From Benchtop to Beside: Patient-specific Outcomes Explained by Invitro Experiment

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**Top Cardiac**

**In-vivo Assessment Of A Novel Ventricular Systole-synchronized, Intraventricular Propelling, Left Ventricular Assist Device For Advanced Heart Failure**

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**Study:** Current left ventricular assist device (LVAD) designs are not synchronized to the cardiac cycle and are not designed for totally implantable wireless operation, design features that are believed to enhance performance and adoption of durable LVAD therapy. We performed in-vivo animal testing of a novel ventricular systole-synchronized, intraventricular propelling pump.

**Methods:** Pump performance was assessed in 6 calves for acute studies with induced severe heart failure and 10 sane calves for chronic safety studies. The LVAD system was implanted via a beating heart minimally-invasive left thoracotomy surgical approach without cardiopulmonary bypass. Animals were sacrificed after 7 (n=4), 21 (n=2), and 30 (n=4) days of device support.

**Results:** In all animals, echocardiography demonstrated optimal pump positioning (pump outlet 1-2cm below the aortic valve) with use of an adjustable fixation system. No mitral valve dysfunction nor suction were observed. Hemodynamic data are shown in the table. D-Dimers remained in the normal range. At sacrifice and necropsy, no clots were identified on the pump impeller, no injury to the aortic or mitral valves were observed nor embolic infarcts in the brain or kidneys, except for one calf (one minimal kidney infarct at Day-7). A novel totally-implantable, wireless operating, intraventricular propelling LVAD system has demonstrated reliable operation in an in-vivo model out to 30 days. These findings support continued development and consideration for first-in-human studies.

<table>
<thead>
<tr>
<th>BP: blood pressure, CO: cardiac output, Hb: hemoglobin, PCWP: Pulmonary capillary wedge pressure</th>
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<tr>
<td>CO baseline (L/min)</td>
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<td>acute studies</td>
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<td>chronic studies</td>
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**Top Bioengineering**

**Optimizing LVAD Speed And Speed Modulation Using Computational Hemodynamics Modeling On A Large Patient Cohort**

Dina Dragoljic, None1, Jasmine Martinez, None1, Gavin Loena, None2, Michael Alldape, None2, Jennifer Beckman, MSN, ARNP3, Song Li, MD2, Claudiais Mah, DO2, Alberto Aliseda, PhD4, Venkat Keshav Chivukula, PhD2, 1Biomedical and Chemical Engineering and Sciences, Florida Institute of Technology, Melbourne, FL, USA, 2Biomedical Engineering, University of North Texas, Denton, TX, USA, 3Cardiology, University of Washington Medical Center, Seattle, WA, USA, 4Mechanical Engineering, University of Washington, seattle, WA, USA

**Study:** This study investigates the interplay between LVAD speeds, speed modulation waveforms, and MAP management to assess their effect on cardiovascular system hemodynamics for optimal performance for a large patient cohort (n=61).

**Methods:** A custom-designed computational hemodynamic lumped parameter model (CHLPM) of the entire human circulatory network that

![Figure 1: (a) Distribution of MAP and CO for n=61 patients before virtual MAP management (b) Distribution of MAP and CO for same patient cohort after virtual MAP management to meet MAP target of 70 mmHg at same LVAD speed. (c) Schematic of speed modulation algorithms and interdependence of several hemodynamic factors on overall system performance.](image-url)
simulates HF with complete LVAD support and incorporates the LVAD's H-Q relationships at various operating speeds was developed and utilized. The model was personalized for each patient according to their measured hemodynamic data using algorithms designed in-house. For each patient-specific model, hemodynamic optimization was performed using virtual MAP management optimization to meet a prescribed MAP target of 70 mmHg. Further, several speed modulation waveforms (such as linear ramp up/down, sinusoidal variation, etc) were investigated to encourage intermittent aortic valve (AV) flow, and to evaluate dependence on synchronization with native cardiac cycle.

**Results:** After performing virtual MAP management for all patients keeping LVAD speed unchanged, 84% (51 patients) overshot the CO target of 5 L/min, while keeping LVAD speed unchanged. Speed modulation enabled the AV to open intermittently, based on preload and afterload. Abrupt changes in LVAD speed such as square waves resulted in a sudden drop in flow through the LVAD, which can be detrimental to hemodynamic performance. A gradual change in the LVAD speed (sinusoidal or linear ramp up/down waveforms) resulted in smoother variations in hemodynamic metrics, indicating the benefit of such waveforms. Flow conditions were strongly influenced when abrupt speed changes occurred during peak systole, indicating a complex interplay between LVAD speed modulation and native cardiac cycle synchronization. Utilizing customized cardiovascular flow models can help optimize LVAD speed as well as speed modulation to improve hemodynamic performance.

**Top Pediatric**

**Influence Of Patient Weight On Vad Outcomes In Pediatric And Young Adult Patients With Dilated Cardiomyopathy - An Analysis Of The Action Registry**

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**Study:** Ventricular assist device (VAD) options vary for children in different weight groups. This study evaluates contemporary outcomes for children in different weight categories.

**Methods:** Data from the Advanced Cardiac Therapies Improving Outcomes Network (ACTION) registry were examined for patients with dilated cardiomyopathy (DCM) in 4 weight cohorts: <8kg (1), 8-20kg (2), 21-40kg (3) and >40kg (4) for devices implanted 3/2013 -10/2020. Device type, adverse event rates, and rates of positive outcome (alive on device, transplanted or ventricular recovery) were analyzed.

**Results:** A total of 222 DCM patients (0–29 year old; median 75 (range 1 - 1681) device days) were identified with 24% (53) in cohort 1, 23% (50) in cohort 2, 15% (34) in cohort 3 and 38% (85) in cohort 4. Of the 272 total implants, paracorporeal pulsatile flow devices (PCPF) were common (95%) in cohorts 1 and 2 and intracorporeal continuous flow devices (ICCF) were common (81%) in cohorts 3 and 4. A small number of ICCF implants (7), all HeartWare HVAD (13-20kg), were used in cohort 2 [Figure]. Stroke was noted in 19%, 12%, 6% and 4% of cohorts 1 thru 4, respectively (Cohort 1 vs 3 - p=0.04; Cohort 1 vs 4 - p=0.001; Cohorts 2 vs 4 - 0.028; all other comparisons-not significant). Major bleeding was noted in 9%, 10%, 18% and 16% of cohorts 1 thru 4, respectively (all comparisons - not significant). Positive outcome was noted in 91%, 94%, 97% and 91% of cohorts 1 thru 4 patients, respectively (all comparisons - not significant). Conclusions: In this contemporary cohort, intracorporeal devices in patients below 20 kg were rare. Above 20 kg, intracorporeal devices accounted for most implants. Stroke rate was higher in smaller cohorts, but bleeding rate was similar across groups. Positive outcomes were attained in over 90% across all weight groups, demonstrating the excellent outcomes that can be achieved for the diverse pediatric and young adult population with DCM using currently available devices.

![Figure: Distribution of device types across all weight categories. PCPF: paracorporeal pulsatile flow; ICCF: intracorporeal continuous flow](image-url)
Top Nursing

Seasonal And Regional Variations In Epistaxis Among Patients With A Left Ventricular Assist Device: A National Multi-center Study

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Study: Left ventricular assist device (LVAD) implantation is a common end-stage heart failure therapy and is associated with bleeding complications. This multicenter study investigates epistaxis occurrence within this patient population.

Methods: An online survey was sent through Survey Monkey® from 14 centers to their patients. Responses were categorized into the following geographical regions: Midwest, Northeast, South, Southeast, and West. Questions addressed risk factors, seasonality, incidence, and management of epistaxis.

Results: A total of 235 patients with LVADs responded to the survey. Most (58%) experienced at least one occurrence of epistaxis. Many could not recall seasonality of their epistaxis (n=35, 26%), but of those who could, most reported epistaxis occurrence in the winter (n=34, 25%). Epistaxis events occurring in the spring were rated as significantly more severe than those in the winter (median: 77 (51, 93) vs 25 (4, 58) on a 1–100 scale, p=0.01). Patients from the West rated their epistaxis severity significantly higher than those from the South (57 (17, 90) vs 14 (4, 39), p=0.026). Of patients with epistaxis, 21% received emergency department (ED) care for management, 10% required admission, and 6% were transfused. Of the 128 patients requiring treatment, 100 (78%) felt it was effective. The majority (n=93, 73%) applied manual pressure, with some requiring packing (n=51, 40%) and cauterization (n=19, 15%). Additionally, 72 patients (31%) had recurrent epistaxis, but rated them less severe than the first (41 (7, 86) vs 33 (7, 61), p=0.006). Patients requiring an ED visit, hospital admission, or blood transfusion had significantly greater reported epistaxis severity (p<0.05 for all). We report the largest and most comprehensive survey of epistaxis in patients with LVADs to date. Further prospective studies are required to investigate the impact on patient outcomes of this common adverse event in patients with LVADs.
Utility Of Protocolized Whole-body CT Imaging Following ECMO Cannulation For Cardiac Arrest
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Study: Evaluate the utility of whole-body computed tomography (WBCT) imaging in detecting clinically significant findings in patients who have undergone extracorporeal membrane oxygenation (ECMO) cannulation for cardiac arrest (extracorporeal cardiopulmonary resuscitation, or "eCPR").

Methods: Single-center retrospective review of 52 consecutive patients from 2017 to 2019 who underwent eCPR and received concomitant WBCT imaging. WBCT images were reviewed for clinically significant findings (compression-related injuries, cannulation-related complications, etiology of cardiac arrest, incidental findings, and evidence of hypoxic brain injury) as well as the frequency of interventions performed as a direct result of such findings.

Results: 38 patients met inclusion criteria for analysis. Clinically significant WBCT findings were present in 37/38 (97%) of patients with 3.3 ± 1.7 findings per patient. An intervention as a direct result of WBCT findings was performed in 54% (20/37) of patients with such findings. An intervention was performed as a direct result of a WBCT finding in 20/37 (54%) of patients with significant findings. Overall there were 37 interventions performed with a mean number of 1.0 ± 1.1 interventions per patient. Of interventions performed, 7/37 (19%) were surgical, 9/37 (24%) were procedural, 11/37 (30%) were medical, and 10/37 (27%) received a recommendation for further investigation. Figure 1 demonstrates distribution of significant findings and subsequent interventions performed by category. Evidence of hypoxic brain injury on WBCT was associated with clinical brain death as compared to those without such findings (10/15 [67%] vs 12/22 [4%], p<0.001), respectively.

In conclusion, whole-body CT (WBCT) imaging in detecting clinically significant findings in patients who have undergone eCPR frequently detects clinically significant findings which commonly prompt an intervention directly affecting the patient’s clinical course. We advocate for protocolized use of WBCT imaging in all eCPR patients.

Figure 1. Distribution of significant findings and interventions by category
Top Renal

Active Circulating Blood Volume During Hemodialysis: A Bench Model
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Study: Innovation in ESKD therapy has remained largely unchanged for decades. Dialysis devices lack the precision and predictive technologies to provide personal and participatory therapy to patients. Hypotensive events due to excessive fluid removal are a common complication of HD. With automated, direct quantification of Active Circulating Blood Volume (ACBV), a fluid removal rate can be more intelligently established and adjusted than the ‘dry weight method’ of today.

Methods: A novel bench model (Fig 1) included a central pump representing the heart and compartments/tubing to represent the central and peripheral circulation. A 4–5% saline solution was circulated in the model. A blood oxygenator was used to simulate lung volume and two sealed containers represented fast and slow circulation compartments. A separate dialysis circuit with blood pump was incorporated. Vascular access was simulated in two modes - a shunt (fistula or graft), and a central venous catheter. Two ultrasound flow-dilution probes were located the arterial and venous lines of the dialysis circuit. Around 50 ml of isotonic saline was released from the saline bag into the physiological model. ABCV was measured by comparing baseline dilution curve to the curve as saline was circulated through the model. To evaluate the accuracy of this technique, we investigated changing cardiac output (CO, 3-7L/min), central venous volume (Vv, 600-1300mL), shunt flow (Qs, 0.6–1.5L/min), vascular access type and HD pump flow (Qb, 200-400mL/min).

Results: Overall percentage error (mean±SD) across all tests with variations on Vv, Qs, CO, Qb, and access type (n=15 conditions, each in triplicate) was 2.6% ± 7.4%. Accuracy of experiments using the shunt was between -3.3% and +11.5% and that of those using CVC was between -6.5% and 7.5%. The presented bench model demonstrates the ability to accurately measure active circulating blood volume.

Top COVID

Outcomes In Left Ventricular Assist Device Patients With Coronavirus Disease-19
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Study: Patients on left ventricular assist device (LVAD) support are at risk for severe disease and complications from coronavirus disease 2019 (COVID-19) due to older age, comorbidities, and an immunocompromised state. We examined the clinical characteristics, treatments, and outcomes for LVAD patients diagnosed with COVID-19.

Methods: Single-center, retrospective analysis of all active LVAD patients 9% (24/270) who presented with symptoms of COVID-19, PCR test positive for SARS-CoV-2, and allowed for a minimum of one month follow up. Baseline demographics, clinical markers, diagnostics, adverse events, treatment modalities, and outcomes were studied.

Results: Twenty-four patients (83% male, 88% destination therapy) with a median age of 65 ± 11.2 years, BMI 26.8 ± 5.9, and 2.6 years (range, 9 days - 6.6 years) of LVAD support were included (Table 1). Patients presented from home (67%), hospital acquired (17%), subacute rehab facilities (12%), and a long-term acute care hospital (4%). Twenty-three patients (96%) required hospitalization; 13 to intensive care and 10 to step-down units. Five patients (21%) required intubation and 15 (63%) supplemental oxygen. Most patients remained on...
home dose Coumadin (88%) and ASA (50%), 54% were placed on systemic heparin. Treatment modalities included: Remdesivir (46%), Steroids (38%), Vitamin C (33%), Zinc (29%), Azithromycin (13%), Tocilizumab (8%), and Convalescent Plasma (4%). Median length of hospital stay was 6.5 days ± 10 (range, 1–52). In hospital COVID-19 mortality was 21%. An additional 2 patients expired at home, 9 days and 6 months after discharge; causes of death unknown, and 1 patient expired during a readmission, 3 months after COVID-19 from a respiratory arrest. Our cohort of LVAD patients tended to be older, of minority ethnicity, and have numerous underlying conditions. LVAD patients who contract COVID-19 are at a high risk of increased morbidity and mortality, and should be closely monitored for progression of the disease.
BIO1-1
Low Blood Flow Silicon Nanopore Membrane Hemodialysis Without Anticoagulation In Swine
Jarrett Mayer, MD1, Jimmy Ly, PhD2, Nathan Wright, Masters, Engineering2, David Maginnis, BA1, Charles Blaha, BA2, Benjamin Chui, PhD2, Tariq Haniff, PhD1, Caressa Chen, MD2, Harini Sarathy, MD2, Lynda A. Frassetto, MD3, Shant Vartanian, MD4, William H Fissell, MD5
Results: Two large-scale and three small-scale devices remained patent for 4 hours. The small-scale SNMHD demonstrated urea and creatinine clearances of approximately 60 and 50 ml/min/m² for 4 hours. The small-scale SNMHD demonstrated urea and creatinine clearances of approximately 60 and 50 ml/min/m², respectively. The low blood flow rates and a large surface-area filter not optimized for blood flow. Systemic and local anticoagulants reduce coagulability but are associated with increased complications, complexity, and costs. We previously prototyped and tested high flux parallel-plate silicon nanopore membrane hemodialyzers (SNMHD) for enhanced hemocompatibility and sustained toxin clearance for up to 30 days without systemic anticoagulation under high-flow (>700 ml/min) arteriovenous implantation. Here, we assess hemocompatibility and clearance for extracorporeal SNMHD under low-flow (<400 ml/min) conditions.
Methods: Small-scale (25 cm² silicon surface area) and large-scale devices (800 cm²) were optimized for blood flow using computational fluid dynamics (CFD). The devices were attached to a healthy minipig within a healthy minipig within a dialysis circuit in order to perform 4-hour extracorporeal blood flow sessions at 300 mL/min via hemodialysis catheters without systemic anticoagulation. The small-scale SNMHD with 10 nm pores were used to measure diffusive clearance with counter-current dialysate flow, while large-scale solid-silicon devices and a conventional hollow-fiber filter control were tested to assess hemocompatibility.
Results: Two large-scale and three small-scale devices remained patent for 4 hours. The small-scale SNMHD demonstrated urea and creatinine clearances of approximately 60 and 50 ml/min/m², respectively. The low blood flow rates and a large surface-area filter not optimized for blood flow. Systemic and local anticoagulants reduce coagulability but are associated with increased complications, complexity, and costs. We previously prototyped and tested high flux parallel-plate silicon nanopore membrane hemodialyzers (SNMHD) for enhanced hemocompatibility and sustained toxin clearance for up to 30 days without systemic anticoagulation under high-flow (>700 ml/min) arteriovenous implantation. Here, we assess hemocompatibility and clearance for extracorporeal SNMHD under low-flow (<400 ml/min) conditions.
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BIO1-3

Novel Stacked Motor In Continuous-flow Total Artificial Heart: First Chronic In Vivo Results
Barry D. Kuban, BS, Christine Flick, BS, Chihiro Miyagi, MD, PhD, Takuma Miyamoto, MD, PhD, Anthony Polakowski, MS, Jamshid H. Karimov, MD, PhD, Kiyotaka Fukamachi, MD, PhD; Biomedical Engineering, Cleveland Clinic, Cleveland, OH, USA

Study: The Cleveland Clinic continuous-flow total artificial heart (CFTAH) features a rotating assembly that is free to move axially within its blood-lubricated hydraulic bearing. It is constrained axially by the magnetic forces between the stator laminates and the permanent magnets within the rotating assembly. These forces must be sufficient to prevent the rotor from moving too far axially where it might contact the pump volutes. When the rotor is within 0.02 inches of the axial center of the stator, these forces are relatively weak, allowing the rotor to move freely in response to the pressure difference between the left and right sides. The purpose of the stacked motor is to increase the axial magnetic forces on the rotor when it is outside of the free-motion range. Here we report the first chronic in vivo study that was performed with a stacked motor CFTAH.

Methods: The stacked motor CFTAH was implanted in a chronic 30-day calf model and started at a mean speed of 3000 rpm with 15% sinusoidal speed modulation at 80 bpm. The mean speed was increased to 3,200 rpm in the Chronic Care Unit on post-operative day (POD) 1. The beat rate was reduced from 80 to 70 bpm on POD 3. The speed modulation was reduced from 15% to 10% on POD 8 and remained at 10% for the remainder of the study with exception of pulse studies. These changes were made to ensure that the power dissipation in the pump stayed below the design maximum.

Results: The pump performed as intended during the study with no anticoagulation and an estimated mean flow of 10.1 (+/- 0.7) l/min and a mean arterial pressure of 94.8 (+/- 14.4) mmHg. Inspection of the pump at autopsy did not show any signs that the rotor had moved axially beyond its design point. The stacked motor has a lower torque capability than the non-stacked design previously used. The torque of the motor is sufficient for normal operation, however, more care had to be taken to prevent operation of the pump at power levels above the nominal design points so as to not overstress the motor.

BIO1-4

Assessment Of Hvad Flow Signals Under Nominal Operation
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Study: HVAD pump waveforms reflect real-time blood flow through the pump and are recorded as logfiles over time. Optimized pump flow includes targeting a pulsatility of 2 liters/minute (LPM) with a minimum flow (trough) >2 LPM. Suction events, depicted by negative deflections in the logfiles (Fig. 1), are often due to ventricular collapse or inflow obstruction, and if left unchecked may lead to significant drops in pump flow and ultimately clinical events. Proper LVAD speed management is crucial to avoid suction events. We sought to characterize the incidence of suction events and pump flow operational conditions in HVAD patients without adverse events to guide device management.

Methods: Logfiles from the ENDURANCE, ENDURANCE Supplemental, and LATERAL clinical trials in subjects with no reported adverse events through support were collected. For every data point, the logfile suction detection algorithm was retrospectively utilized to determine the presence or absence of suction events, classified as Suction and No Suction. Pump flow pulsatility and trough were also characterized.

Results: Analyzed pumps revealed a pump speed of 2720 ± 171 RPM with estimated flows of 4.6 ± 1.0 LPM, flow pulsatility within 2LPM and troughs > 2LPM (Fig. 2). Of the 754,129 unique logfiles assessed, 99% did not indicate a suction event (Table 1). This retrospective study revealed that logfiles in patients without reported adverse events were essentially free of suction events and extreme low pulsatility. Visualization of this long-term flow metric to assess pump performance may assist in optimizing pump speed and VAD therapy management.

<table>
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<tr>
<th>Data Point Classification</th>
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BI01-5

Hyperthermic Extracorporeal Tumor Therapy (HEATT®); Evaluation Of New Sorbents

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Study: Ovarian, lung, pancreatic, and colon cancers are sensitive to 42°C for 120 min. HEATT® combines veno-venous (VV) perfusion, dialysis, and blood sorbent to safely raise average core temperature to 42°C. Following two successful safety trials (advanced lung and ovarian cancer), an adult swine study (n=9) evaluated sorbent units prior to expanded clinical application.

Methods: REDY® dialysis (discontinued) previously balanced electrolyte concentrations altered by hyperthermia. We compared CytoSorb® (charcoal filtration) and single-pass dialysis to the REDY®. Heating, physiology, and chemistries were measured Q 15 min. Blood and urine samples: after start of VV-perfusion and dialysis, after 1 and 2 hrs of target temperature, and after cooling; blood from main perfusion blood line: pre-dialyzer, pre-sorbent, and post-sorbent. Protein analysis and mass spectrometry were analyzed using Mass Lynx software and multiplex cytokine array for 16 pre-selected cytokine panels. Chromatograms both pre- and post-column filtration determined removal of small molecules.

Results: For HEATT®, all the methods resulted in stable hemodynamics, heat transfer, and circuit dynamics. Sorbents had no effect on the heating profile, transfer rate, or time to target temperature. Mean arterial BP, CVP, HR; average pump blood flow rate, and percent diversion were not different. Mass spectrometry was similar between the CytoSorb® and charcoal column. CytoSorb® resulted in the greatest reduction of IL-2, IL-6, IL-8, IL-10, IFNγ, and IL-1β; charcoal resulted in the greatest reduction in IL-1α, IL-1β, TGF-β1, IL-12, IL-18, and TGF-β-1. CytoSorb® was most efficient with electrolyte maintenance. Finally, CytoSorb® removed the greatest number of pro-inflammatory cytokines.

BI01-6

Test Of The Realheart® Tah Hemodynamic Performance With A Hybrid Cardiovascular Simulator

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Study: Heart disease is a leading cause of death worldwide. Due to lack of heart donors, there is the need for alternative therapies, as total artificial hearts (TAHs). In this study we evaluated the hemodynamic performance of the Realheart® TAH.

Methods: The Realheart® TAH is a 4-chamber cardiac prosthesis. It has two pumps working in series, each containing an atrium and a ventricle separated by a valve-plane cylinder. The two pumps can work independently, with same pumping rate but stroke volume adjustable individually. Pressure sensors located in the atria are used to regulate the left/right flow individually and the pumping rate. The Realheart® TAH was connected to a hybrid simulator representing the entire cardiovascular system (except ventricles) including the bronchial circulation. Tests were conducted with the aim to assess the effectiveness of the controller in keeping left/right flow balance under different conditions. Starting from baseline, step changes of model parameters were imposed to reproduce: pulmonary hypertension (5 Wood units), systemic hypertension (23.3 Wood units) and hypotension (8.3 Wood units) and hypovolemia.

Results: the Realheart® TAH adapts its left and right pump flow according to the pressure sensed in the atria. This feature makes the device sensitive to changes of preload. For the hypovolemia test, the pumping rate decreased of 34 bpm and the stroke volume decreased of 17 mL on the left side and of 14 mL on the right side, so to maintain left and right atrial pressures to positive values. For all the other tests, a steady state was reached after the onset of a circulatory parameter change. In conclusion, the unique feature of the Realheart® TAH allows to regulate the flow on the left and right side independently, thus assuring left/right flow balance under a wide range of conditions. Further tests will be conducted to assess the dynamic performance of the controller. Acknowledgement: Scandinavian Real Heart and Medtech4Health from Vinnova (N. 2020–04378)
BIO1-7

Development Of A Mock Circulation Loop To Evaluate Ventricular Assist Device Inflow Cannula Placements Within Single Ventricle Hearts
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Study: Hearts with congenital defects such as hypoplastic left heart syndrome (HLHS) can benefit from staged surgical correction, but can develop systolic dysfunction over time. Such patients are candidates for ventricular assist device (VAD) implantation. However, a recent study showed that over half of VADs are malpositioned within patient ventricles, which can lead to thrombus formation and pump failure. Therefore, this research aims to develop a mock circulation loop to evaluate VAD inflow cannula placements within single ventricle hearts in an effort to minimize VAD malpositioning.

Methods: A mock circulation loop was constructed to model the physiological flow parameters of a post-Fontan HLHS adolescent patient with systolic heart failure. The system consisted of a compliance chamber, fluid reservoir, and ventricular duplicator as shown in the provided figure. Of note, ventricular motion was modeled by deforming a ventricular sac surrounded by fluid controlled by a positive displacement pump. Systolic dysfunction and VAD conditions were tested, and multiple sacs were prepared to evaluate various inflow cannula placements.

Results: The mock circulation loop was able to effectively mimic both heart failure and VAD-assisted flow conditions. Furthermore, the modular design of the system allowed easy testing of multiple VAD inflow cannula configurations. Future work includes using particle image velocimetry to visualize the flow patterns near the VAD inflow cannula, and compare the bench top results to data from previous computational studies.

BIO1-8

Hydraulic Stiffness In Maglev Centrifugal Blood Pump
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Study: The introduction of contactless bearing in ventricular assist devices (VADs) gives the rotor freedom of motion, and the position of the rotor is a balance between hydraulic forces and electromagnetic forces. We define pump hydraulic force function as Fig1. F is the forces acting on rotor by hydraulic system. D is the displacement of the rotor from nominal position. Subscript x and y denote the orientation of forces and displacements. Hydraulic stiffness (Fig2) is of great importance for maglev system controller design. Constant stiffness under different operating conditions minimizes the variation in the transfer function of the plant, minimizing the range of conditions that the controller needs to cope with, and thus improving its robustness.

Methods: Hydraulic radial forces in MP-EX pump head are measured by a customized rig (Fig. 4). The impeller was driven by an external motor via a long shaft. The shaft was connected with the motor through a misalignment coupling, to eliminate the possible radial vibration caused by coaxiality tolerance. Two force sensors were fixed on the shaft, radial forces on the shaft were then measured. The hydraulic radial forces acting on the impeller were then calculated by Fig3.

Results: All results were normalized by kxx at minimum speed and 0 L/min flow rate. Hydraulic stiffness is related to rotational speed, but not related to pump flow rate. The kxy is bigger than kyy and so is kyx than kxx, which indicates the force change on orthogonal direction is bigger than force change along displacement direction. Those phenomena are in consistent with step response results of the controller system. The introduction of hydraulic stiffness could be beneficial for the controller design of maglev centrifugal blood pumps.
Manufacturing Process And Approaches In Prototyping Mechanical Circulatory Support Systems

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Study: In the United States, 50,000 - 100,000 patients require heart transplants or mechanical circulatory support (MCS). The Cleveland Clinic device portfolio includes devices for ventricular assistance (VAD), left atrial assistance (LAAD) for heart failure with preserved ejection fraction, and continuous-flow total artificial hearts (CFTAH). Unique architecture and design features add complexity to device manufacturability, and thus impose specific requirements on the entire process. In this study, the unique steps of the manufacturing, prototyping, and testing of the MCS development process are reported.

Methods: 3D-printing of specific components, using various polymer materials and titanium alloy (Ti-6Al-4V), has been explored for many component types, covering our complete portfolio of devices, including VAD, LAAD, and CFTAH. Other areas investigated include: laser welding of rotor components to provide an impenetrable seam to prevent magnet corrosion; finishing of impeller surfaces using a micro machining process; testing an array of polymer liners on rotors, and; component/assembly identification methods.

Results: With 3D-printing, our results have been encouraging. Prototype components sometimes have a rough-looking surface finish, but when machine-finished, the surface is satisfactory and meets our needs. Examples of 3D-printed titanium components prior to any secondary machining are shown (Fig. 1 A and 1 B). We have produced a laser-welded seam for our rotor assemblies (Fig. 1 C), achieved mirror-like surface finishes on impeller features, and etched serial numbers on titanium components. The proposed validation of polymers, adhesives, and machining techniques for a titanium-polycarbonate seam successfully resulted in a seal, which prevented blood ingress into pump components (Fig. 1 D). Many manufacturing processes and prototyping techniques have been utilized, resulting in MCS systems that are closer to being production-ready.
BIO2-2
Modification Of Hemocompatible Surface Coating For Extracorporeal Artificial Graft
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Study: Development of novel surface modification still remains to be investigated in the extracorporeal circulation technology. We evaluated both anti-thrombotic anti-bacterial properties of new developed tube graft with novel surface coating in ex-vivo mock circulation (EVMC) conditions.

Methods: An EVMC system was assembled using a roller pump, polyurethane (PU) tube (3/8 inch inner diameter, 50 cm length) and priming solution (human blood 40 ml + normal saline 10 ml). We made 5 tube grafts with novel bilaminar surface coating (base coating with acrylic acid in inner layer and hyaluronic acid based hydrophilic coating in outer layer). Flow cytometry (CD61b, CD62p) was used to measure the platelet consumption and activity after 1 hours circulation and performed scanning electron microscope (SEM).

Results: After 1 hours of 5 EVMC experiments, there were no thrombus formation inside all PU tubes. No significant platelet activation and consumption were detected, based on result of flow cytometry study using post-EVMC priming solution. On SEM, almost no platelet aggregation was found on inner surface of PU tube. Our novel surface coating method will be promising technology in extracorporeal circulatory device. Further studies are needed to demonstrate the long-term durability.

Figure 1. No significant platelet activation and consumption with flowcytometric study (Pre VS Post-EVMC)

Figure 2. Almost no platelet aggregation on inner surface of PVC tube with SEM study.

BIO2-3
Patterned Electrospinning: Distinct Fibrous Constructs Influencing Cell Adhesion
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Study: In this study we manipulate the deposition of fibers to specific regions on a collector. We took a flat conductive plate as a collector used in electrospinning and created designs leaving non-conductive and conductive areas on the plate. By making these gaps on the plate we were able to create different designs for the deposition of the fibers.

Methods: The targets were designed and etched onto a copper board. A Poly(lactic-co-glycolic) acid (PLGA) solution was prepared by mixing PLGA in Dichloromethane (DCM) at a ratio of 0.0750 g PLGA/1 mL DCM. A normal electrospinning setup was used for the novel targets 250 uL of the solution was pumped at a fixed rate of 2.50 mL/hr at a horizontal distance of 15 cm using 12kV on a 23 gauge needle. The collector were plastic warped to facilitate removal of the fibers. The microfibers were removed from the plastic and characterized by their mechanical and biocompatible properties.

Results: Modifying collector designs led to significant differences in fiber target coverage ranging from 300 mm² for solid (100% of the target area) to 217.8 mm² for lines (72.6% of the target area). Measured fiber excess, residual open area, and contact angle (hydrophobicity) followed the same trend as fiber target coverage with respect to collector pattern: lines > sinusoids > squares > zigzags > solid. Similarly, the lines design allowed for greatest cell adhesion and retention (258 ± 31 cells), whereas solid exhibited the lowest (150 ± 15 cells); p< 0.05. Our results demonstrate the ability to utilize patterned collectors for modifying macroscopic and microscopic electrospun scaffold features, which directly affect cell adhesion, and retention, offering translational utility for designing specific tissue constructs.
**BIO2-4**

Entelon® (vitis Vinifera Seed Extract) Reduces Degenerative Changes In Bovine Pericardium Valve Leaflet In A Dog Intravascular Implant Model

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**Study:** Inflammation and calcification are major factors responsible for degeneration of bioprosthetic valve and other substitute heart valve implantations. The objective of this study was to evaluate the anti-inflammatory and anti-calcification effects of Entelon150® (consisting of grape-seed extract) in a beagle dog model of intravascular bovine pericardium implantation.

**Methods:** In total, 8 healthy male beagle dogs were implanted with a bovine pericardium bilaterally in the external jugular veins and divided into two groups. Animals in the Entelon150® group (n = 4) were treated with 150 mg of Entelon150® twice daily for six weeks after surgery. The negative control (NC) group (n = 4) was treated with 5 ml of saline using the same method. After six weeks, we measured the calcium content, performed histological examination, and performed molecular analysis.

**Results:** The calcium content of implanted tissue in the Entelon150® group (0.56±0.14 mg/g) was significantly lower than that in the NC group (1.48±0.57 mg/g) (p < 0.05). Histopathological examination showed that infiltration of chronic inflammatory cells, such as fibroblasts and macrophages, occurred around the graft in all groups; however, the inflammation level of the implanted tissue in the Entelon150® group was significantly lower than that in the NC group. Both immunohistochemical and western blot analyses revealed that bone morphogenetic protein 2 expression was significantly attenuated in the Entelon150® group.

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**BIO3-1**

A Computational Model Of The Hemodynamics Of ECPELLA Support

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**Study:** Dual mechanical support with extracorporeal membrane oxygenation (ECMO) and the Impella percutaneous ventricular assist device, termed ECPELLA, is an emerging modality to simultaneously maintain perfusion and unload the left ventricle. ECPELLA hemodynamics are unknown and may be an important determinant of clinical outcomes.

**Methods:** A patient-specific computational model was developed from computerized tomography images of the aortic tree and design of the Impella and peripheral ECMO cannula. Simulations were conducted to analyze the hemodynamic interactions between antegrade flow from the left ventricle and Impella and retrograde flow from the ECMO circuit using dynamic lumped-parameter models to assign aortic exit boundary conditions. Total perfusion from all sources was 5 LPM with continuous Impella flow of 0.5 LPM while ECMO flow was simulated at 90%, 70%, and 50% of total flow to model profound heart failure, early heart recovery, and heart function prior to weaning ECMO. Hemodynamics, mixing cloud dynamics, shear stress metrics, and end-organ perfusion were compared.

**Results:** Increasing cardiac contractility impels the dynamic mixing cloud caudad into the thoracic aorta and increases risk of cerebral hypoxia in the setting of concomitant lung failure. The relative ratio of Impella to ECMO flow determines hemodynamic patterns of ECPELLA support while increasing ventricular contractility expands size of the mixing cloud and changes its location over the cardiac cycle. Computational models of the ECPELLA circulation inform effects of the relative titration of support on end-organ perfusion and systemic hemodynamics.
BIO3-2
Integration Of Physicochemical Gradients Into Regenerative Vascular Grafts To Control The Cellular Response
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Study: During tissue regeneration, bioactive molecule concentration, extracellular matrix architecture and mechanical properties guide tissue formation. Physicochemical gradients can be useful for the rational design of biomimetic tissue-engineered vascular grafts (TEVGs) where recovering the complex structure of native vessels is required. Herein, we manufactured a TEVG with a physicochemical gradient based on the controlled deposition of synthetic and natural polymers.

Methods: A multilayered scaffold was fabricated via electrospinning by blending polyether urethane urea (PEUU) and gelatin at weight ratios of 75:25, 85:15 and 95:5. Electrospun fibers were collected over a stainless steel mandrel. Crosslinking via glutaraldehyde was performed to preserve gelatin structure. Scaffold mechanical properties were analyzed by longitudinal and circumferential tensile strength tests. Surface morphology was examined via SEM. Gelatin content was analyzed with Masson Trichrome stain. Cytocompatibility was evaluated by measuring metabolic activity via a MTT assay. Hemocompatibility was estimated by assaying hemolysis, and platelet aggregation, adhesion, and activation.

Results: We successfully manufactured a bioactive TEVG based on a multilayered structure of PEUU incorporating a gelatin physicochemical gradient. The scaffold has 3,1 mm internal diameter and 1 mm wall thickness. Histology images, longitudinal and circumferential tensile strength tests confirmed the physicochemical gradient. Mechanical properties of the novel TEVG approach those of native non-decellularized porcine carotid arteries. Additionally, it exhibited low cytotoxicity (below 20%) and hemolytic tendency (5%) demonstrating adequate glutaraldehyde quenching and reduced thrombogenicity. This novel manufacturing strategy may provide a route to improve the regeneration of the vascular walls, which is critical to move forward in the clinical implementation of TEVGs.

BIO3-3
Simulation Of Balance Between Platelet Activation, VWF Unfolding Activity, And Surface Cleaning On Thrombus Growth In A Microfluidic Chamber
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Study: Thrombosis in artificial organs entails a balance between platelet activation, deposition, and surface cleaning. These phenomena are affected by shear stress, but to different degrees.

Methods: A multi-constituent thrombus simulation was performed in a microfluidic channel containing a blunt obstacle “hemofoil”, which is representative of many geometries in artificial organs including VAD cannula and impeller blades. Simulations were done at shear rates representative of different operation regimes (Low: 100s⁻¹ Medium: 1000s⁻¹ and High: 5000s⁻¹). The thrombosis model used in this study considers mechanical and chemical activation of platelets, deposition, and cleaning as a function of wall shear stress considering the influence of von Willebrand Factor (vWF). Open Foam was used to solve the the flow and biochemical species conservation equations considering physiological blood constituents concentrations. The fluid was assumed as Newtonian with a constant viscosity of 3.5 cP.

Results: In the low shear case, the central part of the hemofoil remained clean up until 600 s due to low platelet activation levels. For the medium case a thin film of clot formed over the obstacle at the leading edge (~500s) that propagated downstream, in contrast, for the high shear case the thrombus started to form in the downstream blunt edge and propagated upstream. Thrombus deposition at the junction between the obstacle and lateral walls is observed in all three cases due to the low embolization rate computed at the junction. Finally, at 600s, the high shear rate case shows increased thrombus deposition due to high vWF activity. In conclusion, our simulations illustrated the delicate balance between surface cleaning, platelet activation, and vWF unfolding activity that controls thrombus growth at different levels of shear. These simulations will guide further investigations to explore a more comprehensive set of conditions.
BIO3-4

Computational Analysis And Characterization Of Inspired Therapeutics Pediatric VAD V3
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Study: Pediatric heart failure (HF) patients are an underserved population with few options for mechanical circulatory support (MCS) therapy as development efforts for specific pediatric devices continue to fall behind those for the adult population. The Inspired Therapeutics Pediatric VAD is being developed as a pediatric specific MCS solution to provide up to 30-days of circulatory or respiratory support in a compact modular package that could allow for patient ambulation during treatment.

Methods: Hydrodynamic performance (flows, pressures), impeller/rotor mechanical properties (torques, forces), and flow shear stress and residence time distributions of the latest design version, Inspired Pediatric VAD V3, were numerically predicted and investigated using computational fluid dynamics (CFD) software (SolidWorks Flow Simulator). Transient, time-dependent simulations were calculated using the sliding mesh method over a range of pump rotational speeds and flow rates. Both Newtonian and Non-Newtonian (Power Law) fluid models were employed for result comparison.

