription drug abuse group had history of diabetes. Table 1 shows baseline characteristics of the study groups. The 1 year mortality prescription drug abuse, recreational drug abuse and non-drug abuse groups was 17%, 20% and 17% respectively (p=0.9). The occurrence of driveline infection, stroke and GI bleeding was also comparable between the groups (Table 2).

Conclusion: History of prescription drug abuse or recreational drug abuse does not adversely impact outcomes following LVAD implantation. This may be due to better control and reduced recidivism of substance abuse following LVAD.

<table>
<thead>
<tr>
<th>Table 1 Baseline Factors</th>
<th>Opioid for Chronic Pain</th>
<th>Recreational Drug Use</th>
<th>None</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=12</td>
<td>n=5</td>
<td>n=77</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age year (median IQR)</td>
<td>48 (43–55)</td>
<td>35 (28–40)</td>
<td>61 (52–66)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Gender Male</td>
<td>83%</td>
<td>100%</td>
<td>81%</td>
<td>50%</td>
</tr>
<tr>
<td>DM</td>
<td>58%</td>
<td>0</td>
<td>34%</td>
<td>0.06</td>
</tr>
<tr>
<td>BMI kg/m² (median IQR)</td>
<td>35 (28–40)</td>
<td>25 (22–29)</td>
<td>28 (25–31)</td>
<td>0.08</td>
</tr>
<tr>
<td>CKD</td>
<td>14%</td>
<td>20%</td>
<td>28%</td>
<td>30%</td>
</tr>
<tr>
<td>Married</td>
<td>28%</td>
<td>0</td>
<td>58%</td>
<td>0.12</td>
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</table>

<table>
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<tr>
<th>Table 2 Outcome</th>
<th>Opioid for Chronic Pain</th>
<th>Recreational Drug Use</th>
<th>none</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=12</td>
<td>n=5</td>
<td>n=77</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mortality</td>
<td>17%</td>
<td>20%</td>
<td>17%</td>
<td>0.9</td>
</tr>
<tr>
<td>Driveline infection</td>
<td>25%</td>
<td>20%</td>
<td>20%</td>
<td>0.9</td>
</tr>
<tr>
<td>GIB</td>
<td>17%</td>
<td>0</td>
<td>20%</td>
<td>0.5</td>
</tr>
<tr>
<td>Stroke</td>
<td>25%</td>
<td>0</td>
<td>12%</td>
<td>0.3</td>
</tr>
</tbody>
</table>
Surgical And Nursing Management In The Care Of Patients Post LVAD Implant Without The Use Of Blood Products

C. LaBuhn, N. Uriel, G. Sayer, G. Kim, S. Kalantari, J. Raikhelkar, D. Onsager, V. Jeevanandam. Cardiac Surgery, University of Chicago Medical Center, Chicago, IL.

Study: Background: Surgical and nursing management of advanced heart failure (aCHF) in Jehovah’s witnesses (JW) is challenging. LVAD has become a standard of care for heart failure but is rarely performed in this subgroup of patients due to feared consequences of inability to transfuse whole blood products.

Conclusion: No blood can be given to the JW patients. Careful surgical technique, close follow up and monitoring are critical in successful outcomes in JW patients in need of mechanical assist devices. In this study, we have demonstrated similar outcomes and survival in both JW and a control group of DT patients.

Methods: Methods: Data was collected retrospectively from 2012–2017. The JW group was compared to a control group of destination patients. We selected the DT group using propensity matching from the years 2014–2015. Complications including VAD thrombosis, driveline infection, stroke, and gastrointestinal bleed were assessed in the two groups.

Results: Results: We reviewed 31 patients in the Non JW group and 16 patients in the JW group. In this study, we identified 25 (80.6%) patients in the Non JW group vs. 7 patients (69%) in the JW group who developed any of the complications mentioned in Table 1. Among the Non JW group, 7 patients (22%) had multiple complications and in the JW group this occurred in three patients (19%). Despite hemoglobin values as low at 3mg/dl, no blood products were given in the JW group. In addition, 1 year survival was shown to be similar in both groups at 80 and 75%, whereas 3mg/dl, no blood products were given in the JW group. In addition, 1 year survival is slightly higher in the non JW group. In conclusion, survival was shown to be similar in both groups at 80 and 75%, whereas the 2-year survival is slightly higher in the non JW group. In conclusion, close follow up and monitoring are critical in successful outcomes in JW patients in need of mechanical assist devices. In this study, we have demonstrated similar outcomes and survival in both JW and a control group of DT patients.

Table 1

<table>
<thead>
<tr>
<th></th>
<th>DT</th>
<th>JW</th>
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<tbody>
<tr>
<td>Age (mean)</td>
<td>59.6±1.9 years</td>
<td>58.9±2.3 (p=0.82)</td>
</tr>
<tr>
<td>Gender</td>
<td>males (n=22)</td>
<td>males (n=9)</td>
</tr>
<tr>
<td>females (n=9)</td>
<td>females (n=7)</td>
<td></td>
</tr>
<tr>
<td>Etiology of HF</td>
<td>NICM n=18 (58%)</td>
<td>NICM n=11 (69%)</td>
</tr>
<tr>
<td>ICM n=13 (42%)</td>
<td>ICM n=5 (31%)</td>
<td></td>
</tr>
<tr>
<td>Preop Hg</td>
<td>12.5±0.3 g/dl</td>
<td>11.7±0.2 g/dl (p=0.17)</td>
</tr>
<tr>
<td>Preop Platelet</td>
<td>204±11 K/ul</td>
<td>199±23 K/ul (p=0.85)</td>
</tr>
<tr>
<td>LOS (days)</td>
<td>23±2</td>
<td>24±4 (p=0.86)</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>n=5 (16%)</td>
<td>n=2 (12.5%)</td>
</tr>
<tr>
<td>DLI</td>
<td>n=5 (16%)</td>
<td>n=2 (12.5%)</td>
</tr>
<tr>
<td>GIB</td>
<td>n=8 (50%)</td>
<td>n=4 (25%)</td>
</tr>
<tr>
<td>Stroke</td>
<td>n=9 (29%)</td>
<td>n=7 (44%)</td>
</tr>
<tr>
<td>1 yr Survival</td>
<td>80%</td>
<td>75%</td>
</tr>
<tr>
<td>2 yr Survival</td>
<td>61%</td>
<td>44%</td>
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</tbody>
</table>

Emergency Preparedness For Centrimag VAD Patients In The CITCU

M. Nell-Daniels, A. Batista, D. Burns. Cardio-Thoracic Intensive Care Unit, New York Presbyterian Columbia Medical Center, New York, NY.

Study: To standardize: (1) Centrimag VAD set up; (2) Centrimag education to maintain RN knowledge and skills for an emergency console and motor switch.

Methods: Design: Four month prospective quality improvement project for all patients with Centrimag BIVAD, LVAD, and RVAD support. Exclusion criteria: ECMO patients with Centrimag console. The Centrimag standard setup was an interdisciplinary initiative with nursing, perfusion and the VAD team. Sample Size: 20 patients from Sept 2017- Dec 2017 Measurements: Daily audits were done using a 19 item audit tool including the bedside set up, cannula labeling, bedside safety check and mock loop compliance. Audit data was collected to determine compliance. Audits included qualitative data to measure the bedside RN confidence level with an emergent motor and console exchange.

Results: Outcomes:Centrimag VAD support is a high risk low volume therapy. During the four month audit period, compliance with the alarm verification and bedside cart setup increased to 100%. The compliance with mock loop practice was 60%, and will require ongoing training to ensure systematic mock loop practice every shift. During the QI project there were 0% emergencies or safety events related to incorrect centrimag cart set up, or equipment failure. The response to an emergency switch was not tested due to the limitation of zero centrimag motor or console failure. The confidence level of nurses increased from 33% to 100%. This quality improvement project has resulted in standardized process for Centrimag VAD emergency preparedness, and is an ongoing performance improvement measure for the CITCU.
Extended Support With Berlin Heart Can Be Achieved In Children With Low Rates Of Significant Neurologic Events

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Study: The Berlin ventricular assist device (VAD) is the only FDA approved pediatric-specific durable device for bridge to transplantation in children. Prior reports indicate the incidence of neurologic events while on Berlin VAD support is high. We sought to examine the incidence and outcomes of neurologic events in children supported with Berlin Heart.

Methods: We reviewed patients who underwent Berlin VAD insertion at our institution between 2008 and 2017. Outcome measures were neurologic events, survival to transplant and mortality. Clinical and outcome data were collected. Data are presented as median and interquartile ranges.

Results: 26 patients underwent Berlin VAD insertion at 3.45 (0.65–10.75) years of age and a weight of 16 (7.7–29) kg. 22 patients (85%) were transplanted and 1 patient is awaiting transplantation, with a median VAD support duration of 96.5 (41–202) days, accounting for a total of 3239 days of support. Anticoagulation was initiated 24 (24–48) hours after VAD insertion reaching a therapeutic level by post-operative day 3 (2–3) in all patients. 9 patients (35%) had 12 neurologic events (6 strokes, 6 seizures). Among these, 6 patients (23%) had a cerebrovascular event, 5 ischemic and 1 hemorrhagic. 3 of these patients (11%) were removed from the transplant list due to devastating neurologic injury and subsequently died. The other 3 had no significant neurologic deficits and proceeded to undergo heart transplantation. Isolated seizures in 3 patients resolved with medication. All 22 patients who survived to transplantation were discharged without any neurologic dysfunction and 100% are alive at 3 (2–5) years follow-up. Clinically significant neurologic events with Berlin VAD support should be defined as an event that impacts transplant status or mortality. Low rates of such significant neurologic events can be achieved despite prolonged device support. Survival to transplantation and discharge is excellent without residual neurologic sequelae.

Effect Of Age On Hemodynamics in 1/2 Ventricle Sheep Model


Study: Creating a single ventricle animal model with superior cavopulmonary shunt (SCP) is technically complicated and challenging. The purpose of this study was to develop and validate a less invasive animal model for investigating single ventricle patients with SCP.

Methods: 15 lambs (4, 6, and 8 weeks old, n=5 each) were used for this study. Through a median sternotomy, a PTFE graft was inserted between the superior vena cava (SVC) and the main pulmonary artery (PA). Then the SVC was clamped at the right atrial junction to establish 1 and 1/2 ventricle circulation. Flows and pressures were recorded before and after clamping the SVC and percent changes of each value were compared. One way analysis followed by Tukey test was used and a p value of < 0.05 was regarded as statistically significant.