Results: No change in flow and pressure head performance was predicted in Inspired Pediatric VAD V3 compared to the previous device design (V2) while meeting benchmarks based on defined pump design criteria (40 - 150 mmHg at 0.5 - 3.5 L/min). VAD V3 showed an increase in predicted impeller/rotor torques and translation forces due to changes in geometry to accommodate MagLev motor components. At the lowest pump operating point (3000 RPM, 0.50 L/min, 75 mmHg), 79% of the pump volume was in the shear stress range of 0 - 10 Pa with < 1% of the volume in the critical range of 150 - 1000 Pa for blood damage. At higher speed and flow (5000 RPM, 3.50 L/min, 176 mmHg), 65% of the volume resided in the 0 - 10 Pa range compared to 2.3% at 150 - 1000 Pa. The initial computational characterization of the Inspired Pediatric VAD V3 is encouraging and future work will include device prototype testing in a mock circulatory loop and acute large animal model.
BIO3-5

Computational Fluid Dynamic Analysis Of Three Axial Blood Pump Designs
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Study: Studies were made to compare different axial blood pumps geometries. These devices were submitted to real characteristics of the human circulatory system, considering a flow rate of 5 l/min and a pump differential pressure of 100mmHg.

Methods: The geometry of the real models were developed using the CAD tool. To check the pressure and flow performance as a function of rotation, Computational Fluid Dynamic (CFD) modeling of the pumps was performed using the software Star-CCM+. In order to prove the results obtained through the CFD simulation, In Vitro tests will be performed.

Results: The results obtained in the simulation for a rotation of 5500 RPM and a differential pressure of 100mmHg were as follows: (i) Model 1 flow rate of 1.2 l/min; (ii) Model 2 flow rate of 4.8 l/min; (iii) Model 3 flow rate of 7.1 l/min. Model 1 presented a lower flow than the target flow, model 2 close to the target value and model 3 obtained the best result as can be seen in the graph below. The simulated models refuse both as a function of flow and pressure when tested at different levels of rotation. The model 3 was the best because even at low rotation, the necessary flow was obtained. Thus the model 3 design can be a good geometry to be used in a Ventricular Assist Device Design, thus contributing to a good cardiovascular function.

BIO3-6

Computational Fluid Dynamics Evaluation Of Hvad Sintering Transition
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Study: Textured surfaces have been utilized in medical devices such as left ventricular assist devices (LVAD) to promote tissue healing and create a pseudo-intimal lining on the blood contacting surfaces to reduce thromboembolic events. To minimize the potential for thromboembolic events, the HeartWare™ HVAD™ pump inflow sintering features have been modified to increase the sintered surface height (% of the cannula) and expose the transition between smooth and textured surface area.

Methods: Computational fluid dynamics derived wall shear stress (WSS) and velocities were utilized to numerically evaluate the design modifications. Sintered transition and height performance were then compared to the commercial design. A rigid ventricle was utilized with different ventricular wall thicknesses covering wide range of patient population. Grid independence analysis was conducted, and steady-state simulations were performed at different pump flow rates for diastolic and systolic conditions. The cardiac period was represented with the combination of these conditions.

Results: The modified exposed and higher sintered transition was determined to be superior in both WSS and velocities in ventricular wall thickness ranges. This improvement increased up to 62% as compared to the commercial design for varied ventricular wall thicknesses. Higher WSS and velocity profiles suggest that the washing potential of the modified sintered height and transition of the HVAD may be enhanced.
**BIO4-1**

**Hemodynamic Effects Of Sinusoidal Pulsatile Support By The Continuous-flow Total Artificial Heart During A Chronic Animal Model**

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**Study:** The continuous-flow total artificial heart (CFTAH) is a novel device that delivers a non-pulsatile flow in constant speed setting. In a pulsatile flow mode achieved through device speed modulation, the CFTAH is capable of adjusting the pump speed with sinusoidal shape according to physiological need. The purpose of this study was to evaluate the hemodynamic effects of the pulsatile mode of the CFTAH in a chronic animal experiment. In this case, a sinusoidal waveform was used, with the percent pulsatility describing the magnitude of the waveform and speed adjustment.

**Methods:** We conducted a 30-day chronic animal experiment with a calf (88 kg at implant). We performed five pulsatility studies (postoperative day 13, 16, 17, 21, and 23) while the animal was sitting. We collected aortic pressure (carotid artery) and estimated pump flow while running the CFTAH at 2,800 rpm with 0, 5, 10, 15, 20, 25, 30, and 35% pulsatility.

**Results:** The animal was successfully supported by the CFTAH for 30 days without any major complications. Relationships between percent pulsatility, pulse pressures at carotid artery, and flow pulsatility are shown in Table 1. Percent pulsatility and pulse pressure had a strong linear relationship (y = 0.44 x - 4.7, R² = 0.98); flow pulsatility and pulse pressure also had a strong linear relationship (y = 1.0 x - 4.6, R² = 0.98). In conclusions, the CFTAH had successfully created an effective pulse pressure and flow pulsatility in a chronic animal model with a sinusoidal speed modulation mode. Percent pulsatility and pulse pressure, and flow pulsatility and pulse pressure, demonstrated strong linear relationships.

**BIO4-2**

**Impact Of Rotor Speed Modulation On Surrogate Markers Of Thrombogenicity In Contemporary LVADs**

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**Study:** To evaluate the impact of rotor speed modulation sequences of contemporary LVADs on pump thrombogenicity by comparing the effects induced by the Artificial Pulse in the HeartMate 3 (HM3, Abbott, USA) and the Lavare Cycle in the HeartWare HVAD (Medtronic, USA).

**Methods:** Using computational fluid dynamics with high spatial and temporal resolution (10³ elements and 2° per time step), we compared the effect of speed modulation to a baseline case with constant speed and pressure head in both HM3 and HVAD. Mean pump flow was 5 L/min for all cases. Thrombotic risk was assessed via comprehensive evaluation of i) pump washout, ii) stagnation zones, iii) fluid shear stress (FSS) exposure on simulated platelet trajectories, and iv) platelet activation status calculated using the Platelet Activity State (PAS) model.

**Results:** The 95% washout time was comparable across all scenarios, the instantaneous washout rate scaling principally with pump flow rate. Baseline FSS were higher in the HVAD than in the HM3, resulting in 78% of the particles exposed to high/pro-thrombotic FSS (>50Pa) vs. 52% in the HM3 and a 67% higher median PAS. The low amplitude of the Lavare Cycle (+/- 200 rpm) did not significantly impact FSS profiles (Fig 1) nor PAS. In contrast, the 10-fold higher amplitude of the HM3 Artificial Pulse (+/- 2000 rpm) drastically altered the stress-exposure profile (Fig 1), increasing the median PAS by +124% compared to baseline. However, the rapid acceleration from low to high speed (+4000 rpm within a few milliseconds) also reduced flow stagnation regions by up to 91% in the HM3. This study suggests that potential benefits of speed modulation on local washout of isolated fluid pockets warrant further exploration and should be weighed against the need of reducing pro-thrombotic effects of strong rotor accelerations.

![Figure 1: Histograms of particle exposure times to Fluid Shear Stress >50Pa in the HVAD (left) and HM3 (right) with and without speed modulation](image-url)
BIO4-3

Hemodynamics Within The Penn State Failing Fontan Centrifugal Blood Pump Under Steady And Pulsatile Conditions
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Study: Approximately 1 out of every 10,000 children are born with a single functioning ventricle, requiring the Fontan operation to bypass the right heart by joining the inferior (IVC) and superior vena cava (SVC) directly to the pulmonary arteries (PAs). 85% of children are surviving at 20 years post-operation but upon reaching adulthood, patients demonstrate “Fontan failure” and require heart transplantation. Due to the limited donor hearts available, Penn State University is developing an implantable centrifugal blood pump for failing Fontan patients. This study aims to quantify the hemodynamics with the Penn State failing Fontan centrifugal blood pump at both steady and pulsatile inflow conditions using particle image velocimetry (PIV).

Methods: Using an acrylic model of the Fontan centrifugal pump, a mock circulatory loop simulated the Fontan circulation at three steady conditions (Case 1: 4 L/min, 4000 rpm, Case 2: 5 L/min, 4000 rpm, Case 3: 5 L/min, 5000 rpm) and a physiological pulsatile inflow condition (Case 4). PIV quantified the velocity and turbulent stresses at three planes in the IVC, SVC, and PA for all conditions.

Results: For steady cases, an increase in flow rate increased inlet and outlet velocity and turbulent stresses. An increase in rotational speed increased inlet velocity only when directly entering the pump. At the outlet, the Case 2 optimal condition produced a higher velocity than Case 3. The physiological pulsatile condition demonstrated a velocity that varied over the cycle and produced greater outlet turbulence than steady cases. Flow visualization of the Fontan pump provided computational model validation and informed pump design.

BIO4-4

A Genetic Algorithm-based Optimization Framework For Control Parameters Of Ventricular Assist Devices
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Study: in this study, a genetic algorithm-based optimization framework (GAOF) for control parameters of ventricular assist devices (VADs) has been developed. The performance of the GAOF has been evaluated with the optimization of a physiological proportional-integral-derivative (PID) controller that relies on the pump inlet pressure.

Methods: The GAOF (Fig. 1) consists of the user inputs, the in silico environment and the genetic algorithm. Specifically, the user defines the VAD control structure, the objective function (OF), the experiments appropriate for the evaluation, and the corresponding healthy heart data (HHD). Each set of control parameters (individual), is fed to the controller and the VAD-supported heart is simulated. The simulation results are compared with the HHD and the OF is evaluated and assigned to the respective individual as “score”. As long as the convergence criterion of the OF is not met and the maximum number of generations (each generation includes multiple individuals) is not achieved, the individual’s scores are fed to the genetic algorithm. Based on those scores, the GA uses genetic operations (elitism, replication, crossover, and mutation) to create new individuals for the next generation. The process continues for each individual and each generation until an optimum (or multiple) set of control parameters has been identified. The performance of the optimized controllers is further evaluated via dynamic tests.

Results: The GAOF converged to the optimum parameters of the PID controller within 12 generations. The optimized controller, compared to a benchtop proportional controller and the constant speed controller, showed a 37% and 95% reduction of the cardiac output error during a preload variation experiment, respectively. Regardless of the control structure, the GAOF optimizes the controller parameters aiming at the minimization of a user-defined OF, allowing the development of VAD controllers, which meet patient specific requirements.
Results: Torque Control Mode With Left Atrial Assist Device: The Initial In Vitro Results

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**Study:** The left atrial assist device (LAAD) is our novel device designed to be an effective option for the treatment of heart failure with preserved ejection fraction (HFpEF). The LAAD is a mixed-flow pump that is implanted at the mitral valve level and pumps blood from the left atrium to the left ventricle. Although the LAAD can work in constant speed mode like other rotary blood pumps, we have tested it in torque control (TC) mode to improve its function as an assist device. In TC mode, the pump speed changes during each cardiac cycle to maintain a specified torque. We report its performance and efficacy here.

**Methods:** We tested the LAAD performance under four different TC settings (TC mode 0.9, 1.0, 1.25, and 1.5, Amps torque equivalent), using an in vitro mock circulatory loop. A pneumatic mock ventricle was used as a native left ventricle, and three diastolic heart failure (DHF) conditions were created by adjusting the diastolic drive pressure of the pneumatic ventricle to 0 mm Hg (mild DHF), 20 mm Hg (moderate DHF), and 40 mm Hg (severe DHF). The pump speed, pump power, pump flow, and hemodynamics of each TC setting were recorded.

**Results:** With TC mode support, the cardiac output and aortic pressure recovered to normal heart levels at TC mode 1.25 and 1.5, even with the severe DHF condition, which was a result that was similar to the speed control setting of the LAAD. Additionally, the dynamic head curves in the TC mode showed steeper slopes than constant speed mode. The lower pump speed during diastole reduced ventricular pressure, and the increased speed during systole prevented reverse flow in TC modes 1.25 and 1.5 (Figure 1), while maintaining excellent pulsatility. These initial in vitro results support the potential efficacy of TC mode for DHF conditions. DHF is one of the major and typical features of HFpEF patients. Further evaluation, including in vivo experiments, are required.

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**BIO5-1**

**Kinetic And Dynamic Effects On Degradation Of Von Willebrand Factor**

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**Study:** Severe aortic stenosis (AS) and continuous flow left ventricular assist devices (cf-LVADs) are often complicated by acquired von Willebrand Syndrome (AvWS) characterized by the loss of high molecular weight multimers (HMWMs) of von Willebrand factor (vWF). It is known that high blood shear associated with highly irregular and disorganized blood flow in AS and cf-LVADs leads to structural changes of vWF. Interestingly, AvWS is fully corrected on the first day after surgery for AS and quickly disappears after the removal of an implanted cf-LVAD. This suggests that high turbulent blood flow in AS and the devices is responsible for the syndrome. This study is to understand the degradation mechanism of HMWM in terms of exposure time and flow regime.

**Methods:** A custom high shear rotary device capable of creating a fully controlled exposure time and flow regime was manufactured. The rotor features a raised ring around its center, creating a 381 μm gap within the stationary housing. The length of this gap and resulting flow area remain constant so that the exposure time, texp, depends only on flow rate. The system was set so plasma flowed through at 1.75 ml/sec, 0.76 ml/sec, or 0.38 ml/sec resulting in an exposure time of 0.022 sec (n=33), 0.05 sec (n=18), or 0.1 sec (n=33), respectively. The flow was characterized by the Reynolds number, Re, the ratio of inertial forces to viscous forces within flowing fluid. The device was run under 4 conditions where Re = 1500 (laminar, n=18), 3000 (transitional, n=18), 3500 (transitional, n=18), and 4500 (turbulent, n=30). After each run, a 0.5 ml sample solution was collected, frozen in dry ice immediately, and shipped to the Blood Center of Wisconsin for multimer analysis.

**Results:** Destruction of HMWM at a given exposure time increases with the Re. No destruction was observed at laminar flow at given exposure times. The statistical analysis revealed that Re and exposure time are significant factors destroying HMWM. Interaction between Re and exposure time, however, is not always significant (Fig 1).
BIO5-2
Effects Of Loss Of Pulsatility On Von Willerbrand Factor Availability And Activity In Patients On Continuous Flow Ventricular Assist Device
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Study: Diminished pulsatility associated with Continuous Flow Ventricular Assisted Device (CF-VAD) is a major risk factor in the development of acquired von Willebrand syndrome (AVWS) and non-surgical bleeding in advanced heart failure patients. Although the exact mechanisms that contribute to AVWS remain unclear, the reduced production and excessive degradation of endothelial von Willerbrand Factor (vWF) under continuous (non-pulsatile) flow is known to play a major role in the development of non-surgical bleeding. To better understand this phenomenon, we designed a comprehensive approach using in-vitro models and evaluation of blood samples from CF-VAD patients to determine how loss of pulsatility influences the availability and activity of vWF.

Methods: In-vitro studies utilized patient-derived Human Aortic Endothelial Cells (HAEC) cultured in our Vascular Pulse Perfusion Model (VPPM), an extensively validated vessel-on-a-chip model that can recreate both pulsatile and continuous flow. Cell culture media perfused through VPPM was collected after 24 hours of normal flow and after 1, 3, 5 days of continuous flow. Patient blood samples were collected prior to CF-VAD placement and monthly after CF-VAD implant. VPPM perfused media and patient extracted plasma were measured for availability and activity of endothelial vWF.

Results: The VPPM setup (Fig.1) was validated and tested in our lab to mimic hemodynamic stresses associated with normal and continuous flow. The vWF level change (in percentage) measured in VPPM (Fig.2) and patients (Fig. 3) suggested that endothelial vWF production was sensitive to flow pulsatility and exposure to continuous flow resulted in a decrease in endothelial vWF production. More importantly, these results suggest that the VPPM can model the effects of loss of pulsatility seen in CF-VAD patients accurately and serve as a valuable model to evaluate flow modulation protocols.
BIOS-3

Point-of-Care Electrical Impedance Aggregometry Is Effective in Discriminating Platelet Reactivity To Antiplatelet Drugs: The MICELI System

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Study: Cardiovascular therapeutic devices (CTDs) are effective clinically yet fraught with thrombosis. Antiplatelet drugs are utilized to limit CTD-related thrombosis. Patient response to these drugs highly varies, yet are not measured at point-of-care (POC) largely due to bulkiness and complexity of current lab tests. To address this, we prototyped and validated a miniature, easy-to-use, POC electrical impedance aggregometer (EIA) termed MICELI. Here, we tested MICELI as to quantification of platelet reactivity to antiplatelet drugs vs. light-transmission aggregometry (LTA) as a standard.

Methods: Platelet aggregation in ACD-anticoagulated whole blood and platelet-rich plasma of healthy donors (n=30) was evaluated. The effect of clopidogrel, ticagrelor, cangrelor, cilostazol, and tirofiban was tested on ADP-induced aggregation and aspirin - with arachidonic acid and collagen. Platelet aggregation was recorded using the MICELI or BioData PAP-8E aggregometers.

Results: MICELI EIA appropriately detected a dose-dependent decrease in aggregation associated with a coordinate increase in drug concentration for all agents tested. Aggregation in platelet-rich plasma recorded by LTA showed higher sensitivity to antiplatelet agents, though it did not distinguish between different drug doses. Direct inhibitors of platelet surface receptors (P2Y12, blockers and tirofiban) had a more distinct and predictable inhibitory effect on platelet aggregation than inhibitors of platelet metabolic pathways - aspirin and cilostazol. Conclusion: Platelet aggregation in whole blood recorded by MICELI offers an advantage in evaluation of platelet reactivity, as EIA accounts for the modulatory effect of other blood cells on platelet hemostatic function and the pharmacodynamics of antiplatelet drugs in vivo. MICELI EIA is a promising tool for POC monitoring of platelet function for personalized antiplatelet management of CTD-patients.

BIOS-4

Surface Coatings Of Heparin And Hyaluronan - In Vitro And In Vivo Studies On Anti-inflammatory Action

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Study: The inflammatory response to biomaterials is crucial for functional integration of implants but also responsible for fibrosis and scarring. Glycosaminoglycans (GAG) like heparin (Hep) and hyaluronan (HA) represent good candidates due to their immunomodulatory and anti-inflammatory properties. Both Hep and HA were used for covalent and adsorptive immobilization on either glass for in vitro studies or biphasic calcium phosphate particles (BCPP) for in vivo studies in a mouse model.

Methods: Covalent immobilization was done after modification of materials with aminopropyltriethoxysilane to obtain primary amino groups for formation of amide bonds with carboxylic groups of both GAG. Adsorptive immobilization was achieved by layer-by-layer technique with chitosan as polyanion forming 5 bilayers of GAG/CHI. Physical studies were done to study surface properties of materials. In vitro experiments were performed with macrophages studying adhesion, formation of multinucleated giant cells (MNGC) and IL-1beta release as measure of pro-inflammatory response. Animal experiments were done by subcutaneous implantation of BCPP for 15 and 30 days and histochemical analysis and RT-PCR.

Results: Both covalent and adsorptive immobilization on both substrata glass and BCPP was successful. In vitro studies with macrophages showed reduced adhesion of macrophages, formation of MNGC and IL-1beta release as measure of pro-inflammatory response. Animal experiments were done by subcutaneous implantation of BCPP for 15 and 30 days and histochemical analysis and RT-PCR.

Conclusion: Both GAG are potent modulators of inflammatory response with HA particularly effective in vivo indicating their potential to control tissue response after implantation of sensors, percutaneous and other devices.
Leveraging Platelet Zonal Analysis To Quantify Thrombogenic Risk Of LVAD Inflow Cannula Malposition

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Methods: CFD and Lagrangian platelet tracking was used in five virtual patient-derived LV models to simulate blood flow patterns and platelet behavior in the LV implanted with a generic LVAD inflow cannula (orientations ranging from ± 14° from axial alignment). Platelet trajectories for hundreds of thousands of platelets were analyzed for each configuration to determine important characteristics such as residence time (RT) and shear history (SH) using rigorous statistical analysis. The LV was divided into four zones: Zone 1 (aortic root), Zone 2 (LV central core), Zone 3 (exterior ‘donut’ peripheral region), and Zone 4 (apical region around inflow cannula), and platelet behavior in each zone was analyzed using rigorous statistical analysis.

Results: Preliminary analysis indicates zones 1 and 4 are stagnation zones, confirming the risk of platelets accumulating within these zones, potentially forming a nidus of microthrombi. Platelets in zone 3 were found to experience long RTs coupled with high SH, and were statistically significantly different from all other zones using the Wilcoxon Rank-sum Test. High platelet RT and/or SH in the LV zones produce an unfavorable hemodynamic environment where platelet activation is more likely to occur, increasing the risk of thrombotic complications. Through these results, platelet clustering analysis could be utilized as a useful tool to identify specific thrombogenic zones in the LV, such as aortic root or apical zones. Such analysis can lead to determining optimal LVAD implantation configurations for patients based on their left ventricular morphology, thereby reducing complications.

Clinical Trials In Vascular Grafts: Challenges To Implement Results From Animal Studies

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Methods: A review of clinical trials was performed querying “tissue engineered regenerative vascular graft” in ClinicalTrials.gov and within the WHO database i.e., ANZCTR, ReBec, ChiCTR, CRIS, CTRI, RPCEC, EU-CTR, DRKS, IRCT, ISRCTN, JPRN, LBCTR, NTR, PACTR, REPEC, SLCTR. The results were compared to those obtained before on preclinical trials and to databases of approved and commercially available grafts.
BIO5-7

Engineering Of Stable Thermoresponsive Multilayers Based On Cross-linked PNIPAM-grafted-chitosan And Heparin For Cell Sheet Generation
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Study: Poly(N-isopropylacrylamide) (PNIPAM) exhibiting a lower critical solution temperature (LCST) around 32 °C can enable detachment of cell sheets from cell culture substrata by reducing the temperature below LCST. This study focuses on the development of a thermoresponsive polyelectrolyte multilayer (PNIPAM-PEM) using layer-by-layer (LbL) technique. It can help us to understand the physical and biological properties of the sophisticated PEM systems containing PNIPAM.

Methods: PNIPAM with different sizes are covalently grafted onto chitosan (Chi) to obtain different degrees of substitution (DS) of PNIPAM-grafted-chitosan (PChi). Nuclear magnetic resonance spectroscopy and dynamic light scattering are used to analyze DS and conformational change of PChi with temperature. The PNIPAM-PEMs are built at pH 4 with PChi as polycation and bioactive heparin as polyanion. Subsequently, the systems are chemically cross-linked to stabilize the PEM. The growth behavior, thickness, and wetting properties and temperature effects of the PNIPAM-PEM are studied by different analytical methods. In addition, the stability of the PEMs is tested by rinsing with PBS, pH 7.4 and DMEM. Finally, the use of PNIPAM-PEM as cell culture substrate is examined using multipotent mouse stem cells.

Results: PChi with higher DS and sizes show significant increase in the diameter above LCST. They have the ability to form PNIPAM-PEM with heparin. After rinsing with PBS and DMEM, the thickness significantly decreases in non-cross-linked compared to negligible changes in cross-linked PEM. As the temperature changes, the PNIPAM-PEM is slightly more hydrophobic at 37 °C than at 20 °C. Moreover, higher adhesion and spreading of cells on cross-linked PEM are observed. Therefore, the PNIPAM-PEMs with cross-linking provides greater stability as a cell culture system for further investigation of cell sheet generation for engineering of tissues.

BIO5-8

Endothelialisation Of Left Ventricular Assist Device Impeller
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Study: The use of left ventricular assist devices (LVAD) with its artificial surfaces is inter alia limited by the activation of the coagulation system, where thrombus formation results in the exchange of the system. Driven by advances in regenerative medicine, endothelial cell (EC) seeding is considered to be an important tool to optimize hemocompatibility of artificial materials. In order to improve hemocompatibility of LVAD, we established EC monolayer integrity for clinical flow-resistance on the impeller using a new approach using magnetic forces and intracellular superparamagnetic nanoparticles (NP).

Methods: EC were incubated with different nanoparticles concentrations and coatings for various time periods. Nanoparticulate absorption behaviour was visualized by Prussian blue staining. Batches with high intracellular nanoparticle quantities were analysed for cell viability by immunofluorescence staining and proliferation assay, possible cytotoxicity by flow cytometry. Cellular alignment induced by different magnetic forces was examined and transferred to LVAD impeller endothelialisation.

Results: Concentration-, coating- and time-dependent changes in cell viability, proliferation and cytotoxicity could be shown, indicating best results for low concentrated sodium citrate nanoparticles, which were used for subsequent cell migration experiments. Magnetic field sufficiently affected endothelialisation as significantly more NP loaded ECs adhered to the impeller surface compared to the unloaded control group. These results are promising steps towards the improved hemocompatibility of LVAD, as the LVAD itself may provide the needed magnetic field for sufficient flow-resistant endothelialisation.
BIO6-1

Fitting Studies Of A Pediatric Continuous-flow Total Artificial Heart In 32 Pediatric Patients

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Study: The continuous-flow total artificial heart (CFTAH) is our invention for the treatment of end-stage heart failure. Pediatric patients with complex congenital heart disease often experience severe heart failure, but the CFTAH is too big for them. Therefore, we are developing a pediatric CFTAH (P-CFTAH) to determine feasibility for various congenital heart anomalies. This study was designed to evaluate the fitting of a replica of the P-CFTAH in patients of different weights and morphologies.

Methods: The P-CFTAH pump was derived by downsizing the adult CFTAH at a scale of 0.70 (1/3 of total volume). The 3D-printed models of the pump (Fig. 1A) were evaluated for anatomical fit during open-heart surgery (Fig. 1B) for a variety of congenital heart anatomies ranging from 2.9 kg to 30 kg (mean 7.1 ± 4.9 kg) of body weight (BW). The P-CFTAH has been reviewed with a total of 32 patients so far, and the results were divided into two groups (fit and non-fit) after the intraoperative visual assessment of fitting. The pre-op thoracic size (mm) and heart sizes (mm) were measured in their pre-op chest X-rays, and the differences between the two groups and the cutoff lines were statistically analyzed.

Results: Among the 32 patients, 17 were in the fit group, and 15 in the non-fit group. There were significant differences (p < 0.0001) between fit/ non-fit groups for BW, height (Ht), body surface area (BSA), and thoracic and heart size (A, B, C, and D in Fig. 1C). The cutoff values of each are: BW: 5.10 kg, Ht: 63.5 cm, BSA: 0.36 m², A: 137.0 mm, B: 77.0 mm, C: 57.0 mm, and D: 76.0 mm. The area under the curve for all of the parameters except C were >0.93; that of C was 0.88. This study revealed the suitable range of the P-CFTAH with easily acquirable data from the pediatric patients, and the range of proper fit was wide enough to accommodate most of the pediatric patients. Further studies, including the evaluation of pump performance in vivo, are required.

BIO6-2

From Benchtop To Beside: Patient-specific Outcomes Explained By In-vitro Experiment

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Study: Recent analyses show that females have higher early postoperative (PO) mortality and right ventricular failure (RVF) than males after left ventricular assist device (LVAD) implantation; and that this association is partially mediated by smaller LV size in females. Benchtop experiments allow us to investigate patient-specific (PS) characteristics in a reproducible way given the fact that the PS anatomy and physiology is mimicked accurately. With multiple heart models of varying LV size, we can directly study the individual effects of titrating the LVAD speed and the resulting bi-ventricular volumes, shedding light on the interplay between LV and RV as well as resulting inter-ventricular septum (IVS) positions, which may cause the different outcomes pertaining to sex.

Methods: In vitro, we studied the impact of the heart size to IVS position using two smaller and two larger sized PS heart phantoms derived from clinical CT images (Fig. 1A). With ultrasound crystals that were integrated on a placeholder inflow cannula, the IVS position was measured during LV and RV volume changes (dV) mimicking varying ventricular loading states (Fig. 1B). Figure 1 A Two small (blue) and two large PS heart phantoms (orange) on B benchtop. C Median septum curvature results. LVEDD/LV, RV volume changes (dV) mimicking varying ventricular loading states. Results: Going from small to large dV, at zero curvature, the septum starts to shift towards the left; for smaller hearts at dV = -40 mL and for larger hearts at dV = -50 mL (Fig. 1C). This result indicates that smaller hearts are more prone to an IVS shift to the left than larger hearts. We conclude that smaller LV size may therefore mediate increased early PO LVAD mortality and RVF observed in females compared to males. Novel 3D silicone printing technology enables us to study accurate, PS heart models across a heterogeneous patient population. PS relationships can be studied simultaneously to clinical assessments and support the decision-making prior to LVAD implantation.

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**BIO6-3**

**Design Optimization Of The Corwave Membrane Lvad**

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**Study:** CorWave is developing a unique LVAD employing an undulating membrane to propel blood. By changing the oscillation frequency and magnitude, the membrane operation replicates a physiologic pulse. CorWave LVADs have previously completed over 40 implants in ovines with durations up to 2 months. The present studies focused on optimization of the device performance and hemocompatibility to advance towards design freeze.

**Methods:** Pump designs were analyzed and refined using computational fluid dynamics and fluid structure interactions. The blood flow path was investigated by altering fluid path dimensions. The pump control algorithm was modified from open loop to closed loop control mode. Hydraulic testing in a mock circulatory loop and hemolysis measurements in static and pulsatile conditions were then performed in vitro. Membrane position and oscillation during operation were quantified by laser micrometry.

**Results:** In *in silico* simulations, increasing membrane holder skirt length and decreasing flow channel size increased hydraulic performance until the channel size approached the boundary layer thickness. However, to maintain shear stresses of normal physiology (< ~9 Pa) required larger gaps. In vitro testing confirmed that altering the gaps increased hydraulic output by >40%, while reducing the hemolysis by >60%. Implementing closed loop control in concert with motor optimization increased the pump operating range, confirmed by in vitro testing and membrane visualization studies. Building on the foundation of successful animal implants and durability studies, we conducted optimization of CorWave LVAD, seeking to improve pump performance and efficiency, while preserving physiologic shear stress conditions. The robust optimization and new control algorithms yielded significant hydraulic performance increase while improving hemocompatibility. The updated designs have been integrated into new pump designs which will be characterized and evaluated.

**Figure 1: Major parameters with respect to channel diameter.**

**Methods:** Murray’s law, the Hagen-Poiseuille equation, and a previously-developed model of gas exchange in μALs were used to compare μAL designs with capillary heights (Hₜ) between 10 and 100 μm. Designs contained distribution channels and capillaries and were constrained to fit on 6” silicon wafers. Rated blood flow (Qₘ) and total pressure drop (ΔPₘ) were fixed at 0.8 mL/min and 60 mmHg for all designs. Three designs (Hₜ = 30, 60, 100 μm) were modeled using CFD (SOLIDWORKS), implemented via soft lithography, and tested *in vitro* with bovine blood to verify performance.

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**BIO6-4**

**Microfluidic Artificial Lungs: A Parametric Analysis Of Capillary Height**

**Lindsay J. Ma, BS¹, Emmanuel Akor, BS², Alex J. Thompson, PhD², Joseph A. Potkay, PhD²; ¹VA Ann Arbor Healthcare System, Ann Arbor, MI, USA, ²Department of Biomedical Engineering, University of Michigan, Ann Arbor, MI, USA.**

**Study:** Microfluidic artificial lungs (μALs) have been designed with small artificial capillary diameters (10–40 μm) to maximize gas exchange efficiency or with larger diameters (~100 μm) to simplify construction and potentially minimize clotting. However, no study has directly compared the impact of capillary diameter on μAL properties and performance, which is the goal of this work.

**Methods:** Murray’s law, the Hagen-Poiseuille equation, and a previously-developed model of gas exchange in μALs were used to compare μAL designs with capillary heights (Hₜ) between 10 and 100 μm. Designs contained distribution channels and capillaries and were constrained to fit on 6” silicon wafers. Rated blood flow (Qₘ) and total pressure drop (ΔPₘ) were fixed at 0.8 mL/min and 60 mmHg for all designs. Three designs (Hₜ = 30, 60, 100 μm) were modeled using CFD (SOLIDWORKS), implemented via soft lithography, and tested *in vitro* with bovine blood to verify performance.
Results: Gas exchange surface area ($A_{c,g}$) increased with capillary height (Fig. 1) while total blood contacting surface area ($A_{c,b}$) and wall shear stress ($\tau_{w,avg}$) exhibited a maximum and priming volume ($V_{prime}$) exhibited a minimum around $H_c = 40 \mu m$ (Fig. 1). CFD (Fig. 2) results were within 15% of $\Delta P$ and $\tau_{w,avg}$ calculations. In vitro experiments (Fig. 3) confirmed theoretical gas exchange, but measured pressure drop was ~45% lower than theory.

BIO6-5
A Total Artificial Heart Based On A Single Nutating Disc Pump
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Study: The purpose of this study is to evaluate the feasibility of using a single nutating disc pump as a TAH. A nutating pump employs a disc centered in a pumping chamber by means of a spherical bearing and is caused to nutate or wobble, creating a wave action which displaces fluid from an inlet to an outlet. Although, not currently used for mechanical circulatory assistance, they may have better blood handling properties since maximum velocities are less than 10% of rotary pumps. In the 2003 ASAIO Journal (49):123–127, Yusuke Abe demonstrated good blood compatibility and complete circulatory support of a goat for 46 days with a total artificial heart (TAH) comprised of two nutating disc pumps.

Methods: A single nutating disc pump was converted to two parallel pumps by changing the location of the inlets and outlets from radial porting to axial placement such that each side of the disc is a distinct pump as shown in the figure. In so doing, a single nutating disc pump could be configured to simultaneously support the pulmonary and systemic circulation. A nutating disc water meter chamber was modified to create two parallel pumps on opposite sides of the disc. The existing radial ports were plugged with epoxy and axial inlets and outlets were machined. Printed ports were bonded to the modified housings as shown in the figure. A fixture was created to drive the pump with a DC motor. The flow versus speed for the two sides were measured at 10 mm Hg.
Results: The flow, speed and shaft power on shown in the table. Occluding the outlet of one side did not cause an increase in the flow of the non-occluded side suggesting leakage between pumps was minimal. Limitations of the modified water meter pump precluded producing systemic pressures. This preliminary study suggests that a single nutating disc pump could be adapted for use as a TAH and may offer significant improvement in blood handling compared to rotary blood pumps. Design of a first prototype sized for human use is in progress and the feasibility of electromagnetic actuation of the disc is being studied.

<table>
<thead>
<tr>
<th>Hydraulic Test</th>
<th>Speed (RPM)</th>
<th>Shaft power (watts)</th>
<th>Flow 1 (L/min)</th>
<th>Flow 2 (L/min)</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
<tr>
<td>150</td>
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</tr>
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<td>200</td>
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<td>9.7</td>
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</tr>
</tbody>
</table>

BIO6-6

Influencing Factors Contribute To In Vitro Testing Of Extracorporeal Membrane Oxygenation-induced Hemolysis

Chris Hoi Houng Chan, PhD, Katrina K. Ki, PhD, Amelia Zhang, PhD, Cooper Asnicar, BA, Hwa Jin Cho, PhD, Carmen Aino, BA, Mahe Bouquet, BA, Silver Heinsar, BA, Jo Pauls, PhD, Jacky Y. Suen, PhD, John F. Fraser, PhD. 1School of Engineering and Built Environment, Griffith University, Brisbane, Australia, 2Faculty of Medicine, The University of Queensland, Brisbane, Australia, 3School of Mechanical and Mining Engineering, University of Queensland, Brisbane, Australia, 4School Department of Pediatrics, Chonnam National University Children's Hospital and Medical School, Brisbane, Korea, Republic of

Study: In vitro hemolysis testing has been commonly used to determine hemocompatibility of early prototypes of blood-contacting devices such as Extracorporeal Membrane Oxygenation (ECMO). However, poor reproducibility remains a challenging problem due to several unidentified influencing factors which affect the outcome of in vitro hemolysis testing of ECMO. The present study investigated potential influencing factors, such as flow rate, anticoagulation and gender of blood donor, on hemolysis with a specific aim to provide benchmark values for future ECMO development.

Methods: Four ECMO (Permanent Life Support System, Maquet) loops were randomly tested and re-used using citrated (n = 6) or heparinized human blood (n = 12), with two different flow rates of 4 L/min and 1.5 L/min. Equal numbers of female and male blood donors were allocated to each group of testing condition. All in vitro testing of ECMO were performed at 37°C over 6 hours (consistent with ASTM F1841-97 and F1830-97).

Results: Regardless of flow rate conditions, the level of hemolysis remained unchanged for citrated blood, but significant increase in hemolysis was observed in heparinized blood over the 6-hour ECMO circulation. The ratio of normalized index of hemolysis (NIH) of heparinized blood to citrated blood were 11.7-fold at 4 L/min and 16.5-fold at 1.5 L/min. Equal numbers of female and male blood donors were allocated to each group of testing condition. All in vitro testing of ECMO were performed at 37°C over 6 hours (consistent with ASTM F1841-97 and F1830-97).

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The Effects Of Outlet Boundary Conditions On Cerebral Blood Flow And Emboli Transport During Cardiopulmonary Bypass

Bryan Good, PhD; Mechanical, Aerospace, and Biomedical Engineering, University of Tennessee, Knoxville, TN, USA

Study: The risk of postoperative neurologic dysfunction in patients on cardiopulmonary bypass (CPB) remains high despite improvements in protective strategies. Primary risk factors linked to poor outcomes are an increased risk of stroke resulting from higher micro-embolic load and altered cerebral blood flow (CBF). Both factors are strongly influenced by cerebral autoregulation (CAR), which allows the body to maintain adequate CBF despite changes in CPB flow rates and perfusion pressures. Previous studies have investigated the effects of CAR boundary conditions in an ascending aorta model and on emboli distribution in the Circle of Willis (CoW), but none have compared boundary conditions in a full CoW model during CPB.

Methods: In order to accurately model cerebral hemodynamics and the delivery of micro-emboli to the CoW during CPB, improved boundary conditions that mimic CAR are needed in a complete head-to-neck vascular model. A 3D patient cerebral vascular model that incorporates all branches of the aortic, arteries of the neck, and CoW was used to perform computational fluid dynamics simulations with OpenFOAM software. Four sets of outlet boundary conditions of increasing complexity (fixed-pressure, resistance-based, Windkessel model (WKM), and lumped-parameter CAR) were compared as to their effect on CBF distribution and hypoperfusion. Additionally, Lagrangian particle-tracking was incorporated and particles released from the CPB cannula to mimic embolization.