Results: Table 1 shows the baseline data before establishing 1 and 1/2 ventricle circulation. There were no differences in mean arterial blood pressure (ABP), mean pulmonary artery pressure (MAPP), transpulmonary gradient (TPG), and aortic flow among the ages. Pulmonary vascular resistance (PVR) was higher in 4 weeks old lambs compared with 8 weeks old. Table 2 shows the percent changes of the each value after 1 and 1/2 ventricle circulation. There were no differences in PAP and TPG. ABP and aortic flow decreased significantly in 4 weeks old lambs compared with 6 and 8 weeks old lambs. Also, PVR increased significantly in 4 weeks old lambs compared with 6 and 8 weeks old lambs. The hemodynamic effects of 1 and 1/2 ventricle circulation was significantly larger in 4 weeks old lambs. This result suggests that younger age with high PVR has potentially higher risk in this 1 and 1/2 ventricle animal model which is similar in babies undergoing SCP. Therefore this simple 1 and 1/2 ventricle animal model might be useful to investigate effects of drugs or devices to the single ventricle patients with SCP.

Table 1: Baseline data

<table>
<thead>
<tr>
<th></th>
<th>ABP (mmHg)</th>
<th>PAP (mmHg)</th>
<th>TPG (mmHg)</th>
<th>PVR (woods unit)</th>
<th>Aortic flow (mL/kg/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 weeks</td>
<td>536 ± 5.9</td>
<td>13.2 ± 2.9</td>
<td>10.0 ± 3.7</td>
<td>4.48 ± 1.56</td>
<td>177.7 ± 19.1</td>
</tr>
<tr>
<td>6 weeks</td>
<td>53.6 ± 7.9</td>
<td>14.0 ± 1.1</td>
<td>8.2 ± 1.6</td>
<td>3.52 ± 0.91</td>
<td>181.5 ± 26.5</td>
</tr>
<tr>
<td>8 weeks</td>
<td>53.4 ± 4.4</td>
<td>10.8 ± 2.4</td>
<td>7.0 ± 1.2</td>
<td>2.32 ± 0.23</td>
<td>166.8 ± 17.0</td>
</tr>
</tbody>
</table>

Table 2: Percent changes after 1 and 1/2 ventricle circulation (%)

<table>
<thead>
<tr>
<th></th>
<th>ABP</th>
<th>PAP</th>
<th>TPG</th>
<th>PVR</th>
<th>Aortic flow</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 weeks</td>
<td>-23.6 ± 4.9</td>
<td>11.8 ± 21.9</td>
<td>25.1 ± 29.1</td>
<td>88.6 ± 45.0</td>
<td>-33.0 ± 6.9</td>
</tr>
<tr>
<td>6 weeks</td>
<td>-9.5 ± 5.1</td>
<td>2.9 ± 13.5</td>
<td>12.4 ± 23.3</td>
<td>30.0 ± 21.3</td>
<td>-13.1 ± 8.6</td>
</tr>
<tr>
<td>8 weeks</td>
<td>-8.4 ± 6.9</td>
<td>3.6 ± 7.8</td>
<td>12.8 ± 20.4</td>
<td>23.2 ± 13.9</td>
<td>-10.8 ± 6.1</td>
</tr>
</tbody>
</table>
Impella CP Use For Left Heart Decompression While On ECMO In A Pediatric Patient

Study: We present a pediatric case of Impella CP use for left heart decompression while on ECMO.

Methods: This is a case report.

Results: A 17-year-old girl who underwent orthotopic heart transplantation 2 years prior for restrictive cardiomyopathy, presented acutely with symptomatic heart failure and severely decreased LV function and moderate pericardial effusion on echocardiogram. A diagnosis of acute graft rejection was made and she was started on high-dose steroids. She underwent pericardiocentesis and endomyocardial biopsy which was complicated by pulseless VT and cardiac arrest requiring femoral VA ECMO. On ECMO day 2, she developed 2nd degree heart block with minimal pulsatility requiring increased ECMO flows. The following day a TEE was concerning for thrombus related to the aortic sinus without evidence of coronary artery obstruction. On ECMO day 4, as her RV recovered function she developed bloody endotracheal secretions and pulmonary edema concerning for LA hypertension and underwent percutaneous Impella CP device placement for LV decompression via the right femoral artery. She was maintained on ECMO for a total of 15 days and Impella support for 11 days and had complete recovery of her LV function after concurrent treatment for cellular and antibody mediated rejection. Adverse events included significant bleeding from the Impella site, a hematoma by her left external iliac artery, and hemolysis evident by the 6th day of Impella support. She had repair of her L common femoral artery with an interposition graft at ECMO decannulation. She was awake and ambulated during that period and discharged.

Conclusion: The Impella device can successfully be used for left heart decompression while on ECMO in the pediatric population and may be considered as an alternative to balloon atrial septostomy in eligible patients.

Alternative Veno-Venous ECMO Cannulation Strategy On Children For Long-Term Ambulatory Support
K. Maeda,1 K. Ryan,1 C. Conrad,2 V. Yarlagadda1. 1Cardiothoracic Surgery, Stanford University, Stanford, CA, 2Pediatric Cardiology, Stanford University, Stanford, CA.

Study: Veno-venous (VV) ECMO has been widely used for severe lung diseases as a bridge to recovery or lung transplant. Sometimes long-term support is necessary, and ambulation during support is critical for recovery and transplant candidacy. In adults, a percutaneous dual stage double lumen VV cannula is commonly used. Ambulation and long term support in children can be difficult with this approach due to size limitations of the cannulae, recirculation, and lack of cooperation. We developed a new cannulation technique that prevents recirculation and allows for easier ambulation for children.

Methods: Case 1: A 5 year old, 28.6 kg previously healthy girl presented with necrotizing pneumonia with severe bilateral lung consolidation. She underwent percutaneous VV ECMO using 19 Fr Avalon® cannula. She was on percutaneous ECMO for 13 days, but due to inability to wean off sedation and inadequate flow, she was switched to central right atrium (RA) to right ventricle (RV) VV ECMO. A 9 mm Berlin Heart® cannula was inserted into the RA and a 6 mm Berlin Heart® cannula was placed in the RV. Cannulae were tunneled out to the upper abdomen and connected to the ECMO pump. She required ECMO for 74 more days before decannulation. She was awake and ambulated during that period and discharged.

Case 2: A 10 year old, 24.4 kg boy presented with idiopathic fibrosing pneumonitis. He underwent VV ECMO using 27 Fr Avalon® cannula. She was on percutaneous ECMO for 13 days, but due to inability to wean off sedation and inadequate flow, she was switched to central right atrium (RA) to right ventricle (RV) VV ECMO. A 9 mm Berlin Heart® cannula was inserted into the RA and a 6 mm Berlin Heart® cannula was placed in the RV. Cannulae were tunneled out to the upper abdomen and connected to the ECMO pump. She required ECMO for 74 more days before decannulation. She was awake and ambulated during that period and discharged.

Results: This novel central RA-RV VV ECMO cannulation using Berlin Heart® cannulae can be an alternative for children who are not suitable for dual stage VV cannula. This can be performed safely and prevents recirculation. It may be suitable for long-term ambulatory ECMO support as a bridge to recovery or lung transplant.
Direct Measurement Of Neonatal Cardiac Output Utilizing The Costatus Monitor


Study: Knowledge of cardiac output is a valuable tool in the treatment of critically ill patients. Often, cardiac output is measured indirectly using nonspecific clinical markers. Previous methods of direct calculation of cardiac output have involved considerable risk and have not been feasible in the neonatal population. The purpose of this study was to establish the feasibility of directly measuring cardiac output in a neonatal population using the COstatus monitor (Transonic Systems Inc., Ithaca, NY). This monitor provides measurements of cardiac output and hemodynamics via ultrasound dilution.

Methods: The ultrasound velocity of blood decreases with an injection of saline, producing a dilution curve. This monitor utilizes a system of an extracorporeal loop attached to arterial and venous lines to measure cardiac output. There are two clamp-on flow/dilution sensors and a small pump that circulates blood at 9mL/min. Two to three injections of 1mL/kg (3mL maximum) body temperature isotonic saline were injected into the venous loop, allowing for measurement of hemodynamic status.

Results: Cardiac output was measured 54 times in 12 neonates with no adverse events. Infants ranged in weight (0.72–3.74 kg), gestational age (24–41.3 weeks), and day of life (1–13 days). The mean cardiac output of this cohort was 0.43 L/min (SD 0.26) with a mean cardiac index of 197 mL/min/kg (SD 72). In addition, we collected data for central blood volume index, active circulating volume index, and systemic vascular resistance index (Table). The COstatus monitor also provides Qp/Qs and alerts to the presence of a possible shunt when providing the results of a measurement (Image). Our results show that cardiac output measurement via the COstatus monitor is feasible in a neonatal population. Minimal variance was exhibited for all parameters when taking consecutive measurements. Further studies are needed to establish normative cardiac output ranges in neonates, as well as trends during the first week of life.

Conversion Of Failed Single Ventricle Palliation To In Series Circulation And Total Artificial Heart

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Study: Mechanical circulatory support of the post-stage 1 patient poses many challenges. We present a case illustrating a new approach - atrial septation and a total artificial heart (TAH).

Methods: Our patient with hypoplastic left heart post-stage 1 with right ventricle to pulmonary artery shunt was on a second run of ECMO with anasarca and a chest that had been open six weeks. After conversion to bi-caval cardiopulmonary bypass (CPB) and aortic clamping, the ventricular mass and tricuspid valve (with annulus) were resected. This allowed expansion of the open atrial cuff. The atrium was septated with polytetrafluoroethylene (PTFE) patch, creating systemic and pulmonary venous atria. Ringed PTFE grafts were sewn to the newly created atrial cuffs. Berlin EXCOR 6mm cannulas were inserted inside the grafts. Outflow cannulas were connected to the aorta and a shortened Sano shunt to the pulmonary artery using short Dacron grafts. Cannulas were connected to 2 paracorporeal centrifugal pumps. Weaning from CPB was successful using flow probes on both circuits and right and left atrial pressure monitoring lines.

Results: Post-operative support has continued for 3 weeks showing adequate oxygen delivery with venous saturation of 70–80%, fully oxygenated arterial blood (pO2 > 100 mmHg), and estimated flows of both pumps with a cardiac index as low as 3 and as high as 5. Despite the high cardiac output and adequate oxygen delivery, poor vasomotor tone and anasarca has persisted requiring initiation of hemodialysis. Neurological testing has not revealed a significant injury and his neurologic exam is non-focal. For the post-stage 1 patient, atrial septation and creation of an in-series circulation with a TAH which provides excellent mechanical support is possible.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>CO, L/min</th>
<th>CI, mL/min/kg</th>
<th>CBVI, mL/kg</th>
<th>ACVI, mL/kg</th>
<th>SVRI, mmHg*kg/(L/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ± SD</td>
<td>0.43 ± 0.26</td>
<td>197 ± 72</td>
<td>16.6 ± 8.1</td>
<td>76 ± 13</td>
<td>16.4 ± 4.8</td>
</tr>
<tr>
<td>Range</td>
<td>0.11–0.82</td>
<td>125–435</td>
<td>8–40</td>
<td>53–100</td>
<td>5–22.5</td>
</tr>
<tr>
<td>Reproducibility (%)</td>
<td>8.16%</td>
<td>8.13%</td>
<td>8.95%</td>
<td>8.32%</td>
<td>8.59%</td>
</tr>
</tbody>
</table>

*Reproducibility is the coefficient of variation (SD/mean*100%) of consecutive measurements.
Kardiokid Infant Mannequin For Hands-On Training And Simulation
G. M. Pantalos, S. Hall, J. Snider, J. Heidel, A. Riggs, K. Hughes-Miller, K. Martin, C. Ziegler, J. Sparks, A. Calhoun. Cardiovascular Innovation Institute, University of Louisville, Louisville, KY.

Study: Skill and knowledge acquisition and retention is enhanced with high-fidelity, hands-on training, especially when life support technology, such as extracorporeal membrane oxygenation (ECMO) or ventricular assist devices (VAD), are part of the treatment plan. A current limitation to training is that critical care scenarios use either computer-based algorithms to simulate physiologic waveforms on a monitor as the critical care team runs through an exercise, or a simple fluid loop is used in a “wet lab” to teach fundamentals of device operation. While technically correct, these simulators lack clinical fidelity.

Methods: An infant scale circulation simulator mannequin called the “Kardiokid,” has been developed that incorporates key anatomic structures of the cardiovascular system while generating an ECG signal and pulsating physiologic atrial and great vessel pressures and flows (1.0 to 1.5 L/min) by pumping a blood analog fluid through the vasculature. Normal and heart failure hemodynamics can be created with the ECG and blood pressure waveforms acquired from Kardiokid displayed on an actual patient monitor originating from the clinical transducers connected to relevant anatomic locations.

Results: It is possible to cannulate this cardiovascular simulator with clinical cannulae used for veno-arterial ECMO, veno-venous ECMO, or VAD support and to initiate cardiopulmonary or ventricular assist support using clinical systems to maximize the fidelity of the training experience. Situations of change of physiologic status (e.g. hypovolemia, hypertension), anatomic defect (e.g. atrial septal defect), or support system malfunction (e.g. pump stop, cannula kink) can be introduced to add value to the simulation exercise. The goal of this improved simulator is to raise overall staff competence in dealing with a “hands-on” clinical situation requiring life support equipment by enhancing the training experience and to provide a more realistic tool to support root cause analysis for quality improvement.

The Artificial Placenta: Echocardiographic Evaluation In A Premature Lamb Model
M. Caceres Quinones, J. S. McLeod, P. Hala, B. Carr, C. Poling, R. H. Bartlett, G. B. Mychaliska. Department of Surgery, University of Michigan, Ann Arbor, MI.

Study: The Artificial Placenta (AP) is a potential solution for extremely premature infants using an extracorporeal life support system that maintains fetal circulation. There is no data of models describing the use of echocardiography during AP support. The aim of this study was to evaluate the feasibility of using echocardiography for functional assessment during AP support.

Methods: Using 2-D and Doppler Echocardiography we obtained data from premature lambs (n=4) delivered by caesarean section (119–121 days of gestational age) who required support with the AP after 1 hour of failed Mechanical Ventilation. Drainage and reinfusion cannulas were placed in the right jugular vein and umbilical vein, respectively. Functional evaluation of the fetal circulation, cannula placement and complications were assessed at the beginning and then followed up until the end of support. The evaluation included left and right heart function, fetal circulation patency, cannula position and major complications. We compared two groups (n=2 for each group), one supported for more than 48 hours with the ones who did not survived for more than 48 hours. We used descriptive statistics and t-test with p < 0.05 for significance.

Results: Average survival was 6.8 ± 6.7 days. Weight was 3.9 ± 0.3 Kg. No significant differences in the functional evaluation of the left and right ventricle were found (Table 1). Fetal circulation was patent in both groups during the whole support time. Ductus Venosus diameter was higher in the ≤ 48 hours group (p < 0.03) but there was no significant difference in the Ductus Arteriosus size between groups (p = 0.07). One of the lambs from the > 48 hours group developed ascites and one from the ≤ 48 hours group showed signs of Liver congestion. No complications related to cannula positioning were observed (Fig 1). We conclude that echocardiographic assessment of the fetal circulation, cannula placement and complications is a feasible strategy for the evaluation and follow up of premature lambs in a model of AP support.

![Fig 1. Echocardiographic 2D and Color Doppler Imaging](image-url)
A Pediatric Heart Valve Designed For Adaptation To Growth


Study: There are no heart valve prosthetics on the market designed specifically for young children. The overall goal of our work is to develop a pediatric heart valve that will serve the most critical unmet need (valve diameters <15 mm) and eliminate at least one major surgery as the child grows.

Methods: Our current focus is the design of a stent that can achieve passive expansion with somatic growth. Stent geometry and behavior were modeled to meet design constraints using finite element analysis (FEA). Proof of concept designs were manufactured in nitinol via laser cutting. Radial force testing at 37°C was performed on all 9 prototypes. The resulting data was used to update and validate the FEA model for future design iterations. For a complete device, a human femoral venous valve was sutured into the stent and tested for competency.

Results: Nitinol was chosen as the stent material for its super-elastic properties to enable a wide range of operational diameters. For the first design iteration, stent geometry was tuned to achieve low outward expanding forces and maintain a cylindrical shape for a 2-fold change in diameter (5–10 mm; long-term target of 7–14 mm). Stent length was restricted to 15 mm and additional design features were implemented for ease of use in pediatric open heart surgery. Radial force testing revealed that the manufactured prototypes displayed reproducible behavior and provided a baseline of average material properties for FEA model iterations. After integration of a femoral venous valve into the stent (Fig. 1), valve competency via passive backfilling was demonstrated at the fully expanded diameter of 9.5 mm. Additional plans for first generation prototypes include testing valve function at multiple diameters (6–9.5 mm) and compressed stent behavior within ex vivo heart tissue. Current stent designs are being refined to improve manufacturing and valve integration. Next generation devices will be used in further bench testing and implantation in a growing animal model.

Consider Kidney When Accepting Hearts: Impact Of Donor Renal Dysfunction On One-Year Survival In Children

A. Sood, R. Rizwan, F. Zafar, Y. Radzi, D. Morales. Cincinnati Children’s Hospital Medical Center, Cincinnati, Ohio, Cincinnati, OH.

Study: Recipient renal dysfunction has been shown to negatively affects pediatric heart transplant (HTx) outcomes. However, the effects of donor renal dysfunction on HTx outcomes in children are not known. This study describes the effects of donor renal dysfunction on HTx outcomes in children.

Methods: All pediatric (≤17y) HTx from United Network for Organ Sharing database from October 1989 to June 2015 were identified and divided into two groups based on the donor’s glomerular filtration rate (GFR): ≥30 ml/min/1.73m2, “GFR≥30”, & <30 ml/min/1.73 m2, “GFR<30”. Post-HTx 1y survival & long-term survival conditional on 1y were compared between the groups. Multivariate analysis was performed to determine the effect of donor GFR on 1y mortality.

Results: Of 6,630 HTx, 6,143 (93%) were in GFR≥30 group, while 487 (7%) were in GFR<30 group. GFR<30 had worse 1y post-HTx survival compared to GFR≥30 (84% vs. 89%, p=0.004). Long-term survival conditional on 1y was similar between the two groups (p>0.05). Multivariate analysis showed that recipients with ventilator support at transplant and congenital heart disease (CHD) diagnosis were more likely to accept a donor with GFR <30 ml/min/1.73m2 (Odds Ratio, OR: Ventilator 1.59 (1.26–2.00), p<0.001, CHD 1.72 (1.42–2.08), p<0.001). Even in these patients, 1y survival is worse for GFR<30 group compared to GFR≥30 group (CHD: 79% vs 83%, p<0.001; ventilator: 73% vs 78%, p<0.001). In a multivariate model, receiving a donor with a GFR <30 ml/min/1.73m2 was associated with 1y mortality irrespective of recipient’s diagnosis (OR: 1.30 (1.00–1.70), p=0.047).

Conclusion: For HTx, severe donor renal dysfunction adversely affects 1y post-transplant survival. Such donors appear to be accepted for recipients with poor waitlist outcomes such as those with CHD and ventilator support. However, these high-risk cohorts also show worse 1y survival if transplanted with a donor with severe renal dysfunction compared to a donor with better GFR.
Current Status Of The Penn State Infant VAD

1. Surgery, Penn State College of Medicine, Hershey, PA, 2Pediatrics, Penn State College of Medicine, Hershey, PA, 3Comparative Medicine, Penn State College of Medicine, Hershey, PA, 4NIAID, Bethesda, MD.

Study: Mechanical circulatory support for children under 6 years of age remains a challenge. Development of the Penn State Infant VAD started with the Pediatric Circulatory Support contract program in 2005 and subsequently continued through other NIH grant mechanisms. The device features physiologic pulsatile flow, simple preload-sensitive automatic control of pump flow, and cannulation flexibility in providing left, right, or biventricular support, in the setting of congenital anatomic variability.

Methods: The Infant VAD was implanted as a left ventricular assist device (LVAD) in 18–29 kg lambs. 12 LVAD and 5 surgical sham animals were electively terminated after approximately 30 or 60 days. Anticoagulation was by unfractionated heparin targeting thromboelastography (TEG) R times of 2x normal (n=6) or 1x normal (n=6) resulting in negligible heparin activity as measured by anti-Xa assay (<0.1 IU/ml). Statistical t-Test comparing two-samples assuming unequal variances (p < 0.05) was used to compare means of pre and post-operative (>2weeks) data for all the LVAD animals combined, or LVAD and Sham data.

Results: There were no clinically evident strokes or evidence of end organ dysfunction in any of the 12 electively terminated studies. There was no statistical difference between pre and postoperative plasma free hemoglobin, PTT, ACT, platelet aggregation, BUN or creatinine. The % of high molecular weight von Willebrand in the pre-op period (31 ± 6 %) was statistically higher than that in the postop period (22 ± 3%), but the distribution of postop samples remained normal in 15 samples and borderline in 1. The degree of renal ischemic lesions in device animals was not significantly different than that found in 5 surgical sham studies. Five systems tested in the durability loop at ~100 beats/min run for 2811 cumulative days (electively stopped after 379 to 675 days). These results demonstrate reliable performance and minimal device thromboembolism obtained in a very challenging test of low to no anticoagulation.
Berlin Heart Excor Thrombosis Behavior
S. M. Shea, K. Spitzer, M. Carroll, D. N. Ku, S. Deshpande.
Georgia Institute of Technology, Atlanta, GA, Perfusion Services, Children’s Hospital of Atlanta, Atlanta, GA, VAD Program, Children’s Hospital of Atlanta, Atlanta, GA, GWW School of Mechanical Engineering, Georgia Tech, Atlanta, GA, Pediatric Cardiology, Georgia Institute of Technology, Atlanta, GA.