Results: Under a range of perfusion pressures (50–150 mmHg), the fixed-pressure, resistance-based, and WKM boundary conditions experienced no change in CBF, while the CAR conditions led to a decrease in CBF when pressures dropped below normal levels (<80mmHg) and an increase when they exceeded them (>120mmHg). Micro-emboli distribution varied as well with CBF distribution and increased to CoW branches with WKM and CAR boundary conditions.
CAR1-1  
Risk Factors And Outcomes Of Patients Requiring Left Ventricular Unloading On Veno-Arterial Extracorporeal Membrane Oxygenation Support  
Bree Ann C. Young, MD, MS, Chetan Pasrija, MD, Sari Holmes, PhD, Samantha J. Kegel, BS, Douglas Tran, MD, Eric M. Krause, MD, Dawn M. Parsell, BS, Ronson Madathil, MD, Nicole Hays, BS, Lauren E. Levy, BS, Joshua Finkel, BS, Kristopher B. Deatrick, MD; Surgery, Division Cardiac Surgery, University of Maryland, Baltimore, MD, USA  
Study: Veno-arterial extracorporeal membrane oxygenation (VA ECMO) can provide full systemic perfusion in cardiogenic shock, but does not unload the left ventricle. Left atrial hypertension, pulmonary edema, hemorrhage, and further LV dysfunction may result. The need for routine unloading, however, remains controversial. We sought to identify risk factors for LV dysfunction receiving unloading and to compare outcomes of patients who received unloading to those that did not.  
Methods: Patients who underwent peripheral cannulation for VA-ECMO for refractory cardiogenic shock from January 2015 to December 2019 were reviewed.  
Results: VA ECMO patients were analyzed (N=302) and 42 (14%) required LV unloading. Unloading strategies included Impella placement (n=13, 31%), atrial septostomy (n=27, 64%), and both (n=2, 5%). Prior CVA (24 vs 10%, P=0.018) and S-T segment elevation myocardial infarction (STEMI) as indication for ECMO (26 vs 3%, P<0.001) were associated with LV unloading. Hypertension (64 vs 66%, P=0.828), dyslipidemia (50 vs 41%, P=0.289), and ECMO-CPR (eCPR) status (29 vs 24%, P=0.509) were not risk factors for LV unloading. No significant difference was found for age, BMI, gender, and race. ECMO duration (12 vs 6 days, P<0.001), limb ischemia (26 vs 13%, P=0.026), and cardiac/aortic thrombus (21 vs 10%, P=0.037) were higher in patients requiring LV unloading. ECMO mortality was higher (50% vs 21%, P<0.001) and survival to discharge was lower (38 vs 67%, P<0.001) in patients requiring LV unloading. Patients requiring LV unloading strategies on VA ECMO had higher incidence of ECMO mortality and lower survival to discharge at our institution. STEMI patients requiring ECMO may be at highest risk for requiring LV unloading. These results may help guide clinical decision-making regarding VA ECMO initiation, support, and implementing LV unloading strategies.
CAR1-2
Improved Outcomes In Veno-arterial Extracorporeal Membrane Oxygenation For Primary Graft Failure After Heart Transplantation
Aaron Guo, BS, Brandon Jocher, BS, Irene Fischer, MPH, Kunal Kotkar, MD, Muhammad Masood, MD, Akinobu Itah, MD, PhD; Surgery, Washington University School of Medicine in St. Louis, St. Louis, MO, USA

Study: Extracorporeal membrane oxygenation (ECMO) support is a life-saving measure in the acute phase after heart transplant, wherein the allograft primarily may become dysfunctional (PGD) despite maximal pharmacologic efforts. We aimed to formally assess ECMO strategies on outcomes at our single center over the last 8 years.

Methods: 276 heart transplant patients between 1/1/2013 and 9/30/2020 were reviewed. 41 patients were identified who required ECMO for PGD during in-hospital recovery post-transplant. Patients were stratified by transplant before or after January 2017, when our center changed ECMO strategies as described here: before 1/3/2017, we primarily used central (direct through aorta/right atrium) or direct peripheral (percutaneous or open through femoral artery/vein) standard cannulation techniques for VA-ECMO. After January 2017, we introduced the use of cannulation into a chimney graft sewn to the brachiocephalic artery, axillary artery, or aorta; percutaneous venous cannulation was performed through the femoral vein or internal jugular vein. We aimed at earlier extubation and mobilization of post-transplant patient even on VA-ECMO. Primary outcome of interest was survival to discharge. Secondary outcomes included survival to wean from ECMO and 30-day survival from transplant. Clinical data was collected from electronic chart review and Society for Thoracic Surgeons (STS) database.

Results: Survival to discharge before 2017 was 45% (9/20), which improved to 76% (16/21) after January 2017 (p=0.041). Before 2017, median time to ECMO weaning was 4 days with 65% (13/20) survival to weaning. This is compared to after 2017, with median time to ECMO weaning of 5 days with 100% survival to weaning. 30-day survival was 55% (11/20) and 90% (19/21) before and after 2017, respectively (p=0.010). This new modified approach to ECMO after heart transplant is associated with significantly improved outcomes.

CAR1-3
Cerebrovascular Accidents In Patients Supported With Veno-Arterial Extra-corporeal Membrane Oxygenation—Is Duration Of Support Important?
Sheraz Hussain, MD1, Natalia Zera, DO1, Tareq Al Saadi, MD1, Moneeb Asghar, DO2, Muhammad Ali Khan, MD1, Nicole Glowacki, MPH2, David Alexander, None4, Christopher Sciamanna, DO1, Anjali Joshi, MD1, Ambar Andrade, MD1, Muhyaldeen Dia, MD1, Gregory Macaluso, MD1, Nikhil Narang, MD1, Philip Alexander, MD1, Antone Tatooles, MD1, Patroklos Pappas, MD1, William Cotts, MD1, Sunil Pauwaa, MD1; 1Internal Medicine, University of Illinois at Chicago/Advocate Christ Medical Center, Oak Lawn, IL, USA, 2Research, Advocate Christ Medical Center, Oak Lawn, IL, USA, 3Advocate Christ Medical Center, Oak Lawn, IL, USA, 4Department of Cardiovascular and Thoracic Surgery, Advocate Christ Medical Center, Oak Lawn, IL, USA

Study: Veno-Arterial Extra-corporeal Membrane Oxygenation (VA-ECMO) is indicated for refractory cardiac and/or respiratory failure. Adverse events remain considerable despite best practices. We specifically aimed to understand risk factors associated with cerebrovascular accidents (CVA) in patients who underwent VA-ECMO support.

Methods: We retrospectively assessed all VA-ECMO patients from 2007 to 2019 at our institution. We identified those who experienced a CVA while supported by VA-ECMO. Patients with the primary event (CVA) were matched to controls (no CVA) based on age and sex. Comparisons were made between groups using McNemar’s, Mantel-Haenszel, and Wilcoxon Signed-Rank tests where appropriate.

Results: Of the 278 VA-ECMO patients in the registry, 32 patients who experienced a CVA were identified; 24 (8.6%) ischemic and 8 (2.9%) hemorrhagic. Median age was 59.5 years (inter-quartile range: 49–65 years) and 75% of patients were males. Hypertension, diabetes, CAD and CHF were common co-morbidities (Table 1). Cardiogenic shock was the most
common indication for VA-ECMO support in both cohorts, 75% in cases and 71.9% in controls. Cannulation strategies were identified as central or peripheral. There was a significant association of duration of VA-ECMO support with incidence of CVA, with a p-value of 0.03. Regression analysis showed a trend of increased risk of CVA by 4% for each additional day on VA-ECMO, however, this was not statistically significant (Odds ratio: 1.04; confidence interval 1.00–1.08). Most common outcome was death followed by decannulation to recovery and bridge to LVAD. Conclusion Ischemic and hemorrhagic CVAs are not uncommon during VA-ECMO support. Our case control study shows an association of duration of VA-ECMO support with incidence of CVA. This underscores the importance of timely assessment and weaning or bridging of VA-ECMO patients to their next management step.

### Table 1: Characteristics among Stroke patients on VA-ECMO

<table>
<thead>
<tr>
<th>Type of CVA</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ischemic/TIA</td>
<td>24 (75.0%)</td>
</tr>
<tr>
<td>Hemorrhagic</td>
<td>8 (25.0%)</td>
</tr>
<tr>
<td>Days from Cannulation to CVA</td>
<td>9.0 (4.0–16.5)</td>
</tr>
<tr>
<td>On Day of CVA:</td>
<td></td>
</tr>
<tr>
<td>Acute Kidney Injury</td>
<td>20 (62.5%)</td>
</tr>
<tr>
<td>Continuous Renal Replacement Therapy/Hemodialysis</td>
<td>10 (31.3%)</td>
</tr>
<tr>
<td>Hepatic Dysfunction</td>
<td>15 (46.9%)</td>
</tr>
<tr>
<td>Active Infection/Sepsis</td>
<td>11 (34.4%)</td>
</tr>
<tr>
<td>Bleeding requiring operation or transfusion</td>
<td>16 (50.0%)</td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>21 (65.6%)</td>
</tr>
<tr>
<td>Interruption of Anticoagulation</td>
<td>11 (34.4%)</td>
</tr>
</tbody>
</table>

### CAR1-4

Comparing Intraoperative Blood Product Use During Heart Transplantation In Patients With Axillary Impella 5.5 Versus Durable Left Ventricular Device As Bridge Therapy

Rohan M. Goswami, MD1, Alexander Heckman, MD2, Basar Sareyyupoglu, MD1, Parag Patel, MD1, Juan Leoni, MD2, Daniel S. Yip, MD1, Osama Haddad, MD2, Si Pham, MD1, Kevin Landolfo, MD1; 1Department of Transplant, Mayo Clinic Florida, Jacksonville, FL, USA, 2Department of Cardiology, Mayo Clinic Florida, Jacksonville, FL, USA, 3Department of Cardiothoracic Surgery, Mayo Clinic Florida, Jacksonville, FL, USA

**Study:** Increased intraoperative blood product transfusion can potentiate the vasodilatory phenomenon of cardiopulmonary bypass (CPB). Furthermore, increased transfusion is also associated with worse right ventricular function after heart transplantation (OHT). This may increase the need for mechanical circulatory or increased vasoactive support after OHT. As a large volume center utilizing axillary support devices for bridge therapy (BTT) we analyzed their role in minimizing transfusion during OHT compared to left ventricular assist device (LVAD).

**Methods:** We performed a retrospective single center review of patients who underwent OHT from January 1, 2019 to December 31, 2020. All patients with axillary Impella devices and LVAD were included. All transfused blood products, including cell saver were reviewed. Descriptive statistical analysis was performed to assess the significance of product transfusion, CPB, length of stay and post-bypass vasoactive inotrope score (VIS).

**Results:** 82 patients underwent OHT during our study. 15 patients underwent axillary Impella placement (13M and 2F) and 13 had durable LVAD (8M and 5F) at the time of OHT. Average age was 60 in the Impella and 51 in the LVAD group. More product transfusion occurred with LVAD compared to Impella at time of OHT. Comparing all products transfused, only cryoprecipitate (p=0.01), cell saver (p=0.0005) and platelets (p=0.003) were statistically significant. No difference with FFP or PRBC transfusion was noted. Not surprisingly, median VIS score was lower in the Impella group (6 vs 9.8, p=0.05). CPB time was also statistically lower in the Impella group (p=0.003, 179 min vs 224 min). Our data suggests intraoperative transfusion and post-operative vasopressor needs are decreased in patients undergoing OHT with Impella support. We plan to further evaluate this with 1-year survival data in our cohort.
CAR2-1

Does Preimplant LVEDD Impact Clinical Outcomes In Centrifugal Flow LVAD Patients?
Mustafa M. Ahmed, MD1, Francis D. Pagani, MD, PhD2, Lauren Meece, CRNP3, Eric I. Jeng, MD4, Claudia Mahr, DO5, Nader Moazami, MD6, Nahush A. Mokadam, MD7, Joseph G. Rogers, MD8, Mustafa M. Ahmed, MD1, Francis D. Pagani, MD, PhD2, Nader Moazami, MD6, Joseph G. Rogers, MD8, Mustafa M. Ahmed, MD1, Francis D. Pagani, MD, PhD2, Nader Moazami, MD6, Joseph G. Rogers, MD8

Study: Recent literature suggests that patients (pts) with small left ventricles (LV) supported with axial flow left ventricular assist devices (LVADs) have worse survival than those with large LVs. The purpose of this analysis was to define survival in destination therapy (DT) pts supported with the HeartWare™ HVAD™ System in the ENDURANCE and ENDURANCE Supplemental Trials stratified by preimplant LV end-diastolic diameter (LVEDD).

Methods: HVAD pts with baseline LVEDD measurements were stratified into 2 cohorts: small LV (<60 mm) and large LV (≥60 mm). Baseline differences and survival through 3 years were analyzed. Further stratification by LVEDD <55 mm and female gender were also examined.

Results: Of the 604 HVAD DT pts, 487 (80.6%) had baseline LVEDD, 94 with small LV, 393 with large LV. Within the small LV cohort, 42 had an LVEDD <55 mm. Compared to the large LV cohort, small LV pts were more likely male (31.9% vs. 18.8%, p=0.008), had more ischemic heart failure (68.1% vs. 56.0%, p=0.04), lower hemoglobin (11.2 ± 11.9 vs. 11.9 ± 23.1 gm/dL, p=0.004) and mean pulmonary artery pressure (30.1 ± 8.8 vs. 33.0 ± 8.9 mmHg, p=0.02), higher LV ejection fraction (18.5 ± 4.4 vs. 16.9 ± 4.9%, p=0.004), and less moderate/severe mitral regurgitation (48.9 vs. 68.8%, p=0.03). Three-year survival was not significantly different between the two cohorts (57.5% small and 57.1% large LV cohorts, p=0.47, Fig. 1). Three-year survival in pts with LVEDD <55 mm was not significantly different from either the small or large LV groups (p=0.77).

In an analysis limited to 2-years due to small numbers, survival in women was not impacted by LVEDD (<55 mm: 77%, >60 mm: 77%, >60 mm: 78%, p=0.34). Conclusion: This analysis demonstrates that preimplant LV size does not significantly affect 3-year survival in DT HVAD patients. Additionally, women with very small LV (<55 mm) had comparable mortality outcomes as those with larger LV size.

CAR2-2

The Effects Of Baseline Right Ventricle Function On Mortality And Morbidity In Patients Undergoing Hvad Implant With A Thoracotomy Approach
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Study: To examine the effects of baseline right ventricular (RV) dysfunction, defined as the central venous pressure (CVP) to pulmonary capillary wedge pressure (PCWP) ratio and pulmonary artery pressure index (PAPi) score, on survival and adverse events in patients receiving the HeartWare™ HVAD™ System, via thoracotomy.

Methods: HVAD patients enrolled in the LATERAL trial with both CVP (or RAP) and PCWP values and PAPi score at baseline were eligible in this analysis (n=130). Patients were separated into three cohorts of RV dysfunction: Mild: CVP/PCWP < 40% (n=58), Moderate: CVP/PCWP 40% - 60% (n=55), and Severe: CVP/PCWP > 60% (n=17). In the LATERAL trial, patients with a mean CVP > 20 mmHg on multiple drips or RV ejection fraction < 15% with clinical signs of severe right heart failure were excluded. Differences in baseline characteristics, adverse events, and survival through six months were analyzed.

Results: Baseline characteristics were largely similar, except for more females in the CVP/PCWP > 60% cohort. The PAPi score was significantly different among the three CVP/PCWP groups (Mild: 5.4 ± 4.6 vs Moderate: 2.6 ± 1.3 vs Severe: 1.6 ± 0.6, p<0.0001) (Table 1). There were no differences in rates of hemorrhage or ischemic stroke, gastrointestinal (GI) bleed, renal failure or right heart failure requiring a right ventricle assist device (RVAD) in the first six months (Table 1). Six-month survival was also similar amongst the three cohorts of RV dysfunction: Mild: 95%, Moderate: 90%, and Severe: 85%, p=0.57 (Figure 1). Conclusion: In the prospective, single-arm, multi-center LATERAL trial, the severity of baseline RV dysfunction did not affect mortality and rates of adverse events at six months in patients who received the HVAD system via a thoracotomy approach.
Car2-3
Air Exposure Role In The Inflammatory Response Related To Cardiopulmonary Bypass
Mark Langley, BS, MS1, Matthew D. Johnson, MD1, Joseph Hill, BS, MS1, Terry Major, BS, MS1, Orsolya Lautner-Csorba, PhD1, Adrianna Kayden, BS1, Bailey Schneider, BS1, Daniel Drake, MD2, Jonathan Haft, MD2, Alvaro Rojas-Peña, MD3, Robert Bartlett, MD1, John Toomasion, CCP1; 1Surgery, University of Michigan Medical School, Ann Arbor, MI, USA, 2Surgery, Cardiac Surgery, University of Michigan Medical School, Ann Arbor, MI, USA, 3Surgery, Transplant, University of Michigan Medical School, Ann Arbor, MI, USA

Study: Cardiopulmonary bypass (CPB) during cardiac surgery is associated with a systemic inflammatory response (SIR) from leukocyte and platelet activation. Air exposure, foreign surface blood contact, ischemia-reperfusion injury, and operative trauma are all causes. A porcine model was developed to characterize the specific role of controlled air exposure during CPB.

Methods: Swine (n=14) were cannulated via the right atrium and aorta through a right mini-thoracotomy, supported on CPB for 2 hours and recovered. Air exposure (A, n=9) had a 20–25% blood shunt in which air was mixed at an approximate 4–5:1 ratio to mimic cardiotomy suction and venting. Control animals (C, n=5) were placed on CPB in which no air was administered. Blood samples were collected throughout the CPB period and daily for up to 7d. At termination, tissue samples were sent for histopathological analysis. Groups were compared using the Mann-Whitney U-test.

Results: In this model, air exposure did not result in any significant differences in morbidity or organ injury related to SIR. Granulocyte activation, measured by CD11b expression (242 MFI vs. 224 MFI, p=0.218) and platelet activation, measured by P-selectin expression (385 vs. 435 MFI, p=0.219) were not different between groups A and C, respectively. Additionally, there were no differences in free plasma hemoglobin (3.0 vs. 2.1 mg/dL, p = 0.114) or serum lactate levels (2.1 vs. 1.2 mmol/L, p=0.196). Histopathology did not show any differences in inflammation-related organ injury. These findings suggest that air exposure of this duration may not be as significant a factor in CPB-related inflammation, and that other potential causes may play a larger role. 
CAR2-4
Calcium Homeostasis And Right Ventricular Function Following Left Ventricle Assist Device Therapy
Kristin Stawiarski, MD, Olayinka Agboola, MD, Riya Bonde, None, Pramod Bonde, MD; Bonde Artificial Heart Lab, Yale School of Medicine, New Haven, CT, USA

Study: Heart failure progression has been linked to abnormal calcium homeostasis in myocytes. Its implication on right ventricular function has not been evaluated in end-stage heart failure patients undergoing left ventricular assist device (LVAD) placement. We investigated the impact of hypocalcemia on right ventricular function, post-operative recovery to explant and all-cause mortality over a 24-month period post LVAD.

Methods: Study group comprised of 177 patients receiving LVAD therapy from June 2011 and October 2018. Preoperative parameters were used to stratify patients into hypocalcemia [(serum calcium < 8.7 mg/dL) n=40, female = 7] or normocalcemia [(8.7- 10.2 mg/dL) n=108, female=30] groups. Patients with missing data were excluded (n=29). Baseline and adverse outcomes were compared using Fishers exact test. The association between the hypocalcemia and 24-month mortality was examined via cox regression models. A Kaplan-Meir plot and log-rank statistics were used to compare survival across patient groups.

Results: The LVAD cohort consisted of mainly males aged 60 with a greater number of patients in the hypocalcemia group receiving LVADs as a destination therapy (77 vs. 63%, p=0.09). The history of chronic kidney disease was similar (21 vs. 28%, p=0.36). Baseline left ventricular ejection fraction approximated 20% in both groups. However, the hypocalcemia group had a smaller left ventricular end systolic and end-diastolic volume comparatively (55 vs 62mm, p=0.01 and 62 vs 69 mm, p=0.004). 24-month survival was equal across groups (Log-Rank p=0.13). There was no difference in mortality seen on either the unadjusted (HR= 1.42 (0.89 - 2.7) (p=0.31)) or adjusted modelling (HR= 1.42 (0.89 - 2.7) (p=0.14)) or adjusted modelling [1.39 (0.86 - 2.24) (p=0.18)]. Hypocalcemia was associated with increased right ventricular assist device use (23 vs 8%, p=0.02) but LV recovery was equivalent (12 vs 7%, p=0.33). Persistent hypocalcemia maybe a prognostic marker for right ventricular failure in patients receiving LVAD therapy.

CAR2-5
Clinical Implication Of Optimal Heart Rate In LVAD Patients
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Study: Heart rate (HR) reduction therapy using ivabradine has demonstrated its prognostic implication in patients with heart failure with reduced ejection fraction. However, clinical implication of optimal HR in patients with left ventricular assist device (LVAD) remains unknown.

Methods: The cohort included all consecutive patients undergoing LVAD implantation between 2014 and 2018. The subjects who were not in sinus rhythm and/or whose follow up period was less than one year were excluded from the study. Ideal HR was calculated as follows: 96 - 0.13 × (deceleration time [msec]). The impact of “HR difference”, defined as the difference of HR between the actual HR at discharge and the calculated ideal HR, on one-year mortality and heart failure readmissions was investigated.

Results: A total of 143 patients (55 years old, 101 males) were identified and stratified into three groups considering their HR differences: (1) optimal HR group (N = 49; HR difference <27 bpm); (2) sub-optimal HR group (N = 47; HR difference 27–42 bpm); (3) abnormal HR group; HR difference >43 bpm; Figure 1A). There were no significant differences in the baseline characteristics and medications among the groups. Abnormal HR group had significantly higher one-year cumulative event rate compared with optimal HR group (38% vs. 16%, p = 0.029; Figure 1B) with a hazard ratio of 1.66 (95% confidence interval 1.09–2.51) adjusted for age, body surface area, ischemic etiology and destination therapy. In conclusion, non-optimized HR negatively affected clinical outcomes in LVAD patients. Implication of aggressive HR optimization in LVAD patients is the next concern.
CAR2-6

Psychosocial Characteristics And Two-year Outcomes In Patients With Ventricular Assist Devices
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Study: Patient selection for durable left ventricular assist device (LVAD) implantation involves a comprehensive medical and psychosocial evaluation to determine candidacy. We aim to evaluate the patient psychosocial risk profile and its impact on 2-year outcomes after VAD implantation.

Methods: This study was a single center, retrospective analysis of 237 patients who underwent durable LVAD implantation between 2015 and 2017. Patients were evaluated for psychiatric history, education, social support, cognitive function, and screened for depression and anxiety. Based off these criteria, the patients who were deemed low or low-moderate risk were assigned to the “low-risk” group and those who were moderate, moderate-high, or high risk were assigned to the “high-risk” group. Statistical analysis was performed using Chi-Square and Student’s t-tests, wherein p<0.05 was considered statistically significant.

Results: Of 237 patients, 138 patients were low psychosocial risk and 99 were high-risk. High risk patients were found to be younger (58 ± 13), more likely to have a history of illicit drug use (42 [42.9%] vs 25 [18.3%]), and more often lacked post-implant social support (85 [85.9%] vs 133 [96.4%]). There was no difference in two-year survival, days to first readmission, or mean number of readmissions within the first two years. High-risk patients were more likely to experience pump hemolysis and less likely to be waitlisted or transplanted (see Table). Psychosocial characteristics play a significant role in determining a patient’s candidacy for LVAD implantation. While patients with high-risk characteristics were statistically more likely to experience pump hemolysis, no difference was observed in readmission rates, driveline infection, bacteremia, CVA, pump thrombosis, GI bleed, hemorrhage, or overall survival at 2 years. This study highlights the importance of a multidisciplinary approach to patient evaluation. Further research with longer term follow-up is needed.

Table. Primary and Secondary Outcomes by Psychosocial Risk Stratification in VAD Recipients (n=237)

<table>
<thead>
<tr>
<th></th>
<th>Low Risk</th>
<th>High Risk</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>61 (53-70)</td>
<td>58 (46-65)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Male</td>
<td>105 (76.1%)</td>
<td>72 (77.9%)</td>
<td>0.56</td>
</tr>
<tr>
<td>Device:</td>
<td></td>
<td></td>
<td>0.29</td>
</tr>
<tr>
<td>HeartMate 2</td>
<td>67 (48.6%)</td>
<td>51 (51.5%)</td>
<td></td>
</tr>
<tr>
<td>HeartMate 3</td>
<td>16 (11.6%)</td>
<td>5 (5.3%)</td>
<td></td>
</tr>
<tr>
<td>HeartWare</td>
<td>54 (39.1%)</td>
<td>41 (41.4%)</td>
<td></td>
</tr>
<tr>
<td>Psychosocial Characteristics:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hx of Psychiatric Diagnosis</td>
<td>32 (23.2%)</td>
<td>27 (27.3%)</td>
<td>0.47</td>
</tr>
<tr>
<td>Pre-VAD Employed</td>
<td>128 (92.8%)</td>
<td>83 (83.8%)</td>
<td>0.07</td>
</tr>
<tr>
<td>Presence of Post-VAD Social Support</td>
<td>133 (96.4%)</td>
<td>85 (85.9%)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Highest Completed Education</td>
<td></td>
<td></td>
<td>0.11</td>
</tr>
<tr>
<td>≥ High School</td>
<td>104 (75.4%)</td>
<td>83 (83.8%)</td>
<td></td>
</tr>
<tr>
<td>≥ Bachelors</td>
<td>34 (24.6%)</td>
<td>16 (16.2%)</td>
<td></td>
</tr>
<tr>
<td>MOCA (Montreal Cognitive Assessment)</td>
<td>24 (22.0%)</td>
<td>21 (17.2%)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>PHQ-9 (Patient Health Questionnaire)</td>
<td>6 (3-9)</td>
<td>9 (5-15)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>GAD-7 (Generalized Anxiety Disorder)</td>
<td>2 (0-5)</td>
<td>7 (3-12)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>TERS (Transplant Evaluating Rating Scale)</td>
<td>31 (29-34)</td>
<td>38 (34-44)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Alcohol Use</td>
<td>111 (81%)</td>
<td>77 (78.6%)</td>
<td>0.64</td>
</tr>
<tr>
<td>Tobacco Use</td>
<td>92 (67.2%)</td>
<td>69 (70.4%)</td>
<td>0.60</td>
</tr>
<tr>
<td>Illicit Drug Use</td>
<td>25 (18.3%)</td>
<td>42 (42.9%)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Outcomes:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2-Year Survival</td>
<td>110 (80.3%)</td>
<td>76 (77.6%)</td>
<td>0.61</td>
</tr>
<tr>
<td>Number of Readmissions Within 2 years</td>
<td>3 (2-6)</td>
<td>4 (2-7)</td>
<td>0.22</td>
</tr>
<tr>
<td>Complications:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drive Line infection</td>
<td>46 (33.6%)</td>
<td>44 (44.9%)</td>
<td>0.08</td>
</tr>
<tr>
<td>Bacteremia</td>
<td>44 (32.1%)</td>
<td>33 (33.7%)</td>
<td>0.80</td>
</tr>
<tr>
<td>CVA</td>
<td>24 (17.5%)</td>
<td>18 (18.4%)</td>
<td>0.87</td>
</tr>
<tr>
<td>Thrombosis</td>
<td>8 (5.8%)</td>
<td>10 (10.2%)</td>
<td>0.21</td>
</tr>
<tr>
<td>Hemolysis</td>
<td>9 (6.6%)</td>
<td>16 (16.3%)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>GI Bleed</td>
<td>58 (42.3%)</td>
<td>41 (41.8%)</td>
<td>0.94</td>
</tr>
<tr>
<td>Waitlisted for Transplant</td>
<td>41 (29.7%)</td>
<td>16 (16.2%)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Transplanted</td>
<td>39 (28.3%)</td>
<td>11 (11.1%)</td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>
CAR2-7
Correlation Of Liver Biopsies And Outcomes In Patients Undergoing Evaluation For Advanced Heart Failure Therapies
Sanika Tolia, DO, Nikhil Narang, MD, Jessica Pillarella, MD, Anjali Joshi, MD, Christopher Sciamanna, DO, Sunil Pauwaa, MD, Gregory Macaluso, MD, Antone Tatooles, MD, Piotroklos Pappas, MD, William Cotts, MD, Ambor Andrade, MD; Advocate Christ Medical Center, Oak Lawn, IL, USA
Study: Patients with end-stage heart failure undergoing evaluation for left ventricular assist devices (LVAD) or orthotopic heart transplant (OHT) may often have evidence of hepatic dysfunction that necessitates liver biopsy to rule out liver cirrhosis. We aimed to evaluate liver biopsy findings and their respective impact on adverse events, candidacy for LVAD/OHT, and two-year survival.
Methods: In this single center, retrospective analysis, we evaluated 4,536 patients who were referred to the advanced heart failure team for evaluation between 2008–2020. We found 48 patients who underwent liver biopsy and assigned those with absent or sinusoidal fibrosis (grade 1) to low-risk and those with central, bridging, and portal fibrosis or cirrhosis (grades 2–4) to high risk. P-values less than 0.05 were considered significant.

<table>
<thead>
<tr>
<th>Table 1: Demographic Variables and Baseline Findings</th>
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</thead>
<tbody>
<tr>
<td>Variable</td>
</tr>
<tr>
<td>Demographic:</td>
</tr>
<tr>
<td>Age</td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td>Cardiac:</td>
</tr>
<tr>
<td>HeartMate 2</td>
</tr>
<tr>
<td>HeartMate 3</td>
</tr>
<tr>
<td>HeartWare</td>
</tr>
<tr>
<td>Biventricular VAD</td>
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<tr>
<td>Ischemic Etiology</td>
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<tr>
<td>Non-ischemic Etiology</td>
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<tr>
<td>Inotrope Therapy</td>
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<tr>
<td>Intra-Aortic Balloon Pump</td>
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<tr>
<td>Liver:</td>
</tr>
<tr>
<td>Congestive Etiology</td>
</tr>
<tr>
<td>Hepatitis C</td>
</tr>
<tr>
<td>Alcoholic</td>
</tr>
<tr>
<td>Drug Induced</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>MELD-XI</td>
</tr>
<tr>
<td>Ascites</td>
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<tr>
<td>Status:</td>
</tr>
<tr>
<td>Palliative Therapy</td>
</tr>
<tr>
<td>VAD</td>
</tr>
<tr>
<td>VAD and OHT waitlist</td>
</tr>
<tr>
<td>Transplanted</td>
</tr>
<tr>
<td>Complications:</td>
</tr>
<tr>
<td>Fulminant Liver Failure</td>
</tr>
<tr>
<td>Bacteremia</td>
</tr>
<tr>
<td>Thrombus</td>
</tr>
<tr>
<td>Major Bleed</td>
</tr>
<tr>
<td>GI Bleed</td>
</tr>
<tr>
<td>Arrhythmia</td>
</tr>
<tr>
<td>Cardiogenic/Septic Shock</td>
</tr>
</tbody>
</table>

Results: We found 14 patients who had low-risk pathology compared to 34 patients with high-risk pathology on biopsy. There was no significant difference in age, etiology of heart failure or echocardiographic and hemodynamic parameters among both groups. While high-risk patients more often required paracenteses for ascites, there was no difference in MELD-XI (Model for End-Stage Liver Disease excluding INR), baseline labs, or etiology of liver dysfunction. Although the grade of fibrosis did not correlate to outcome of VAD or OHT, patients with a higher grade of fibrosis showed an increased trend of requiring palliative care. Survival at 1 and 2-years and cause of death were similar among both groups. These results suggest that the grade of fibrosis on biopsies may not directly correlate with adverse events and survival in patients undergoing evaluation for advanced heart failure therapies. The limitations of our study include the small sample size. Larger patient populations and extended follow up is needed for further analysis.
CAR2-8

The Use Of Oncostatin M To Quantify Inflammatory Burden With MCS Therapies

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Study: Oncostatin M (OSM) (a member of IL-6 cytokine family) is a sensitive indicator of inflammation. We report, for the first time, its use to assess baseline and peri-procedural states of inflammation for 3 Mechanically Circulatory Support (MCS) therapies in comparison to conventional cardiac surgery with cardiopulmonary bypass (CPB).

Methods: Plasma OSM levels (pg/mL) were measured by ELISA in blood samples collected from patients receiving Ventricular Assist Devices (VADs), Total Artificial Hearts (TAHs), Veno-Arterial Extracorporeal Membrane Oxygenation (V-A ECMO) and, as controls, Coronary Artery Bypass Grafting (CABG). Samples were collected within 12 hours before and 4–8 hours after the procedure.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Baseline inflammation</th>
<th>Impact of procedure</th>
<th>p-values</th>
</tr>
</thead>
<tbody>
<tr>
<td>CABG (n=17)</td>
<td>233 ± 107</td>
<td>312 ± 140</td>
<td>79 ± 1.34</td>
</tr>
<tr>
<td>V-A ECMO (n=25)</td>
<td>821 ± 253</td>
<td>1128 ± 335</td>
<td>307 ± 204</td>
</tr>
<tr>
<td>VAD (n=41)</td>
<td>566 ± 196</td>
<td>1958 ± 243</td>
<td>1392 ± 283</td>
</tr>
<tr>
<td>TAH (n=4)</td>
<td>440 ± 423</td>
<td>2660 ± 475</td>
<td>2220 ± 186</td>
</tr>
</tbody>
</table>

Table 1. Data are expressed as mean ± SEM. Student’s t-test

Results: Pre-implant OSM levels of V-A ECMO patients were higher than CABG patients (p=0.04) while levels in TAH and VAD patients fell in-between. Post-implant OSM levels of VAD, TAH and V-A ECMO patients were all higher than those of CABG patients (p<0.0001, p=0.012 and p=0.032 respectively). The difference between pre- and post-implantation (Delta) values in TAH patients and VAD were higher (both p<0.0001) than those of CABG patients (Table 1).

Conclusion: Not surprisingly, decompensated patients in urgent need of V-A ECMO exhibited the greatest level of baseline inflammation. However, the added burden of inflammation due to the V-A ECMO procedure was more like CABG with CPB than the implantation of TAHs which markedly intensified the inflammatory state while VAD implantation fell in-between. This methodology and the resultant characterization of the inflammatory burden with MCS therapies should prove useful for patient- and device-specific outcomes analyses and for providing guidance for best use.

CAR3-1

Gastrointestinal Bleeding In Patients With HeartMate 3 And HVAD Left Ventricular Assist Devices: Incidence, Risk Factors And Outcomes

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Study: Continuous-flow LVADs (cf-LVADs) have demonstrated superiority in patient survival and quality of life compared with pulsatile-flow LVADs, but cf-LVADs have a higher risk of gastrointestinal bleeding (GIB). The aim of this study was to characterize incidence, risk factors and outcomes of GIB in HeartMate 3 (HM3) and HVAD recipients.

Methods: This single-center study, included 113 consecutive patients (Age: 59.6±11.6 yrs, female: 13.3%, BMI: 27.9±5.2kg/m², HM3/HVAD: n=57/56) implanted between 2014 and 2017. Primary outcome was freedom from GIB one-year following implant, secondary outcomes included etiology, outcomes and independent risk factors of GIB.

Results: 18.6% suffered GIB after a median time of 66 (5–333) days, 42.9% had at least one recurrent GIB event. The incidence of GIB was non-significantly lower in HM3 vs. HVAD patients (15.8% vs. 22.4%, p=0.32), without differences in recurrent GIB (33.3% vs. 50.0%, p=0.66). 90.5% GIB patients presented with melena and 9.5% with hematochezia. In 63.2% of the GIB group, the total number of PRBCs was 0–5, 6–10 in 21.1% and >10 in 15.8%. The most common treatment included temporary cessation of anticoagulation (47.4%), reduction of antplatelet therapy (26.9%) and endoscopic intervention (15.8%). On the event day, patients with GIB were less on ACE inhibitors or AT1 receptor blockers (GIB: 41.2% vs. control: 90.4%, p<0.001). Multivariate cox-proportional hazard model with GIB as time-dependent covariate showed no association with increased mortality [HR 0.99, 95% CI 0.93–1.01; p=0.72]. In addition, temporary RVAD implant was an independent risk factor for GIB (HR 2.55, 95% CI 1.05–6.46; p=0.035). GIB is common in cf-LVAD patients, but no effect on survival or specific device superiority was found. Further studies are needed to investigate possible mechanisms by which right heart failure and temporary RVAD support increases the incidence of GIB.
CAR3-2

Bleeding While On LVAD: Analysis Of The Competing Role Of Acquire Von Willebrand Disease And Antithrombotic Strategy
Alessandra Marasi, MS4, Patrizia Della Valle, MS5, Loris Pozzi, MS5, Elisabetta Pattarini, MS5, Giuseppe Giardina, MS4, Marina Pieri, MD4, Anna Mara Scandroglio, MD4, Alberto Redaelli, PhD5, Alberto Zangrillo, MD4, Armando D’Angelo, MD4.

Methods: The von Willebrand factor i) antigen level (vWf:Ag) and ii) activity of high-molecular weight multimers (collagen binding test, vWf:CB) were measured in 53 patients implanted with the HVAD (n=28, 53%) or the HeartMate3 (n=25, 47%). Values were measured preimplant (PRE) and at short-term (t1: <3mo) and long-term (t2: >12mo) follow up and compared between patients who did (n=26, 49%) and did not suffer from bleeding complications (n=27, 51%). Furthermore, incidence of bleeding events was correlated with AT regimen, as aspirin was discontinued in the bleeding group following a bleeding event.

Results: Preoperative characteristics and coagulation profile were comparable in the two groups. Median follow up was 324 days (IQR: 226–468). The vWf:Ag and vWf:CB decreased significantly post-implant (vWf:Ag: p<0.0001; vWf:CB: p<0.0001), and patients showing abnormal vWf activity to antigen ratio (vWf:CB/vWf:Ag ratio <0.7) increased progressively with increasing time of support (PRE: 26%, t1: 58%, t2: 74%; p<0.0001). However, no differences were noted for all vWf assays between bleeders and non-bleeders, indicating comparable acquired vWf deficiency in the two groups, irrespective of the development of bleeding events. Moreover, no differences were recorded in the vWf profile of patients implanted with the HVAD or the HeartMate3. Following aspirin discontinuation, only 3 patients had recurrence of bleeding. This study highlights that acquired vWf disease is not pivotal in the pathobiology of bleeding in the setting of LVAD support with continuous-flow pumps, and suggests that aspirin-free AT strategy is the only clinically reliable approach to reduce bleeding. The interplay between these two mechanisms warrants further studies.

CAR3-3

Synergistic Effect Of Shear And Adp On Thrombus Growth On Zta And Ti6Al4v Surfaces
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Study: In this work, we characterize real-time platelet deposition onto clinically relevant surfaces and examine how the interplay of shear, platelet agonist, and artificial surface can facilitate thrombogenesis.

Methods: Fresh whole blood was collected from healthy patients. Platelets were extracted, fluorescently labeled with mepacrine and resuspended in hemoglobin-depleted red blood cells to a final hematocrit of 25% and a platelet concentration of 2.6 ± 0.43 x 10⁸ per mL. A parallel-plate flow chamber with an interchangeable, 10 mm square coupon was designed to test deposition on titanium alloys (Ti6Al4V) and zirconium toughened alumina (ZTA). A membrane-based agonist delivery system was placed upstream of the deposition site to uniformly mix ADP to a final concentration of 0, 5, or 10 nM. Blood was perfused to generate a wall shear rate of 400 s⁻¹ 1000 s⁻¹. Platelet deposition images were obtained in real-time using an inverted epifluorescence microscope. Surface coverage fractions and mean aggregate sizes were calculated at 10-second intervals using a custom Matlab program. Statistically significant differences in surface coverage fraction rates were extracted across the two shear rates for each given combination of ADP and material surface.
CAR3-4
Eliquis: Alternative Anticoagulation For Heartmate 3 Ventricular Assist Device
Katherine R. Whitehouse, MPH, Divya Avula, None, Devan Costelle, ARNP, MSN, Christina L. Dunbar-Matos, DO, Jaimin R. Trivedi, MD, MPH, Mark S. Slaughter, MD; Department of Cardiovascular and Thoracic Surgery, University of Louisville, Louisville, KY, USA

Study: Patients with left ventricular assist devices currently require long-term anticoagulation with Warfarin. Warfarin requires frequent blood tests and is associated with adverse events when not in the therapeutic range. Eliquis is a possible alternative which is potentially better for compliance and requires no additional testing. The purpose of this study is to compare adverse events in patients with a HeartMate 3 LVAD receiving Eliquis versus Warfarin.