Study: We present patient-specific data on thrombosis location and history in the EXCOR.

Methods: The Berlin Heart log was used to collect data on thrombosis. The pump was examined for deposits which were recorded in real time by clinicians. We reviewed the logs, neuro events, and outcomes for 10 pts. Thrombi were given a numeric strength converted from the letter key provided by Berlin Heart. The pump is divided into numbered sections based on the provided log diagram. Pt data is presented using area plots. A normalized incidence of thrombosis was calculated. ANOVAs were performed in MATLAB to look for significance across pump sections.

Results: Logs were reviewed for 10 pts for a total of 775 pump days. All of the pts were maintained per the Edmonton protocol. No mortality occurred, and all pts were bridged to transplantation. All pumps had thrombosis. Thrombosis incidence over time for one pt is shown in Fig 1. There was no relationship with the level of anticoagulation and thrombosis. Cumulative thrombus burden is shown in Fig 2. Normalized incidence of thrombosis in individual sections is shown in Table 1. Sections 9, 10 (outflow), and 3 (inflow) had the highest incidence of thrombosis followed by sections 2 and 6. Sections 7 and 11 (edge of pump, outflow) were consistently low in thrombus across all pts. Multiple sections often develop thrombus concurrently (Fig 1). Thrombus formation in the EXCOR occurs only in a few specific areas. Since materials are similar throughout the pump, flow and design changes may reduce thrombus formation in the troublesome spots.

Fig 1. Thrombosis incidence over 24 days in one pt. Incidence is separated by pump section. S indicates a stroke. C indicates a pump change. Inset is a diagram of the pump with the sections labeled by number. The sections are colored according to intensity of thrombosis burden (Table 1).

Table 1. Normalized incidence of thrombosis by section. Red and orange boxes indicate high thrombus (inflow and outflow). White and green boxes denote the lowest incidence.
Peri: Infant Phantom For Pericardial Access With Direct Visualization

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Study: Pericardiocentesis is a lifesaving procedure requiring percutaneous access of the pericardial space through a subxiphoid approach, often with ultrasound guidance. Procedural risks such as needle puncture to the myocardium or surrounding organs can cause serious complications. To minimize these risks, we created Peri, an infant phantom for pericardiocentesis under direct visualization. Our hypothesis is direct visualization will better educate inexperienced cardiologists in gaining pericardial access in infants.

Methods: A hard plastic, hollow body doll was used to create a 2-month-old infant phantom (Fig 1a). A 1.25” by 2” window was cut into the abdomen of the doll, and the chest surface was mapped to create a chest plate. Urethane foam (Rogers Solutions) 0.25” thick was used as a skin window and secured in place with the chest plate. In the back of the doll, a 3.25” by 4” window was cut out and replaced by a 3D printed removable back plate. A 3D heart model was segmented from a CT scan using Mimics Research software and printed with a plastic and rubber material blend (Stratasys Inc.). The heart was placed inside a lambskin condom to mimic the pericardium and fixated to a stand on the back plate using magnets. Two clinical fellows used Peri to access the pericardial space 3 times. With the phantom in the supine position, a trocar was inserted in the subxiphoid area, and a thoracoscope was used to visualize the thoracic cavity and surrounding structures (Fig 1b), which was notably similar to in-vivo images (Fig 1c).

Results: Both fellows accessed the pericardium in 3.28 mins and 2.28 mins respectively, which was confirmed with saline injection into the pericardial space. After the procedure, both fellows were given a questionnaire in which they “strongly agreed” direct visualization improved confidence in executing the percutaneous technique. Future studies are needed to demonstrate training with ultrasound plus direct visualization is better than ultrasound alone.

Stent Angioplasty Of The Ductus Arteriosus As An Early Palliative Procedure For Pulmonary Atresia: Single Institution Experience

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Study: Pulmonary atresia (PA) is a congenital heart defect that consists of a complete underdevelopment of the pulmonary valve and thus no antegrade pulmonary blood flow. The entire pulmonary circulation is dependent on the persistence of the ductus arteriosus (DA). In fact, during fetal development blood flows through the DA in a reversed direction, subjecting it to abnormal forces that result in a tortuous shape and an acute angle between the DA and the descending aorta. In consequence, the angiographic approach is difficult when attempting stent angioplasty (SA) to guarantee pulmonary blood flow. The aim of this study was to define the clinical characteristics of patients with pulmonary atresia intervened with SA as a first stage in the development of medical devices for this procedure.

Methods: A retrospective cohort of patients diagnosed with PA and intervened with SA at Fundación Cardioinfantil, between 2009 and 2017 was analyzed. Demographic characteristics, the frequency of diagnosis, procedure type and morphologic characteristics of the DA were evaluated.

Results: During the study period, 60 patients had an echocardiographic diagnosis of PA. The results are presented in Table 1. In addition to the descriptive results obtained, a pulmonary branch growth was observed after SA as well as an increase in McGoon index. Furthermore, data showed a 50% freedom from reintervention at 6 months after SA, time that was considered enough so that patients could be taken to a second stage or corrective procedure. The results obtained have given us preliminary insights about the clinical and morphologic characteristics of the DA in pulmonary atresia and have defined SA as an effective early stage palliative procedure. The complete characterization will assist the development of medical devices such as guiding catheters and stents for effectively performing this palliative treatment in every DA despite its different and tortuous morphology.

Table 1. Descriptive results.

<table>
<thead>
<tr>
<th>Diagnosis of PA</th>
<th>n = 60</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex, female n (%)</td>
<td>28 (46.7)</td>
</tr>
<tr>
<td>Age days, median</td>
<td>12.50</td>
</tr>
<tr>
<td>Weight kg, mean (SD)</td>
<td>3.3 (2.0)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Diagnosis, n (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>PA + Ventricular septal defect</td>
<td>14 (23.3)</td>
</tr>
<tr>
<td>PA + Intact ventricular septum</td>
<td>33 (55)</td>
</tr>
<tr>
<td>PA + Others</td>
<td>13 (21.7)</td>
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</table>

<table>
<thead>
<tr>
<th>Procedure, n (%)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>SA</td>
<td>39 (65)</td>
</tr>
<tr>
<td>SA + pulmonary valvuloplasty</td>
<td>12 (20)</td>
</tr>
<tr>
<td>Failed SA</td>
<td>3.0 (5.0)</td>
</tr>
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<td>SA + atrioseptostomy</td>
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<td>Other</td>
<td>4.0 (6.6)</td>
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<table>
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<td>DA diameter, mm</td>
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<td>DA longitude, mm</td>
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<td>Left pulmonary branch diameter postSA, mm</td>
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<tr>
<td>McGoon index, postSA</td>
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<td>Freedom from reintervention at 6 months % (SD, months)</td>
<td>50 (2.34)</td>
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</table>
Hepatic Effects After Support On The Artificial Placenta
J. S. McLeod,1 J. T. Church,1 B. Carr,1 C. Poling,1 M. Caceres Quinones,1
P. Hala,2 E. M. Perkins,2 R. Rabah,3 M. A. Arnold,4 R. Bartlett,1 G. B. Mychaliska4. 1Surgery, University of Michigan, Ann Arbor, MI, 2Rush Medical College, Chicago, IL, 3Pediatric and Perinatal Pathology, CS Mott Children’s Hospital, Ann Arbor, MI, 4Division of Pediatric Surgery, CS Mott Children’s Hospital, Ann Arbor, MI.

Study: The Artificial Placenta (AP) offers a potential solution to the problem of prematurity by providing extracorporeal life support while fetal circulation remains intact. The AP’s effects on the liver are unknown. The aim of this study was to evaluate hepatic effects after AP support.

Methods: Premature lambs were delivered (119-121d; term=145d) and either placed directly on the AP (n=3) or transitioned to the AP after respiratory failure on the ventilator (n=3). Drainage and reinfusion cannulas were placed in the right jugular vein and umbilical vein, respectively. Early (ETC; 115-121d) and late (LTC; 125-131d) tissue controls were delivered and immediately sacrificed. TPN with Intralipid® was used for nutritional support while on the AP. After experiments, livers were prepared with H&E stains. Livers were scored by a pathologist for cholestasis, hepatocyte injury, congestion, fatty change, and amount of extramedullary hematopoiesis (EMH) (0-none; 1-mild; 2-moderate; 3-severe). Descriptive statistics and t-tests were used to compare groups. P<0.05 was considered significant.

Results: Average survival was 15 ± 3 days. Average weight was 2.94 ± 0.51 kg. AP livers exhibited significantly more cholestasis (2.7 ± 0.8) compared to ETC (0.0 ± 0.0; p=0.001) and LTC (0.0 ± 0.0; p<0.001). One AP lamb had moderate hepatocyte injury; however, there was no significant difference between the AP group (0.3 ± 0.8) and the tissue controls (ETC 0.0 ± 0.0; p=0.30; LTC 0.0 ± 0.0; p=0.30). More hepatic congestion was found in the AP group (1.0 ± 0.9) than ETC (0.0 ± 0.0; p=0.01) and LTC (0.0 ± 0.0; p=0.01). Fatty changes in the AP group (0.7 ± 1.0) were not significantly more than ETC (0.0 ± 0.0; p=0.11) and LTC (0.0 ± 0.0; p=0.11). There was significantly more EMH in both ETC (1.0 ± 0.0) and LTC (1.0 ± 0.0) compared to the AP group (0.2 ± 0.4; p<0.001). Representative images are shown in Figure 1. The cholestatic changes may be due to the use of Intralipid®, a soybean based fat emulsion. The difference in EMH may reflect maturity of the liver during AP support.

Figure 1. Hepatic Changes during Artificial Placenta Support
A. Healthy Tissue Control with Mild Extramedullary Hematopoiesis (Score 1)
B. Severe Cholestasis (Score 3) and Moderate Fatty Changes (Score 2)
C. Moderate Hepatocytic Injury and Necrosis (Score 2)
A Successful Bridge To Lung Transplantation Record
C. H. Wigfield,1 C. Alex,2 1Lung Transplantation, Advocate Christ Medical Center, Oak Lawn, IL; 2Lung Transplantation, Charles Alex, Oak Lawn, IL.

Study: The utility of ECMO in acute respiratory failure is established. VV and VA support options have a role as bridge to lung transplantation (LTx). We report a record support duration demonstrating the scope and sustainability for patients with complex medical management with successful LTx after 6 months ECMO dependence.

Methods: Case report with device support review, surgical and critical care management assessment. The pre transplant evaluation phase and LTx procedure is discussed.

Results: A 47 yo driver sustained multiple life-threatening injuries requiring pelvic fixation, several open skeletal and abdominal surgeries as well as median sternotomy for hemoperricardium. During the prolonged critical care phase he developed ARDS requiring VV-ECMO support. Recurrent oxygenation insufficiency resulted in re-cannulation and eventually VA support via PA graft. Despite multiple systematic attempts the patients could not be separated from the ECMO circuit during the prolonged recovery phase. Multiple metabolic derangements and secondary organ impairments were corrected with further unsuccessful efforts to wean the ECMO due to manifest fibrotic lung damage. Detailed evaluation and pre-listing optimization of the patient included extubation and mobilization with continued ECMO support. Intense physiotherapy and pulmonary exercise regime was required to re-instate breathing pattern and muscle strength. Strategic LTx planning included a single LTx performed and a priori post-operative ECMO continuation. The total support time on ECMO was xxxx days. The LTx was complicated by ISHLT grade 2 primary graft dysfunction. He was successfully bridged to recovery with ECMO separation at xxx days. The patient was discharged to rehabilitation and is home, now over 8 months post transplant.

Conclusions: The case presents a record duration for successful bridge to LTx with ECMO support. Exceptional efforts and perseverance with motivated patients may result in survival and functional status despite complex adversity.

A Novel Application For PFC-Based Fluids: Oxygenator Performance Tests
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Study: The design of membrane oxygenators is a complex process. One essential part to evaluate the devices are performance tests which are currently performed in vitro using animal blood. In order to reduce the effort of these performance tests, we propose a technical fluid as a blood substitute. For testing of design iterations, this would also facilitate the use of rapid prototyping materials to which blood often reacts poorly. Hence, the time and cost efficiency of the design process will increase. The proposed blood substitute should have the same characteristics as blood regarding fluid dynamics and gas exchange. Here, a proof of concept of the use of perfluorocarbon (PFC) based emulsions in an oxygenator performance test is presented. These fluids consist of highly viscous droplets in a Newtonian liquid and show high oxygen transfer rates, both similar to blood.

Methods: Emulsions consisting of PFC, distilled water, and Pluronic F-68 as emulsifier were manufactured by high-pressure homogenisation. The fluids were characterised regarding droplet size, viscosity, and oxygen transfer rate. Droplet size was measured by laser diffraction spectroscopy and viscosity by means of a cone-plate rheometer. The oxygen transfer rate was characterised in a test loop based on ISO 7199, in which the dissolved oxygen was measured by two clark electrodes. Additionally, the volume fraction of PFCs in the fluids was varied: 20 vol% and 50 vol%.

Results: The fluid shows a shear dependent viscosity, qualitatively similar to blood (see fig. 1). The difference is ascribed to the small droplet size (max 139.3 nm). The oxygen transfer rate was characterised in a test loop based on ISO 7199, in which the dissolved oxygen was measured by two clark electrodes. Additionally, the volume fraction of PFCs in the fluids was varied: 20 vol% and 50 vol%.

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A New Model For Developing An Ex Vivo Lung Perfusion Program
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Study: The shortage of quality donor lungs remains a major limitation for lung transplant programs. Despite performing over 700 lung transplants at our institution, there is a significant wait list time for our patients. EVLP is currently being investigated as a method to increase the donor pool. Given our high volumes, we are unable to allocate perfusionists for the EVLP program and considered an alternative model with trained EVLP specialist nurses. We describe our experience starting an EVLP program with this model.

Methods: Our EVLP program was started as part of the multicenter study using the XVIVO® machine (Novel trial). Ten ICU nurses were trained to set up and run the machine. Ten unsuitable-for-transplant lungs were procured for training purposes. The cannulation techniques, pump run and lung assessment protocols were standardized. Following training runs, all personnel were credentialed and systems were put in place including rosters for the EVLP surgeon, pulmonologist and nurses. The setup and EVLP run was done by the EVLP nursing team per protocol.

Results: Six pairs of lungs, four from DCD donors and two from brain dead patients were procured with the intention to transplant. The four DCD lungs showed progressive improvement in all physiologic parameters. Three of these lungs were successfully transplanted and one was declined as patient withdrew consent. The other two pairs were turned down for progressive worsening of physiologic parameters with frothy secretions on bronchoscopy and worsening lung radiographs. There were no issues with management of the EVLP circuit. In summary, we successfully established a new EVLP program using a unique multidisciplinary model that involved key participation from the nursing staff and pulmonologists. We find this model is a feasible, safe and sustainable method to establish a successful EVLP program.

In Vitro Evaluation Of Hemocompatibility Of MPC Coating For Membrane Oxygenator Application
S. Song, J. Kim, C. Hwang. Biomedical Engineering Research Center, Asan Medical Center, Seoul, KOREA, REPUBLIC OF.

Study: Anticoagulation of membrane surface is essential to not only reducing complications but also extending longevity of oxygenator service life. The MPC material has been reported as a suitable choice of coating to improve hemocompatibility. In this study, we aimed to fabricate hemocompatible membrane oxygenator through synthesis, coating and in vitro evaluation of MPC coating on in house developed membrane oxygenator.

Methods: To improve stability of MPC coating layer, MPC was polymerized with hydrophobic and crosslinkable functional group, with butyl-methacrylate(BMA) and silane-methacrylate(SMA) respectively. MPC, BMA and SMA was copolymerized with reflux and precipitation process and PMB(MPC-co-BMA) and PMBS(MPC-co-BMA-co-SMA) copolymer powder was achieved. PMB, PMBS1%, 2% and 5% were synthesized to optimize hemocompatible coating compound. Hemocompatibility of PMB and PMBS coated cover slips were evaluated with protein adhesion, platelet adhesion with fibrinogen solution and fresh human blood plasma. For in vitro blood compatibility test, membrane oxygenator was fabricated with polymethacrylic housing filled with polymethylpentene hollow fiber membrane and potted with centrifuge. In vitro recirculating blood test loop were filled with whole blood and circulated for up to six hours.

Results: The SEM images indicated that PMBS has more stable than PMB coating under the conditions of this study. The lower protein adhesion was observed in both PMB and PMBS group. According to these results, we suggested that the 2 percent of PMBS is the best option for membrane surface coating then we coated with PMBS2% for in vitro test. Comparisons of coagulation test results indicated that the anticoagulation was improved in the PMBS2% coated membrane. These results can be applied to medical devices required high hemocompatibility including blood oxygenator. This research was supported by the Ministry of Health & Welfare, Republic of Korea (HI14C0746, HI14C0517)
Successful 30-Day Sheep Studies Of A Wearable Pumping Artificial Lung

**Study:** The Paracorporeal Ambulatory Assist Lung (PAAL) is an oxygenator and blood pump integrated into a compact unit that is wearable and enables patient mobility. The PAAL is meant to provide long term respiratory support as a bridge to transplant or recovery. This work aims to evaluate the extended in vivo performance of the PAAL in a 30-day sheep study.

**Methods:** The PAAL was connected to healthy adult sheep via cannulation of the right external jugular with a dual lumen cannula. PAAL pump speed was set at the highest setting possible without frequent suction and kept constant throughout the study. Following surgery, sheep were recovered and housed in a fixed tether pen while wearing the PAAL in a holster. Anticoagulation was maintained via a continuous heparin infusion. PAAL blood flow rate was measured continuously while device blood gases were taken at least twice per week. Blood cell counts, chemistry, plasma free hemoglobin (PfHb), and platelet/leukocyte activation were measured weekly.

**Results:** Two of three animals survived the study duration without device exchange. PAAL blood flow rates were variable early in the study before stabilizing at 1.3–2.1 L/min over the final two weeks. Blood at the PAAL outlet was always fully saturated and trends in oxygenation were primarily determined by blood flow rate. PfHb did not substantially increase relative to baseline values with the exception of an increase following a blood transfusion. Platelet and leukocyte activation remained less than 20% for all animals. Explanted devices exhibited minimal thrombus deposition on the fiber bundle and more significant thrombus underneath the impeller. Complications were acceptable and included the following: a hematoma in one animal lead to anemia and required a blood transfusion and the third study was prematurely terminated on postoperative day 8 due to a fractured cannula (corresponding data excluded from primary analysis). This study is ongoing, but results thus far indicate positive PAAL performance in an extended use setting.

Development Of An Ultra Compact Durable Ecmo System With Built-In Monitors And Long-Term Evaluation In Chronic Animal Experiments For 4 Weeks
N. Katagiri, Y. Takewa, T. Tsukiya, T. Mizuno, D. Takeshita, D. Akiyama, E. Tatsumi. Artificial Organs, National Cerebral and Cardiovascular Center Research Institute, Suita, Osaka, JAPAN.

**Study:** ECMO system has been used for over days to weeks to treat patients with severe respiratory/circulatory failure, while device exchanges and complications due to its poor durability and thrombo-resistant property are still risks in long-term use. In addition, lack of portability and operability due to large and complicated apparatus are also problematic issues. We have been developing a compact durable ECMO system which can solve these problems. In this study, we developed a prototype of a compact ECMO system with built-in monitor functions and evaluated its durability and biocompatibility in a series of chronic animal experiments.

**Methods:** This system is consisted of a pre-connected blood circuit unit, a pump driver unit integrating with measurement instruments and a gas bomb unit. Prototype of the circuit unit was consisted of a centrifugal pump (BIOFLOAT NCVC) with hydrodynamically bearings, a membrane oxygenator (BIOCUBE6000) and built-in sensor connectors. The entire blood-contacting surface of the circuit was treated with heparin bonding material (T-NCVC). Prototype of the driver unit was made as extremely compact (W290 x D205 x H260 mm, 6.6 kg). Veno-arterial bypass ECMO using the prototype system was conducted for 4 weeks using adult goats (48.0, 49.5, 49.0 kg). Heparin was continuously administrated to control ACT between 150–200 sec.

**Results:** In all cases, the ECMO could run for 28 days without any device exchange and monitored stably. 2.5 L/min of bypass flow rate could be maintained stably. O₂ and CO₂ transfer rates were kept at sufficient levels (134 ± 30 and 111 ± 21 ml/min, respectively). After the experiments, thrombus formation was hardly observed in the each blood circuits including the built-in sensor connectors. In conclusions, the ultra compact ECMO system was developed and demonstrated long-term durability, stability of monitor function and thrombo-resistant property for 4 weeks.
A Low-Cost, High-Throughput Methodology For Assessing Anticoagulants And Surface Coatings For Artificial Lungs

Study: Hemocompatibility testing of surface coatings and anticoagulants using protein solutions or platelet-rich plasma are of limited value because 1) results vary from in vitro or in vivo whole blood studies and 2) evaluation of surfaces at single time-points can be misleading. Animal studies, on the other hand, would be ideal to avoid due to the ethical and monetary cost. To address these issues, the effectiveness of a low-cost, high-throughput, in vitro, whole blood method for evaluating new anticoagulants and surface coatings was examined.