Methods: 35 patients underwent HM3 implantation between 01/01/2016 to 01/31/2021. The groups compared were Eliquis (n=15, 43%) and Warfarin (n=20, 57%). All patients received 325 mg aspirin daily. Stroke, bleeding, and death were identified as primary outcomes after LVAD implant. Univariate nonparametric statistical analysis was performed.

Results: There was a statistically significant difference (p < 0.05) in platelet surface coverage rate on Ti6Al4V at a shear rate of 1000 s⁻¹ vs. 400 s⁻¹ (Table 1 and Figure 1b). Across all other material and ADP combinations, there were no statistically significant differences across the two shear rates. Mean aggregate sizes were greater with larger fluctuations on Ti6Al4V surfaces with 5 nM ADP for a shear rate of 1000 s⁻¹ than for 400 s⁻¹, indicating embolization. Large fluctuations were also visible across both shear rates with 10 nM ADP on Ti6Al4V but were absent with 0 nM ADP and on ZTA surfaces with 10 nM ADP.

<table>
<thead>
<tr>
<th>Table 1: Patient Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Warfarin (n=20)</strong></td>
</tr>
<tr>
<td>Age in years (range)</td>
</tr>
<tr>
<td>Male Gender</td>
</tr>
<tr>
<td>BMI (range)</td>
</tr>
<tr>
<td>Creatinine at time of implant (range)</td>
</tr>
<tr>
<td>History of Stroke</td>
</tr>
<tr>
<td>Mean Pulmonary Artery Pressure (range)</td>
</tr>
<tr>
<td>Ischemic Cardiomyopathy</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
</tr>
<tr>
<td>Hypertension</td>
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<tr>
<td>Peripheral Arterial Disease</td>
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<tr>
<td>Bridge to Transplant (BTT)</td>
</tr>
<tr>
<td>INTERMACS Profile 2</td>
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<tr>
<td>INTERMACS Profile 3</td>
</tr>
<tr>
<td>INTERMACS Profile 4</td>
</tr>
</tbody>
</table>

Results: The median duration of treatment with Eliquis was 148 days (37–606 days). The groups were comparable in terms of age (56 v. 54 years, p=0.19), gender (male, 85% v. 75%, p=0.45), and renal function (Cr 1.5 v. 1.4, p=0.79). The Eliquis group had significantly higher mean pulmonary artery pressure (41 vs 34, p=0.03) and there were more (p < 0.05) ischemic cardiomyopathy and INTERMACS profile ≥ 3 in the Warfarin group (Table 1). At 1 year, thrombotic complications and death were not different between the groups (Table 2). The two deaths in the Eliquis group were from right heart failure. The Eliquis group had clinically lower rates of bleeding complications (5% v. 30%, p=0.1).

The adverse events of bleeding, stroke and death were similar in HM3 patients receiving Warfarin or Eliquis. Eliquis may be a safe alternative anticoagulant therapy in HM 3 LVAD patients. Additional studies are needed to confirm our findings.
CAR3-5

Influence Of Textured Surface Topography Parameters On Biological Response As Target Application In VAD Inflow Cannula

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Study: In MSC clinical experience a positive effect of various surface modifications was observed, and above all, the ability to control tissue ingrowth in the context of the external surfaces of the inflow cannula. In comparison smooth surface of the cannula results in tissue overgrowth into the lumen flow and may be a source of emboli.

Methods: The paper presents the influence of different topographic properties to the biological response including in vitro and in vivo trials. The aim is to obtain textured surfaces, which will stimulate cells for proliferation resulting in scar tissue formation to reduce inflammatory processes and risk of pump emboli. In the first stage various surface configurations of the Ti6Al7Nb obtained with the Vacuum Sintering technology were characterized. During the process parameters such as size and shape of powder grains were changed. Surfaces were characterized by wettability, profilometry, digital microscope and scanning electron microscope. Then cell culture was carried out using wettability, profilometry, digital microscope and scanning electron microscope. Cell culture was carried out using fibroblasts to exclude a cytotoxic effect of the surface modifications and to determine cells proliferation. The implantation using rabbits as a model within the in vivo trials included histological assessment and evaluation of tissue-implant adhesion strength.

Results: The results have shown that surfaces are characterized by roughness in the range of Ra=14–35µm, porosity in range 44–74% and wettability ≈100°. The cross section images revealed complex 3D morphology. Whereas SEM images highlighted the presence of empty micro spaces that may stimulate cell growth. The material has not shown any cytotoxic effects, and strength of the adhesion of the muscle tissue to the sample was in range 2-5N. The surfaces presented potential to stimulate cardiomyocytes to grow due to complex 3D morphology, high degree of roughness and porosity.

Project supported by: National Science Centre, Poland: 2018/31/N/ST8/01085 and NCBiR: RH-ROT/266798/STRATEGMED-II

CAR3-6

Platelet Microparticles Paradoxically Promote Thrombin Generation While Inhibiting Platelet Aggregation

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Study: Increasingly, mechanical circulatory support (MCS) has been recognized as being hampered by a coincident paradox of thrombosis and bleeding (MCS). Platelet dysfunction resulting from MCS hypershear stress plays a major role in this device-related coagulopathy. Previously we demonstrated that MCS hypershear exposure promotes platelet proapoptotic behavior and extensive generation of platelet-derived microparticles (PDMPs). Here, we characterize PDMPs as to their effect on platelet hemostatic function.

Methods: PDMPs were derived from human platelets after shear stress and sonication. PDMP surface receptors GPIb, αIIbβ3, and P-selectin were characterized by flow cytometry. Fluorescent nanobeads SPHEROTM were used as size standard. Prothrombinase activity was evaluated by chromogenic thrombin generation assay. ADP mediated platelet aggregation in plasma was assayed via light-transmission aggregometry.

Results: PDMPs demonstrated increased levels of adhesion receptors αIIbβ3, P-selectin, and GPIb. Strikingly, the surface expression of αIIbβ3 and P-selectin on PDMPs exceeded that of platelets by 400% and 900%, respectively. PDMPs promoted factor Xa activation of prothrombin alone; or synergistically with resting or ADP-activated platelets (Fig. 1A). Simultaneously, incubation of platelet-rich plasma with PDMPs resulted in a 14% decrease of platelet aggregation amplitude induced by ADP compared with control (Fig. 1B). Our data reveal the concomitant dual role of PDMPs in platelet hemostatic function - i.e promoting thrombin generation while inhibiting platelet aggregation. PDMP promotion of thrombin generation stimulates clotting. Conversely, PDMPs enriched adhesion receptors concurrently appear to block platelet-platelet interactions thus impairing platelet aggregation. Our findings underscore the role of PDMPs as central actors in device-related coagulopathy, paradoxically promoting both a thrombotic and bleeding phenotype.

![Figure 1. Platelet-derived microparticles (PDMPs) promote thrombin generation and inhibit platelet aggregation. A - thrombin generation; B - representative curves of platelet aggregation in plasma induced by ADP. Mean ±SEM presented on bar graph, n=5 independent experiments.](image-url)
DEMONSTRATING THE SYNERGISTIC EFFECTS OF SHEAR AND SURFACE ROUGHNESS PROFILE ON THROMBOSIS IN VADs

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Study: In VADs, pathological shear is known to enhance thrombosis. Their Ti-alloy surfaces are often roughened on the micron scale accidentally during manufacture or deliberately for biocompatibility; however, little is known on how surface roughness affects thrombosis. Delineating the combined effects of shear and surface roughness on thrombosis is critical to future VAD design.

Methods: This study used microfluidic devices with roughened Ti6Al4V surfaces to create shear-controlled, clinically relevant micro-scale environments to quantify thrombosis via platelet aggregation. Ti6Al4V surfaces were roughened using diamond microparticles of various diameters. A blood analog of hemoglobin-depleted red blood cells and platelet-rich plasma with fluorescent mepacrine-labeled platelets, was perfused through the microdevices. Two surface roughness levels were used: mirror finish, and surfaces roughened by 6–12 µm particles. For both roughness degrees, three shear rates were used: 400, 1000 and 2000 s⁻¹. Platelet aggregation was visualized with fluorescent microscopy and total aggregate area was obtained from processed images.

Results: In Figure 1, blue, orange and purple markers represent shear rates of 400, 1000 and 2000 s⁻¹ respectively, and Figures 1 and 2 reflect deposition on mirror finished and 6–12 µm particle-roughened surfaces respectively. At 2000 s⁻¹, percentage of total surface covered by platelet aggregates was high at all roughness levels. At all three shear rates, when surface coverage exceeded ~2%, large fluctuations were observed, indicating the embolization of larger aggregates. In the latter half of the perfusion time at 2000 s⁻¹, the surface coverage percentages fluctuated more on the roughened surface than on the mirror finished surface, with maximum peak-to-peak amplitude 1.5 times higher on the rough surface. This demonstrates that pathological shear and surface roughness combined lead to thrombus embolization.
CAP1-1
The Use Of Veno-Venous Extracorporeal Support To Rescue Patients Who Experience Respiratory Failure Following General Thoracic Surgery
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Study: Postoperative acute respiratory distress syndrome (ARDS) following a general thoracic procedure is associated with high morbidity and mortality. Extracorporeal membrane oxygenation (ECMO) offers an alternate means of cardiopulmonary support in the setting of refractory respiratory failure. We report indications and outcomes patients who after complex general thoracic surgery who developed ARDS requiring ECMO support.
Methods: We performed a retrospective analysis of all patients requiring ECMO support in the post-operative period following a general thoracic surgical procedure from January 2003-December 2019. Exclusion criteria include those who underwent a cardiac procedure, cardiothoracic transplantation, or required ECMO only for intraoperative support.
Results: 44 instances of postoperative VV ECMO were utilized in 41 patients who underwent a surgery with the thoracic surgical service. Esophageal procedures were the most common index operations performed (42.8%) followed by lung resection (33.3%). Median time to ECMO initiation from the index operation was 10 days (range 1 day to 28.9 months). Median length of ECMO support was 8.29 days (range 18 hours to 31 days). Majority of patients were cannulated in an urgent (71.43%) or emergent (23.81%) fashion. ECMO related complications included bleeding in 8 patients. 30-day survival was 69.1% for the entire cohort and 54.7% of patients discharged from the hospital. Of the patients with adequate follow-up of 90 days, 90.48% of patients who were discharged were still alive.
Conclusion: Extracorporeal membrane oxygenation is a safe and viable means of cardiopulmonary support that can provide a survival advantage for patients who experience severe refractory respiratory failure following a complex general thoracic surgery.

CAP1-2
Association Of Caloric Intake And Mortality During Veno-Arterial Extracorporeal Membrane Oxygenation In Adults
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Study: Evidence for the optimal amount of nutritional caloric delivery during veno-arterial extracorporeal membrane oxygenation (VA-ECMO) is inconclusive. The aim of this study was to describe the relationship between caloric intake during VA-ECMO support and 30-day mortality.
Methods: Adult patients who received VA-ECMO for 25 days between 2015 - 2019 at a quaternary referral center were included. Caloric goal was calculated as 25 kcal/kg/d. Three categories were defined based on the cumulative caloric goal met throughout ECMO support: very-low caloric intake (VCI, <20% goal); hypocaloric nutrition (HN, 20–50% goal) and higher caloric intake (HCI, >50% goal). Multivariable cox regression was used for 30-day survival adjusting for age, SOFA score and reason for ECMO.

Conclusion: Extracorporeal membrane oxygenation is a safe and viable support that can provide a survival advantage for patients who experience severe refractory respiratory failure following a complex general thoracic surgery.
Impact Of Tracheostomy In Patients Receiving VV ECMO
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Study: Veno-venous extracorporeal membrane oxygenation (VV ECMO) is utilized for critically ill patients with respiratory failure. Given that these patients often require extended periods of ventilation, we examined the role of tracheostomy on outcomes of patients supported with VV ECMO.

Methods: We conducted a retrospective review of all patients at our institution who received VV ECMO between 2016 and 2020. Patients were divided into two groups based on whether they received a tracheostomy while on ECMO. Demographics, baseline characteristics, and outcomes were collected, reviewed and summarized. The primary outcome measure was survival to hospital discharge. Secondary outcome measures included length of ICU and hospital stay, as well as adverse events related to the tracheostomy procedure. Multivariable analysis was performed to identify predictors of in-hospital mortality. Patients receiving tracheostomy were divided into an “early” and “late” tracheostomy group based on median days to tracheostomy following ECMO cannulation and separate outcomes analysis was performed.

Results: 150 patients met inclusion criteria, 32 received a tracheostomy. Discharge survival was similar amongst the groups, no tracheostomy 61%, tracheostomy 53.1%, p=0.658. Predictors of mortality on multivariable analysis included RESP score (Odds Ratio [OR] 0.831, p=0.015), and BUN (OR 1.026, p=0.011). Tracheostomy performance was not predictive of mortality (OR 0.837, p=0.658). Bleeding requiring intervention was the most common complication after tracheostomy, occurring in 18.7% of patients. Early tracheostomy (less than 7 days after ECMO initiation) resulted in shorter ICU (25 vs. 36 days, p=0.043) and hospital (33 vs. 47, p=0.017) length of stay. Conclusions: Tracheostomy can be performed safely in patients receiving VV ECMO. Mortality in VV ECMO patients is predicted by severity of underlying disease. Performance of tracheostomy does not impact survival. Early tracheostomy may decrease length of stay.
NURS-1
It’s Not Only The Pump: Assessment Of Human Factors Of Wearable Components And User Experience Of Patients With Left Ventricular Assist Devices
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Study: Despite design improvements in left ventricular assist devices (LVADs) over the past decade, limitations of external, wearable components affect patient quality of life. The aim of this study was to describe both user experience and human factor issues of two contemporary LVADs.

Methods: This single-center, cross-sectional study of LVAD outpatients who were at least 3 months post-LVAD implantation was conducted from July to October 2020. Before developing a 16-item survey (multiple-choice and 4-point Likert scale), a literature review and 2-round Delphi method involving 9 VAD clinicians were used to generate and select items in 6 domains: power supply, emergency or challenging situations, wearability, ability, mobility and freedom to travel, user modifications, lifestyle and housing adaptations.

Results: 58 patients (Age: 61.6±1.5yrs, female: 13.8%, HM3/HVAD: n=39/19) completed the one-time survey after a median of 853 days on device. 10.3% reported problems changing power supply and 21.1% unintentionally disconnected the driveline (HVAD: 26.3% vs HM3: 5.6%, p=0.041), but only 13.5% felt unprepared for possible technical emergency situations, consequently 84.6% think equipment retraining was not necessary. Against the recommendation 74.1% sleep with batteries (HVAD: 44.4%, vs HM3: 88.9%, p=0.001). Weight and size of the transport bag was criticized by 65.3% (HVAD: 50.0% vs HM3: 71.4%, p=0.035), thus 24.1% wear an own carrying system, 38.9% adapted their clothing to wearable peripherals, 42.1% modified parts of their wearables and 65.3% even had to adapt their housing to cope with life on LVAD support. 66.7% still drive a car themselves (HVAD: 88.9% vs HM3: 56.4%, p=0.018), but mobility is reduced due to limited wearability: only 18.9% went abroad (3.7% by plane) and 40% use less public transport than before implantation. 66.7% still drive a car themselves (HVAD: 88.9% vs HM3: 56.4%, p=0.018), but mobility is reduced due to limited wearability: only 18.9% went abroad (3.7% by plane) and 40% use less public transport than before implantation. To conclude, HVAD and HM3 wearables still have many human factors issues and potential for improved user experience.

NURS-2
Impact Of Outpatient Cardiac Rehabilitation On Patient Health Status In Left Ventricular Assist Device Patients
Laura Coyle, APRN-BC1, Colleen Gallagher, BSN1, Laura Rosner, BSN1, Pam Dooley, MSN1, Mark Parson, BSN2, Gardner Yast, MD1, Sunil Pauwaa, MD2, Antonete Tatooles, MD2; 1Advocate Christ Medical Center, Oak Lawn, IL, USA, 2University of Michigan, Ann Arbor, MI, USA.

Study: Left ventricular assist device (LVAD) implantation effectively improves hemodynamic performance, however these patients still have many of the peripheral pathological changes present in end stage heart failure. The available evidence for exercise training to improve exercise capacity, functional and nutritional status, and quality of life in LVAD patients is limited. We examined patient health status (PHS) before and after cardiac rehab (CR), barriers to participation, and its clinical safety.

Methods: A retrospective analysis was performed on 57% (27/47) of patients (median age 56 ± 15 years, 89% male) who attended outpatient CR between 5/1/2018 and 2/1/2020 at our center. PHS was assessed by comparing exercise time, 6-minute walk test (6MWT), gait speed, New York Heart Association (NYHA) classification, hand grip strength, body mass index (BMI), mini nutritional assessment (MNA), dietary fat screener, patient health questionnaire-9 (PHQ-9), and Dartmouth cooperative functional assessment (Dartmouth COOP) before and after completing a 12-week CR program. Clinical demographics, adverse events, and cause for premature termination of CR were documented.

Results: Median time from implant to CR was 209 ± 189 days, with 90 ± 18 days in CR, to average 28 ± 7 sessions. There were significant improvements in PHS (Table 1) and 0.4% (3/749 sessions) adverse events. 43% (20/47) of patients did not complete CR: 6 medical complexities, 6 conflict of interest, 3 childcare issues, 3 COVID-19 concerns, 1 return to work, and 1 lacked referral. Outpatient CR provides an opportunity for LVAD patients to safely receive supervised, high-quality exercise interventions that significantly improve overall patient health status. Despite improvements in exercise capacity, muscular strength, functional status, and quality of life, there was no difference in nutritional status or weight loss after a 12-week CR program.

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<th>Parameter</th>
<th>Pre-Cardiab Rehab</th>
<th>Post-Cardiab Rehab</th>
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<td>Time Spent in Exercise (min)</td>
<td>34 ± 2.2</td>
<td>43 ± 2.7</td>
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<td>Weight (kg)</td>
<td>94 ± 23.7</td>
<td>96 ± 22.7</td>
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<td>BMI (kg/m²)</td>
<td>30.0 ± 5.9</td>
<td>31.1 ± 6.1</td>
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</tr>
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<td>NYHA (class)</td>
<td>4.5 ± 0.4</td>
<td>3.9 ± 0.4</td>
<td>&lt;0.001</td>
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<tr>
<td>NYHA Classification</td>
<td>2.3 ± 0.6</td>
<td>1.8 ± 0.5</td>
<td>0.012</td>
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<tr>
<td>Gait Speed (m/s)</td>
<td>3.4 ± 1.2</td>
<td>4.3 ± 1.2</td>
<td>&lt;0.001</td>
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<tr>
<td>Hand Grip Strength (lbs)</td>
<td>34 ± 9.0</td>
<td>38 ± 10.6</td>
<td>&lt;0.001</td>
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<td>MNA</td>
<td>13.9 ± 2.1</td>
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<td>Dietary Fat Screener</td>
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<td>PHQ-9 Survey</td>
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<td>1.59 ± 1.8</td>
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<td>Dartmouth COOP Survey</td>
<td>20.2 ± 3.5</td>
<td>18.3 ± 4.7</td>
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ASAIO NURSING/ ALLIED HEALTH ORAL ABSTRACTS

NURS-3
Prophylactic Antibiotic Therapy For Prevention Of Driveline Infections
Colleen LaBuhn, APNP, Vika Kagan, APNP, Karen Meehan, APNP, Justin Okray, PA-C, Shana Creighton, APNP, Anna Chinco, RN, Katie O’Halloran, APNP, Jon Grinstein, MD, Sean Pinney, MD, Valluvan Jeevanandam, MD; University of Chicago Medical Center, Chicago, IL, USA

Study: Driveline infections in patients with left ventricular assist devices (LVAD) have long been an adverse event that has been difficult to eliminate. Driveline infections lead to an increased morbidity and mortality and a decrease in quality of life for patients. This review served to determine if using antibiotics as prophylactic therapy can affect infection rates and increase survival in patients who have had trauma or manipulation of the driveline. Trauma or manipulation can consist of a controller drop, driveline tug.

Methods: A retrospective chart review was done at a large academic medical center. We reviewed all patients implanted with an LVAD within the past 5 years. Patients were divided by infection vs non-infection; patients were then evaluated by who was treated with prophylactic antibiotic therapy and who developed an infection post antibiotic therapy compared to patients that developed an infection with no prophylactic therapy. We then reviewed survival rates within that cohort of patients.

Results: A total of 258 patients were evaluated for driveline infection. Of those, 73 (28%) patients had developed a driveline infection. Of those 73, 62 (84%) were not treated with prophylactic antibiotic therapy and 11 (15%) received prophylactic antibiotics. Mortality within the group of patients with no prophylaxis therapy was 25 (40%) vs 1 (9%) p=0.03 in the patients that were treated with prophylaxis antibiotic therapy.

NURS-4
There Is Only One Time To Get It Right: Establishing An Ex Vivo Lung Perfusion Program Using The Organ Care System
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Study: Lung transplantation is a well-established life-saving treatment for end-stage respiratory failure patients who do not respond to other medical or surgical interventions. However, donor lung availability remains a primary constraint to transplantation. The Organ Care System (OCS) (TransMedics, Andover, MA) is one type of ex vivo organ perfusion technology that can expand the donor pool while reducing organ recovery time limitations. Establishing a program of this magnitude can be challenging and requires thoughtful interdisciplinary collaboration. We present our single-center initial experience in establishing an OCS lung program. To our knowledge, this is the first report of such a study.

Methods: The interdisciplinary team involved in each OCS Lung recovery from May 2019 to January 2021 (n=23) participated in an email-based debriefing. A multidisciplinary team of transplant coordinators, surgeons, and perfusionists retrospectively reviewed each case and completed root cause analyses and corrective action when necessary. We also annually reviewed the process of establishing our OCS lung program to document specific challenges and benefits. We constructed four main themes from the qualitative analysis: clinical protocols, strategic restrictions, administrative needs, and operational aspects.

Results: A total of 70 debriefing responses were received and reviewed, with three to five personnel contributing after each recovery. In total, the debriefing responses contained 90 unique issues. Thematic categorization revealed that most challenges occurred outside of the recovery process. We provide documentation of the specific components in each area identified (Table 1,2). This study demonstrates that a framework for establishing a program of this magnitude requires a concerted interdisciplinary effort to succeed. This qualitative review provides insight that can assist other institutions seeking to establish an ex-vivo lung perfusion program.

<table>
<thead>
<tr>
<th>Table 1: Challenges Encountered Establishing an OCS Lung Program</th>
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<td>Billing + Reimbursement</td>
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<th>Table 2: Benefits of Establishing an OCS Lung Program</th>
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<td>Comparable Net Margin to the Standard of Care</td>
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<tr>
<td>Favorable Economic Impact</td>
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Topical Tranexamic Acid Application For Refractory Epistaxis In Patients Supported On Left Ventricular Assist Device Therapy

McKenna Schimmel, BS1, Sarah Schettle, PA-C2, Lindsay Moreland-Head, PharmD1, John Stulak, MD1, Andrew N. Rosenbaum, MD1, 1University of Vermont Medical Center, Burlington, VT, USA, 2Department of Cardiovascular Surgery, Mayo Clinic, Rochester, MN, USA, 3Mayo Clinic, Rochester, MN, USA, 4William J von Liebig Center for Transplantation and Clinical Regeneration, Mayo Clinic, Rochester, MN, USA

**Study:** Mucosal bleeding is common in patients supported on continuous flow left ventricular assist devices (CF-LVADs). Although standard local therapies are often utilized, there is scant data on use of topical tranexamic acid (TXA) for refractory epistaxis in this population.

**Methods:** All patients implanted with continuous flow LVADs between 2007 and 2019 at a single institution were evaluated. Retrospective chart review was utilized to identify patients treated with topical TXA for epistaxis, and descriptive statistics were applied.

**Results:** Ten patients treated for epistaxis with topical TXA were identified (mean age 62 ± 13 years, 20% female, 70% HeartMate II, 30% HeartWare). All patients had prior episodes of epistaxis and TXA was administered at 3.1 ± 1.7 years after implant. Mean hemoglobin on presentation was 9.1 ± 4.1 g/dL, platelet count 167 ± 77 x10^3/L, and INR 2.7 ± 1.5 (mean goal 2.1–2.8). Three patients were on no aspirin, four were on 81 mg daily, and three were on 325 mg daily. Three were being actively treated for thrombosis after topical TXA administration. 90% later experienced recur.

Ban). Three patients required transfusion of two units of red blood cells. Among the most common adjunctive therapies, 90% were treated with oxymetazoline spray, 60% underwent nasal packing, and 30% were treated with rose geranium spray. No patients developed new hemolysis or pump thrombosis after topical TXA administration. 90% later experienced recurrent epistaxis. TXA may be a short-term adjunctive agent for refractory epistaxis among patients supported on CF-LVAD therapy, and no pump-related adverse effects were seen. Further work should elucidate the role of TXA prospectively in the management of CF-LVAD associated epistaxis.

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VAD Patient Adjustment: Personal Perceptions Related To The VAD Driveline & External Components

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**Study:** Ventricular Assist Devices (VADs) create unique challenges and complexities due to the external equipment. The purpose of the study was to explore the VAD patient experience and describe how patients construct the impact of the VAD, including driveline and external components, on daily life and self-care.

**Methods:** The study used a general qualitative methodology with a purposeful sampling of 20 VAD recipients. Interviews were transcribed. Data were analyzed via content analysis and managed with Atlas.ti V8. Researchers achieved redundancy, identified themes, and provided exemplars.

**Results:** VAD participant’s perceptions of the VAD driveline and external components were very impactful to the patient adjustment process. Additionally, the participant’s perceptions of how others regarded the device and external components were significant to one’s self-concept and influenced daily life. Wearables and accessories (e.g., belts, vests, pants, bags) that manage the external equipment had the potential to positively or negatively impact the participant’s self-confidence, personal perception of safety, and daily activities. Some participants that chose to wear the VAD equipment outside of clothing perceived others to regard the equipment as a public safety and security risk. Participants also expressed various situations where they were detained at a security checkpoint, asked to remove the device from their body, or were observed suspiciously by police. Additional influences on adjustment included conflicting perceptions of what activities they could participate in due to the device. These perceived limitations often created psychological side effects and hindered individuals from achieving normalcy. Learning how to manage external equipment and trying various wearables can be time-consuming and costly. This study demonstrates the need for best practice guidelines and recommendations for managing VAD external components to optimize VAD adjustment.
NURS-7
**Novel Approach To LVAD Education For Patients And Caregivers During COVID-19**

**Christyline L. Black**, RN, BSN, Kirk L. Nelson, MS,
Lisa M. Fowler, MS, Patrick B. Prestemon, RN,
Christina A. Cheyne, MS; Advanced Heart Failure, VAD Team, UR Medicine, University of Rochester Medical Center, Rochester, NY, USA

**Study:** In March 2020, a novel method of Left Ventricular Assist Device patient and caregiver education was implemented due to COVID-19 visitor restrictions.

**Methods:** LVAD training was restructured to utilize the UR Medicine VAD resources website (www.vadresources.urmc.edu,) from the “evaluation for LVAD” phase, through the “preparation for discharge” phase. LVAD education aimed to foster independence with equipment, power and alarm management, and driveline dressing changes. Short daily sessions at the bedside were completed prior to discharge. Patients were taught to change their own driveline dressings by bedside RN staff. They demonstrated proficiency with education by live demonstration and completing a “patient review” test, tracked in the electronic medical record. Caregivers were required to complete remote LVAD education if able, using the website. Some caregivers required additional educational materials be sent by mail, including the Abbott “LVAD Patient Education Program” DVD. Rarely, a caregiver not able to use the website, attended a single training session in the Advanced Heart Failure clinic. Rare driveline dressing training was also conducted in the clinic, using a CPR mannequin with a foley catheter mimicking driveline placement.

**Results:** 62 of the 81 LVAD implants from 2020 were done during visitor restrictions. 55 of the 62 survived to discharge with an average length of stay of 22 days. Utilizing short daily educational sessions for hospitalized patients, and offering needs-based learning for caregivers yielded benefit to patients, caregivers, RN staff, and VAD coordinators. Improvement in patient retention was seen on review tests and greater patient independence resulted. Patients appreciated more review time with shorter, less exhausting sessions that reduced interruption on nursing activities. Remote learning benefitted caregivers by offering convenience and reduced loss of work days and travel expenses.

NURS-8
**Mentorship Matters: An Assessment Of An Interdisciplinary Student Mentorship Model In A Robust Clinical Research Program**

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Pamela Combs, PhD; Cardiac Surgery, University of Chicago Medicine, Chicago, IL, USA

**Study:** Despite the widespread study of mentoring and its proven benefits in academic and organizational contexts, the impact of interdisciplinary mentorship on clinical research remains unclear. We sought to analyze a single center’s multidisciplinary ambassadorship program in order to identify unique elements of a mentorship model that can lead to the significant growth of a clinical research initiative and contribute to the effective mentorship of the next generation of researchers and healthcare professionals.

**Methods:** We utilized a multi-analysis approach to analyze the strength of a mentorship program in a large academic medical institution. We collected quantifiable and qualitative data by comparing pre- and post-program research output and by surveying all alumni and research students about their experiences.

**Results:** Within three years of the program’s conception (2017–2020), the number of active studies significantly increased by 633% (3 to 22), research team personnel increased by a factor of 4 (2 to 8), and the total number of grants awarded to the program increased from 0 to 4, with $28,000 received in 2020 alone. Furthermore, the number of manuscripts published per calendar year skyrocketed from 10 in 2016 to 52 in 2020. Program students represent geographical diversity from 7 different states, with their matriculation spectrums ranging from undergraduates to surgical residents (n=11). Students are currently working on an average of 2.9 projects (ranging from 1–7), and 9 students (82%) are published authors of an abstract or manuscript. All students were mentored by cardiac surgeons, thoracic surgeons, heart failure specialists, nurses, and clinical research coordinators, and all agreed that program mentors provide opportunities to learn more about their discipline.
ENSURING VAD EDUCATIONAL OPPORTUNITIES FOR STAFF DURING COVID-19: A NEW PLATFORM FOR EDUCATION

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Study: VAD programs are mandated by The Joint Commission to ensure that staff have VAD education and competency training. In 2020 VAD programs were challenged during the COVID-19 pandemic due to the inability of staff to meet in-person. VAD programs needed to create virtual platforms to ensure that staff were trained.

Methods: The Massachusetts General Hospital (MGH) VAD Program in collaboration with MGH Norman Knight Nursing Center for Clinical and Professional Development created 3 virtual platforms for training: VAD Awareness (for employees), VAD Educated (for nurses), and VAD 101 (for providers). Presentations were recorded on Zoom video conferencing and posted on a learning system where staff were assigned to take a course. Pre and post tests were given, and nurses could obtain nursing contact hours (CEUs). Presentations were also housed on a VAD Share Point site; accessible via computer and smartphone. VAD education was held via video conference during the pandemic. Remote access enabled staff to take classes which were previously held in-person allowing for continuing education and CEUs. Staff attendance varied from 10–50 attendees per session and evaluation forms revealed a high success rate. Staff who were unable to attend and who would have missed sessions, now had the ability to enroll when convenient. A clinical library of courses was created and assigned for staff to prove compliance with annual education.

Results: VAD programs can ensure training compliance despite the COVID-19 pandemic by using virtual platforms and clinical libraries. Coordinating efforts with the nursing education department offers an opportunity for Joint Commission survey readiness - further expanding access to educational opportunities.
PEDS2-1

Bridging Failing Fontan Patients To Heart Transplantation—Successful Development Of A Novel Cannula For Sub-pulmonary Mechanical Circulatory Support

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Study: Successful surgical palliation in children with a single ventricle morphology (SV) led to an increasing number of patients suffering from failing of the Fontan circulation. The absence of a sub-pulmonary (SP) ventricle, leads to protein-losing enteropathy, hepatic and renal dysfunction, and plastic bronchitis. The only therapeutic option is a heart transplantation as a systemic ventricular assist device (VAD) is often not enough to better end-organ function. The aim was to design a novel venous cannula (VC) as an additional component of the EXCOR-VAD™ to enable standardized sub-pulmonary (SP) mechanical circulatory support (MCS).

Methods: Based on published successful surgical case series, a VC for SP support as an additional component of a para-corporeal VAD (Berlin Heart EXCOR™) has been designed. The VC is connecting the upper and lower Vena cava and leads the blood flow to the EXCOR pump which is connected to the pulmonary artery. The VC will facilitate a standardized implantation of a SP VAD in SV patients for the first time. The device will be able to provide supra-physiological and pulsatile pulmonary blood flow and decongest the venous system. In several steps, the VC was flow optimized in terms of Computerized Fluid Dynamics (CFD) in terms of diameter and angulation and went through several animal studies and a final virtual fitting based on magnet resonance imaging data of palliated SV patients. The device can be used for SP support alone or in combination with a systemic VAD.

Results: The final design of the VC reflects the special requirements of the complex anatomy of Fontan patients and enables a standardized implantation for SP MCS. The VC recently gained CE approval and an observational, prospective, international, multicenter, non-randomized registry is planned to observe the clinical outcome of the patients in a bridge-to-transplant setting.

PEDS2-2

Alteration In Cerebral Blood Flow During Pediatric Continuous Flow Ventricular Assist Device Use

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Study: Alterations in blood flow of central retinal vessels (CRVs) detected by Doppler ultrasonography are reflective of changes in cerebral blood flow due to changes in intracranial pressure or poor cardiac output (Figure 1). There is continuity of the optic nerve sheath and the subarachnoid space where cerebral spinal fluid freely flows and hemodynamic alterations of the distal most CRVs are directly reflective of changes in cerebral perfusion. Patients on continuous flow ventricular assist devices (VAD) have variable pulse pressure based on native heart function. However, evaluation of cerebrovascular pressure has not been well studied in this population and how native hemodynamics may impact long term cerebrovascular indices. Our preliminary data demonstrates potential clinical value of studying Doppler waveforms of the distal CRVs within the optic nerve sheath.

Results: Both patients had significant vascular dilation, venous congestion, and collateralization of ophthalmic vessels (Figure 2). One patient’s native cardiac function was enough to retain a degree of pulsatile flow in ophthalmic circulation, showing less venous congestion and vascular dilation than her male counterpart with completely non-pulsatile flow (Figure 2A).
The study team also obtained ophthalmic Doppler flow images of the male 2 days and 10 days after he underwent a heart transplant (Figure 3). On day 2, the only differences in his ophthalmic ultrasound images were return of pulsatile flow; however, at 10 days post-op, he no longer had vascular dilation, venous congestion, and the collateralization was not being utilized to the same degree (Figure 3).

**Figure 3A.** Color Doppler of the central retinal vessels and collateralization with ventricular assist device in place.

**Figure 3B-3C** Color Doppler showing less collateralization and normalizing central retinal vessel flow at day 2 (B) and day 10 (C) after heart transplant.

**PEDS2-3**

**Ventricular Assist Device After Pediatric Heart Transplant**

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**Study:** Implantation of a ventricular assist device (VAD) for early and late graft failure after heart transplant (HTx) is a rare event in pediatrics. In the last 5 years we have counselled families about the need for VAD in those deemed high risk for graft failure (ex: high pulmonary vascular resistance or single ventricle). In addition, we have taken an aggressive approach to VAD early post-HTx to avoid the impact of right ventricular failure and low cardiac output. Therefore, we sought to describe our single center experience with VAD support following HTx.

**Methods:** This is a retrospective analysis of all pediatric patients implanted with a VAD following HTx between 01/05 - 12/20.

**Results:** There were 11 patients who underwent VAD insertion post-HTx (45.5% male, median age 6.1 (IQR 3.9, 7.9) median weight 17.6 Kg (IQR 13.5, 24)). The most common diagnosis was congenital heart disease (n=8), followed by restrictive cardiomyopathy (n=2) and myocarditis (n=1). Almost half (45.5%; n=5) were implanted after 2015 and 4/5 of these patients had a plan for possible VAD insertion. Time of implant post-HTx varied, with the median time being 0 days (IQR 0.11) and the longest being 9.2 yrs. Early graft failure occurred in 9/11 patients (8 RVAD and 1 BiVAD), with 6 (5 RVAD and 1 BiVAD) implanted in the operating room. There were 2 patients who required RVAD on day 2 and 11 post-HTx and 1 who was converted from ECMO to BiVAD on day 5. Two additional patients underwent insertion for cardiac allograft vasculopathy (CAV) at a median time of 5.7 yrs (IQR 2.2, 9.3) post-HTx. Total time on VAD support was a median of 17 days (IQR 6, 115), with the longest being 478 days. Over 60% of the patients were weaned from support or retransplanted (n=7, 63.6%) with 4 (36.4%) dying or converted to ECMO. The outcome of VAD support following pediatric HTx is encouraging. For those where a need for VAD was predicted, outcomes were excellent (100% survival). Unplanned insertion or those with CAV had worse outcomes. While these results are promising, further work to verify these findings is needed.
Novel Cannulation Strategies In Pediatric VAD Patients

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Study: Variations in size, anatomy, and physiology of pediatric patients presents challenges for ventricular assist device (VAD) placement. We report cannulation of the left atrial appendage (LAA) in 2 patients, with preserved left ventricular (LV) size and function and small left atrium (LA), and use of a dilatable PTFE outflow graft in 3 patients.

Methods: Patient 1 (Pt 1) is 7.2 kg with histiocytoid cardiomyopathy with preserved biventricular size and function but malignant arrhythmias. Pt 1 had bi-VAD placement with LV apical cannulation. 5 days later, inflow cannula reconfiguration was required due to LV competition causing obstruction. LA was cannulated with a 10-mm ringed PTFE graft, invaginated into the LAA, secured to a Berlin arterial cannula. Pt 2 is 30 kg with history of heart transplantation for dilated cardiomyopathy (DCM) complicated by graft vasculopathy, placed on ECMO for in-hospital arrest. 6 days later, bi-VAD was placed. Due to preserved LV size and function, LAA was cannulated with a 14-mm ringed PTFE graft attached to a 9-mm Berlin arterial cannula.

Pt 3 is 5.5 kg with DCM with severely depressed LV function and mixed mitral disease. Off-pump Left VAD was implanted, facilitated by a tapered 6mm dilatable PTFE graft secured to a 10-mm Berlin arterial cannula. Pt 4 is 12.5 kg with a history of partial atrioventricular septal defect, requiring mitral valve replacement, admitted with mitral stenosis and decreased LV function. Pt 4 underwent off-pump left VAD placement facilitated by a 6-mm expandable ePTFE graft. Pt 5 is 12 kg with severe heart failure. Off-pump VAD was implanted. 6-mm expandable ePTFE graft was used for outflow cannulation, with partial aortic clamping only.