Methods: PDMS-coated polypropylene (PP) fiber samples (0.25" x 0.5") are placed in 1.5 mL PP tubes. The fiber is exposed to ovine whole blood in the tube and shaken on a rocker plate for 15, 30, 60, or 90 minutes under different treatments (i.e. drug doses, surface types). Each condition is done in triplicate. The log of average weight change across replicates is recorded. Here we report results from heparin (0, 0.25, 1, 2 U/mL), rivaroxaban (0, 0.18, 0.54, 0.88 μg/mL), and bovine serum albumin (BSA) coating. For the BSA case, both tube and sample are soaked in 40 mg/mL BSA for 1 hour before the experiment, and blood is heparinized to 0.25 U/mL.

Results: The weight change for the heparin case was correlated with longer incubation time and lower drug dose (p < 0.001, Fig 1). The 0.25 U/mL heparin showed benefit in the first 30 minutes but did not differ from the 0 U/mL case after the 60-minute mark, highlighting the importance of evaluating at multiple time points. A similar trend was seen in rivaroxaban (p < 0.01, not shown). The results from BSA coating vs. uncoated (Fig 2) suggest that there may be only mild benefit of the coating in the first 30 minutes, and this wears off after 60 minutes. The temporary effect may be due to the displacement of BSA by other plasma proteins. Future studies will investigate the effectiveness of new, zwitterionic coatings using this method.

![Figure 1: The effect of heparin (N = 8) on fiber weight change over time](image)

![Figure 2: The effect of BSA coating (N = 7) on fiber weight change over time](image)

An Advanced Lumped Parameter Model For The Simulation Of ECMO Therapy
K. Hugenroth, S. Groß-Hardt, M. Neidlin, U. Steinseifer, T. Schmitz-Rode, J. Arens. 1Department of Cardiovascular Engineering, RWTH Aachen University, Aachen, GERMANY; 2Monash Institute of Medical Engineering and Department of Mechanical and Aerospace Engineering, Monash University, Melbourne, AUSTRALIA and Department of Cardiovascular Engineering, RWTH Aachen University, Aachen, GERMANY.

Study: Lumped parameter models (LPM) are representations of the cardiovascular system utilizing analogies to the electric circuit. The advantages of these models compared to 3D simulations include low calculation times and the possibility to rapidly gain an overview of the hemodynamic conditions in the whole circulatory system of a specific patient. The aim of this work was to develop a LPM of the cardiovascular system which, in contrast to other models, includes oxygen and carbon dioxide transport as well as the mechanism of autoregulation (vasodilation and vasoconstriction). These effects play a major role in ECMO applications.

Methods: A LPM of the flows and pressures in the cardiovascular system was developed based on existing models and subsequently supplemented by a model of gas exchange as well as autoregulation. It was then tested with clinical data for a healthy cardiovascular system as a basis for further extensions, which included simulations for patients on ECMO support. All model extensions were validated using clinical data.

Results: The modified LPM is able to reproduce the dynamic behavior observed in the cardiovascular system. The flow, pressure and gas exchange results were verified by clinical data. The model describes not only the hemodynamic conditions, but also the oxygen saturation in the cardiovascular system. It can thereby simulate key factors for ECMO therapy and facilitate the decision on new therapy strategies. Moreover, the simulation times are very low, making it a valuable tool for the calculation of transient boundary conditions for 3-D simulations in order to achieve additional results with high temporal and spatial resolution.
Technical Indicators To Evaluate The Degree Of Large Clot Formation Inside The Membrane Fiber Bundle Of An Artificial Lung In An In Vitro Setup

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Study: One of the most common technical complications with ECMO is clot formation. Clots within membrane oxygenators (MOs) lead to an increase in blood flow resistance and reduced gas transfer capabilities. In up to 27% of patients on long-term ECMO a device exchange is required, despite systematic anticoagulation and surface coating. Dornia et al. investigated heparin-coated MOs after ECMO with Multidetector Computed Tomography. A major area for clot formation was identified close to the blood inlet in the venous part inside the devices. However, thrombus formation did not correlate with ECMO support time or any patient characteristics.

Methods: Based on these findings we designed a study that focuses purely on technical, MO specific parameters, such as the membrane oxygenator pressure drop (dpMO) and the O₂ and CO₂ gas transfer. The aim of this study was to investigate whether a range of large clot volumes can be correlated with the dpMO as well as the gas transfer performance to identify a reduction in device performance early. Based on clot positions and sizes reported by Dornia et al., silicone clots with a volume of 30–85 mL were introduced into the venous part inside the devices. The performance of a total of six Quadrox-i Adult MOs was tested in vitro with fresh heparinized slaughterhouse porcine blood at blood flow rates of 0.5, 1, 2, 2.5, and 5 L/min, refer to Fig 1.

Results: dpMO increased with silicone clot size as expected. For a blood flow rate of 5 L/min a reduction in dpMO transfer rate of 12.7% from 315 to 275 mL/min was observed for a clot sizes increase from 0 mL to 85 mL. However, a decrease in CO₂ exhaust gas concentration was observed even for low blood flow rates, refer to Fig 2. Experiments are currently repeated to get more evidence. These preliminary results suggest, that monitoring the CO₂ exhaust gas at the MO gas outlet combined with monitoring of the dpMO during patient treatment could be an earlier indicator for thrombus formation in the future.

OCS Ex-Vivo Lung Perfusion Maintains Endothelial Integrity Associated With Reduced Severe PGD Grade

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Study: INSPIRE trial revealed significant reduction of PGD grade 3 using the Organ Care System (OCS) for lung preservation compared to controls. In order to analyze endothelial mechanisms initiated by cold vs. normothermic preservation, blood and perfusate samples of INSPIRE patients were assessed for proteins involved in endothelial integrity.

Methods: Plasma pre Tx, at T0, T24 and perfusion solutions (PS) from 33 OCS patients and 26 control patients were analysed for 100 cytokines, angiogenic factors, soluble receptors and serum proteases by multiplex protein assays. Donor and recipient demographics, total cold ischemic times (CIT) and PGD grades were assessed and correlated with protein levels.

Results: Clinical evaluation (OCS/control) revealed recipient age 50/49 years, diagnosis: idiopathic fibrosis (n=17/10), cystic fibrosis (n=7/8), pulmonary hypertension (n=3/3), emphysema (n=6/5), CIT 258/549 min. OCS group indicated no cumulative PGD grade >2 compared to 19% PGD grade 3 in the controls. Our previous data showed less IRI by significantly reduced immune modulators (e. g. IL-6, IL8, CXCL10) in OCS. Additionally, OCS plasma levels at T0 were significantly lower for sCD31, ICAM-1, PAI-1, leading to a higher PAI-1/uPA ratio of 82, which correlated with warm preservation but not with CIT compared to 67 in controls. Moreover, lower VCAM-1, IGFBP-1, Ang-2, uPA, sHer2/neu, sVEGFR2 concentrations were detected in OCS. Plasma levels of ligands for endothelial receptors, e. g. endoglin and PIGF correlated with CIT. In contrast to IL-6, there was no correlation of these proteins to PGD in controls. Of note, in OCS, none of these proteins correlated with CIT. In PS, significantly higher concentrations of these proteins were measured, indicating similar negative feedback loops as described for cytokines. Normothermic lung preservation initiates an anti-inflammatory cascade and a tissue-protective milieu resulting in an improved graft function and reduced IRI.
Refractory Hypoxemia During VV ECMO: Are 2 ECMO Circuits better Than One?


- Burn Center, US Army Institute of Surgical Research, Fort Sam Houston, TX, Department of Medicine, Brooke Army Medical Center, Fort Sam Houston, TX, Department of Surgery, Brooke Army Medical Center, Fort Sam Houston, TX, Multi-Organ Support Technology Task Area, US Army Institute of Surgical Research, Fort Sam Houston, TX, Traumatology, Surgical Critical Care and Emergency Surgery, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA.

Study: The Extracorporeal Life Support Organization algorithm for optimizing blood flow and gas exchange in patients on venovenous extracorporeal membrane oxygenation (VV ECMO) recommends increasing cannula size, adding an additional drainage cannula, decreasing patient temperature, and the use of neuromuscular blocking agents (NMBA) if oxygenation goals are not being met. We report a case of refractory hypoxemia that was treated with the addition of a second ECMO circuit.

A 16 year old male with a 76% total body surface area burn developed severe ARDS. The patient was placed on VV ECMO with a right femoral vein 29 French (F) multi-stage drainage cannula and a right internal jugular vein 23 F return cannula. Despite an adequate blood flow rate of over 4 liters per minute (LPM) and a sweep gas flow of 11 LPM using a Cardiohelp device.

On ECMO day 6 the decision was made to add a second 25 F drainage cannula in the left femoral vein and a 21 F return cannula in the left internal jugular vein with these cannulas being connected to a second Cardiohelp device.

Results: Within 24 hours of dual ECMO therapy, the patient’s oxygenation improved, vasopressors were discontinued, and lactate decreased while he was on concomitant CRRT with 500ml/hr of ultrafiltrate removal. See Table 1. Addition of a second ECMO circuit can improve oxygenation and hemodynamics in the setting of refractory hypoxemia when management has been previously optimized. Table 1. Summary of Gas Exchange and Hemodynamic Improvements with the Addition of a Second ECMO Circuit.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>With 1 ECMO Circuit</th>
<th>With 2 ECMO Circuits</th>
</tr>
</thead>
<tbody>
<tr>
<td>PaO2</td>
<td>39 mmHg</td>
<td>88 mmHg</td>
</tr>
<tr>
<td>FiO2</td>
<td>100%</td>
<td>60%</td>
</tr>
<tr>
<td>Oxygenation Index</td>
<td>46.1</td>
<td>13.5</td>
</tr>
<tr>
<td>Vasopressor requirement</td>
<td>Epinephrine, norepinephrine, vaspressin</td>
<td>Vasopressin</td>
</tr>
<tr>
<td>ECMO blood flow</td>
<td>4.2 LPM</td>
<td>8 LPM</td>
</tr>
<tr>
<td>Sweep Gas flow</td>
<td>11 LPM</td>
<td>9 LPM</td>
</tr>
<tr>
<td>Arterial Oxygen Saturation</td>
<td>75%</td>
<td>97%</td>
</tr>
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</table>
ASAIO PULMONARY ABSTRACTS

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Tethered Liquid Perfluorocarbon Coating Prevents Thrombus Formation During 6 Hour Heparin Free Extracorporeal Circulation
T. R. Roberts,1 P. Singha,1 S. Ande,1 K. N. Sieck,1 B. M. Beely,1 J. Choi,1 H. Handa,1 L. C. Cancio,1 A. I. Batchinsky1. The Geneva Foundation, Tacoma, WA; 1University of Georgia, Athens, GA. 1University of the Incarnate Word, San Antonio, TX, 1US Army Institute of Surgical Research, San Antonio, TX.