Results: 3 of 5 patients have been transplanted at 49, 68 and 202 days. All transplanted patients are alive and doing well. 2 patients, supported for 115 and 150 days, are awaiting transplant. No patient experienced a thromboembolic event or surgical bleeding. There has been no reoperation for cannula obstruction, thrombus formation, or scarring.
New Quality Improvement Initiatives In Pediatric Heart Failure Through The ACTION Collaborative Learning Network

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Study: PROs are considered key in VAD clinical care and device trials in adults. PRO use in children and young adults on VAD support has been hampered by poor response rates, data collection burden, and lack of VAD-specific content. We tested feasibility of electronic PRO data collection from VAD patients/parents in the Advanced Cardiac Therapies Improving Outcomes Network (ACTION).

Methods: Patients/parents enrolled at 6 ACTION sites 7/20-11/30/20. Patient Reported Outcomes Measurement Information Systems (PROMIS-25 parent proxy or PROMIS-29 adult self-report; 1, 3, 6 months post-implant) and network-derived measures (weekly x4) were used. Network measures were developed with family and provider input and tested for content, length. These included: Take ACTION symptom checklist, parent survey, visual analog quality of life (VAS QOL) scale. Descriptive summary statistics were performed.

Results: 22 patients (median age 5.4 yrs (IQR 0.5, 19.0)) enrolled. Median time from implant was 67 days (IQR 34.5, 323). Enrollment was 91.7% among those eligible. Attrition and measure missingness were zero. Patient symptoms: fatigue (37%), stress with dressing changes (43%), sadness (45%), activity limitations (55%). Parental concerns: financial stress (43%), parent sadness (48%), parent worry (55%). Mean parent-reported child VAS QOL was 5.4/10. Post-implant median PROMIS T scores illustrated impaired physical function with normal median scores in other domains. Clinically significant depression, anxiety, pain interference, cognitive impairment were reported by 1/5 (20%) adult VAD patients. Clinically significant depressive symptoms and anxiety were reported by parent proxy for 1/3 (33%) of pediatric VAD patients, with fatigue and pain interference in 2/3 (67%).
PEDS3-1

Growth Adaptive Stent Design For Pediatric Heart Valves
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Study: There are no heart valve prosthetics on the market designed to accommodate growth in young children born with valve defects. Our objective is to create a pediatric heart valve that will expand while maintaining function over a doubling in valve diameter (7 to 14 mm) as the patient grows from infancy to age 5–6 years old.

Methods: Leveraging the results from previous work we optimized stent designs and analyzed them using non-linear finite element analysis (FEA). The analysis examined the geometries and output radial forces, stresses, and strains. Configurations with no self-contact and radial forces of interest were manufactured using ASTM F 2063 Nitinol via laser cutting. To inform stent design, custom tissue testing apparatuses have been constructed to collect mechanical property data from cardiac tissue at the site of implantation. The first test setup is a uniaxial tester for ex vivo, isolated tissue samples. A second method is under development to provide in vivo measurements in a non-destructive manner from preclinical animal models.

Results: Different configurations involved increasing the number of springs in a series for a less stiff stent and incorporating more rounded geometry to disperse stress. Three stent geometries were prototyped to achieve a 2-fold diameter expansion with various expansion forces. The FEA predicted radial forces between 2–5 N per stent at the most compressed state. Stents will undergo radial force testing and dimensional analysis to assess correlation with our FEA models. Data collected to date from the custom tissue testing apparatus suggests that the designed stent radial force is capable of falling within a safe threshold at the site of implantation. Ongoing biomechanical testing will guide the design of the next iteration of stents as well as provide a more comprehensive understanding of the complex mechanical effects of growth-adaptive stent implantation.

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PEDS3-2

A Silicon Nanopore Membrane Oxygenator For An Artificial Placenta
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Ben Chui, PhD, Jarrett Moyer, MD, Peter Oishi, MD,
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Study: Extremely preterm (EPT) infants have high morbidity and mortality due to underdeveloped lungs, exacerbated by ventilator-induced lung injury (VILI). Conventional hollow-fiber membrane oxygenators are limited by need for high-dose anticoagulation, excessive pressure drop, and large priming volumes. We are developing an artificial placenta oxygenator comprised of rigid flat-plate gas exchange membranes constructed from a silicon nanopore membrane (SNM) backbone covered with silicone. These membranes allow unprecedented control of the blood flow path, improving hemocompatibility and reducing both priming volume and pressure drop.

Methods: SNM with 500 nm pores were adhered to a 5 µm silicone layer via oxygen plasma bonding. The membranes were tested in both bench-top water studies and a pig model. Simultaneously, a mathematical model for oxygen transfer into blood was developed, validated against empiric data, and used to guide design of a clinical-scale device.

Results: Individual membranes showed a normalized oxygen flux of up to 390 mL/min/m². The mathematical model correlated strongly with empirical data (r = 0.99, p <0.01). Using the model, we identified a design consisting of 20 parallel channels. This device has a membrane surface area of 0.16 m², an oxygen flux of up to 6.4 mL/min, a priming volume of 5.5 mL, and a pressure drop of 18 mmHg at a blood flow of 100 mL/min. This work demonstrates the potential feasibility of an SNM-based oxygenator to provide sufficient oxygen to support an EPT infant. Improvements in priming volume, pressure drop, and hemocompatibility may overcome shortcomings of hollow-fiber membranes.
Hepatic Function After Artificial Placenta Support With Total Parenteral Nutrition

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Study: The artificial placenta (AP) promotes organ development and reduces organ injury in a lamb model of extreme prematurity. Its effects on the liver and the influence of total parenteral nutrition (TPN) during AP support are unknown. This study evaluates hepatic outcomes after AP support with TPN administration.

Methods: Premature lambs (116-121d estimated gestational age [EGA]; term =145) were cannulated for AP support with jugular vein drainage and umbilical vein reinfusion. Lambs received TPN with SMOFlipid (SMOF; n=7) or Intralipid (IL; n=5). After 7 days, animals were euthanized. Early (ETC; 118±3d EGA; n=7) and late tissue controls (LTC; 128±3d EGA; n=7) were delivered and euthanized. Histologic liver evaluation included 5 components: cholestasis, hepatocyte injury, congestion, fatty change, and extramedullary hematopoiesis (EMH), each graded from 0 to 3 (0=none; 1=mild; 2=moderate; 3=severe). Groups were compared by ANOVA followed by Tukey’s multiple comparisons or linear mixed effects models.

Results: SMOF and IL groups had similar hemodynamics, blood gases, ALT, ALP, GGT, and total bilirubin. Both groups had increases from baseline to day 7 in total bilirubin (IL 2.6±2.3 to 7.9±4.4; SMOF 0.3±0.1 to 5.5±2.3) as well as ALT and GGT (p<0.001 for all). The SMOF group also had increases from baseline to day 7 in direct bilirubin (0.3±0.2 mg/dL to 1.8±1.4 mg/dL; p=0.006) and AST (27±5 to 309±242; p<0.001), and a decrease in INR (1.72±0.2 to 1.4±0.2; p=0.048). These were not measured in the IL group. On liver histology, IL showed more cholestasis than SMOF; both groups showed more than tissue controls. The IL group alone showed hepatocyte injury and had more congestion than controls. All livers had mild-moderate EMH. Lambs supported by the AP with TPN administration maintain normal hepatic function and sustain minimal hepatic injury. SMOFlipid is associated with decreased cholestasis and hepatic injury versus Intralipid.
PEDS4-2
Implementation Of Pediatric ECMO Safety Rounds For Real-time Quality Improvement
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Study: Our Pediatric ECMO Program implemented ECMO Safety Rounds (ESR) as a quality improvement (QI) initiative. Objectives were to ensure implementation of protocols, immediately correct quality/safety deficiencies, and provide real-time education to nurses and perfusionists. Our specific aim was to track compliance with this process-improvement bundle and identify areas to target with QI efforts, with a long-term global aim of reducing quality/safety variances and patient harm over time.

Methods: Our team initiated Pediatric ESR in September 2019. Two process-based QI bundles were developed: (1) Circuit Safety - 35 bundle elements, including maintenance and emergency checks; (2) Patient Safety - 13 bundle elements focused on nursing practices specific to minimizing patient harm. Pediatric ESR consisted of these two bundle assessments performed by designated ESR clinicians at the bedside with the patient’s nurse and perfusionist. Credit for bundle compliance was awarded only if all elements were properly met. Noncompliant elements were addressed in real-time. All data was recorded in REDCap database.

Results: 36 Pediatric ESRs were completed (Sept. 2019 - Jan. 2021). Monthly bundle compliance was reported using run charts. Median compliance with both bundles appeared to improve over time, with their most recent centerlines both at 67% compliance (Figure 1). Analysis of individual bundle elements revealed that 19/48 (40%) safety items were deficient at least once during the 36 ESRs (Table 1). Any individual bundle element with greater than 2 noncompliance events prompted our team to target interventions addressing these lapses, including new protocols and education, conducting multidisciplinary reviews, and collaborating with ancillary departments. We conclude that Pediatric ESR provides real-time assessment of compliance, immediate corrective and education measures, and actionable data to drive performance improvement around observed vulnerabilities in ECMO protocols.

<table>
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<th>Safety Items Noncompliance Data Points</th>
<th>Bundle</th>
<th>Noncompliant Events (n)</th>
<th>Noncompliance Rate (%)</th>
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</table>

ASAIO PEDIATRIC ORAL ABSTRACTS
PEDS4-3

Utilization Of Novel Technology To Optimize Cardiac Rehabilitation In Children Supported With Ventricular Assist Devices During The COVID-19 Era

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Study: Cardiac rehabilitation is critical for successful ventricular assist device (VAD) support in children. Regular in-person rehabilitation can be a challenge, particularly during the COVID-19 era.

Methods: We present 2 cases of adolescents supported with VADs in whom wearable devices and a virtual exercise platform were used to augment cardiac rehabilitation.

Results: A 17-year-old male with tachycardia induced cardiomyopathy underwent LVAD implantation as a bridge to decision. The distance from the hospital and COVID restriction made frequent visits for cardiac rehabilitation not feasible, yet aerobic activity was critical for myocardial remodeling. A 15-year-old severely obese female with dilated cardiomyopathy underwent LVAD implantation as a bridge to candidacy. Engaging her in physical activity was a challenge, but a necessary component of her evaluation for bariatric surgery. For both patients, wearable devices (Fitbit Versa 2) were placed to monitor and incentivize activity. Exercises were designed based on available resources and include walking up stairs and using resistance bands. Despite no palpable pulse both patients had a pulse that registered on their wearable device, which helped to monitor rehabilitation. Devices were paired with the MyHeart CHOP application, a virtual platform for home exercise training that includes individualized exercise prescriptions and the opportunity for virtual communication with a pediatric cardiac exercise physiologist. In the >1 month since incorporation of wearable technology, both patients have participated in rehabilitation sessions on >50% of eligible days (25/31 d, 19/33 d) and are being considered for VAD explant and bariatric surgery. Technology-based remote rehabilitation programs are a promising and feasible option for children supported with VADs during the COVID era, and may be an underutilized method by which to optimize outcomes.

PEDS4-4

Numerical And Experimental Approach To Characterizing Static And Dynamic BLDC Motor Performance With Different Radial-Gap To Facilitate Maglev System Design For A Pediatric LVAD

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Study: A miniature magnetic levitation (maglev) system was proposed to eliminate mechanical wear in an implantable pediatric LVAD. The maglev system comprises permanent magnet rings to levitate the rotor radially and active maglev control to stabilize the rotor axially. To avoid high shear stress on the blood, the motor gap can be enlarged, but this would compromise motor performance. Thus, it is essential to characterize the relationship between motor performance and motor gap to determine an appropriate brushless DC (BLDC) motor size. We varied the rotor size and investigated the radial force generated by rotor-stator eccentricity and the torque generation capacity as a first step in the development of the maglev system.

Methods: A BLDC motor model was established in COMSOL 5.4 and validated based on the unmodified motor specifications. The torque constant was determined numerically for varied rotor diameters; additionally, the numerical model also computed the magnetic force generated by rotor-stator eccentricity. To validate the numerical results, the radial force was measured by a torque transducer mounted on a micrometer-driven stage. The magnetic force was then recorded with the relative radial displacement between the rotor and stator.

Results: The numerical model accurately matched the unmodified motor specifications (torque constant: 3.60 vs. 3.62 mNm/A; speed constant: 2651 vs. 2640 rpm/V; terminal resistance: 8.37 vs. 8.38 Ohm). As the rotor diameter decreased from 3.8 mm to 3.0 mm, the torque constant reduced by 32%, showing a linear relationship between motor gap and torque constant. The numerical and experimental static forces differed by an average of 7.4%, validating the numerical model adequately to predict the radial force for the future maglev system design. This model could be expanded to include more geometric variables, thus accelerating the design process for pediatric LVADs.
PED54-5
Sustaining Effective RVAD Anticoagulation In The Face Of Massive Neurological Injury: A Case Illustration
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Study: Stroke is a rare but important complication in pediatric mechanical circulatory support (MCS). Given concerns of obligate anticoagulation, neurological intervention after stroke may be underutilized. It is important to have a collaborative and established relationship between cardiology, ICU and neurosurgery to ensure timely assessment and intervention. This case of a massive neurological event after right ventricular assist device (RVAD) implant illustrates a successful immediate neurological intervention and long-term RVAD course, leading to ultimate transplant and neurological recovery.

Methods: A 9-year-old male with severe Ebstein’s anomaly with severely enlarged right ventricle was undergoing an EP procedure and suffered a cardiac arrest, requiring ECMO support with transition to Centrimag RVAD support. On POD 2 he became obtunded with a massively enlarged right pupil and found to have a large right sided frontotemporal parietal ischemic stroke with herniation. He underwent an emergent hemicraniectomy and intracranial drain. In the early post neurosurgery course, anticoagulation was held for about 4 days. Low dose bivalirudin was started at that time with frequent imaging. Chronically with and without bone flap surgery-VAD Program guideline provides a novel approach and potential opportunity to help successfully bridge children with severe obesity to heart transplantation.

PED54-6
Development Of A Guideline For Pediatric Bariatric Surgery After Ventricular Assist Device Implantation—Challenges And Opportunities
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Study: Severe obesity in children with end-stage heart failure requiring ventricular assist device (VAD) support is challenging due to the relative contraindication for heart transplantation with a body mass index (BMI) > 35 kg/m². Despite increasing reports of bariatric surgery in adult VAD recipients, no data exists in pediatrics.

Methods: A 15-year-old female with severe obesity (BMI 46 kg/m²) and dilated cardiomyopathy underwent LVAD implementation as a bridge to candidacy. To optimize her opportunity for successful weight loss, pediatric bariatric surgery was proposed, and a multidisciplinary working group was organized to coordinate complex VAD-Bariatric Surgery management.

Results: Our center developed a guideline summarizing our novel, combined Pediatric Bariatric Surgery-VAD program. This program involves VAD placement followed by 4-6 months of medical weight loss management prior to laparoscopic sleeve gastrectomy. Challenging issues identified include risks of post-bariatric nutritional and vitamin deficiencies affecting hydration and anticoagulation. This is addressed through vitamin supplements and mandatory fluid intake goals. Psychologists trained in pediatric bariatric surgical care and pediatric heart transplantation are critical to this process. This novel guideline outlines recommended selection criteria for pediatric VAD and bariatric surgery candidacy, VAD driveline site placement, peri-operative VAD and bariatric surgery care, post-bariatric nutrition and anticoagulation management, medical and psychosocial evaluation and counseling for weight loss, guided exercise training while on VAD support, pharmacologic management for weight loss (liraglutide), comorbidity evaluation and management. This Pediatric Bariatric Surgery-VAD Program guideline provides a novel approach and potential opportunity to help successfully bridge children with severe obesity to heart transplantation.
Clostridium difficile Infection In Pediatric Pulsatile Flow LVAD: Successful Management Of A Life-threatening Complication

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Study: Infection is one of the most common adverse events in pediatric patients with ventricular assist devices (VAD), with antibiotics frequently used for management. The resultant disruption of normal bacterial flora in the colon can cause Clostridium difficile (C. diff) infection. C. diff is a known contributor to morbidity in adults on mechanical circulatory support (MCS), however, its burden in pediatric LVAD cases is not reported.

Methods: We describe the presentation, management, and lessons learned from a 27-month old child with left ventricular noncompaction, restrictive cardiomyopathy, and severe malnutrition who received a Berlin Heart ® (BH) EXCOR left ventricular assist device (LVAD) and developed C. diff with numerous complications.

Results: The patient underwent implantation of a 15cc BH with left atrial cannulation via a transseptal approach. He developed a fever on post-operative day (POD) 6 and started on broad spectrum antibiotics; although initial cultures did not reveal a clear source of infection, antibiotics were continued due to a high concern for sepsis. On POD 10 he developed abdominal distention, tenderness, and profuse diarrhea. Abdominal ultrasound showed thickened loops of bowel and portal venous gas. C. diff toxin assay was positive on POD 11. Due to profound dehydration, he developed acute kidney injury and incomplete VAD filling. A pump exchange was performed on POD 19 due to concern for thrombus. Enteral vancomycin was given rectally for ileus. He required 12 days of bowel rest and 21 days of parenteral nutrition. After 14 days of antibiotics the patient recovered and is awaiting transplant. Conclusion: C. diff infection in MCS is a life-threatening complication and poses significant challenges to fluid balance, VAD hemodynamics, and nutritional support. Antibiotics, which can predispose to C. diff infection, should be used judiciously.
ASAIO PULMONARY ORAL ABSTRACTS

PULM1-1

Experimental Measurements Of Blood Damage In Geometrical Variants Of Membrane Based Microfluidic Devices

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Study: The advancement of membrane based microfluidic devices, such as dialyzers and oxygenators, plays a crucial role on the development of portable dialyzers and oxygenators that may decrease patient complexity and mortality. The potential for such devices to damage blood has not been studied and could benefit from in vitro analysis of prototype devices. Geometrical mixing elements disrupt flow and have been proposed to increase transport, but these features engender the risk of additional stresses and damage. In this study physical models of microfluidic devices of varying geometries were used to study how the flow-mediated shear stress developed inside the microfluidic channels initiates the damage of red blood cells.

Methods: Four geometric variants (baseline, herringbone, reduced gap, and reduced port) of the blood side of a micro-fluidic oxygenator were fabricated to analyze the blood damage behavior with a reduced volume recirculating loop driven by peristaltic pumps. Blood was circulated 620 times through each device at a flow rate of 100 ml/min and sampled periodically to determine Hemolysis (fHb according to the Cripps method converted to Index of Hemolysis, IH%). The slope of a linear regression between IH% and number of passes through the device (IH%/pass) was used as a comparative measure of damage and compared to results from a prior numerical model.

Results: All devices caused low levels of damage (<0.001 IH%/pass). The reduced gap and reduced port device were observed to be showing the most amount of blood damage and the baseline device the least. Marginal increase of blood damage was observed on devices with herringbone mixture compared to the baseline.

PULM1-2

Effect Of Oxygenator Geometry On Performance Characteristics

Chris Dacey, CCP, Greg Johnson, PhD, Patrick Murawski, BS, Anthony McCoppin, Other, Robert Svitek, PhD, CardiacAssist, Inc. dba TandemLife, Pittsburgh, PA, USA

Study: The EOS® and TandemLung® are membrane oxygenators designed for long term extracorporeal membrane oxygenation (ECMO). Both devices operate by the same principle, blood flowing across a bundle of polymethylpentene hollow fiber membranes where O₂ diffuses into the blood and CO₂ diffuses out of the blood. The EOS and the TandemLung are both wound into a cylindrical, annular shape. However, the inner and outer fiber bundle dimensions, the housing geometry, and the blood flow path through the two devices is different. The dimensional and geometric differences may lead to differences in performance that are important to consider when choosing which oxygenator to use for a given clinical scenario in terms of gas exchange, pressure drop, set-up, priming, and hemolysis.

Methods: The differences in the two designs were evaluated in vitro with a mock loop consisting of a reservoir, blood pump, and the test oxygenator. The loop was primed with 12 L of bovine blood and maintained at 37°C and venous conditions: O₂ saturation 65 ± 5%, Hemoglobin 12 g/dL, pH 7.4. Gas exchange and pressure drop measurements were taken at flowrates up to 5 L/min through the test device. In a separate experiment, two identical flow loops were constructed, and blood was pumped through each oxygenator for 6 hours at 5 L/min. Plasma free hemoglobin was measured over time to evaluate the hemolysis generated by blood flowing through each oxygenator design.

Results: Gas exchange was comparable between the two devices at approximately 300 mL O₂/min despite the EOS oxygenator having a smaller priming volume and surface area than the TandemLung. The pressure drop was higher for the EOS oxygenator at 225 mmHg compared to the TandemLung at 55 mmHg at 4.0 L/min. The lower pressure drop and geometric flow path of the TandemLung led to easier set up and priming compared to the EOS. Hemolysis was acceptable for both designs. This study demonstrated that oxygenator fiber bundle design leads to performance tradeoffs to be considered when choosing an oxygenator for a given clinical scenario.
PULM1-3
Piv Validated CFD Analysis Of A Paired Membrane Umbrella Double Lumen Cannula For Failing Fontan Support
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Study: The current solution to the ventricle patients is the Fontan circulation or total cavopulmonary connection (TCPC). However, TCPC will nullify the heart's function and lead to organ dysfunction. Thus, extracorporeal mechanical support is needed to solve failing TCPC induced issues. A novel double lumen cannula (DLC) is proposed to the Fontan patients after TCPC surgery in order to provide cavopulmonary assistance (CPA). The distribution of blood flow will be studied using both experimental and simulation results. Besides, the performance of DLC will be evaluated.
Methods: An In vitro Fontan model including a double lumen cannula, a CentriMag Acute Circulatory Support System and a reservoir is set up to simulate a Fontan patient. A 36% glycerin-water solution with viscosity of 3.47 cST is used as the flow. The range of flow rate is 3~5 L/min and a flow split is set to 55: 45 for inferior vena cava (IVC) to superior vena cava (SVC) and 50: 50 for right pulmonary artery (RPA) to left pulmonary artery (LPA), respectively. A Particle Image Velocimetry (PIV) with a laser is used to trace the fluorescent polymethyl methacrylate (PMMA) particles in the flow. PIV data are processed at three planes from both the IVC and SVC. The CFD simulation is based on the DLC geometry model with the laminar flow pattern, since the Reynolds number is smaller than 2000. Rigid, impermeable and no-slip wall condition and pressure-velocity coupling method are used.
Results: Comparison between the experimental and computational results indicate that both the flow distribution is very similar. The highest velocities are always observed on the mid-plane. Besides, the maximum velocity increase with the increase of mass flow rate as expected. Moreover, the umbrella sealed very well and no flow passed through it. The flow distribution acquired at three planes in the DLC can be used as validation data for computational modeling. The numerical analysis of DLC achieves a good agreement with flow distribution obtained from the experiment.

PULM1-4
Deep Vein Thrombosis: AI/ML Strategies To Determine The Impact Of Coronavirus On Blood Rheology And Venous Valve Integrity
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Study: Deep venous thrombosis (DVT) is said to be the most preventable cause of death in hospitals today (Centers for Disease Control, February 2020). This silent killer most frequently starts in the lower extremities as a small thrombus that initially forms in a valve pocket located behind a venous valve leaflet. Failure to initiate preventative measures to reduce the risk of DVT can result in the development of life-threatening pulmonary emboli (PE) and chronic venous insufficiency (CVI). These risks are currently exacerbated by the current SARS-CoV-2 pandemic that has increased the frequency of DVT formation and PE in patients through mechanisms that are not fully understood. The current study is using artificial intelligence (AI) and machine learning (ML) to evaluate changes in blood rheology, venous blood flow, and venous valve configuration that can lead to increased risk of DVT, PE, and CVI.
Methods: In our model, AI/ML is used to evaluate previously recorded images of normal and abnormal cadaver veins and venous valves. Using these data, we can predict that previous DVT formation produced the observed leaflet damage and will increase the risk of CVI and future DVT formation. The contribution that changes in blood rheology could make to venous blood flow abnormality will also be assessed. We leverage the latest advances in image processing to quantify the valve leaflet geometry with respect to the susceptibility to recurrent DVT.
Results: Based on this data, AI/ML will predict, on a patient-by-patient basis, the probability of deep venous thrombosis formation. This will allow healthcare professionals to determine when preventative measures are most appropriate. It will also allow physicians to assess whether a patient has an increased risk of developing a future DVT and/or CVI insufficiency. With this information patient care can be improved and the debilitating and life-threatening complications of DVT can be substantially reduced.
PULM2-1

Right Ventricular Failure In A Chronic Sheep Model Of Pulmonary Hypertension
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Study: Decompensated right ventricular failure (RVF) due to pulmonary hypertension (PH) is fatal, with limited medical treatment options. Developing and testing novel therapeutics for PH requires a clinically relevant large animal model of increased pulmonary vascular resistance and RVF. Here, we present the latest development of our previously published ovine PH-RVF model utilizing pulmonary artery (PA) occlusion and left PA ligation. The data suggest that this PH-RVF model is a versatile platform that can control the severity of the disease as well as the RV’s phenotypic response.

Methods: Adult sheep underwent left PA ligation, and placements of a main PA cuff and an RV pressure monitor, both connected to subcutaneous ports (Fig 1A). Subjects underwent chronic progressive PA banding every 2-4 days for 9 weeks with sequential measurement of RV pressure, PA cuff pressures, and mixed venous blood gas (SvO₂). At the initiation and endpoint of the PH-RVF model, ventricular function and dimensions were assessed using echocardiography.

Results: Twelve sheep underwent PH-RVF development. RV mean and systolic pressure increased during the model, from 28 ± 8 and 58 ± 8 mmHg, respectively, to 44 ± 8 and 93 ± 18 mmHg at Week 9 (mean ± standard deviation). Echocardiography demonstrated characteristic findings of PH-RVF, most notably as RV dilation, increased wall thickness, and septal bowing (Fig 1B). Furthermore, the longitudinal trends of SvO₂ and PA cuff pressure (Fig 1C) demonstrate that our PA banding strategy can elicit varying RV phenotypes. A faster PA banding strategy led to precipitous decline in SvO₂, whereas a slower, more paced strategy allowed for better compensation and maintenance of physiologic SvO₂. One animal that experienced the faster PA banding strategy developed several liters of pleural effusion and ascites by week 9 of the PH-RVF model. This ovine PH-RVF model is therefore a valuable tool for studying RV adaptations during PH.

PULM2-2

Comparison Of Ex Vivo Versus In Vivo Extracorporeal Circulation Models On Coagulation Outcomes
Teryn R. Roberts, PhD, George T. Harea, BS, Andriy I. Batchinsky, MD; Autonomous Reanimation and Evacuation Program, The Geneva Foundation, San Antonio, TX, USA

Study: Ex vivo hemocompatibility testing of extracorporeal life support (ECLS) devices lacks standardization and clinical guidance. Variables including blood source, anticoagulation, circuit design and outcomes complicate meaningful, translational conclusions. We implemented a sequential device testing approach involving both a 6-hour ex vivo and multi-day in vivo model where blood source, anticoagulation, test device and outcome measures are standardized between models. The objective of this study was to compare coagulation metrics for 6 hours blood circulation ex vivo versus in vivo using the same ECLS system. Hypothesis: Coagulation outcomes differ between models.

Methods: We performed a cross-study comparison of a 6-hour ex vivo swine donor blood circulation model (n=4) and a 72-hour in vivo ECLS model in unjured swine (n=5). In both studies, the same pediatric ECLS device with heparin coating (Maquet/Getinge; Germany) was used and heparin administered to target activated clotting time (ACT) 125-160s. Coagulation was assessed at circulation start (baseline/BL), 3-hours, and 6-hours via complete blood count, PT/apTT, fibrinogen, D-dimer, ATIII, TEG, platelet aggregometry and plasma free hemoglobin (PFHb). A one way and two way repeated-measures mixed model were used to assess within group (Dunnett adjustment) and between group differences (Tukey adjustment), respectively (two-sided, p<0.05 significant).

Results: Using the same heparin protocol, ACT and aPTT did not differ between studies. No difference in D-imer, ATIII or fibrinogen were observed. Platelet loss was similar between groups, but platelet aggrega-
**PULM2-3**

**Evaluation Of The Lifesparc® Pump And Tandemlung® Oxygenator For 14 Days In A Calf Model**

Greg Johnson, PhD, Patrick Murawski, BS, Mike Linehan, BS, Ruben Hartogs, BS, Robert Svitak, PhD; TandemLife dba CardiacAssist, Inc., Pittsburgh, PA, USA

**Study:** The LifeSPARC® Pump and TandemLung® Oxygenator comprise an extracorporeal membrane oxygenation (ECMO) circuit that can provide full cardiopulmonary support. The LifeSPARC® is a centrifugal pump with a magnetic pivot bearing that can generate a flowrate of 8 L/min, and the TandemLung is a radial flow oxygenator that uses plasma resistant fibers and has pressure drop less than 75 mmHg at 5 L/min. The entire circuit is compact, with a priming volume of 375 mL. In this study, the system was used to provide Veno-Venous ECMO support in (n=9) calves (average weight 85 kg) for 14 days via a Protek-Duo® dual lumen cannula placed in the inferior vena cava.

**Methods:** Pump flow was maximized based on available intravascular volume. Oxygenator performance was monitored daily by measuring blood inlet and outlet oxygen content. Hematocrit, plasma free hemoglobin (PFH), LDH, platelet counts, and white blood cells were monitored throughout the study. The safety of the system was evaluated by noting clinically significant adverse events and by performing gross pathology and histopathologic examination following euthanasia at the end of the study.

**Results:** Eight of the nine animals survived the duration of the study. One animal died on day 12 due to an acute coagulopathy. Bleeding at the insertion sites necessitated transfusion in five of the animals. PFH and LDH levels remained within normal limits throughout the experiment, though there were transient spikes in PFH following transfusions not attributed to the device. The LifeSPARC® Pump and TandemLung® Oxygenator demonstrated acceptable reliability and safety in vivo for 14 days.

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**PULM2-4**

**In Vitro Gas Exchange Performance Of A Pulmonary Assist Device Designed To Support Chronic Lung Disease Patients**

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**Study:** Over 15 million Americans suffer from chronic lung disease, resulting in over 168,000 deaths and 726,000 hospitalizations each year. Transplant is the only curative treatment, but there are only 2,700 transplant surgeries each year. Thus, there is a continuing need for long-term respiratory support. Current extracorporeal membrane oxygenation (ECMO) cannot be used as permanent therapy due to rapid oxygenator clot formation, which causes failure within 1-4 weeks, and large bulky circuits that make patient ambulation impossible without support staff. The purpose of this study was to test gas exchange performance of a new Pulmonary Assist Device (PAD) with a smaller fiber bundle (0.9 m$^2$) and lower prime volume for use in a compact, low thrombogenicity ECMO system designed to support chronic lung disease patients.

**Methods:** Bovine blood was citrated, heparinized, then conditioned to AAMI venous standards in a circuit containing a centrifugal pump, commercial gas/heat exchanger, and a blood reservoir. For O$_2$ transfer measurement, blood was pumped at 1, 2, and 3 L/min with 100% O$_2$ provided as sweep gas at twice the blood flow rate. At each flow rate, duplicate blood gas samples were drawn from the inlet and outlet of the PAD and analyzed to determine PO$_2$, PCO$_2$, pH, and hemoglobin concentration. For CO$_2$ transfer measurement, blood was pumped at 2 L/min through the PAD with 100% O$_2$ delivered as the sweep gas at 2.5, 5, and 7.5 L/min. At each flow condition, duplicate blood inlet and sweep gas outlet samples were drawn and analyzed for PCO$_2$.

**Results:** The CO$_2$ transfer rates were measured as 110 ± 2.4, 140 ± 8.7, and 155 ± 6.1 ml/min at O$_2$ sweep gas rates of 2.5, 5, and 7 L/min, respectively. O$_2$ transfer rates and outlet oxygen saturations were measured as 66.3 ± 0.71 ml/min and 99.8%, 105 ± 1.7 ml/min and 95.9%, and 121 ± 1.6 ml/min and 91.3%, at blood flow rates of 1, 2, and 3 L/min, respectively. The PAD provides sufficient gas exchange to serve as a booster lung for patients with chronic lung disease.
PULM3-1

The Outcomes Of Mobile Intensive Care Unit With Double Lumen Catheter Cannulation At Referring Facility For Veno-venous Extracorporeal Membrane Oxygenation Interfacility Transfer
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Study: To assess the feasibility of interfacility transfer with mobile intensive care unit (MOBI) after single double lumen catheter cannulation at referring facility for veno-venous extracorporeal membrane oxygenation (VV-ECMO).

Methods: This is a single center retrospective data analysis. We utilized our institutional data from 2015-2019. We divided 2 groups, patients who had interfacility transfer with MOBI after single double lumen cannulation for VV-ECMO (group A) and patients who had single double lumen cannulation for VV-ECMO at our institution (group B). Cannulation was performed at referring facility by either transport team or a surgeon at the referring facility under fluoroscopic guidance. MOBI consisted of ECMO physician (either a surgeon or an intensivist), respiratory therapist, ECMO nurse, and transport nurse. Two groups were compared pre support, complications during the ECMO support, and survival.

Results: There were 20 patients in group A and 33 patients in group B. Average age were 48.4 ± 13.5 and 45.1 ± 18.0 in group A and B respectively. Pre ECMO pH, PCO2, PO2, and SaO2 were 7.3 ± 0.2, 7.2 ± 0.2 (p=0.08), 59.3 ± 24.2mmHg, 65.0 ± 21.6mmHg (p=0.27), 66.6 ± 45.0mmHg, 69.8 ± 26.3mmHg (p=0.18) in group A and B respectively. There were 13 and 18 complications in group A and B during the ECMO support (p=0.57). Circuit component clots 4 and 5 (p=0.72), circuit exchange 2 and 3 (p=1.00), creatinine 1.5 - 3.0, 1 and 5 (p=0.39), creatinine >3.0 and 3 (p=0.35), renal replacement therapy 4 and 6 (p=1.00). 50.0% and 69.7% of patients came off from ECMO support, 50.0% and 91.2% of patients survived to discharge (p=0.35). Double lumen catheter cannulation at referring facility with MOBI demonstrated good results.

PULM3-2

Outcomes In Patients Requiring Recannulation For Venovenous Extracorporeal Membrane Oxygenation
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Study: Little data exists regarding second-run venovenous extracorporeal membrane oxygenation in adults. The purpose of this study is to determine outcomes in patients who undergo multiple runs of VV-ECMO within the same hospitalization for respiratory failure.

Methods: The ELSO database was used to identify all patients over age 18 with respiratory failure who required recannulation for multiple episodes of VV-ECMO support during the same hospital stay from 1998 to 2018. Patients who underwent lung transplantation were excluded from analysis. The primary outcome was survival to discharge. Patients were categorized as survivors or non-survivors and univariate analysis was performed to compare the two groups.

Results: A total of 500 patients requiring multiple runs of ECMO for respiratory failure were identified. Of these, 12.2% (61) underwent more than two runs. Patient demographics, laboratory data, and circuit variables are shown in Table 1. Survival to discharge occurred in 272 patients (54.4%). Survivors were slightly younger than non-survivors with a mean age of 43 years (range 30-55; p<0.01) versus 49 years (34-60). Survivors and non-survivors had similar arterial blood gases prior to initiation of ECMO and a total of 21 patients (11 survivors, 10 non-survivors) underwent pre-ECMO arrest. No statistical difference was found between duration of initial or last ECMO run between groups. More non-survivors experienced neurological (14% v 3%; p<0.01) complications as well as gastrointestinal bleeding while on ECMO (12% v 6%; p=0.02). Surgical, mechanical, renal, infectious, and other complications were similar between the two groups. This is one of the first studies that evaluates adult patients undergoing multiple runs of VV-ECMO for respiratory failure. Survival to discharge was slightly lower at 54.4% than overall survival according to the ELSO. Neurologic and gastrointestinal complications were significantly higher in non-survivors.

<table>
<thead>
<tr>
<th>Table 1. Study population demographics and preoperative data.</th>
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<tr>
<td><strong>Non-Survivors (n=228)</strong> &amp; <strong>Survivors (n=272)</strong> &amp; <strong>p-value</strong></td>
</tr>
<tr>
<td>Age (mean [range])</td>
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<tr>
<td>Gender (Male)</td>
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<td>Weight (kg, mean [range])</td>
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<tr>
<td>Initial ECMO Run (hours)</td>
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<td>Last ECMO Run (hours)</td>
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**Notes:** Abbreviations: IPC= interstitial pulmonary fibrosis, CF= cystic fibrosis.
Utilization And Outcomes Of Extracorporeal CO\textsubscript{2} Removal: Systematic Review Meta-Analysis Of Pumpless And Pump-Based Approaches

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Study: Extracorporeal carbon dioxide removal (ECCO\textsubscript{2}R) is a valuable technique of providing respiratory support to patients suffering from hypercapnic respiratory failure. We sought to evaluate the existing literature evidence in aggregate and compare the subgroups of patients supported on pump-based and pumpless ECCO\textsubscript{2}R devices.

Methods: An electronic search was performed to identify all relevant studies published between 2000-2019. Demographic information, medical indications, perioperative variables, and clinical outcomes were extracted for systematic review.

Results: This analysis included 25 studies comprising 826 patients. 60% of patients (497/826) were supported on pump-based ECCO\textsubscript{2}R therapy. The most frequently observed indications for therapy were acute respiratory distress syndrome (ARDS) [69% (95%CI: 53-82%)] and chronic obstructive pulmonary disease (COPD) [49% (95%CI: 37-60%)]. Mean duration of support was 6 (95%CI: 4-7) days. Mean time in the ICU was 18 (95%CI: 10-25) days and mean hospital stay was 34 (95%CI: 10-58) days. PaCO\textsubscript{2} decreased from 63.1 (95%CI: 55.6-70.7) mmHg pre-intervention to 48.2 (95%CI: 41.5-54.9) post-intervention (p<0.01). In-hospital mortality was 30% (95%CI: 22-38%). When compared to the pumpless ECCO\textsubscript{2}R subgroup, the pumped ECCO\textsubscript{2}R subgroup had lower rate of presentation with ARDS [52% (95%CI: 33-69%) vs 94% (95%CI: 76-99%), p<0.01] and COPD [42% (95%CI: 32-53%) vs 76% (95%CI: 42-93%), p=0.06]. ICU length of stay was significantly shorter in the pumped group compared to pumpless ECCO\textsubscript{2}R [15 (95%CI: 7-23) vs 42 (95%CI: 17-67) days, p=0.05]. Mean blood flows were comparable [0.08 (95%CI: 0.5-1.2) vs 1.2 (95%CI: 0-2.6) liters, p=0.57]. In-hospital mortality was not significantly different [27% (95%CI: 18-38%) vs 36% (95%CI: 24-51%), p=0.26]. Conclusion: Despite effective CO\textsubscript{2} removal, mortality associated with ECCO\textsubscript{2}R remains high. No ECCO\textsubscript{2}R approach appears to have a distinct advantage over the other.
A New Strategy For Treatment Of Patients With Type 1 Cardiorenal Syndrome With The Impella Microaxial Ventricular Assist Device

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Study: We evaluated the use of the Impella 5.0 and 5.5 heart pumps as a strategy to treat CRS and to improve candidacy for heart transplantation or permanent LVAD implant in a Type 1 CRS patient population who had developed diuretic resistance and/or inotropic therapy intolerance at a single U.S. center.

Methods: A chart review of patients diagnosed with CRS Type 1 from October 2018 to March 2020 treated with the Impella 5.0 or Impella 5.5 heart pumps prior to RRT was conducted. The trigger for primary Impella heart pump therapy in CRS Type 1 patients was diuretic resistance and/or inotropic therapy intolerance. Patient demographic, procedural, hemodynamic, blood laboratory results, and outcomes data were obtained and analyzed.

Results: All patients exhibited improvement in both cardiovascular hemodynamic and renal function. The eGFR demonstrated significant improvement from baseline after 24 hours on Impella support (Pre-Impella eGFR 25 ± 8 mL/min, Post 24 hour Impella 34 ± 13 mL/min, p-value = 0.002), and after 7 days on support (Post 7 days Impella 51 ± 18 mL/min, p-value < 0.001). Patients exhibited reduction in both the pulmonary capillary wedge pressure (pre-Impella 36.6 ± 8.71 mmHg to post-Impella 18.4 ±7.3 mmHg, p-value = 0.02) and central venous pressure (pre-Impella 20 ± 6.95 mmHg to post-Impella 8.88 ± 6.4 mmHg p-value <0.001) with sustained mean arterial pressures throughout support duration. Impella was explanted for recovery in three patients, bridge to durable VAD in nine patients, and bridge to transplant for one patient. This case series demonstrates the feasibility in using Impella pump support to improve cardiovascular and renal function in patients with CRS Type 1. Primary Impella in place of high dosage diuretics, inotropes, and RRT may be used as strategy for improved candidacy in CRS Type 1 patients for the long-term treatment of heart failure.
Optimization Of Filtration Flow Rate During Cell-free And Concentrated Ascites Reinfusion Therapy

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Study: Cell-free and concentrated ascites reinfusion therapy (CART) is a safe and effective treatment for refractory ascites caused by advanced cancer or cirrhosis. Fever is the most problematic adverse event in CART. Since filtration flow rate is considered to be associated with fever, low flow rate (< 50 mL/min) was used. However, to prevent a decrease in blood pressure and renal damage after ascites drainage, it is desirable to start reinfusion earlier by processing ascites in a shorter time. In this study, to optimize the filtration flow rate, we examined the condition of fever during CART when ascites processing was performed with different filtration flow rates in the same patient.

Methods: Six patients with advanced cancer underwent 30 sessions of CART with ascites processing at two different filtration flow rates (50 mL/min or 100 mL/min). Ascites processing was performed using the CART equipment (M-CART), filtration filter (AHF-MOW), and concentration filter (AHF-UP). Prophylactic infusion of steroids (prednisolone 20 mg or 30 mg) was administered in all the cases.

Results: Twelve sessions of CART were performed at a flow rate of 50 mL/min (low-flow group), and 18 sessions were performed at a flow rate of 100 mL/min (high-flow group). The body temperatures of the low-flow group and the high-flow group before CART were 37.1 ± 0.5 °C and 37.0 ± 0.6 °C, respectively, with no significant increase in body temperature after CART. The degree of increase in body temperature of the low-flow group and the high-flow group before CART were 37.1 ± 0.5 °C and 37.0 ± 0.6 °C, respectively, with no significant increase in body temperature after CART. Since filtration flow rate is considered to be associated with fever, low flow rate (< 50 mL/min) was used. However, to prevent a decrease in blood pressure and renal damage after ascites drainage, it is desirable to start reinfusion earlier by processing ascites in a shorter time. In this study, to optimize the filtration flow rate, we examined the condition of fever during CART when ascites processing was performed with different filtration flow rates in the same patient.

Renal Oral Abstracts 2023

Some Rheological Effects On Dialyzer Transport Characteristics

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Study: The significant reduction of in-vivo compared to in-vitro dialyzer clearance has been explained by the viscosity of plasma and by the reduced diffusivity (D, [m^2/s]) of solutes in plasma compared to that in crystalloid solutions regularly used for in-vitro dialyzer characterization. The validity of this hypothesis was examined in a series of lab-bench experiments using homogenous viscous test solutions.

Methods: Low- and high-flux (LF, HF) dialyzers with identical membrane material, identical membrane area and capillary geometry, but with different hydraulic membrane permeability were studied (Polyflux 21L, Polyflux 210H, Gambro Dialysatoren GmbH). Dialute solutions of neutral dextran (70 kDa, Dextran 70, Carl Roth) and anionic alginate (>300 kDa, Algizoon, bizoon GmbH) simulating the range of relative viscosities and colloid osmotic pressures expected under in-vivo conditions were used to perfuse the dialyzer blood compartment. Blood- and dialysate side urea clearances were measured with standard dialysis equipment and corrected by the magnitude of internal filtration (IF) quantified by a mathematical model. The resulting clearance (K') was used to determine the diffusive dialyzer mass transfer coefficient (K', [m/s]) using Michaels' equation. Results were compared to predictions form the in-series boundary layer resistance model for solute transport across hollow fiber membranes and analyzed using the Wilson-plot (Fig. 1, theory shown by full lines).

Results: For a 4 to 6-fold increase in viscosity K' only decreased with alginate solutions. This decrease corresponded to the expected increase in overall transport resistance (1/K') as predicted by theory after correcting for effects of variable IF in both HF and LF dialyzers (Fig. 1a). The correction for IF was not effective for alginate solutions where 1/K' decreased with decreasing D in-spite of comparable relative viscosity and in-spite of identical magnitudes in IF (Fig. 1b). The mechanisms for this discrepancy remain to be examined.
Wearable Device For Measurement Of Intraperitoneal Volume In Peritoneal Dialysis

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Study: The goal of this design is to provide an easy-to-use, wearable bioimpedance (BI) sensor with a custom circuit design that can measure impedance across the abdomen during peritoneal dialysis (PD) treatment. This information can later be used to work as a feedback system for a cycler PD pump through the circuit design and a signal processing unit. The pump can be activated at the optimal time for refilling and will stop pumping once a target IPV is reached. PD is an alternative to hemodialysis as a treatment where fluid waste is filtered through the peritoneum rather than directly from the blood. Presently, PD machines cannot accurately and continuously measure the intraperitoneal fluid volume (IPV) during treatment. This limits the efficacy of the treatment and can cause pain to the patient due to overfilling of the peritoneum with dialysate. Figure 1. Wearable Measurement Device (Top) Connected to Model Abdomen and DF50 (Bottom)

It has been previously theorized that an inverse linear relationship exists between IPV and BI in patients, but this has not been tested with an electrode placement simplified for patient comfort, an issue in the past.

Methods: The methodology continuously records changes in BI as IPV is adjusted in 500mL increments in a simulated abdomen, through the addition of ionized water in the interior cavity, from an empty state (0mL) to a filled state (2000mL). These results were gathered from a DF50 device that was integrated with the model abdomen and fabric.

Results: Through in-vitro testing in a model of a human abdomen, an inversely proportional relationship between IPV and BI of -0.0273 Ω/mL across the abdomen was confirmed, providing a linear model for the calculation of IPV by the signal processing unit that can then be stored digitally. These early results prove that using BI as a continuous and linear measurement of IPV during PD is feasible, and that this device shows promise in being able to optimize the use of PD with patients undergoing this treatment at home.
A New PD Catheter To Provide Faster And More Complete Drainage Of The Peritoneum; In Vitro Studies
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Study: Tenckhoff catheters drain the peritoneum slowly, with decelerating flow at the end of drainage and varying residual volumes. We have designed a catheter (Channel Catheter) with long flow channels along the surface to diminish fluid velocity on outflow and inflow. Small holes connect each channel to a central lumen. We compared outflow rates of Tenckhoff and Channel catheters in a realistic physical model of intraperitoneal hydraulics.

Methods: The model was a 5-liter tank half-filled with bowels simulated by sections of 1” diameter cellulosic dialysis tubing partially filled with saline. The PD catheter was placed in the middle of the bowels, 1.5 L free fluid was added to the tank, pressure was applied to the bowel loops, and catheter outflow rate was measured at -100 cm H2O hydrostatic pressure. For the Channel catheter outflow rate was over 1200 ml/min regardless of applied bowel pressure, and flow did not decelerate as free fluid diminished (Figure 1). For curled Tenckhoff catheters (3.5 mm ID), outflow was about 300 ml/min when 14 cm H2O pressure was applied to the bowels, and flow decelerated near the end of outflow (Figure 1).

Results: The Channel Catheter should provide faster and more complete drainage of the peritoneum than the Tenckhoff catheter. It also should avoid the deceleration which makes “end of outflow” unclear to patients on peritoneal dialysis. The catheter may also aid in Hyperthermic Intraperitoneal Chemotherapy (HIPEC), a flow-through procedure which requires very high outflow rates.

Figure 1. (Left) Channel Catheter, with a straight intraperitoneal portion of 8 mm diameter containing four grooves of 1 mm diameter with numerous holes in the bottom of each groove. (Right) Rate of fluid outflow from a Channel Catheter in the physical model of the peritoneum, showing that outflow rate remains stable at all levels of simulated intraperitoneal pressure (blue line) and rate of outflow from a Tenckhoff curled tip catheter in the same model (red line).
Collapsing Glomerulopathy In COVID Patient—A Case Report
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Study: In the era of the COVID pandemic, although COVID-related pneumonia is the dominant presenting illness in a majority of these patients, with significant number of patients developing renal failure. Collapsing Glomerulopathy has been described in few cases with renal failure who has African lineage with an APOL1 risk variant allele.

Methods: This case report is focused on acute kidney injury (AKI) associated with Collapsing Glomerulopathy in the setting of COVID associated pneumonia. A middle aged African American female presented with pneumonia developed an acute worsening of renal function with proteinuria. Renal biopsy revealed Focal Segmental Glomerulosclerosis with a collapsing lesion and very extensive effacement of foot process along with significant tubular injury.

Results: Collapsing Glomerulopathy (CG) was first characterized in the setting of HIV infection. It was also described in other viral infections, some drug therapies and auto immune diseases. CG has been recently described in few patients of African ancestry during COVID pandemic. It is characterized by a disruption of autophagy and mitochondrial homeostasis which ultimately induces glomerular epithelial cell death. A common denominator for many etiologies of CG is the activation of interferon. Polymorphisms in Apolipoprotein L1 (APOL1) gene in African ancestry predisposes them to chronic kidney disease. Although precise mechanism by which APOL1 gene interacts with interferon signaling pathways is unclear, experimental work has shown that interferon markedly up-regulates levels of APOL1. Acute Kidney Injury is present in one third of patients infected with COVID-19. CG in setting of COVID has been only described in patients with African lineage. This suggests that the presence of genetic predisposition of both African descent and high risk APOL1 variants in the presence of cytokine mediated acute injury secondary to the virus may be the culprit.
COVID3-1
Outcomes Of COVID-19 Patients With Right Ventricular Dysfunction Supported On Extra-corporeal Life Support
Jordan Graham, MD, Bindu H. Akkanti, MD, Kha Dinh, MD, Rahat Hussain, MD, Sachin Kumar, MD, Ismael A. Salas de Armas, MD, Angela Nascimbene, MD, Sriram Nathan, MD, Biswajit M. Kar, MD, Igor D. Gregoric, MD; Advanced Cardiopulmonary Therapies and Transplantation, The Univ. of Texas Health Science Center-Houston, Houston, TX, USA.

Study: The aim of this study is to investigate whether right ventricular (RV) dysfunction is predictive of higher mortality in patients placed on veno-venous (VV) or veno-arterial (VA) extracorporeal membrane oxygenation (ECMO) due to coronavirus disease-2019 (COVID-19).

Methods: All patients who were diagnosed with COVID-19 acute respiratory distress syndrome (ARDS) and received ECMO support between 2020-2021 were retrospectively identified. Patients were excluded if there is no documented echocardiogram during the hospital stay or if point-of-care ultrasound examinations were undocumented. Transthoracic Echocardiogram (TTE) measured RV function.

Results: There were 52 COVID-19 patients who were placed on V-V ECMO or V-A ECMO since the beginning of the COVID-19 pandemic. Of these, 61% had RV dysfunction/failure. Of note, 5 patients did not have a TTE done while on V-V ECMO/V-A ECMO. When grouped by the presence or absence of RV failure, there was no statistical difference in baseline characteristics (hypertension, dyslipidemia, diabetes, history of coronary artery disease/peripheral artery disease, and tobacco use). In the RV dysfunction group, the mortality rate was 59% vs. 33% in those without RV dysfunction (Table 1 and Figure 1). In conclusion, COVID-19 ARDS patients with RV dysfunction appear to have a higher mortality rate than those without RV dysfunction. Due to the small cohort size, this trend did not reach statistical significance. Future studies should be done to further understand the impact of COVID-19 on the cardiovascular system.

Table 1. Demographics & Characteristics of 47 consecutive patients with COVID-19 placed on ECMO

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Patients with RV dysfunction (n=32)</th>
<th>Patients without RV Dysfunction (n = 15)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years, mean ± sd)</td>
<td>44±10.9</td>
<td>45±12.7</td>
<td>0.79</td>
</tr>
<tr>
<td>Male (n, %)</td>
<td>23 (72%)</td>
<td>7 (47%)</td>
<td>0.09</td>
</tr>
<tr>
<td>Race Black</td>
<td>5 (16%)</td>
<td>3 (20%)</td>
<td>0.30</td>
</tr>
<tr>
<td>Race White</td>
<td>11 (34%)</td>
<td>5 (33%)</td>
<td>0.94</td>
</tr>
<tr>
<td>Race Asian</td>
<td>1 (3%)</td>
<td>1 (7%)</td>
<td>0.57</td>
</tr>
<tr>
<td>Length of Stay (days, mean ± sd)</td>
<td>59±21.5</td>
<td>46±24.8</td>
<td>0.35</td>
</tr>
<tr>
<td>Days on ECMO Support (mean ± sd)</td>
<td>34±23</td>
<td>28±18</td>
<td>0.29</td>
</tr>
<tr>
<td>Pulmonary emboliis diagnosed during admission (n, %)</td>
<td>3 (9%)</td>
<td>0 (0%)</td>
<td>N/A</td>
</tr>
<tr>
<td>Mortality Rate (n, %)</td>
<td>10 (59%)</td>
<td>3 (13%)</td>
<td>0.09</td>
</tr>
</tbody>
</table>

COVID3-2
How Should ECMO Be Utilized During Conditions Of Severe Scarcity? A Population Study
Max Shin, BA, Jason J. Han, MD, William L. Patrick, MD, Akhil Rao, BS, Mark Helmers, MD, Amit Iyengar, MD, Salim Olla, PhD, John I. Kelly, MD, Jacob T. Gutsche, MD, Christian A. Bermudez, MD, Marisa Cevasco, MD; University of Pennsylvania, Philadelphia, PA, USA.

Study: Extracorporeal membrane oxygenation (ECMO) is a valuable rescue option for select COVID-19 patients; however, societal preferences regarding its allocation remain unknown.

Methods: A 26-question survey regarding ECMO utilization and allocation was distributed to a nationally representative sample via Amazon Mechanical Turk with minimal incentive ($0.20). Participants were stratified by age (&lt or &gt 40 years) to assess whether belonging to an age group where ECMO is more clinically relevant would influence people’s responses. Standard descriptive statistics were utilized.

Results: In total, 1,041 responses were included. They were 37.9±12.6 years old, generally Caucasian (65%), and college-educated (66.1%). Many reported working in a healthcare setting (22.5%) and having a friend or family member who was admitted to the hospital (43.8%) or died from COVID-19 (29.9%). Given a hypothetical scenario regarding themselves or their immediate loved ones, participants were overall hesitant to initiate ECMO (NPS -24.4, -19.6, respectively). Over half (54%) reported they would be unwilling to stay on ECMO for &gt1 week without signs of recovery. However, at a policy level, participants were highly supportive of ECMO utilization. When presented with a scenario where resources became extremely scarce, a near consensus (96.7%) desired the continued use of ECMO to treat COVID patients. Most advocated for prioritizing those with highest likelihood of recovery (50%) followed by those who were sickest regardless of survival chances (31.7%) (Figure 1). When stratified by age, patients &gt 40 years old were more likely to prefer distributing ECMO on a first-come first-serve basis (21.5% vs. 13.3%, p<0.05).

Table 1. ECMO Rationing

<table>
<thead>
<tr>
<th>Should ECMO be an option under extreme national resource shortages? n (%)</th>
<th>Total Population</th>
<th>Age ≤ 40</th>
<th>Age &gt; 40</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, always</td>
<td>378 (46.3)</td>
<td>232 (34.0)</td>
<td>146 (40.8)</td>
<td>0.180</td>
</tr>
<tr>
<td>Yes, for those &gt;50% recovery</td>
<td>463 (44.5)</td>
<td>316 (46.3)</td>
<td>147 (41.1)</td>
<td></td>
</tr>
<tr>
<td>Yes, for those &gt;90% recovery</td>
<td>166 (16.0)</td>
<td>113 (16.5)</td>
<td>53 (14.8)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>34 (3.3)</td>
<td>22 (3.2)</td>
<td>12 (3.4)</td>
<td></td>
</tr>
</tbody>
</table>
COVID3-3
VV ECMO And Oxy-RVAD As Therapeutic Modalities For Respiratory Failure In COVID-19 Patients: Preliminary Experience
Kelli Hu, None, Viktoria Kagan, ARNP, MSN, Rebecca Rose, Other, Karen Meehan, Other, Justin Okray, PA-C, Shana Creighton, Msn, ACNP-BC, Colleen LaBuhn, ARNP, MSN, Valluvan Jeevanandam, MD, Tae Song, MD, Sandeep Nathan, MD, MS; Cardiac Surgery, University of Chicago, Chicago, IL, USA.

Study: COVID-19 carries a high mortality rate in severe cases and in those that develop severe acute respiratory distress syndrome (ARDS). Veno-venous extracorporeal membrane oxygenation (VV ECMO) can offer mortality benefits in cases of COVID-19 associated ARDS. Here we describe our center’s initial experience with COVID-19 patients requiring VV ECMO support.

Methods: We retrospectively reviewed all COVID-19 patients who were placed on VV ECMO or oxy-RVAD support from May 2020 to January 2021 at a high volume academic medical institution. Collected data included patient demographics, length of support, type of cannulation, LOS after decannulation, and survival to discharge.

Results: A total of 16 patients required VV ECMO support for COVID-19 associated ARDS. Of these, 5 were subsequently converted to an Oxy-RVAD (31.25%). The median length of VV ECMO support and LOS after decannulation was 25.37 days and 8.62 days, respectively. In total, 9 patients survived to discharge (56%) and 3 are currently admitted (18.75%). Our data adds to the support of using VV ECMO to treat ARDS.

Further, we demonstrated how oxy-RVAD can offer additional ambulatory and right ventricular support for patients who develop RV dysfunction.

COVID3-4
Low-flow Respiratory Dialysis System To Improve Refractory Hypercarbic Respiratory Acidosis In COVID-19
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Study: COVID-19 has led to significant morbidity and mortality worldwide. While lung protective ventilation leads to improved mortality, it may also lead to the detrimental consequence of severe hypercapnic respiratory failure. In these cases, low flow dialysis system such as ECCO2R may have a potential role. Hemo-Lung, a ECCO2R device by Alung technologies was granted EUA by FDA in setting of COVID-19 and objective of the study was to evaluate the clinical outcomes of patients supported on low-flow extracorporeal carbon dioxide removal in the setting of COVID-19.

Methods: This is a retrospective cohort analysis of patients that have been supported with ECCO2R in the setting of hypercapnic respiratory failure secondary to COVID-19. Those with discharge data available were evaluated for outcomes from centers across the United States that have utilized this device.

Results: In total, data is currently available from fifty-three patients that have been supported on the Hemo-Lung in setting of COVID-19 ARDS with discharge status known. The primary outcome studied was survival at 48hrs post cannulation and secondary outcomes studied included mortality and adverse events. Hemo-Lung was also utilized in two sites that did not have established ECMO programs. The average age of the cohort was 55 years of age with a BMI of 33.41 with no significant difference between survivors and non-survivors. The median duration of Hemo-Lung in survivors was 8.9 days in survivors and 6 days in non-survivors with no statistical significance. Seventeen percent of the patients (25% survivors, 13% non-survivors) were bridged from Veno-Venous ECMO to Hemo-Lung or were cannulated with Hemo-Lung for persistent respiratory acidosis after decannulation from Veno-Venous ECMO. Two patients had adverse events due to vascular access complications. The overall survival at 48 hrs post cannulation was 85 percent in the cohort with survival at discharge of 30 percent.
COVID3-5

A Safe Bedside Protocol For Dual Lumen RIJ Cannulation For Venovenous ECMO In COVID-19 Patients With Severe ARDS

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Study: In appropriately selected patients with COVID-19 ARDS, venovenous extracorporeal membrane oxygenation (VV ECMO) may offer a promising bridge to lung recovery. Cannulation for VV ECMO via a RIJ dual-lumen catheter technique vs. conventional technique may provide improved delivery of oxygenated blood by utilizing bical venous drainage and improve overall survival. Placement of RIJ dual-lumen catheters, however, requires guidance by either fluoroscopy or transesophageal echocardiography (TEE) to minimize risk of cardiac perforation, vascular injury, or malposition. Transport to the operating room is not always feasible in unstable patients. Here we describe our center’s experience developing a bedside protocol for RIJ dual lumen cannulation under TEE guidance, with special attention to infection control, as well as patient and personnel safety.

Methods: COVID-19 patients were selected for VV ECMO by a designated panel. Bedside cannulation was performed by a small, multi-disciplinary team, equipped with an "ECMO Go-Bag" of surgical equipment. Cannulation was achieved by RI venous access and TEE monitoring during placement of distance-marked wires, dilators, and ultimately the dual-lumen catheter. Room choreography is shown in Figure 1. Surgical prep is shown in Figure 2. Example TEE imaging is shown in Figure 3.

Results: We cannulated 15 patients for VV ECMO via RIJ dual lumen catheter cannulation between 3/1/2020 and 12/31/2020. Mean duration of VV ECMO was 859 hours, and survival to discharge is 53% with 2 patients still in the hospital after decannulation. There were no major cannulation-associated complications.
Platelet Function At The Intersection Of COVID-19 Cytokines And Mechanical Circulatory Support: A Closed Loop In Vitro Study

Kaitlyn R. Amman, PhD, Sami B. Musliman, None, Samuel M. Miller-Gutierrez, BS, Yana Roka-Moia, PhD, Marvin J. Slepian, MD; University of Arizona, Tucson, AZ, USA.

Study: A pathophysiologic component of severe COVID-19 is release and circulation of pro-inflammatory cytokines or “cytokine storm,” with associated thrombus formation and embolization often occurring. Compromised patients often require extracorporeal oxygenation and mechanical circulatory support (MCS), further imparting blood flow disturbances which amplify thrombosis. Central to these processes is the platelet. The dynamic interaction of MCS flow/shear + inflammatory cytokines and their propensity for altering platelet function remains unknown. We hypothesized that platelet aggregability is modified in an MCS + pro-inflammatory cytokine environment. We examined platelet aggregation as a function of time, exposing platelets to COVID-19-associated cytokines under MCS flow in vitro.

Methods: An Impella 5.5 was affixed in a Tygon closed loop and positioned with outflow cannula in a 1-inch tube region, maintained at 60mmHg pressure. Porcine PRP, obtained via centrifugation of fresh, anticoagulated (10% ACD) whole blood was used as circulating fluid. Cytokines alone or “COVID-19 cocktail” of porcine IL-6 (4.5 ng/mL), IL-1β (0.5 ng/mL), IL-8 (2.7 ng/mL), and TNFα (1 ng/mL) were added to PRP and circulated at 5 L/min. At 0, 1, and 4 hrs, platelet aggregation with ADP (0.5 ng/mL), IL-8 (2.7 ng/mL), and TNFα (1 ng/mL) were added to PRP and collagen (5ug/mL), or calcium ionophore (CaI; 5uM) was determined using light transmission aggregometry.

Results: Shear/flow exposure in the cytokine environment led to a decrease in agonist-mediated aggregation (53% w/ADP, 57% w/collagen) compared to resting. Fig. 1 depicts (A) ADP-mediated platelet aggregation (area-under-curve; AUC) and (B) collagen-mediated platelet aggregation at each timepoint, standardized to resting PRP. A non-significant decrease in aggregation was observed with SuM Cal. These findings suggest that in the setting of shear, cytokines are pro-aggregatory; however they are inducing effects via specific pathways or receptors.

A Virtual Collaborative Heart Failure Shared-care Clinic For Underserved Patient Populations In The Covid-19 Pandemic.

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Study: In the Mountain West, there is less access to centers that provide advanced heart failure therapy (AHFT) such as mechanical circulatory support (MCS) and heart transplantation. Many patients in the broader areas of New Mexico may be unaware of AHFT treatment options. They have to travel great distances and across state lines for AHFT with additional fears related to the COVID-19 pandemic. In order to overcome these obstacles, we initiated a virtual collaborative shared-care (VCSC) model for underserved patient populations.

Methods: The University of Utah AHF program began virtually collaborating with a private cardiology practice in Albuquerque, New Mexico. This collaboration involved meeting monthly virtually in clinic for early identification and safe implementation of treatment strategies for patients with AHF in the setting of a pandemic. This clinic allowed a MCS nurse and AHF cardiologist to remotely connect and consult with the New Mexico cardiologist and prospective patients.

Results: In these VCSC clinics, we achieved joint patient care planning safely and efficiently during the pandemic. Potential AHFT patients were identified earlier in their disease process and enhanced trust and understanding was fostered between providers and patients. A total of 20 AHF patients were evaluated. Two patients received successful elective durable MCS implantation. Two patients were identified and began evaluation for heart transplantation. The remaining patients are being closely followed through VCSC. Since the COVID-19 pandemic outbreak in the United States, we have used this VCSC approach to reach underserved patients. This approach demonstrates shared effort to deliver efficient and effective care to underserved patient population that may benefit from AHFT. Future efforts to utilize VCSC clinics should be considered, and additional research is needed to assess patient and provider satisfaction of this approach.
P1

“Digital Dance”: Signatures Of A Demi Plié Via Stretchable Electronic Wearable Sensors

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**Study:** Dance is a form of artistry that has increasing medical value. To be effective dance must be performed correctly with exacting body and limb movements. In classical ballet, classes/training are specifically designed to promote proper muscular engagement and alignment, fostering accuracy and safety. We developed a range of wearable sensors using stretchable electronics that may be utilized to define and quantitate human motion. Here we evaluated the movements of the demi plié, the most foundational ballet move, using these sensors —examining the path of knee motion and orientation of the pelvis. We hypothesized that deviations in motion signatures are identifiable between subjects correctly vs. incorrectly performing demi pliés.

**Methods:** Stretchable motion sensors (BioStamps) were placed on the left tibialis anterior and sacrum of three classically trained, injury-free, collegiate-level dancers as they participated in all three of the following conditions: (1) correct demi pliés, (2) incorrect demi pliés with an anterior pelvic tilt, and (3) incorrect demi pliés with a posterior pelvic tilt. For all conditions, acceleration and gyroscope data was collected in the X, Y, and Z axes.

**Results:** In all cases knee and pelvic motion signatures were detectable, clearly defined and analyzable. Inter-participant variations of knee movement during correct demi pliés were found. One-way ANOVA indicated knee range of motion across conditions was insignificant with an average amplitude of -0.775g (p>0.05). In contrast, sacrum acceleration was significantly different between all three conditions, with conditions 2 and 3 having the same amplitude but opposite directionality (p<0.01). Hence wearable sensors offer the potential for tracking limb and other body element movement during classical ballet and related dance forms. This approach offers great potential for enhanced accurate and safe dance —for both artistry and medical dance therapy.

P2

Thrombogenic Activity Of Von Willebrand Factor Under Shear On Biological Substrates In A Microfluidic Device

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**Study:** A crucial component of the coagulation cascade is the von Willebrand Factor (vWF). This bloodborne glycoprotein functions by connecting platelets in the freestream to the subendothelial matrix in high shear flows. Left ventricular assist devices (LVADs) apply pathological shear significantly higher than that of physiological conditions. The primary goal of this study is to observe the adhesive behavior and thrombogenic contribution of vWF on biomaterials, leading to novel strategies to reduce thrombosis mediated by implanted devices.

**Methods:** A microfluidic channel was fabricated to serve as a base for collagen and cultured endothelial cells (ECs). Human type I collagen was diluted to 100ug/mL and used to coat the channel area. Human pulmonary artery ECs were passaged and adhered to an initial fibronectin coating. Titanium alloy Ti-6Al-4V was polished to a mirror finish to mimic surface conditions within an LVAD. Conjugated antibodies specific to vWF were acquired to allow for immunofluorescent microscopy. Platelets were stained through incubation with lipophilic dye DiOC₆. Micro-particle image velocimetry was used to quantify the flow.

**Results:** Deposition of isolated vWF onto a collagen substrate was characterized, demonstrating that shear rate has a direct effect on deposition of vWF multimers or mechanically cleaved monomers, while having little effect on the chemically fragmented subdomains generated by ADAMTS13. Investigating vWF deposition in low shear conditions is crucial in understanding how high shear alters adhesive function. This study has taken a step towards understanding the behavior of vWF under physiological conditions in relation to the presence of biomaterials.
Digitizing the Range of Motion in Bicep Curl Exercise: Signatures of Exercise Movements of Motion via Stretchable Electronic Wearable Sensors

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Study: Analysis of motion signatures during exercise training is beneficial in prediction, diagnosis and treatment of improper musculoskeletal activation. In the "COVID/post-COVID" world, at-home exercising has become a new standard, placing unprecedented reliance on the individual to maintain proper form, independent of outside coaching. Recognition of abnormalities in muscular activity in 3-dimensions will allow for accurate monitoring of human exercise techniques. We developed wearable sensors utilizing stretchable electronics capable of monitoring triaxial acceleration and angular velocity; as well as EMG. We hypothesized that these sensors, would capture exercise muscular activity, generating a "signature" for analysis of improper and proper form.

Methods: Wireless, stretchable sensors (BioStampRC, MC10) were placed on the dominant right arm of regular gym attenders (1M, 2F). All subjects were healthy controls and free from neuromuscular diseases. Subjects were asked to perform a series of bicep curl exercises with various dumbbell weights that activated a variety of limb muscles over a fifteen-minute session. EMG, angular velocity, and acceleration were measured for all participants, both pre-and post-workout.

Results: A clearly defined and analyzable bicep curl motion signature was detectable for all cases. The average time of repetition for five series of one bicep curl variation across subjects was 3.79 ± 0.17 s. EMG activation of the biceps brachii, triceps brachii, brachioradialis, and medial deltoid were compared for the whole range of motion. The biceps brachii showed statistically significant differences (p < 0.05) with an average EMG reading of 9.66 ± 0.169 mV activation, while the triceps brachii, brachioradialis and medial deltoid show statistically insignificant differences (p > 0.01). These signatures of motion demonstrate clear potential for tracking musculoskeletal activation during strength-and-conditioning exercises. The use of wearable sensors and motion capture offers opportunity for improved form and safety of strength training exercises for both athletic training and strength rehabilitation.

Remote Joint Motion Flexibility Assessment Utilizing a Cell-Phone Based Capture and Analysis System

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Study: Human motion while a primary component of daily living is often one of the first life functions effected by aging and disease. Joint flexibility is vital element of normal human motion often compromised by injury and arthritis. Ready characterization of joint compromise and flexibility is a desired goal to aid diagnosis and management. Previously we developed a smart phone-based motion analysis tool, MoCa, able to characterize overall human movement. Here we advance this method to be able to capture and characterize body component movements indicative of joint flexibility. We hypothesized that this tool will effectively capture and quantify the movement of large and small joints defining their flexibility. We specifically determined the angle (degrees) produced in a select series of range of motion routines.

Methods: Normal volunteers (n=4, 2M/2F, average age= 22±2) placed visual markers (1cm2) on lateral aspects of ankle-knee-hip joints, or forearm-wrist-fingers. Subjects performed a defined knee and wrist flexion and extension protocol which was captured by local smartphone. Images were sent to investigators and then analyzed remotely using the MoCa system to assess extent of flexibility (flexion and extension) for both large-joint and small-joint movement. The protocol was purposely performed with a remote analysis component to demonstrate utility for telehealth applications.

Results: The smart-phone MoCa2 system was able to capture motion of both large and small joints. Utilizing the markers placed, the system had the resolution to calculate the extent of joint motion to determine overall flexibility. After setting the maximum peak flexion as "zero," the average maximum peak extension angle was calculated as 73 ± 2° for the knee joint and 59 ± 3° for the wrist joint (see figure). These measurement now serve as a baseline for future analysis of normal volunteers over a range of ages; and subsequently patients with a range of arthritides. The digital recording of joint range of motion has the potential to expand the realm of telehealth within medicine and surgery, offering the capability to assess and track joint flexibility with illness, injury, treatment and following joint replacement procedures as well.
**P5**

**Successful Resuscitation Of Ex-vivo Hearts After Twelve Hours Of Cold Ischemia Using Normothermic Perfusion**

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**Study:** The current standard for organ preservation is cold storage up to 6hr, with resuscitation upon transplantation. Being able to extend organ preservation length could impact the limitations of heart transplantation. This study aims to assess heart resuscitation and organ viability using a novel normothermic ex-vivo heart perfusion (NEVHP) system with continuous hemofiltration (HF) after 12hr of cold ischemia.

**Methods:** Hearts from 6-10kg piglets were procured after antegrade cardioplegia. Cannulae placed in the aorta, pulmonary artery, and left ventricle (LV) maintained the NEVHP circuit. An LV pressure balloon allowed for hemodynamic monitoring. After procurement and cannulation, hearts (n=3) were stored in University of Wisconsin solution at 5 degrees centigrade for 12hr. The circuit was primed with heparinized platelet- and leukocyte-reduced blood. Hearts then underwent NEVHP for 8hr with in-parallel HF (Prismaflex HF1000) at 1cc/hr/g cardiac tissue and Filter Replacement Fluid infusion at an equal rate to maintain circuit euvoolemia. Hemodynamic and laboratory data were compared using paired student’s t-tests (p<0.05 considered significant).

**Results:** All hearts were viable at 8hr, at which point they were electively terminated. Mean LV systolic pressure was 43.6±9.8 mmHg (Figure 1A). Mean coronary resistance was 0.64±0.10 mmHg/mL/min/100g tissue (Figure 1B). Mean oxygen consumption was 5.45±0.68 mL/min (Figure 1C). Mean serum lactate was 2.58±0.21 mmol/L (Figure 1D). These values did not significantly change from the time of NEVHP initiation to hour 8. Average weight gain was 6±2 grams. All hearts had an increased inotropic and chronotropic response to epinephrine at hour 8. NEVHP successfully resuscitates donor hearts after 12hr of cold ischemia without significant deterioration in tissue viability at 8hr. This has potential to increase organ availability for transplantation by circumventing the time restrictions imposed by geographic location.

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**P6**

**Use Of Three Dimensional Echocardiography To Determine Impella Device Positioning And Potential Impact On Hemolysis**

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**Study:** Cardiogenic shock (CS) is a state of hypoperfusion due to low cardiac output and insufficient oxygen delivery to end-organs. Temporary percutaneous ventricular support devices (pVADs) have been increasingly employed to treat refractory cardiogenic shock. Impella (Abiomed, Danvers, MA) devices are continuous flow, catheter-based pVADs that provide circulatory support using a microaxial rotor. The company’s user manual suggests placing the inflow port (IP) 3.5cm below the aortic valve (AV). However, there is limited evidence to support what positions reduce adverse outcomes. We developed a novel three-dimensional echocardiography (3DE) analysis protocol to measure the distance between the device and intracardiac structures. We then assessed the association of various echocardiographic-based measurements with hemolysis.

**Methods:** Using the QLAB software (Philips, Amsterdam, Netherlands) we analyzed 198 3DE full volume PLAX acquisitions TTE studies from 112 patients. The AV, MV, and apical axis are used to orient the coordinate system. The XY plane is orthogonal to the apical axis. The YZ plane intersects both the AV and MV coaptation points. Three positions were marked along the Z axis to measure the device in the XY plane.

**Results:** We performed a longitudinal analysis using Generalized Estimating Equations. All analyses were adjusted for age and gender. The odds ratio for correlation of LVEDD to the occurrence of a hemolysis event was significant at 0.5, indicating a 50% decreased risk of a hemolysis event for every 1 cm increase in LVEDD (p = 0.029). For continuous LDH, a 1 cm increase in LVEDD was correlated with a decrease in LDH by 426 u/l/cm. There was a nonsignificant trend toward a correlation between MV-IP distance and LDH greater than 600 g/dL (p=0.061). For time between implantation and time between study, one additional day was correlated with a decrease in LDH by 86 u/l/days.

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ASAIO DISPLAY POSTER ABSTRACTS

P7

Vasoactive Inotrope Score And Outcomes In Patients Bridged To Heart Transplantation With Axillary impella 5.5 Vs Durable Left Ventricular Assist Device

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Study: Optimization prior to heart transplantation (OHT) is key to improved outcomes and reduced post-operative complications. Higher vasoactive inotrope scores (VIS) have been associated with worse outcomes in the critically ill. As a result of advances in device technology and recent UNOS listing changes, durable left ventricular assist devices (LVAD) have been thought to confer limited benefit in patients awaiting OHT as bridge therapy (BTT).

Methods: We performed a retrospective single center review of patients who underwent orthotopic heart transplantation between January 1, 2019 and December 31, 2020. All patients with axillary impella or LVAD were evaluated. Descriptive statistical analysis was performed to assess VIS, cardiopulmonary bypass time (CPB) and length of stay.

Results: 82 patients underwent OHT during our study period of which 28 (34%) utilized a device as BTT. 15 (54%) underwent axillary impella placement and 13 (46%) had durable LVAD. Average age was 60 in the impella group and 51 in the LVAD group (8M and 5F). Median VIS score was lower, p=0.05, in the impella group (6, IQR 4-12) compared to the LVAD group (9.8, IQR 7-14). CPB time was statistically shorter when comparing impella vs. LVAD groups, p=0.009 (179 min vs. 221 min). Multivariate analysis did not demonstrate a statistically significant difference between VIS score and time from transplant to discharge (p=0.277). Median days from transplant to discharge was 12 (IQR 11-15) in the impella group and 14 (IQR 12-32) in the LVAD group. This data demonstrates the potential benefits of axillary support prior to transplantation with a significantly lower VIS, likely due to improved pre-transplant optimization leading to statistically shorter CPB times and less post-cardiotomy shock. Larger studies and pooled center data may provide further insight into the benefits of impella support as BTT for OHT.

P8

Creating SARS-CoV-2 (COVID-19) Sample Collection Test Kits

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Study: The rapid transmission of COVID-19 exceeded the availability of commercially produced detection methods. An interdisciplinary collaboration was organized to identify, validate, and implement a component fabrication and assembly process for sample collection test kits used to detect COVID-19 by RT-PCR analysis to meet clinical and research needs at the University of Louisville.

Methods: A review of commercial kits determined six components were needed: (1 & 2) a 6”x9” biohazard bag with a document pouch was use for the kit container and sample transport bag, (3) instructions for use (reviewed by public health nurses) were printed on stickers and adhered to the biohazard bag, (4) a sterile 15 mL centrifuge vial with a sealed cap was used for the sample vial, (5) sterile viral transport media prepared from a CDC recipe was dispensed into the vials, and (6) a sterile nasopharyngeal swab (FDA Class 1 device) with a domed, open lattice tip designed from a CDC recipe was dispensed into the vials, and (6) a sterile nasopharyngeal swab (FDA Class 1 device) with a domed, open lattice tip designed from a CDC recipe was dispensed into the vials.