Study: Heparin administration during extracorporeal life support (ECLS) is a necessity leading to complications. Applying an omniphobic coating called tethered liquid perfluorocarbon (TLP) to ECLS materials may obviate the need for heparin. We used field emission scanning electron microscopy (FESEM) to investigate effects of TLP coating in a 6 hr in vivo study. We hypothesized that TLP reduces thrombus deposition on ECLS circuitry compared to standard circuitry coated with immobilized heparin (IH).

Methods: Swine (50 kg) were placed on veno-venous ECLS (1 L/min; 19 F catheter). In the TLP group (n = 3), TLP was applied to ECLS circuits (membrane oxygenator (MO), tubing, catheter). In the control group (n = 3) circuits with IH (Bioline®) were used. Neither group received heparin past a bolus during cannulation. After 6 hrs ECLS, circuits were flushed and fixed in 3% glutaraldehyde in 0.1M sodium cacodylate buffer. Samples from the inlet, center and outlet of the MO were dehydrated in ethanol and coated with gold-palladium. FESEM was used to assess surface deposits; and energy dispersive spectroscopy was used to measure wt.% fluorine to evaluate presence of TLP. Percent area thrombus deposition on MO sheets was determined by 3 reviewers using ImageJ (NIH; Bethesda, MD). Data are means ± SEM.

Results: This is the first in vivo application of TLP coated ECLS circuitry. FESEM revealed cellular deposits and thrombus on IH MO fibers, which were reduced on TLP MO sheets (Fig 1). Fluorine was detected on all TLP MOs (23.45 ± 2.16 wt.%) and wt.% did not differ between layers (p > 0.05) showing TLP presence after use. Thrombus area was numerically higher for IH MOs vs. TLP (Fig 2). This study identifies TLP as a promising antithrombogenic agent which, pending multi-day testing, may enable heparin-free ECLS.

Fig 1. FESEM images from IH vs. TLP. Note significant clot deposition on controls vs thrombus-free surfaces on TLP.

Fig 2. Percent area thrombus deposition on MO sheets from IH vs. TLP.

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Chronic In-Vivo Study Of A Lung Support Device With Incorporated RAS-Q® Technology
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Study: The RAS-Q® technology combines proven PMP-fiber bundles with compliance elements. This allows an adapted flow environment and low pressure loss at high performance. A novel device with RAS-Q® technology is optimized for the specific requirements of paracorporeal pumpless lung support, connected between the Pulmonary Artery (PA) and Left Atrium (LA). Its compact size results in mobile and conscious patients, allowing Pulmonary Arterial Hypertension (PAH) treatment and bridge-to-transplant/candidacy.

Methods: The support device was validated in six acute in-vivo trials (sheep, 53 ± 7 kg). The results were used for the transition to chronic trials. Three chronic trials (sheep, 57 ± 5 kg) were conducted with the goal to validate the implantation procedure and feasibility of the paracorporeal lung support over a period of 2 days. For the chronic trials, LA was connected using a 24 Fr cannula, PA was connected using a graft (d=14 mm). Tubing and cannula were subcutaneously tunneled and connected extracorporeally to the device. Flow rates and pressures were measured in the extracorporeal circuit.

Results: Gas exchange was measured in-vitro, following ASTM standards (>65 mLO2/LBlood; >58 mLCO2/LBlood). In acute trials with induced PAH, cardiac output (CO) was reduced to 1.3 ± 0.9 L/min from 3.1 ± 0.5 L/min baseline. With RAS-Q®, CO was restored to 3.03 ± 0.6 L/min. In the chronic trials, all animals recovered from anesthesia, showed normal behavior and digestion. Sufficient cardiac and pulmonary support was achieved over the complete trial period. Support conditions adapted passively to the activity of the animals. RAS-Q’s unique low pressure loss and integrated compliance allow lung support to adapt to patient needs. It lowers RV afterload and restores the CO in the otherwise-failing circulation. Chronic trials proofed its feasibility as a respiratory assist system for paracorporeal lung support. Further chronic trials up to 14 days are in preparation.
In Vitro Characterization Of A Modular Pump Lung Capable Of Multiple Respiratory Assist Applications


University of Pittsburgh, Pittsburgh, PA, ARDS and ECMO Center Köln-Merheim, University Witten-Herdecke, Köln, GERMANY.

Study: The Modular Extracorporeal Lung Assist System (ModELAS) is a wearable pump lung that utilizes a modular design to enable multiple types of respiratory support. The ModELAS pump can be configured with hollow fiber membrane bundles of varying surface areas to accommodate adult or pediatric patients as well as full respiratory support or low flow CO₂ removal. The resulting versatility drastically increases the patient population to benefit from the ModELAS relative to typical systems not meant for low flow CO₂ removal. This study used CFD and in vitro methods to evaluate ModELAS performance in a variety of respiratory assist applications.

Methods: The ModELAS configured with a 0.3 m² bundle (ModELAS-0.3) was evaluated for pediatric support at flows of 1–2.5 L/min. Configuration with a 0.65 m² bundle (ModELAS-0.65) was evaluated for adult support at 1–3.5 L/min and low flow CO₂ removal at 250–750 mL/min. Pump curves were obtained for each bundle over the relevant flow rates using a blood analog. Gas transfer was evaluated in bovine blood for each bundle and flow rate range. The normalized index of hemolysis (NIH) and therapeutic index of hemolysis (TIH) were measured in bovine blood for the ModELAS-0.3 at 2.5 L/min and ModELAS-0.65 at 500 mL/min, respectively.

Results: CFD results showed minimal flow stasis in the blood flow path and uniform intra-bundle flow for all conditions. The ModELAS generated targeted blood flow rates in each setting against the resistance associated with the corresponding intended cannulas. The ModELAS-0.3 and ModELAS-0.65 achieved O₂ transfer rates of 105 and 207 mL/min, respectively, at the maximum intended flow rates. The CO₂ removal rate of the ModELAS-0.65 was 83 mL/min at a blood flow rate of 500 mL/min. Hemolysis was low with an NIH of 0.029 g/100 L and TIH of 0.142 g/100 min for the ModELAS-0.3 and ModELAS-0.65, respectively. Thus the ModELAS meets the targeted pumping and gas transfer specifications for the described applications and exhibits low blood damage.

Incorporating RAS-Q Technology Into Portable CO₂ Removal Device


Enmodes GmbH, Aachen, GERMANY, ARDS and ECMO Center Köln-Merheim, University Witten-Herdecke, Köln, GERMANY.

Study: Chronic obstructive pulmonary disease (COPD) is the fourth most common cause of death worldwide. In the US alone, 130,000 patients die from COPD each year. These patients require a long-term stable CO₂ removal device with efficient gas exchange and hemocompatible blood flow, as an alternative to lung transplantation and permanent invasive ventilation. The RAS-Q® technology combines proven PMP fiber bundles with compliant elements, resulting in a passive respiratory assist system for patients with pulmonary arterial hypertension. In this study, we conceptualized an ECCO₂R system, combining the RAS-Q® technology with an optimized blood pump for patients with end-stage COPD.

Methods: The passive RAS-Q® system was already proven in blood trials according to ASTM standards and acute animal trials. Combined with a Rotaflow blood pump and a 20 Fr AVALON Elite double-lumen cannula, three acute animal trials (pig, 39 kg) were conducted to validate the concept of an active system with RAS-Q® technology. Based on these results, a concept for an active system was optimized for COPD patients, including first in-vitro testing of the novel CO₂ removal oxygenator.

Results: In-vivo measured CO₂ removal of the passive gas exchanger with 0.6 m² was 80–100 ml/min at 500 mlblood/min, pressure loss was 3 mmHg. Based on these findings, a new double-chamber gas exchanger with incorporated blood flow guidance by the compliance elements was designed and manufactured, with a gas exchange area of 0.95 m². In-vitro tests showed low pressure loss of 10 and 58 mmHg at flows of 1 and 3 lpm, respectively. Ink testing revealed improved washout of the ECCO₂R system. The current ECCO₂R system can provide high CO₂ elimination required for mobilization of COPD patients. In the next step, an optimized, directly driven blood pump will be integrated into the system, which will be cannulated from right atrium to pulmonary artery. This will enable mobile extracorporeal support for COPD patients.
Intergraft Pivotal Trial: A Novel AVG Minimally Invasive Anastomotic Device For AVG Creation

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Study: A novel InterGraft™ Vascular Connector System includes a venous and arterial connector that are designed for use with a 6mm commercial AV graft. This novel device and technique are hypothesized to diminish vessel surgical trauma, minimize outflow stenosis, reduce blood flow turbulence, and reduce steal. Phraxis, Inc., has undertaken a pivotal study of the InterGraft™ device in the North American population to test these hypotheses. The purpose of this abstract is to describe the current progress of the trial and to explore the outcomes of the roll-in (operator training) phase of the study.

Methods: The study is a prospective, multicenter, non-randomized, historical control study designed to evaluate the InterGraft™ in 104 subjects. The primary endpoint is cumulative patency at 6 months, i.e. the proportion of subjects free from loss of the study graft for hemodialysis. Secondary endpoints include acute procedure success, primary unassisted patency at 6 months, time to first cannulation, and major adverse events.

Results: To date 55 subjects have been enrolled in the main study. To date 15 subjects have been enrolled in the roll-in phase of the study. Of these 15 subjects, the average age is 54, 20% are females, 60% are black. Three of the 15 subjects received a venous connector only due to anatomical considerations. In another three subjects the arterial anastomotic connector was converted to a sutured anastomosis. The venous anatomostic success is 100%. The arterial anastomotic success is 75%, with 25% conversion to the traditional sutured method. Of the 15 subjects, one died prior to the 6 month follow-up period and one subject was lost to follow-up. Two of the AVG were infected and, therefore, had to be removed. The remainder of the AVGs (11) were patent at 6 months (primary patency 78.6% in evaluable subjects). Seven of these eleven AVG did not require intervention during the 6 month follow-up period.

Evaluation of the Time-averaged Solute Clearance values in Hemodialysis with Intermittent Infusion (I-HD)

M. Mineshima, T. Abe, D. Kamei. Clinical Engineering, Tokyo Women’s Medical University, Tokyo, JAPAN.

Study: Since 2007, we have been using the I-HD to improve the peripheral circulation of dialysis patients and reduce the occurrence of hypotension during HD treatment. In a typical I-HD session, we infuse 200 mL of ultra-pure dialysate by backfiltration, namely, from the dialysate side to the blood side through the dialysis membrane, at about 150 mL/min every 30 min, and filtrated alternately at the same volume from the patient at a constant rate after each infusion. Thus, I-HD is regarded as an on-line HDF with a very small replacement volume. However, the solute removal characteristics in I-HD have not yet been clarified.