Results: Feedback from kit users was acceptable with over 11,500 kits distributed to date. This rapid, collaborative development process provided effective sampling test kits to support COVID-19 research and clinical screening.
Modulation Of COVID-19-associated Cytokines In Mechanical Circulatory Support: A Closed Loop In Vitro Study
Kaitlyn R. Ammann, PhD, Sami B. Muslmani, None, Samuel M. Miller-Gutierrez, BS, Yana Roka-Moia, PhD, Marvin J. Slepian, MD; University of Arizona, Tucson, AZ, USA

Study: Severe COVID-19 infection results in pulmonary and cardiac compromise, often requiring extracorporeal oxygenation and mechanical circulatory support (MCS). Accompanying severe COVID-19 is a burst of hyperinflammatory cytokines referred to as “cytokine storm.” Prior studies have shown MCS shear forces alter circulating protein structure and function, e.g. von Willebrand factor, yet it is unknown what effect MCS device flow and shear has on COVID-19-associated cytokines. We hypothesize that MCS-generated flow alters cytokine binding, structure, or function. Utilizing a closed loop in vitro we investigated alterations of COVID-19-associated cytokines following circulation with MCS (Impella 5.5 or CentriMag).

Methods: CentriMag or Impella 5.5 were affixed in a Tygon closed loop. Impella was positioned with outflow cannula in a 1-inch tube region and maintained at 60 mmHg pressure. Porcine platelet poor plasma (PPP) obtained via centrifugation of fresh, anticoagulated (10% ACD) whole blood was the circulating fluid. Cytokines alone or “COVID-19 cocktail” containing porcine IL-6 (4.5 ng/mL), IL-1β (0.5 ng/mL), IL-8 (2.7 ng/mL), and TNFα (1 ng/mL) were added to PPP prior to filling loops. Loops were run at 5 L/min and sampled at 0, 1, and 4 hrs for analysis of cytokine binding via ELISA, compared to resting.

Results: Cytokine-antibody binding was altered following circulation, indicative of flow-mediated modulation of cytokine epitope availability. After 4 hrs, an increase in IL-6 antibody binding was observed with Impella, and a similar increase in IL-8 detected with CentriMag. No significant change was noted for IL-1β or TNFα after 4 hrs circulation with Impella, and a similar increase in IL-8 detected with CentriMag. No significant change was noted for IL-1β or TNFα after 4 hrs circulation with Impella, and a similar increase in IL-8 detected with CentriMag. No significant change was noted for IL-1β or TNFα after 4 hrs circulation with Impella, and a similar increase in IL-8 detected with CentriMag.

Future investigation, e.g. with whole blood, is required to define additional mechanistic aspects of these cytokine alterations to offer potential clinical utility for informing improved therapy.
**P11**

**Bedside Dual-lumen Internal Jugular VV-ECMO Cannulation In A Jehovah’s Witness Patient For COVID-19**

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**Study:** Jehovah’s Witness patients may not consent to receiving allogeneic blood products. It is well established that blood transfusions are often needed during veno-venous extracorporeal membrane oxygenation (VV-ECMO) given the inherent, acquired coagulopathy. There is a theoretical and ethical concern of offering ECMO without being able to transfuse blood products. To our knowledge, no one has reported the use of VV-ECMO for Jehovah’s Witness patients in the COVID-19 era.

**Methods:** Here we present the first reported case of successful use of veno-venous ECMO for refractory ARDS due to COVID-19 infection in a Jehovah’s Witness patient.

**Results:** The patient is a 36-year-old Jehovah’s Witness with hypertension, obesity, depression and diabetes who presented with acute hypoxic and hypercarbic respiratory failure with COVID-19 ARDS requiring mechanical intubation, renal replacement therapy and eventual VV-ECMO therapy via right internal jugular size 32Fr dual-lumen catheter. He was cannulated at the bedside utilizing TEE guidance and with only a heparin IV bolus at the time of initiation. His hospital course was notable for deep venous thrombosis secondary to heparin induced thrombocytopenia and thrombosis requiring systemic anticoagulation. He did not require blood transfusions. Adjuncts included vitamin B12, folate, epoetin alfa-epbx, iron, and pediatric tubing for phlebotomy. The patient was weaned and decannulated after 21 days on VV-ECMO and survived. He was discharged home where he resumed riding his bicycle. Initial hemoglobin was 10.9 g/dL, nadir was 4.8 g/dL, and discharge was 8.1 g/dL. Post-recovery cognitive scores demonstrated results in the low average range on tests of learning, processing speed, and executive functioning.

VV-ECMO was successfully used as a treatment modality in a patient who did not consent to blood transfusions. Patient choice in blood consent should not be an absolute contraindication to pursuing VV-ECMO.

**P12**

**ASAIO, YOU Can Do THIS**

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**Study:** There is a way forward from this dilemma! ASAIO can help resolve-circumvent the current COVID dilemma, of having to choose between providing best protection and care for the most endangered, verses allowing societies to reopen and build their economies.

**Methods:**

Suggested Design Principles:
1. Design for EARLY application. Stocked and inexpensively trained-ready In most locations around the World. 2. Design for EASY, perfect, automatic CO2-vacuum priming during opening box,, as operator turns his-her attention to cannulation. 3. Select-develop most EFFICIENT membrane oxygenator, which cannot accumulate or embolize air, because all blood passages are upwardly inclined and therefore needs not be so intensively monitored. 4. Fail-safe pneumatic or emergency manual-pedal powered pump

Suggested Implementation: Encourage ongoing series of Early Conventional ECMO (by others) to demonstrate comfort and hoped-for survival. Research CO2-vacuum packaging in can and bag. Consider alternative oxygenators. Easier to go with what already exists. Landé-Edwards LEMO Membrane Oxygenator (Kolobow?). Best use silicone membrane for days to weeks-long ECMO. Excellent flat- plate, press-housing. Proven folded manifold. Stand housing on side or “on pointe” with plates and fluid paths vertical (or nearly vertical) to facilitate air elimination. Multiple non-critical tradeoffs available to idealize upward blood and downward gas flow patterns. Efficient silicone-surfaced hollow oxygenating fibers membrane spacing screens, likely. Microfluidic “capillaries” possible.

**Results:** ASAIO, We can do this!
Heartmate 3 Implantation In A Severely Calcified Left Ventricular Apex
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Study: Ischemic cardiomyopathy (ICM) is the second most common indication for durable left ventricular assist device (LVAD) implantation. These patients may present with calcification of the left ventricular apex, which may make LVAD implantation challenging. We present successful use of the PhotoFix, decellularized bovine pericardium patch, during implantation of Heartmate 3 (HM3) in a heavily calcified left ventricular (LV) apex.

Methods: 72 year old male with end stage ICM secondary to coronary artery disease, aortic insufficiency, atrial fibrillation, TIA, diabetes, and chronic kidney disease presented in acute decompensated heart failure and underwent evaluation for LVAD implantation. Pre-operative echocardiogram revealed scarring of the anteroseptal myocardium and aneurysmal deformity of the apical myocardium. CT chest demonstrated severe calcification of the LV apex. He was deemed a suitable candidate for LVAD implantation with concomitant aortic valve replacement and preoperative planning included determination of ideal LVAD inflow cannula and outflow graft placement. As suspected, following sternotomy, extensive calcification of the LV apex was visualized preventing ideal placement of the inflow sewing cuff. Patch ventriculoplasty of the LV apex was performed utilizing the PhotoFix membrane. A portion of the calcific wall was debrided and the sewing cuff of the HM3 was secured to the PhotoFix membrane. An intraoperative transesophageal echocardiogram confirmed adequate positioning of the inflow cannula. Patient was discharged home after 39 days. Patient continues to do well at home with stable VAD function 18 months post-surgery.

Results: LVAD candidates can have complex comorbidities which present unique surgical challenges for LVAD implantation. Our case shows successful LV reconstruction with HM3 implantation utilizing the PhotoFix patch with implantation directly into the membrane.
EPBio1

Quantification Of Thrombosis Threat Levels In Clinically-Relevant Circulatory Assist Devices
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Study: Published in its initial form in 1999, the Cornell thrombosis model has evolved in its complexity and sophistication to simulate thrombogenesis within medical devices. Like other CFD-based models, presence of thrombus is predicted to exist within a device when a single threshold metric is exceeded. However, even the best models are not exact predictors of thrombosis, and predicted locations and extents of thrombosis based on a binary threshold can be misleading and unrealistic. The purpose of this study is to introduce the concept of thrombosis threat levels and to apply it to several clinically-relevant VADs.

Methods: High fidelity CFD is performed on six well-known circulatory assist devices. To consistently capture blood shearing effects, mesh generation is performed to intentionally match near-wall mesh resolution in each device. Thrombosis simulations are performed using the Cornell model and identical model parameters. Thrombosis threat levels are defined by a sequence of interval thresholds on thrombus volume fractions. Direct comparisons are made between each device based on predicted thrombosis threat levels.

Results: As expected, degrees and locations of thrombosis threat significantly vary between the six devices, but reflect engineering intuition well. Results from this study represent an initial standard, numerical protocol, and preliminary database of thrombosis threat levels that can be used to compare thrombotic behaviors in other existing and future devices. Standardized thrombosis threat levels can serve as an efficient diagnostic tool for designers, clinicians, and regulators.

EPBio2

Identifying The OperatingEnvelope Of A Motion Capture System For The Future Of Telemedicine
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Study: Active movement is vital for human function and health. There is a need to better assess movement and motion in clinical medicine in an objective way. A smartphone-based motion capture (MO2CA) system presents a solution to not only better assess human motion in clinical setting, but also virtually via telemedicine. The MO2CA system has recently demonstrated its capability to accurately capture human walking on a treadmill without defining the full range of efficacy and parameters of use. Therefore, in this study, we aimed to define and delineate the operating envelope of the MO2CA system in order to determine the parameters of the system that can be used in the healthcare setting.

Methods: By using single marker and multiple targets spaced at varying distances apart, implementing and tracking a moving target, and varying lighting conditions we were able to identify the operating envelope of the MO2CA system.

Results: Our results show that MO2CA system is able to track a single target within the boundary from 1 ft to 18 ft, multiple targets from 1 ft to 11 ft, a moving target with minimal errors from 2 ft to 8 ft and can accurately identify a target from 1 ft to 18 ft under specific lighting conditions (100, 200, and 300 lumens). Thereby, we defined the practical operating envelope of the system. These results suggest that the MO2CA system has the efficacy at a range of distances, light intensities, speeds, and target sizes. With the current COVID-19 pandemic, the MO2CA may be utilized in facilitating the expansion of telemedicine for a variety of remote clinical assessments including functional and range of motion examinations, hospital discharge evaluations and response to therapy and rehabilitation at home.
EPBio3

Characterization Of Atrial And Ventricular Cannulation For Biventricular Circulatory Support
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Study: In patients with biventricular heart failure, biventricular assist device (BVAD) may be needed for hemodynamic support. BVAD inflows can be established through cannulation of either atrial (AC) and/or ventricular (VC) chambers, and there is no consensus on optimal cannulation technique. This study aimed to characterize BVAD performance related to cannulation types (AC and VC).

Methods: Both methods of cannulation (AC and VC) were tested on a mock loop using dual pulsatile ventricles with valves (ABS000; ABIOMED) paired as the native ventricles and a continuous-flow total artificial heart (CFTAH) as BVAD. The CFTAH is double-ended centrifugal pump with one rotor and two volutes. Pressures were collected at the inlet and outlets of the ABS000s (LAP, RAP, AoP, PAP) and the CFTAH (Lin, Rin, Lout, Rout). Two flows exiting the CFTAH (LPF, RPF) and total flow (TO), exiting systemic resistance, were monitored. Several heart failure conditions were simulated with adjustment of the pneumatic pressures of the ABS000.

Results: Trends between the AC and VC were similar where RAP, Lin, and Lout decreased, and AoP, PAP, TO, LPF, and RPF increased with increased support. The trends differed in LAP with an increase during AC as oppose to a decrease during VC. As a result, with this set up, balance was more suitable during VC. TO was higher with AC, even though LPF and RPF were lower. This meant the flow going through the aortic valve (TO - LPF) and pulmonary valve (TO - RPF) was higher with AC. The increased TO and valvular flow favor AC for introducing BVAD to the native heart in these conditions.

EPBio4

3D Image Modelling - registration Of Image Modalities For In Depth Analyses Of Tissue Samples
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Study: MALDI mass spectrometric imaging (MALDI MSI) is a powerful tool for the analysis of the distribution of biomolecules in tissue samples. However, for a detailed analysis of MALDI MSI data, a correlation of molecular and histologic data, is crucial. By combining MALDI MSI data and histological data, more detailed information are obtained compared to separate analysis of the data. Therefore, we setup a method for fusion of MALDI MSI data sets and histological staining date in a 3D model presenting a biomolecule distribution of the whole organ. We developed, established and validate an algorithm for the automatic registration including cross-evaluation of the multimodal data sets. This multimodal image approach will improves molecular analyses of tissue samples clinical research and diagnosis.

Methods: We fused mass spectrometric data as well as histological and immunohistochemical staining methods in this study. Histological tissue sections of a completemice kidney was used for proving and evaluating the approach. MALDI MSI data were accumulated using the Rapiflex mass-spectrometer (Bruker-Daltonic). Hematoxylin-eosin and Gomori staining were chosen for histological staining. For immunohistochemical double staining and immunofluorescence, we stained collagen type I, smooth muscle actin and cell nuclei.

Results: By developing, establishing and validating a mathematical registration approach, a perfect superposition of the individual histological sections mass spectrometric data was achieved. The fusion of the data also offers the option of virtual incision of the organ from any angle and level. The algorithms were adapted to for automatic data fusion offering a high-throughput approach for clinical diagnostics as well as the possibility to involved artificial intelligence in its interpretation in research in the future.
EPBio5

Suspension Force Evaluation Of Active Magnetic Bearing For Blood Shear Stress Device

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Study: We recently proposed a blood shear stress device (BSSD) to evaluate the blood damage caused by individual LVAD components. The BSSD mitigates blood damage by employing a brushless DC motor, an active magnetic bearing (AMB) to stabilize axial translation, and passive magnetic bearings to stabilize radial translation and tilt. In this study, we evaluate the magnetic forces induced within the AMB by a control current and AMB rotor-stator gap.

Methods: The AMB comprises a rotor with a permanent magnet (PM) ring (magnetized axially) and a stator with a winding (Fig. 1A). The PM’s outer diameter is 9 mm and the inner diameter is 7 mm. Two PM thicknesses (1 mm and 2 mm) were tested. We varied the control current from ~2 A to 2A and the rotor-stator gap from 0.1 mm to 0.5 mm. We measured the magnetic forces experimentally (Fig. 1B). A force gauge holds a PM; for example, at a 0.2 mm gap with a current of ±0.5A, the stiffness was 1.22N/A with a 1 mm PM versus 1.35N/A with a 2 mm PM. We could obtain sufficient current stiffness to control the proposed BSSD rotor. When the bias flux and control flux strengthen each other at small gaps and high current, the stiffness is reduced. We intend to use higher saturation magnetic flux density materials to avoid magnetic saturation and improve AMB efficiency in the future.

Fig. 1A: Active magnetic bearing assembly  Fig. 1B: Force measurement experimental setup

Results: Magnetic force generated by the 1 mm and 2 mm PM is shown in Fig. 2A and 2B, respectively. We examined current stiffness (magnetic force/control current) and found that the stiffness is lower with a thinner PM; for example, at a 0.2 mm gap with a current of ±0.5A, the stiffness was 1.22N/A with a 1 mm PM versus 1.35N/A with a 2 mm PM. We could obtain sufficient current stiffness to control the proposed BSSD rotor. When the bias flux and control flux strengthen each other at small gaps and high current, the stiffness is reduced. We intend to use higher saturation magnetic flux density materials to avoid magnetic saturation and improve AMB efficiency in the future.

Fig. 2B: Force versus current with 1 mm PM

Fig. 2B: Force versus current with 2 mm PM

EPBio6

Endothelialization Spreading Mechanics: An In-silico Model For The Rational Design Of Surface Functionalized TEVGs

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Study: Endothelialization of Tissue Engineered Vascular Grafts (TEVGs) is a key step to assure its functionality due to the critical regulatory activity of endothelial cells. Endothelial progenitor cells (EPCs) in the bloodstream attach and spread to the TEVG’s surface through cell membrane integrins. To favor such interactions, the TEVG’s lumen can be functionalized with peptides with strong affinity for EPCs. Herein, we studied optimal ligand distribution to improve integrin-TEVG interaction and spreading mechanics through a finite element model implemented in COMSOL Multiphysics 5.5®.

Methods: Cell adhesion process was evaluated based on high affinity integrin’s traction forces present during the cell cytoskeleton remodeling through stress fibers. Forces were included in the computational model considering the change of state between an undeformed cell and the deformed cell after integrin binding to a fraction of available peptides on the TEVG surface. The effect of blood flow shear stresses was included by means of a fluid-structure interaction model between the cell geometry and the laminar blood flow throughout the TEVG. Pulsatile conditions were established to mimic the physiological blood flow baseline.

Results: Velocity fields showed a parabolic behavior across the TEVG section with flow perturbations surrounding the cell domain. The pressure distribution exhibited a gradient related to the vessel resistance. Contour plots reflected the pulsatile flow evidenced by time-spatial dependent values. Higher stress values found in the lower region of the cell domain correlate with the presence of focal adhesions. To achieve higher deformations and allow cell spreading, the peptide availability on the TEVG surface should reach about 70% of the total number of the high affinity integrins on the EPC surface. This model contributes to provide relevant insights for optimizing TEVGs surface functionalization for a successful endothelialization process.
EPBio7

Chemical Polishing Method To Improve The Surface Roughness Of FDM Printed Component Of Blood Wetted Devices

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Study: 3D Printing is one of the best ways to convert the ideas into prototypes, especially in the development of medical devices. It requires a greater number of iterations to develop the device. The components printed with FDM printer will have a surface roughness value of more than 20 μm. Most of the blood-wetted prototypes like blood pumps need a surface roughness less than 1 μm. Therefore, the aim of this research was to develop a methodology to improve the surface roughness quality of 3D printed components of blood-wetted devices like blood pumps.

Methods: A multiple test samples of the same dimensions printed using FDM 3D printer with Nylon, ABS, and PLA material. By studying their material chemistry, Nylon was most reactive with formic acid and ABS with acetone and PLA with dichloromethane. The surface roughness (Ra value) of each test sample was taken before and after the chemical process. 45 test samples were prepared for each material and exposed/dipped in the chemical in different durations of time, accordingly the surface roughness was measured. Then top sample with the improved surface roughness was sent to an autoclave sterilization process. Each sample was placed inside a container with 15 ml of human blood and was kept in a horizontal motion, to check any form of hemolysis.

Results: Out of all the materials, their combinations and the dipping time of 135 seconds for Nylon material in formic acid improved the surface roughness from 17.5 μm to 1.73 μm shown in Fig: 1 and Fig: 2 shows a Nylon 3D printed parts (left - before treating with formic acid and right - after treating with formic Acid) and there is no significant change in the hemolysis in the Nylon material.
**Design Of A Mock Circulatory Test Loop With LV Simulator For A Centrifugal Flow Blood Pump**

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**Study:** Heart disease is attributed as the highest cause of death in the world. Due to a chronic shortage of donor’s hearts, mechanical solutions are being considered. Many Ventricular Assist Devices (VADs) are being developed in an effort to increase life expectancy for end-stage heart failure patients. The objective of this research was to develop and validate a model of a Mock Circulatory Loop (MCL) with a Left ventricle simulator which is a simulation of the heart proximal systemic circulation. This resembles the environment in which the LVAD will be operating. Thereby, a hydraulic system has been constructed that will be used to mimic congestive and end-stage heart failure patient’s conditions to optimize the characteristics of the LVAD, specific to each patient. By using this in-vitro test loop, the effect of the LVAD pressure on the left ventricle is studied and pressures are found.

**Methods:** This model uses an LV simulator which is operated with a stepper motor mechanism. The precise movement of the stepper motor was controlled using Arduino software, thereby enabling an efficient way to replicate the systolic and diastolic movements of the chamber belongs to each heart failure patient. An aortic compliance chamber, an atrial compliance chamber, and a reservoir were included in the loop. Different parts of the system were modeled and 3D printed. Pressure, flow sensors, and DataQ system were integrated to get the required plots for pressures of LV chamber and LVAD pump.

**Results:** A MCL was successfully setup and run with the LVAD connected to it as shown in the fig: 1 and 2. The LV pressure corresponding to each patient was setup and the effect of the LVAD was studied accordingly. The MCL mimicked the LV and aortic pressures within the range of human heart. The pressure plots obtained are shown in fig 3. This testing method was found to be efficient for pre-clinical trials to optimize the characteristics of the LVAD specific to each patient.
CFD Study Of Heart Valve With Implicit Fluid-structure Interaction And Autonomous Cartesian Cut-Cell Mesh

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Study: Artificial heart valves are crucial replacement devices for related disease. Computational Fluid Dynamics (CFD) is a low-cost/risk approach to evaluate device performance and blood clotting risk. Due to close leaflet-to-blood density ratio, especially for biological heart valves, the added mass effect (AME) is significant and presents great numerical challenge for fluid-structure interaction (FSI) solver. CONVERGE CFD®, which needs no user meshing and has implicit FSI solver, is used to model an idealized 3D mechanical heart valve (Banks, 2018) with large AME, and compare with published simulation data.

Methods: With mesh created automatically on-the-fly, the domain volume is strictly conserved. Adaptive Mesh Refinement (AMR) is used to refine the mesh based on local velocity gradient. Newtonian blood is used for the high shear rate. Local velocity field is visualized and valve motion is compared with literature for different density ratios. Grid uncertainty is evaluated.

Results: The velocity field is visualized, overlaid with grid to demonstrate the mesh's good orthogonality/aspect ratio, and only refined where it is needed (Fig. 1). The leaflets motion matches well with the literature, not sensitive to the given small density ratios, which has dominant AME over inertial effect (Fig. 2). The valve open/close timing is accurately captured. Grid sensitivity study on the rotational velocity also suggests small grid uncertainty for the studied mesh sizes (150% to 15% of the baseline resolution, Fig. 3). Time steps as large as 2ms can be achieved within a few hours wall time on a desktop, without stability issue. The results suggests the method is an accurate/efficient way to model heart valves with AME challenge, with potential to apply in other blood-tissue interaction problems.
A General Protocol For Lumped-parameter Model Input Identification To Simulate Resting Cardiovascular Physiology

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Study: Lumped Parameter Network (LPN) models can simulate cardiovascular physiology with closed-loop cardiac feedback, and have been applied to surgical planning, medical device design, etc. However, the determination of appropriate LPN input parameters, remains a challenge. In this work, we address this gap by describing our protocol (Fig 1A) which given the subject attributes, i.e., age, height, and weight, provides suitable parameter values for an LPN model (Fig 1B) that reflects the typical hemodynamics of a healthy subject at rest.

Methods: We obtain target hemodynamic parameters (THP) as a function of the subject attributes from existing literature. In the protocol, we use a neural network which predicts critical LPN inputs such as those governing the ventricles, and a scaling procedure for the LPN inputs of the systemic components. The scaling procedure operates on a reference set of LPN inputs which reflect nominal hemodynamics. We use a previously proposed neural network architecture designed specifically for non-linear regression to predict the critical LPN inputs, using the THP as the predictors. The training data for the neural network was obtained by running the LPN with 151,456 combinations of the critical LPN inputs and recording the corresponding hemodynamic outputs. To test the protocol performance, we have used 100 realistic combinations of the attributes, and have compared the protocol output to the THP.

Results: All simulated hemodynamic parameters (SHP) in the protocol test set fall within clinically normal ranges, exhibit good agreement with the THP, and the maximum deviation of the SHP from the THP fall within the 95% confidence intervals for the THP predictions. In all test cases, the mean PA pressure and both the left and right mean atrial pressures also lie within clinically normal ranges (≤ 20, 7, and 10mmHg respectively). Therefore, our proposed protocol can simulate typical, healthy, resting hemodynamics for a given set of subject attributes.
**EPBio11**

**Using CFD And FSI To Improve The Numerical Modelling Of Positive Displacement Artificial Hearts**

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**Study:** The Realheart®, a total artificial heart developed by Scandinavian Real Heart, mimics the mechanics of the native heart by translation of an atrioventricular (AV) plane. Past numerical models of the Realheart® were not flow-driven but relied on prescribed motion of AV and semilunar (SL) valves. The objective was to develop a new modelling strategy, combining computational fluid dynamics and fluid-structure interactions that generalized the pumping mechanics of the Realheart®, using only the essential and most challenging modelling aspects.

**Methods:** A fluid cylinder containing two bileaflet mechanical heart valves, representing the AV (upstream) and SL (downstream) valves (fig 1a) was modelling in Fluent (Ansys Inc). A restriction (fig 1b) represented the resistance of the downstream vasculature. The Navier-Stokes equations were solved assuming Newtonian rheology. Overset meshing allowed for a refined leaflet boundary (fig 1c). The 6DOF solver computed the leaflets’ rotation, whilst the AV overset mesh zone underwent vertical sinusoidal translation, achieving rotation and translation of the AV valve.

![Figure 1](image1.png)

**Results:** A modelling strategy has been successfully developed that defines AV plane translation and AV/SL valve rotation. The SL valve opened at 0.15 s as fluid was pushed through the domain by the AV valve, and closed at 0.43 s, due to backflow (fig 2). Fluttering occurred upon SL valve opening, due to high pressures caused by downward AV motion. When the SL valve fully opened, fluid followed the leaflet motion, moving from the cylinder wall towards the center, forming a faster flowing central region (fig 1d). Further work will replace the constriction with a Windkessel model to capture physiological conditions and improve modelling flexibility. Additional studies will be used to understand the interplay between stroke parameters, and efficiency and valve leakage.

![Figure 2](image2.png)

**EPBio12**

**Treatment By Heated, Oscillating Flow Decreases Viable Biofilm On Luminal Surface Of Indwelling Central Venous Catheters In Rats Infected With Staphylococcal Epidermidis**

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**Study:** Medical device infections caused by biofilms are a leading cause of bloodstream infections and cost hospitals millions annually. Biofilm infections are resilient, providing protection from host defense and antimicrobial treatment. Treatment can require removal and replacement of the device, which is costly and increases morbidity and mortality. We have previously shown that modest levels of heat decreases biofilm viability and increases detachment in biofilm flow cell systems. This work applies the knowledge from these in-vitro studies, to an in vivo animal model. The overall aim is to apply elevated temperature and fluid shear stress via heated, oscillatory flow to infected central venous catheters (e.g., hemodialysis catheters).

**Methods:** Jugular-vein catheters were surgically implanted in Sprague-Dawley rats and inoculated with *S. epidermidis* by direct injection, followed by biofilm growth for 72 hours. Heparinized saline at room temperature or 48°C was cycled in and out of the catheter for 2 hours. Catheter segments were visualized using scanning electron microscopy (SEM) and surrounding tissue was sent for histopathologic examination. Quantitative culture was performed on blood, organ, and catheter samples.

**Results:** SEM showed biofouling is visually reduced but not eradicated with heat treatment. Quantitative culture confirmed a 3-log reduction in bacterial load on the tip of treated vs untreated catheters. Histopathology of the surrounding vein and skin track show evidence of thermal injury associated with heat treatment. However, the treatment had minimal effect on core body temperature. This work confirms that heated, oscillating flow is a plausible remediation method to debride biofilm from catheter surfaces. Future work will focus on identifying a therapeutic window where the benefits of biofilm clearance are balanced with preventing thermal injury to the surrounding tissue.
EPBio13
Observation Of White Thrombus Formation Around Tavi Models Including Leakage Flows By Optical Systems In Vitro And The Evaluation By CFD Analysis For Pulsatile Flow
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Study: There is a possibility of leakage flow for TAVI (Transcatheter Aortic Valve Implantation) valve and a high risk of thrombus formation near the valve. Then it is necessary to find out the mechanism of thrombus formation by the leakage flow of TAVI. In our previous studies, effects of the shear rate on the thrombus formation rate at wall on orifice flow were examined by observation of thrombus formation by optical system, and found that the thrombus formation rates near the reattachment point increases with shear rates. This study describes observation of thrombus formation around TAVI models including leakage flows by optical systems in vitro, and the evaluation method by CFD analysis with thrombus formation model.

Methods: Experimental objects are orifice pipe flow and the orifice flows with small leakages (Fig.1) for observation of thrombus formation. Each leakage size h is 0mm, 0.5mm, 1mm respectively in case of 20 mm diameter pipe with stenosis to simulate valve part. The target flow filed with blood plasma of pigs is illuminated by laser sheet, and the images are taken by high speed CCD camera. Once the thrombus formation starts, the scattering wave can be detected by this system. The movies for three kinds of geometries and two flow rates (3 and 5l/min). As for CFD analysis with finite difference method, the momentum equations and transport equation of species with chemical reaction are used.

Results: As for visualization results, Fig. 1 shows typical distribution of thrombus formation area at h= 0, 0.5, 1mm. Due to the increasing of leakage size, the thrombus formation area on the outer wall is decreasing. In case of leakage size h=0.5 and 1mm, these areas correspond to wake size at the back side of the stenosis by CFD result (Fig.2). It is considered that there is a possibility to use the length ratio of wake and recirculation area as an index of thrombus formation rate by comparing CFD result and visualization result.

EPBio14
Rational Design Of TEVGs: Insights From Kinetic Modeling Of Protein Adsorption
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Study: The currently available small diameter vascular grafts (<6mm) present several long-term limitations, mostly related to their low regenerative capacity, which has prevented their full clinical implementation. Alternatively, Tissue Engineered Vascular Grafts (TEVGs) provide a route for superior regeneration but show significant thrombogenicity. This process exhibits considerable complexity as it involves the interplay of several variables. Computational modeling and simulation emerge as tools to study and optimize the rational design of small diameter TEVGs. This study aims to model the correlation between mechanical-hemodynamic-biochemical variables on TEVGs’ protein adsorption as it appears central to thrombogenicity and ultimately to their regenerative potential.

Methods: Here, we addressed this challenge by implementing a two-way Fluid-Structure Interaction (two-way FSI) model in ANSYS Fluent 2019R3® and ANSYS Transient Structural® software. Experimental pulsatile pressure was included as a user-defined function (UDF). Subsequently, a kinetic model, linked to two-way FSI velocity profiles, of the protein-surface interaction between albumin and fibrinogen, and the intima layer of the TEVGs, was implemented in COMSOL Multiphysics5.3®.

Results: The two-way FSI model provided physiological baseline of wall shear stress distributions and velocity profiles compared to previous rigid wall models. TEVG wall properties appear therefore critical to understand responses under different hemodynamic stimuli. In addition, the kinetic model showed saturation times of 1.39s for albumin adsorption and of 0.8s for fibrinogen adsorption on the TEVG’s intima layer. These results suggest higher affinity for fibrinogen adsorption. Our computational models provide a robust platform to study multiparametrically the performance of TEVGs in terms of protein adsorption, which is key to approach to their rational design.
EPBio15

Experimental And Numerical Studies Of A Centrifugal Heart Pump Used For Total Artificial Heart (TAH)
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Study: Literature reports exhaustive studies are being performed on TAH. In view of this, it is proposed to simulate an extracorporeal centrifugal heart pump used in TAH. This work involves design, development and analysis of a continuous flow centrifugal heart pump with bearing less magnetic levitation (TAH). A simulation model was designed in Creo 2.0. Analysis was performed in ANSYS work bench to generate Head-Discharge curves for studying the performance of the centrifugal pump. An experimental model was also fabricated using Mark Forged Mark Two 3-D Printing to analyze the pump performance.

Methods: Parametric study was performed in detail on fluid flow parameters -- shear strain, strain rate, velocity gradient, pressure, viscosity-- assuming blood as a working media. A mock circulatory loop was designed and fabricated for the experimental studies to validate the CFD predictions. Prototype that was fabricated is ~ 0.4kg. The blood flow rate was varied from 4L/min to 9L/min with speed ranging from 3000-5500 rpm. The density of the blood was taken as 1060kg/m³ and the viscosity as 0.0035 kg/ms. The designed impeller has six blades with a blade angle of 22.5°. Blood compatibility was evaluated in vitro. Flow rate and fluid pressures were measured using laboratory sensors. The figures below detail velocity and turbulence contours generated from the study.

Results: The variation of velocity inside casing of centrifugal pump is shown in Fig.1. A study was performed for input of 4500 rpm and the flow rate at 6L/min. It can be observed that disturbance is larger at the outer most part of the casing and smaller at the center entry, as expected from the magnitude of the centrifugal force as a function of radial position. Fig. 2 shows turbulence intensity inside the pump. A fixed input of 4500 rpm, 6L/min is taken for the study. It can be seen that the turbulence intensity is of about 0.4064 at outer most part of the casing while it is maximum at center of about 0.669.

EPBio16

Comparative Studies On Six And Four Bladed Centrifugal Heart Pump Used For Left Ventricular Assisted Device (LVAD)
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Study: Comparative Studies on Six and Four Bladed Centrifugal Heart Pump Used for Left Ventricular Assisted Device (LVAD). This study investigates the number of blades on LVAD performance. A numerical model of impeller with casing was generated in CFD Work Bench; the number of blades was varied between 2 to 10. Six and four bladed centrifugal heart pump simulated models are shown below as an illustration for the purpose.

Methods: The design specifications considered followed the standard literature, e.g., speed - 300-5500 rpm, flow rate 3-9 L/min, density–1060kg/m³, viscosity – 0035 kg/ms, blade angle-- 22.5°. A k-ε model was used for the analysis using boundary conditions defined as per the specifications in ANSYS Fluent Workbench. To validate the CFD results a mock-up loop was used to generate H-Q (Head-Discharge) curves experimentally.

Results: As an illustration, the components of six, bladed centrifugal pump fabricated in Mark Forge Mark Two 3D printing using Onyx material is shown in Figure 1. Formic Acid was used to improve the surface finish of the models. The experiment was performed both with glycerin as well as water in the mock-up loop. Figure 2 shows the wall shear for six bladed is more than four bladed pump. It is observed that max wall shear is 65.33 Pa for six bladed centrifugal pump while 98.3 for four bladed pump. Hence, six bladed pump is more suitable than four bladed pump.
**EPBio17**

**Patients With Ductal-dependent Circulation: Computational Simulations On Real Geometries**

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**Study:** Congenital heart disease originates as an abnormal formation of the heart or major blood vessels. Abnormalities with ductal-dependent pulmonary blood flow are risky because the newborn’s life depends on keeping a connection between the aorta and the pulmonary arteries to assure proper oxygenation. The clinical options are stenting the Ductus Arteriosus (DAS) or placing an artificial shunt (MTBS). Even though MTBS has been used for decades, recent studies have demonstrated that DAS is a reasonable alternative. Procedure selection depends on the availability of trained physicians and infrastructure, patient condition, and technical aspects, such as anatomical features and ductal tortuosity. Therefore, we study the ductal circulation from a fluid mechanics perspective, to develop a helping decision-making tool.

**Methods:** We built a 3D ductal reconstruction in silico from magnetic resonance and computed tomography images, for 7 patients. These 3D models were imported into a multiphysics simulation software to conduct CFD simulations, using a module of Single-Phase Laminar Flow interface (with Navier-Stokes equations for incompressible fluid flow). Blood was modeled as a Casson fluid. Boundary conditions were complete developed flow at the aortic section inlet and outlets (pulmonary arteries, coronary arteries and downstream aorta). A non-slip condition was defined for the vessel wall. Pressure drop was used to estimate differences between the studied ductal morphologies after conducting a sensitivity analysis over the parameters of interest. To validate the simulation results, we compared the calculated mean velocity with that measured by echocardiograms.

**Results:** The results of our models indicate a significant pressure drop for patients with both tortuous ductus and narrower ductal diameter. These findings suggest that geometrical features might impose a higher flow resistance, which in turn, may explain the limited performance observed for the DAS procedure.

**EPBio18**

**Ostomy Skin Barrier Biomaterials—A Unique Percutaneous Adhesive Challenge**

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**Study:** Effective ostomy dejecta containment appliances are reliant upon the adhesive interface around the percutaneous stoma, a fixation interface with additional challenges. Modern ostomy pouches are affixed to the peristomal skin by “barriers” composed of biomaterials including silicone and hydrocolloids, which offer adhesion and absorption. Absorption is an important design feature, as urostomies continually release urine, ileostomies release enzymatically active intestinal contents and colostomies release fecal matter. Individuals with ostomies typically wear barriers for varied durations, depending on ostomy type, output volume, activity and skin condition considerations. Given stoma surgery can be a permanent procedure, many users are reliant on their disposable adhesive barriers over years or decades. Ostomy barriers must reliably adhere to and protect the skin, while not limiting range of motion or choice of activities. Recent advances in ostomy materials have incorporated skin friendly components and added functionality, such as pH buffering. An overview of modern ostomy adhesive solutions will offer instructive examples and novel insights for other artificial organ technologies reliant upon long-term percutaneous access.
EPBio19

Ostomy Products, The Original Artificial Internal Organ?

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Study: An ostomy is the surgical creation of a percutaneous communication between the lumen of a hollow organ and the skin in order to pass waste material (dejecta). In order of number of surgeries per year, the major categories of ostomy are colostomy, ileostomy, and urostomy, which are performed in over 140,000 patients a year in the United States for conditions including autoimmune or inflammatory bowel disease, trauma, and cancer. These patients add to the existing population of 750,000-1 million Americans living with ostomies, reliant on external collection products to replace the dejecta retention functionality of the excised or bypassed colon, small bowel, or bladder. The first description of these ostomy product “artificial organs” was provided in 1743 by Heister, who described the use of a tin and cloths to capture dejecta. The first patent for an ostomy appliance was granted in 1913, to be followed by a reusable rubber pouching system affixed with belts and adhesives in 1920. Following major advancements in materials and improved understanding of human factors, these Class I, non-sterile medical devices now utilize plastic films, filters and skin-friendly adhesives designed for comfort, discretion, and dignity. A review of the history and evolution of ostomy products will offer instructive examples and novel insights for other artificial organ technologies reliant upon long-term percutaneous access.

EPBio20

In Vitro Study Of Novel Pulsatility Modes In LVAD Therapy: Intraventricular Hemodynamics And LVAD Dynamics Under A Wide Range Of Preloads And Afterloads

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Study: This study aims to investigate the effect of novel VAD pulsatility modes on the flow-pressure relationship, for a wide range of operating and physiological conditions. These conditions are determined by different timing and magnitude of the Left Ventricle (LV) preload, as well as the systemic resistance and capacitance. The hemodynamics of the LV and ascending aorta are then characterized.

Methods: Time-resolved Particle Image Velocimetry (PIV) experiments are performed, in order to collect the velocity fields in coronal and sagittal planes across a patient-specific LV. High temporal resolution flow rate and pressure measurements are obtained in LV model in a flow loop mimicking the systemic circulation, including preload and afterload as the resistance and capacitance are controlled independently. Using a novel pulsatility mode, the influence of LVAD pulsatility on the ventricular hemodynamics is fully characterized. The effect of peak intraventricular pressure and the timing between the preload cycle and the initiation of the LVAD speed modulation is included.