Methods: An in vitro study using human plasma was carried out to evaluate the solute clearance (CL) values for a polyethersulfone hemodiafilter, MFx-15Seco, Nipro Corp., Japan. The urea, creatinine, uric acid, inorganic phosphate and β2-microglobulin (BMG) CL values were evaluated at a filtration flow rate (Qf) of -200 to 50 mL/min under blood and dialysate flow rates of 200 mL/min and 500 mL/min. A negative value of Qf represents the infusion flow rate through the dialysis membrane from the dialysate to the blood side. Furthermore, we introduced a fluid and solute transfer model for a dialyzer to estimate the CL values under various conditions of I-HD. Effects of a single infusion volume, infusion flow rate and infusion cycle on the time-averaged CL values were estimated using this model.

Results: For example, the CL values estimated from the experiments were -0.0005Qf +0.1065Qf +192.1 mL/min for urea and 0.0006Qf +0.3935Qf +62.72 mL/min for BMG. No obvious differences of CL values between the experimental data and the estimated value were obtained in HD treatment with no infusion. In a simulation analysis using the model, no obvious differences of the CL values were observed among various infusion patterns. The solute removal characteristics in I-HD did not differ significantly from those in typical HD treatment.

Machine Learning Facilitates Early Detection Of Ureteropelvic Junction Obstruction

A. R. Porras, 1 B. M. Sprague, 2 E. S. Blum, 3 R. D. Sussman, 4 S. Holzman, 2 R. S. Zee, 1 H. G. Pohl, 1 M. Linguraru 1, 2 Sheik Zayed Institute for Pediatric Surgical Innovation, Children’s National Health System, Washington, DC, 2Department of Urology, Children’s National Health System, Washington, DC, 3Medstar Georgetown University Hospital, Washington, DC.

Study: Patients with congenital ureteropelvic junction obstruction (UPJO) are at risk of renal function deterioration. While diuresis renography (DR) provides useful metrics by which pyeloplasty can be recommended such as drainage half-time (T1/2) and drainage after 30 minutes (C30), many studies report limited accuracy of these metrics, which often translates into several longitudinal studies before a final diagnosis can be made. In this study, we improve previously developed machine learning-based diagnostic models by extending our training data and we compare their performance with T1/2 and C30.

Methods: We studied retrospective patients who underwent DR for suspected UPJO at our institution between 2009 and 2015, with endpoint of pyeloplasty or discharge. We added 18 patients to the cohort of 59 patients from previous study, and we retrained our machine learning models on the larger population. Six features from the DR curves that optimized the diagnostic accuracy were selected using leave-one-out cross validation. We compared the performance of the previous and new models in the new patient cohort to predict from the first DR study which patients would proceed to pyeloplasty. We also compared these models with the traditional metrics T1/2 and C30.

Results: The retrained six feature model in the current study population had an accuracy of 92% (91% sensitivity, 94% specificity), and the older five feature model had an accuracy of 87% (100% sensitivity and 68% specificity). Both machine learning models were better predictors of requiring pyeloplasty than the T1/2 and C30 (82% and 79% accuracy respectively). These results indicate that machine learning models may be better suited to analyze the dynamics of DR than the traditional metrics. While further study is warranted, machine learning models could lead to earlier detection of severe UPJO and may reduce the number of DR performed prior to surgical management.
Combining Cation And Anion Exchange Sorbents To Remove Uremic Toxins

S. R. Ash,1 D. J. Carr.1 Indiana University Health Arnett & HemoCleanse Technologies, LLC, Lafayette, IN; HemoCleanse Technologies, LLC, Lafayette, IN.

Study: Solutions containing both cations and anions have long been purified by treatment with combinations of cation and anion exchangers. A common example is deionization of water, in which cations are exchanged for H+ ions and anions for OH− ions, which then combine to form water. A combination of cation and anion exchangers might remove a majority of the small and charged uremic toxins that are present in the gut, benefitting patients with ESRD. In this study, a combination of H+-loaded cation exchanger and OH−-loaded anion exchanger was tested for removal of uremic toxins from solutions simulating intestinal fluid concentrations of ESRD patients.

Methods: Zirconium phosphate (ZP, a cation exchanger), and zirconium oxide (ZO, an anion exchanger), were each first tested in aqueous solutions for their capacity and affinity for individual electrolytes. Then solutions representative of small bowel and colon conditions were tested with H+-loaded ZP alone or in combination with OH−-loaded ZO. Electrolytes and ammonium of the treated solutions were assayed by flame photometry and spectrophotometric methods and pH electrode was used.

Results: ZP alone removed some of the cations but produced significant drop in pH due to release of H+. Combining ZP and ZO resulted in remarkably high binding of K+ and PO4− (3–5 mEq/g) compared to current oral sorbents (which remove on the order of 1 mEq/g). The ZP/ZO combination also drastically reduced pH changes. Ca2+ and Mg2+ removal by the sorbents was modest. Na+ was not removed but with more thorough H+ loading of ZP, it would be effectively removed. NH4+ removal was modest, but modifications of ZP with much higher capacity are being tested. Our in vitro studies show that oral ingestion of 40 grams of ZP/ZO could remove half of the daily load of K+ and PO4−. An improved mixture could also remove significant amounts of Na+ and BUN (in the form of NH4+). Zirconium compounds have had minimal toxicity in animal and clinical studies. Use of ZP/ZO sorbent could delay the need for dialysis in some patients with ESRD.
New IEC Standards On PD & HD, As Well As AAMI TIR On Sorbent-Based HD

F. P. Wieringa. Connected Health Solutions, IMEC, Eindhoven, NETHERLANDS.

Study: The past 4 years IEC TC 62D/MT20 “Dialysis Devices” has worked hard to overhaul the particular standards IEC 60601-2-16 (for hemodialysis devices) and IEC 60601-2-39 (for Peritoneal dialysis devices). New within IEC 60601-2-16 is that the scope of the old edition 4 excluded sorbent-based HD systems. Within its’ scope now includes sorbent-based HD as well, but for edition 5 sorbent-based HD systems are no longer excluded. To help sort out specific aspects of sorbent-based HD systems, reference is included to the AAMI Technical Information Report (TIR) 77 about Sorbent-based hemodialysis regeneration system. AAMI TIR 77 contains a number of specific junctions to IEC 60601-2-16. Major change within IEC 60601-2-39 is on alarm systems. All these 3 new documents will appear in 2018.

Methods: This is a disseminative article

Results: This is a dissemination article

Dialysis Chair With Leadless ECG Measurement

I. D. Castro Miller1; F. P. Wieringa2. 1Connected Health Solutions, IMEC, Leuven, BELGIUM, 2Connected Health Solutions, IMEC, Eindhoven, NETHERLANDS.

Study: Unobtrusive and cheap measurement of ECG may be useful for a more patient centered care in chronic dialysis, since arrhythmias are quite common comorbidities. Yet the placement of ECG electrodes forms a hassle for nurse and patient, leadwires and cables form an extra limitation of freedom to move and even if the electrodes would cost just 30 cents per treatment, this already pressures on the reimbursement margin. We developed a wireless system for capacitive ECG measurement through clothing without any need for disposables. An implementation into a dialysis chair is presented here, but this also might be e.g. a bed. The system utilizes a matrix of capacitive electrodes that are part of the chair polstering which are used for motion artifact reduction algorithms. The system dynamically adapts its robustness and signal quality according to the environmental conditions. Optimizations including bias resistance and cancellation of common com mode signals. Automatic selection of electrode pairs and dynamic adaptation to prevent front end saturation is demonstrated.

Methods: During the Dutch national heart foundation congress, we placed 20 healthy volunteers in such a capacitive ECG chair, and wirelessly coupled the registered ECG unto a user interface test setup of the NeoKidney Portable Artificial Kidney (see picture).

Results: Picture caption: Left the “through clothing” ECG setup. Right the user interface test setup of the NeoKidney Portable Artificial Kidney. We registered usable ECGs up to the level of 3 layers of clothing (undershirt, shirt and sweater). The ECG signal allows good automated detection of the QRS-complexes and R-wave derived heart rate (HR) and heart rate variability (HRV). A built-in quality indicator allows to discern movement artifacts during repositioning, etc. thus assuring that only valid HR and HRV values are displayed.
ASAIO RENAL ABSTRACTS

Hemocompatibility Of Small Form Factor Microfluidic Filtration System With Nitride Membranes
D. G. Johnson, K. Hill, A. Salminen. Biomedical Engineering, University of Rochester, Rochester, NY.

Study: In bench top studies we have shown that NPN membranes have the ability to clear urea and middle weight proteins while retaining albumin without any degradation in clearance rates over 12 hours. Surface functionalization may be necessary to meet the standards set by the current hemodialysis filter materials. Here we report on the hemocompatibility of the silicon nitride membranes and compare them to standard surfaces, showing an improvement in TAT, C3a, and platelet activation for both untreated silicon nitride and PEGylated silicon nitride.

Methods: Counter flow devices and static microdialysis experiments were used to measure the effects of PEGylation on the clearance and hemocompatibility (see Figure 1A). Single-pass bench-top dialysis experiments were designed to measure the effects of fouling on membrane permeability. Albumin and Cytochrome C Separation “Microdialysis experiments aimed to probe the NPN membranes for BSA and cytochrome C separation through diffusion. “Serum” comprised of 1 mg/ml BSA and cytochrome C. Hemocompatibility: The concentration of thrombin-antithrombin complex (TAT) and C3a complement measured via ELISA kit was used as the indicator of coagulation and immune activation, respectively. Platelet Adhesion and Activation: 20 µL of PRP was pipetted into each microchannel and kept in the incubator for 2 hr.

Results: See Figure 1B for single pass results. Results for microdialysis (Figure 1D) showed significant reduction in both BSA and cytochrome c over 24 hours, more so for the latter. Overall, data suggests the membranes are less permeable to albumin than cytochrome c, a characteristic very beneficial for dialysis use. The favorable hemocompatibility results of the native silicon nitride are encouraging but better results may be needed for long-term contact of the membrane in biological systems. Recent work has reported on methods for functionalizing the material in the original membranes (pnc-Si).

Development Of A Multi-Ring Type Roller Pump Unit Equipped To A Compact And Convenient Ascites Purification Machine For Cell-Free And Concentrated Ascites Reinfusion Therapy (CART)
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Study: Cell-free and concentrated ascites reinfusion therapy (CART) is an effective and safe therapy for the refractory ascites. Since filtration and concentration process of ascites during CART is complicated and expensive machine is necessary, CART is difficult to be performed at the small and medium sized hospitals in Japan. Therefore, it is necessary to develop a new low-priced CART machine which can be used easily and safely. In this study, we developed a multi-ring roller pump unit equipped to a compact convenient low-priced ascites purification machine for CART.

Methods: A multi-ring roller pump unit equipped to a compact and convenient ascites purification machine for CART.
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