Results: The stagnation and recirculation inside LV, as well as the aortic root/LVAD outflow graft anastomosis, is highlighted and quantified. The thrombogenic potential is calculated from measurements of 1- Residence Time and 2- Shear Stress History along platelet trajectories (obtained from PIV/PTV measurements). Two other metrics of LV thrombogenicity, the Stagnation Index (SI) and the Ventricle Stagnation Index (VSI), are also reported, in an effort to quantify the impact of LVAD pulsatility in reducing intraventricular stasis. The effect of afterload, preload and synchronicity of the LVAD cycle with native heart systole and diastole is characterized, in order to emphasize the impact of the instantaneous pressure difference across the pump on LVAD performance in the presence of a strong unsteadiness in its angular velocity.
Development Of A Computational Framework For Predicting Thrombosis And Thromboembolism: Reynolds Number Effects In A Backward-facing Step

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Study: Work is presented on the development of a thrombosis & thromboembolism (T&TE) computational model which incorporates a reduced-order model of the coagulation cascade and can be run at high Reynolds number. This work is of interest for evaluating thrombosis risk in high-Reynolds number blood-contacting biomedical devices such as artificial hearts and blood pumps.

Methods: The biochemical reactions included in the model are based on a reduced-order model of the coagulation cascade and are converted to their Lagrangian forms. The coagulation modeling results in the production of thrombin, which numerically activates platelets and polymerizes fibrinogen to fibrin. Activated platelets and thrombin combine to create source terms in a subsequent T&TE model, whereby cohesive links and cohesive stresses are formed, allowed to interact with the flow, and break. Simulations have been run of clots forming in a backward-facing step geometry to match benchmark MRI data. Several flow rates were simulated to investigate the impact of Reynolds number (ranging from 100 to 5000) on clot formation in this particular geometry.

Results: There is a strong trend toward clot volume decreasing with increasing Reynolds number. Simulations at Reynolds number 5000 did not clot, suggesting that the chaotic flow structures and higher levels of shear stress prevent clot growth. Thrombosis is found to be strongly dependent on Reynolds number, with high shear stress restricting clot growth.
EPCardiac1

A Systematic Review Of Continuous Flow Bi-ventricular Assist Devices
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Study: As the incidence of heart failure increases, so too has that of biventricular failure. While transplantation remains the gold standard therapy, the need for durable mechanical circulatory support has grown. We therefore sought to conduct a systematic review of continuous flow venricular assist devices in a biventricular configuration (CF-BiVAD).

Methods: An electronic search of PubMed and Cumulative Index to Nursing and Allied Health Literature (CINAHL) databases was performed using the keyword “BIVAD”. Pediatric studies, those related to temporary circulatory support, extracorporeal VADs, and total artificial heart were excluded as well as any single case reports (Fig). Studies were reviewed to identify discrete variables, including indication at implant, INTERMACs level at time of implant, timing of implant, the mean age and BMI of implanted patients, and the anticoagulation/antiplatelet regimens employed post implant. Outcomes of interest included mortality rate and the incidence of thrombus, bleeding, infection, stroke and renal failure.

Results: 22 studies met inclusion criteria with a total of 1277 patients. No single variable was consistently reported throughout studies, with only 4 reporting all 5 adverse effects. INTERMACs level at implant and anticoagulation/antiplatelet regimen were reported in less than 50% of studies. Of those reporting mortality, there was a wide range of follow-up, from less than 6 months to >10 years, and the survival rate mortality was similarly widely variable. Additionally, more than 50% of studies failed to isolate CF-BiVAD from alternative biventricular support, such as temporary support platforms, TAH, and pulsatile VADs. Therefore high-quality quantitative analysis is not possible. In conclusion, the CF-BiVAD literature has a very heterogenous reporting of data. Standard reporting criteria may allow for future analyses to determine which patient characteristics portend a favorable outcome with CF-BiVAD implantation.

EPCardiac2

2-year Outcomes Of LVAD Patients With Chronic Kidney Disease
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Study: Left ventricular assist devices (LVAD) are an effective long-term option for end-stage heart failure patients. Patients with concomitant renal dysfunction are presumably at increased risk for adverse events post implant. Our study sought to determine the outcomes of patients with chronic kidney disease (CKD) stages 3-5 who receive LVAD therapies.

Methods: CKD stages 3-5 patients implanted with LVADs between January 2015 and December 2018 were evaluated. Patients lost to follow up or undergoing second LVAD implant were excluded. CKD stages were stratified by eGFR <15-59, utilizing the eGFR within 24 hours of LVAD implant.

Results: Our study found 154 patients who underwent LVAD implant with CKD stage 3-5. Prior to implant, 59.1% of patients had diabetes and 76% had hypertension. Ninety percent of patients had CKD stage 3 and 10% had stage 4. The median eGFR prior to LVAD implant was 44, at 1 week: 49, 1 month: 56, 3 months: 53, and 6 months: 50. The median eGFR at 1 and 2 years was 51. Adverse events included: 64.3% bleeding (including gastrointestinal bleeding, epistaxis, and mediastinal hemorrhage), 33.1% driveline infection, 34.4% bacteremia, 22.7% hemolysis, 24.7% stroke/TIA, and 12% were sent home on inotropes for right ventricular dysfunction. Post-operatively, 19.5% required renal replacement therapy (RRT) and 3.2% of those persisted to have renal dysfunction requiring hemodialysis (HD) at the time of discharge. Furthermore, 12.3% required HD at some point after their initial discharge. Of these patients, 76.6% were implanted as destination therapy, while 15.6% progressed on to heart or heart-kidney transplantation. The 1-year survival rate was 77.3%, the 2-year survival was 61.7%. Our findings suggest that patients may successfully undergo LVAD implant, despite concomitant renal dysfunction. While these patients still experience adverse events, the survival rates suggest that these patients should still be considered for LVAD implant, especially if they are to be listed for transplantation.
A New Cardiac Overload Index To Assess Risk Of Right Heart Failure During Speed Optimization For LVAD Patients

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Study: Right ventricular failure (RVF) is a severe event that increases peri-operative mortality after Left Ventricle Assist Device (LVAD) implantation. LVAD speed profoundly influences preload and afterload for both left and right circulations. This study focuses on the relationship between LVAD hemodynamic optimization, LV, RV preload and afterload in the context of development of RVF.

Methods: Between 2015 and 2019, 50 consecutive patients received LVAD implantation (Heartmate 3) at San Camillo Hospital in Rome. 38 who underwent pump speed optimization were included, and appropriate consent was obtained. Pre and post optimization hemodynamic data were collected. We defined a new index - Cardiac Overload Index (COI) as follows: COI = (CVP/MPAP)×(PCWP/MAP)×CO (i.e. an overload corrected cardiac output) that incorporates the preload to afterload ratio for both left and right circulations. COI was analyzed pre and post speed optimization for the patients that developed late RVF (RVF group) in comparison to the subset that did not (no RVF group), using statistical significance analysis.

Results: 10 patients had late RVF after LVAD implantation. Median COI Pre-optimization was not statistically significant for both subsets of patients (9.65 vs 10.05), indicating that it is not straightforward to know the risk of late RVF apriori. However after speed optimization, those that developed late stage RVF had a statistically significantly greater increase in median COI compared to the subset that did not develop late stage RVF (26.88 vs 18.89, p<0.05). This indicates that the RV was working harder for the subset that eventually developed RVF, i.e. was overloaded in the RVF group. This demonstrates that the COI metric could potentially be used as a predictor for those that may develop RVF. This index, which can be easily calculated during routine standard of care, could be used during follow-up to stratify the different hemodynamic profiles and modify therapeutic strategies.

Table 1: Pain Scores

<table>
<thead>
<tr>
<th></th>
<th>Pillow (n=14)</th>
<th>Sternasafe® (n=14)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-operative Pain</td>
<td>0.93 +/- 2.43</td>
<td>2.43 +/- 3.00</td>
<td>0.159</td>
</tr>
<tr>
<td>Day -1 Pain</td>
<td>6.44 +/- 2.65</td>
<td>4.00 +/- 2.92</td>
<td>0.061</td>
</tr>
<tr>
<td>Day -7 Pain</td>
<td>4.82 +/- 3.21</td>
<td>3.00 +/- 2.45</td>
<td>0.16</td>
</tr>
<tr>
<td>Day -14 Pain</td>
<td>3.5 +/- 2.56</td>
<td>2.63 +/- 2.56</td>
<td>0.506</td>
</tr>
<tr>
<td>Day -21 Pain</td>
<td>3.43 +/- 1.99</td>
<td>1.75 +/- 2.43</td>
<td>0.166</td>
</tr>
<tr>
<td>Day -30 Pain</td>
<td>3.42 +/- 0.289</td>
<td>0.71 +/- 1.25</td>
<td>0.041*</td>
</tr>
</tbody>
</table>

EPCardiac4

Sternasafe® or Pillow: A Randomized Trial For Pain Management Following Median Sternotomy

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Study: Patients who undergo median sternotomy are often advised to use pillows for extra support to their sternum when engaging in high pressure movements such as coughing or deep breathing. However, there is concern regarding the effectiveness of this solution and the ability for patients to consistently utilize the pillow. The Sternasafe® support device, an elastic band continuously worn circumferentially around the thorax, has been offered as a potential replacement. We compare pain levels in post-operative cardiac surgery patients who utilized either a standard pillow or the novel SternaSafe® support device.

Methods: A parallel, randomized, open-label trial with 1:1 allocation compared pain management among cardiac surgery patients using a standard pillow or SternaSafe® support device. Resting pain levels (0-10 with zero being no pain) were recorded pre-operatively, one day post-operatively, and in each of the subsequent four weeks. A P-value <0.05 was considered statistically significant.

Results: Twenty-eight patients met inclusion criteria. There were no significant differences in demographics or comorbidities between groups. While reported pain was less in the Sternasafe® group at all post-operative timepoints, only post-operative day +30 reached statistical significance (p=0.041) (Table 1). Reduced patient reported pain on post-operative day +1 only approached statistical significance (p=0.061), likely due to small sample size. Expanded trials should be conducted to further assess SternaSafe efficacy and patient satisfaction.

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**EPCardiac5**

**Early Diagnosis Of LVAD Thrombosis Via Time-Frequency Analysis Of Circadian Patterns Of Pump Parameters: Are We Ready For Clinical Translation?**

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**Study:** In the setting of LVAD implantation, no clinically reliable tools exist for the early diagnosis (prediction) of pump thrombosis (PT). We showed that time-frequency analysis (TFA) of the HVAD log files allows diagnosis of the early stage of development of PT according to the detection of instability/disruption of circadian patterns of pump parameters several days before clinical manifestation of the thrombotic event. Aim of this study was to test the potential for effective clinical translation of this tool, that is, to assess its real-time early diagnostic capability.

**Methods:** We analyzed 173 log files of 48 HVAD patients simulating longitudinal real-time data acquisition and analysis. In detail, the 30-days log files records were discretized into consecutive windows of 24-hours duration and iteratively acquired and processed via TFA. This way, we simulated the real-world scenario, i.e., longitudinal analysis of pump parameters over the time of support. Data analyzed include 24 files (14%) associated with a clinical diagnosis of PT and 149 (86%) controls. The tool was instructed to automatically identify a log file of the PT group according to the detection of instability of the circadian rhythm in pump power consumption for at least 2 consecutive days.

**Results:** Sensitivity and specificity of the tool were 95% and 84%, respectively. Early signs of a forthcoming PT were identified 10±8 days prior to its clinical manifestation. Importantly, false positives analysis highlighted patient-specific profiles characteristics affecting the physiologic circadian pattern, irrespective of PT development. This study confirms the potential for effective clinical translation of TFA of the log files for the early diagnosis of a forthcoming PT. Incorporating this tool on board of the HVAD controller might dramatically improve the timing of diagnosis of PT, with important implications in terms of efficacy of non-invasive intervention.

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**EPCardiac6**

**Development Of A Novel Integrated Organ Perfusion Chamber And Reservoir For Ex-vivo Perfusion System**

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**Study:** Heart transplant is the standard treatment for end-stage heart disease. The waitlist greatly exceeds the number of donor organs. Hearts are conventionally donated following brain death. The technique of donation following cardiac death (DCD) has become an alternative pathway for donation. At present it is difficult to obtain an assessment of organ viability for transplant. A system that can characterize organ viability could greatly expand the donor pool. We are developing an ex-vivo perfusion system for recovery and viability assessment of hearts donated via DCD. An integrated organ perfusion chamber and reservoir have been developed for the ex-vivo perfusion system.

**Methods:** Initial chamber/reservoir design criteria included: 1)Volume placement of a human heart, 2) mesh/pseudo-pericardium to support the heart, 3) reservoir holding 500 mL to 1L of perfusate, 4) incorporation of sensors for monitoring of temperature, flow, perfusion pressures. Three design iterations were investigated; each successive prototype improvement based on ease of manufacturing and clinical use. Figure 1 displays our prototype development photos (V0.03 is the current design).

**Results:** Our V0.03 prototype met all design requirements. A brief survey was taken by cardiovascular perfusionists as regards our final Figure 1 prototype (V0.03). The survey was based on a Likert scale with 1 being the worst and 5 being the best. The results were: Ease of Heart Fit 5/5, Ease of Heart Monitoring 3/5, Ease of Interfacing to Circuit 5/5. Based on feedback, future prototypes will be modified accordingly to incorporate additional sensors for measurement of organ biomechanic viability over time in a smaller overall footprint. The successful design and testing of an integrated organ perfusion chamber and reservoir were completed. Users appreciated the design and made important suggestions which we will incorporate in our next design iterations.
Characterization Of A Multi-Scale Computational Model And A Mock Circulatory Loop To Simulate Cardiogenic Shock

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Study: Before conducting costly animal studies and high-risk clinical trials, pre-clinical tools including computational models and benchtop mock circulatory loops (MCLs) are being used more frequently to evaluate device performance. However, the accuracy and credibility of these tools are highly dependent on their ability to reproducibly assess device performance while closely mimicking pathophysiologic hemodynamics. In this study, a multi-scale cardiovascular computational model and an MCL are comprehensively characterized to replicate the hemodynamics associated with cardiogenic shock (CS), which is an end-stage heart failure condition often requiring ventricular assist device therapy. Credibility and reliability of the model are demonstrated using input parameter uncertainty quantification.

Methods: The target pathophysiologic hemodynamics of the CS condition include a cardiac output (CO) of 3 L/min, 110 bpm heart rate (HR), blood pressure of 80/50 mmHg, and a mean left atrial pressure > 15 mmHg. These target conditions were first generated using the MCL, representing the left heart. Ten replicate tests were performed to quantify the uncertainty in CO, HR, and systemic vascular resistance (SVR). Subsequently, a sensitivity analysis was performed using the multi-scale computational model to quantify the uncertainty in model outputs (i.e., peak systolic and diastolic pressures, mean left atrial pressure, and stroke volume) due to the uncertainty in model inputs (i.e., CO, HR, and SVR) measured experimentally.

Results: The MCL and computational model closely mimic the target hemodynamics of the CS condition, and the pressure waveforms (Figure 1) show good agreement between the experimental measurements and the numerical predictions. The uncertainty estimates of key outputs demonstrate the credibility and reliability of the MCL and model in simulating relevant pathophysiologic hemodynamics for pre-clinical device performance evaluation.

Bloodless Stage II Norwood Palliation In A 6kg Jehovah’s Witness Patient

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Study: While maneuvers such as acute normovolemic hemodilution (ANH), retrograde autologous priming (RAP), and modified ultrafiltration (MUF) have proven efficacious in the reduction and occasional elimination of heterologous blood administration, their use adds complexity to the procedure, may result in low intraoperative nadir hematocrits, and must sometimes be abandoned due to hemodynamic instability or mechanical difficulty. We report a case of successful Stage II Norwood palliation in a 6kg Jehovah’s Witness patient without the use of heterologous blood.

Methods: Our standard 3/16 x 1/4 CPB circuit was further miniaturized by adding a 3/16 pump boot, and mounting the circuit so that the top of the venous reservoir was at the level of the patient’s right atrium. The pump was positioned as close to the table as possible, and the arterial and venous lines were pulled taught before trimming to minimize their lengths. These modifications resulted in a total static prime volume of 100 mL. The patient’s pre-operative hematocrit of 45% was reduced to 32% upon initiation of CPB, and fell to a nadir of 26% following cardioplegia administration. After hemofiltration, the hematocrit was raised to 30%, where it remained through rewarming and termination of CPB. Following decannulation, 100 mL of autologous blood was sequestered from the circuit. This volume was reinfused by the anesthesiologist, resulting in a post-pump hematocrit of 35%. Hemostasis was secured, and the patient was transported to the ICU with an uneventful post-operative course.

Results: This case illustrates the ability of aggressive circuit miniaturization and positioning to enable bloodless cardiac surgery in a small, complex patient, without the use of adjunctive maneuvers such as ANH, RAP, or MUF. This simple, safe, and repeatable approach requires no manipulation of pre-operative hemodynamics, results in less profound intraoperative hemodilution, and allows rapid reversal of anticoagulation following cessation of CPB.
Case Study: Baseline Hemodynamics Including Aortic And Pulmonary Flows In A Survival Bovine Model
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Study: Large animal models have played an increasingly valuable and expanding role in the preclinical setting by providing invaluable data for the safety and efficacy evaluation of new therapies, devices, or disease models. This case aimed to provide baseline hemodynamic values, including aortic and pulmonary flows for a bovine model at rest and during exercise. This study will help device engineers, researchers, and manufacturers to understand the normal bovine cardiovascular physiology for technical consideration during device development for preclinical trials.

Methods: A calf weighing 80.9 kg underwent left lateral thoracotomy. Fluid-filled pressure lines (aortic pressure [AoP], right atrial pressure [RAP], left atrial pressure [LAP], and pulmonary artery pressure [PAP]) and left and right flow probe lines were implanted. Flow probes (Transonic Systems Inc., 24 mm) were then placed on the aorta and pulmonary artery. The calf was continuously monitored throughout the postoperative period. Physiologic pressures, animal vital signs, aortic and pulmonary flows, and pulmonary and systemic vascular resistance were recorded hourly. Treadmill exercise evaluations were conducted, pressures (AoP, RAP, LAP, and PAP) and flow rates (aortic and pulmonary) were monitored to determine the animal’s hemodynamic response to exercise. All hemodynamic data were described as means, standard deviations, and a 95% confidence interval.

Results: The hemodynamic data obtained with the animal at rest in the ICU of our laboratory is depicted in Table 1; parameters such as heart rate, pressure, flows, and vascular resistances were included. Pressures and flow rates at baseline and during treadmill trials were compared in Table 2. The average treadmill trial duration was 22.5 min with an average distance walked of 674.5 m. Figure 1 depicts the flow rate through the aorta, and pulmonary artery, a steady increase in flow rates is observed.
**EPCardiac10**

Validation Of Numerically Predicted Shear Stress-Dependent Dissipative Losses Within A Rotary Blood Pump

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**Study:** Computational fluid dynamics find widespread application in the development of rotary blood pumps. Yet, corresponding simulations rely on shear stress computations that are afflicted with limited resolution while lacking validation. This study aimed at the experimental validation of integral hydraulic properties to illuminate global shear stress resolution across the operational range of a novel rotary blood pump.

**Methods:** Pressure head and impeller torque were numerically predicted based on unsteady Reynolds-averaged Navier-Stokes simulations, and validated on a testbench with integrated sensor modalities (flow, pressure, torque). Validation was performed by linear regression and Bland-Altman analysis across 9 operating conditions. In power loss analysis, in-silico hydraulic power losses were derived based on the validated hydraulic quantities and compared with in-silico shear-dependent dissipative power losses. Equal in theory, discrepancies among both terms provided a measure of in-silico shear stress resolution.

**Results:** In-silico and in-vitro data correlated with low discordance in pressure (r=0.992, RMSE=1.02mmHg), torque (r=0.999, RMSE=0.034mNm) and hydraulic power losses (r=0.990, RMSE=0.015W). Power loss analysis revealed numerically predicted dissipative losses to be up to 34.4% smaller than validated computations of hydraulic losses. This study confirmed suitability of uRANS settings to predict integral hydraulic properties. However, numerical credibility was hampered by lacking resolution of shear-dependent dissipative losses.

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**EPCardiac11**

Effect Of Ischemic Time During Cardiac Transplantation On Survival Outcome Within Certain Patient Groups

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**Study:** Numerous studies have shown that an increase in donor age or a mismatch in donor-to-recipient gender can have a negative effect on overall survival following heart transplantation (HTx). However, due to a shortage of donor hearts, the ability to fully individualize HTx is greatly limited. Fortunately, superior surgical techniques can be used to offset the relative risks associated with an appropriate, yet imperfect, match. One such area of interest is by decreasing ischemic time as supported by many studies; however, there are limited investigations on the extent of this relationship within specific patient groups. Our study aims to determine the relative effects of prolonged ischemic time during HTx on survival outcome within different donor/recipient age and gender groups.

**Methods:** We retrospectively analyzed 65,396 patients within the UNOS registry between the ages of 20-79yrs who underwent HTx from 1987-2020. Patients were ultimately stratified into 16 groups based on donor age (≤30yrs and >30yrs) and gender, and recipient age (20-50yrs and >50yrs) and gender. Survival outcomes were then analyzed based on ischemic time (≤4hrs and >4hrs) using log-rank tests and Cox-regression.

| Table 1 |
|------------------|------------------|------------------|------------------|
| **Sample Population** | **Significance (p<0.05)** |
| n=65,396 |  
| **Donor Group** | **Recipient Group** |  
| Male (78.0%) | Male (77.8%) | .015*  
| Female (22.2%) | Female (22.2%) | .960  
| Young n=10,257 | Old n=16,894 |  
| Male (86.1%) | Male (86.1%) | .645  
| Female (13.9%) | Female (13.9%) | .286  
| Young n=3,160 | Old n=4,496 |  
| Male (45.7%) | Male (45.7%) | .455  
| Female (54.3%) | Female (54.3%) | .515  
| Female (42.1%) | Female (42.1%) | .040*  
| Young n=6,242 | Old n=12,771 |  
| Male (83.1%) | Male (89.0%) | .000*  
| Female (16.9%) | Female (11.0%) | .083  
| Old n=30,589 | Female (37.8%) |  
| Male (50.3%) | Male (50.3%) | .343  
| Female (40.7%) | Female (40.7%) | .062  
| Young n=3,763 | Old n=7,833 |  
| Male (61.9%) | Male (61.9%) | .092  
| Female (38.1%) | Female (38.1%) | .051  

**Results:** The log-rank test results for each patient group comparing the survival outcome between both ischemic time periods are listed in Table 1. Findings revealed the following three significant groups: young male donors to young male recipients, young female donors to old female recipients, and old male donors to old male recipients. These three groups were then further analyzed to obtain their survival rates at 1, 5, and 10 years after HTx, as well as median hazard ratios, which are listed.
Table 2

<table>
<thead>
<tr>
<th>Significant Groups (Donor : Recipient)</th>
<th>Ischemic Times</th>
<th>Survival Rate</th>
<th>Hazard Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1yr</td>
<td>5yr</td>
</tr>
<tr>
<td>Young Male : Young Male</td>
<td>≤4hrs</td>
<td>91%</td>
<td>79%</td>
</tr>
<tr>
<td></td>
<td>&gt;4hrs</td>
<td>80%</td>
<td>75%</td>
</tr>
<tr>
<td>Young Female : Old Female</td>
<td>≤4hrs</td>
<td>90%</td>
<td>78%</td>
</tr>
<tr>
<td></td>
<td>&gt;4hrs</td>
<td>85%</td>
<td>70%</td>
</tr>
<tr>
<td>Old Male : Old Male</td>
<td>≤4hrs</td>
<td>87%</td>
<td>72%</td>
</tr>
<tr>
<td></td>
<td>&gt;4hrs</td>
<td>82%</td>
<td>67%</td>
</tr>
</tbody>
</table>

in Table 2. From our study, while there are other groups that appear to trend towards significant, such as old female donors to old female recipients, surgeons should be especially conscious about ischemic times for the three significant groups mentioned previously to maximize patient survival outcome.

EPCardiac12
Temporary Left Ventricular Assist Device As A Bridge To VA ECMO Decannulation
Annika M. Gallandt, BA1, Jacob C. Richards, BA1,
Stanley B. Wolfe, MD1, Jerome C. Crowley, MD, MPH2,
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Study: The Impella 5.5 temporary left ventricular assist device was approved for use in the United States in September 2019. Early studies show promising rates of survival and recovery of native heart function. We aimed to review our institution’s experience using the Impella 5.5 to facilitate venoarterial extracorporeal membrane oxygenation (ECMO) decannulation.

Methods: Patients who underwent ECMO and Impella 5.5 therapy in the same admission were identified through an institutional database. Retrospective chart review was performed.

Results: Eleven patients received ECMO and Impella 5.5 support (82% male, mean age 58). Cardiogenic shock following myocardial infarction was the most common indication for ECMO. Seven patients received concomitant ECMO and Impella while four patients were placed on Impella at ECMO decannulation. The mean SAVE score was -2 and mean pre-ECMO LVEF was 16%. Inotrope scores decreased after ECMO cannulation and continued to trend down following Impella insertion (Figure). Patients spent 106 ± 60 hours on ECMO and 239 ± 149 hours on Impella support. Two patients experienced embolic stroke and three required new dialysis during support. One patient had the Impella purge line clot requiring the device be explanted. Seven (64%) survived to ECMO decannulation, Impella removal, and ICU discharge. The Impella 5.5 is a useful adjunct to ECMO when used to expedite decannulation. Additional research is needed to determine if this practice provides a survival advantage over historical experience.
ASAIO ELECTRONIC POSTER ABSTRACTS

EPCardiac13

A Universal Device To Convert A Continuous Flow Assist Device To A Pulsatile Flow Device
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Study: Continuous follow assist devices (CFAD) are used more often than pulsatile flow assist devices (PFAD). Despite the benefit of providing more physiologic type flow that mimics native circulation, PFADs contain more components which account for more complications and more complex management. Some complications with withdrawal of CFAD for recovery or heart transplant are attributed to lack of pulsatility. Presented here is a concept of a universal converter device that can be added inline to any other CFAD to convert the flow from continuous to pulsatile. After initial implantation and stabilization with a CFAD, adding this converter will potentially provide the benefits of pulsatile physiologic flow.

Methods: The device is made of 2 components connected in parallel, each made of an outer and a rotating inner chamber, and a flexible diaphragm. The 2 components are working in tandem, one serving as a reservoir and the other as a pumping chamber in cycles determined by the user. Both chambers have an inlet and an outlet opening, placed in a specific alignment to direct the flow in one direction only. The compression of the diaphragm, timed to rotation of the chamber, creates the pulsatile flow. A microprocessor controls the timing of the rotation of the inner chamber, that dictates the duration of flow, and the force that is applied on the diaphragm, analogous to heart rate and contractility respectively.

Results: The idea behind this concept is to generate pulsatility for other assist devices. This device has no conventional valves or major moving components and it is failure free; if deactivated, it will not block or affect the flow. Conversion of continuous flow to physiologic pulsatile flow can potentially prevent some CFAD complications especially those seen with withdrawal of CFAD.

EPCardiac14

Bicarbonate As An Alternative To Heparin In Impella Purge Fluid: Understanding The Biochemical Basis
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Study: The Impella® pumps are microaxial flow pumps that use a purge fluid containing heparin. The absence of heparin in the purge fluid increases the risk of biobuildup in the purge gaps (Figure 1A). Sodium bicarbonate may interfere with biobuildup by depressing fibrin assembly, improving major blood protein stability, and influencing biobuildup lysis via buffering effect. This study evaluated bicarbonate-based purge solution (BBPS; 25mEq/L-D5) to support the purge patency of Impella devices using benchtop and animal model.

Methods: The impact of BBPS on bovine serum albumin's stability (BSA; as a model protein) was evaluated using HPLC in a ratio of blood mixed with the purge (blood to purge fluid =6:4). Human blood coagulability was investigated with BBPS using thromboelastography (TEG). Next, BBPS was also evaluated in a 14-day ovine model (n=3) using Impella 5.5 pumps. We selected Impella 5.5 as a challenge pump due to low purge flow and a longer indication of use. The controller data of purge flow, purge pressure, and motor current trends were analyzed.

Results: HPLC analysis showed a 50% reduction of BSA oligomer in BBPS than heparin-purge fluid due to neutralization of the acidic pH of D5 (Figure 1B). TEG data showed similar clot strength (MA) with BBPS and heparin-purge solution; however, the rate of lysis (LY 30) was significantly increased with BBPS Vs. heparin-based purge solution (1.5% vs. 0%, respectively). In the animal study, purge pressure, purge flow, and motor current were stable with BBPS. The preliminary data indicate that the use of BBPS maintains the Impella pump’s purge reliability. BBPS could simplify overall systemic anticoagulation management and support of heparin intolerant patients.
EPCardiac15
Log Files Analysis Demonstrates Circadian Variation Over The First-year Post Implantation Of Continuous Flow-left Ventricular Assist Device
Joel Graham, MEng; Tanvir Kahlon, MD; Jaimin Trivedi, MBBS, MPH; Christina Dunbar-Matos, DO; Mark Slaughter, MD; Joel Graham
Post Implantation Of Continuous Flow-left Ventricular Assist Device Log Files Analysis Demonstrates Circadian Variation Over The First-year EPCardiac15

Methods: Retrospectively compiled device parameter data were downloaded from all available controller log files for patients implanted from 9/2010 through 9/2020 at a single center. Controller log data including flow (LPM), speed (RPM), and power (W) were collected every 15 minutes and analyzed using LabVIEW software. Device parameter data was averaged by the hour for each patient and normalized using the daily average for 1-year post LVAD implant. BSA at time of implant was used to index flow. Logfiles were excluded if the day included a speed change, if power was outside of expected operation range, or less than 30 days of data was available.

Results: Circadian data was analyzed for 19,378 controller log-days in 119 patients (165 ±93 days per patient) for 1-year following surgical implant. Average and standard deviation parameters for flow, index flow, speed, and power were 4.96 ± 0.87 LPM, 2.40 ± 0.37 LPM/m2, 2736 ± 119 patients (165 +/- 93 days per patient) for 1-year post LVAD implant. BSA at time of implant was used to index flow. Logfiles were excluded if the day included a speed change, if power was outside of expected operation range, or less than 30 days of data was available.

Conclusion: While blood pressure and heart rate variability are typically considered the markers of circadian variation, our study demonstrates that LVAD flow can be used as a surrogate marker of cardiovascular autonomic function in LVAD recipients.

EPCardiac16
LVAD Implantation Off-pump Through Median Sternotomy Vs Sternal Sparing Approach
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LVAD Implantation Off-pump Through Median Sternotomy Vs Sternal Sparing Approach

Study: There remains debate on best surgical approach for left ventricular assist device (LVAD) implantation. A sternal sparing procedure is done through right and left minithoracotomies with a small subxiphoid incision. We compared this sternal sparing approach to the conventional median sternotomy in patients who received a LVAD without the use of cardiopulmonary bypass support (also known as “off pump”).

Methods: At our center, 80 patients received an LVAD (Heartware ventricular assist device, Medtronic) that was implanted off-pump from January 2013 till September 2020. Patients who had biventricular support or any other additional procedures were excluded from the analysis. Thirteen patients underwent the Sternotomy Sparing procedure. The other 67 patients underwent a classical median Sternotomy. We compared their short-term postoperative outcomes (30-days).

Results: Preoperatively, both groups had similar demographic, functional and hemodynamic characteristics as well as INTERMACS scores. Compared to the Sternotomy group, the Sternal Sparing group patients had significantly longer anesthesia (421±50 vs 302±58 min; p=0.0003) and surgery time (291±68 vs 204±51 min; p=0.0026). The sternal sparing procedure had more operative bleeding (median 900 mL [range, 500-1000 mL] vs 500 mL [350-700 mL]; p=0.03). There was a trend toward more blood transfusions and platelet doses in Sternal Sparing group patients (1.5 [1-2] vs 1.0 [1-3] RBC units; p=0.81, and 2.0 [2-2] vs 1.0 [1-2] platelet doses; p=0.44); however, this did not reach statistical difference. Duration of mechanical ventilation (20 [18-47] vs 21 [16-68] hours, p=0.72) as well as hospital stay (20 [18-27] vs 21 [15-34] days, p=0.15; Sternal sparing vs Sternotomy group, respectively) were similar between groups.

Conclusion: These data indicate that the sternal sparing approach did not result in a significant benefit regarding duration of surgery and bleeding when compared with the conventional sternotomy.

Figure 1. Flow index and Normalized index of flow for post-operative day and number of patients. Indexed Average flow data for all patient days over one year.
First Isolated Single-ventricle Working Porcine Heart Model

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Study: Isolated heart models have been used for years with the great advantage to focus on cardiac performances and they constitute an important substrate for reproducing physiological parameters, testing pathological modifications and therapies. Single-ventricle (SV) congenital heart diseases result usually with palliative ‘Fontan’ circulation associated with morbidity and mortality despite recent advances in the management of SV. Establishing a SV porcine isolated heart model allows to investigate the physiology of SV cardiac function and reproducing the pathological variations seen in humans. Possible therapies including different mechanical circulatory supports (MCS) could be tested on this model.

Methods: We chose pig hearts due the similar characteristics with human heart anatomy and physiology. After the standard cardiac harvesting, 3 pig hearts were converted in SV functioning organs by creating an atrial septal defect via right atriotomy and a ventricle septal defect via right ventriculotomy. The main pulmonary artery was divided above the pulmonary valve and closed off. SV hearts were connected to the apparatus and re-perfused with heparinised pig blood and maintained at temperature of 38ºC. The apparatus was set in resting or working conditions, by tuning preload and afterload, and hemodynamic data were collected by echocardiography, electrocardiography, and pressures in all cardiac chambers.

Results: Isolated SV isolated pig heart is easily reproducible which shows a decrease in the cardiac function during time, which could be the substrate for testing therapies, particularly MCS devices. SV ex-vivo pig heart model provide a tool to study cardiac responses in resting and working conditions and to assess variations observed in SV patients and responses to different pharmacological, electrical and mechanical modifications. Absence of neuro-humoral response is a disadvantage but reproducibility and accuracy of data make this platform an elegant tool for cardiovascular research.

Figure: Comparison of (a) cardiac output (CO), b) rotary blood pump flow (RBPQ), c) mean aortic pressure (MAP), d) left ventricular end-diastolic pressure (LVEDP), e) left ventricular stroke work (LVSW) and f) pressure volume area (PVA), during rest and exercise.
**EPCardiac19**

**Performance Evaluation Of Artificial Pulses Produced By A Programmable Centrifugal VAD In A Mock Circulatory Loop**  
Britton E. Richardson, None, Gavin A. D’Souza, PhD, Masoud Farahmand, PhD, Jean E. Rinaldi, MEng, Luke H. Herbertson, PhD; Center for Devices and Radiologic Health, U.S. Food and Drug Administration, Silver Spring, MD, USA

**Study:** Artificial pulses can be generated by controlling the rotor speed of continuous flow ventricular assist devices (VADs) to improve patient hemodynamics by augmenting pressure and flow pulsatility. Pulsatility can potentially prevent thrombus deposition, improve endothelial cell growth, and augment cardiovascular response. However, there are no established pass-fail criteria or quantifiable metrics for characterizing VAD pulsatility. The purpose of this study was to characterize the influence of artificial pulses generated by a programmable in-house VAD on the pathophysiological hemodynamics of a heart failure patient simulated in a mock circulatory loop (MCL).

**Methods:** A centrifugal pump was programmed to represent a VAD and generate artificial pulses of varying shape, pulse width, amplitude, and frequency. The programmable VAD was integrated within an MCL, which simulated the left heart hemodynamics of a heart failure patient. Six asynchronous speed modulation algorithms, including multiple step functions and sineTransform waves, were compared to non-pulsed steady flow devices. Key parameters such as total cardiac output, VAD flow rate, aortic pressure, and left ventricular pressure were measured for each inputted artificial pulse algorithm.

**Results:** Asynchronous pulses were characterized in the MCL over the entire VAD operating range, in terms of the atrial, ventricular and aortic pressures and flows, phase shift, and ejection fraction. The figure below shows baseline pressure and flow waveforms for a steady flow VAD providing 80% support for a simulated heart failure patient. The VAD maintained native pulsatility while supporting a total mean blood flow rate of 4.6 L/min at 90 bpm. This study is a first step for developing standard pre-clinical test methods to effectively evaluate the impact of asynchronous and synchronous artificial pulses on the flow performance of VADs earlier in the total product life cycle.

**Figure 1:** Shows the schematic of the VAD system (CFD, pump controller, VAD model) and the mock circulatory loop (left arm, left ventricular, aorta, coronary, systemic, and pulmonary circulatory circuits). (A) displays the aortic pressure waveform obtained using the VAD; with 80% VAD support, VS; aorta pulse; Ewave pulse; (B) displays the aortic pressure waveform obtained using the VAD; with 80% VAD support, VS; aorta pulse; Ewave pulse.

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**EPCardiac20**

**Laparoscopic Sleeve Gastrectomy Supported With A Temporary Micro-axial Flow Pump In A Patient With Alstrom Syndrome**  
Luis A. Hernandez Mejia, MD, Nader H. Hanna, MD, Kevin Leung, MD, Monica Segura, MD, Diana Miranda Ruiz, MD, Jose Sleiman, MD, Eduardo Perez, MD, Abdullah Sarkar, MD, Manojna Nimmagadda, MD, Steven Minear, MD, Edward Noquera, MD, Lilibeth Ferrin, MD, Gaston Cudemus, MD, Nicolas Broazi, MD, Cedric Sheffield, MD, Emad Hakemi, MD, Raoul Rosenthal, MD, Mauricio Velez, MD, Elsy V. Navas, MD, Jaime Hernandez-Montfort, MD; 1Cardiology, Cleveland Clinic Florida, Weston, FL, USA, 2Internal Medicine, Cleveland Clinic Florida, Weston, FL, USA, 3Anesthesia, Cleveland Clinic Florida, Weston, FL, USA, 4Cardiothoracic Surgery, Cleveland Clinic Florida, Weston, FL, USA, 5General Surgery/Bariatric Surgery, Cleveland Clinic Florida, Weston, FL, USA

**Study:** Alstrom syndrome (AL) is a rare cause of dilated cardiomyopathy (DCM), hearing impairment, Morbid Obesity (MO), and type 2 diabetes. Patients with MO are often excluded from heart transplant (HT) or left assisted ventricular devices (LVAD). Bariatric surgery has been successfully used for weight loss as a bridge to HT. Transitions to durable replacement among patients with heart-failure cardiogenic shock (HF-CS) requiring temporary support remains elusive.

**Methods:** 26-year-old with history of Alstrom Syndrome (DCM, MO) and chronic kidney disease transferred from an outside facility due to HF-CS secondary to ventricular tachycardia. In our facility patient, BMI 58, clinically volume overloaded and echo showed EF 21%, with moderately decreased RV function and RVSP 46 mmHg. He underwent right heart catheterization that showed RA 29mmHg PAP 55/25/39 mmHg and PCWP 25 with CO 4.5L/min and CI 1.6 L/min/m². He was started on diuresis and inotropes. Based on his prohibitive risk for replacement therapies (LVAD/HT) laparoscopic sleeve gastrectomy (LSG) supported with Impella CP for weight loss was offered as a bridge to decision. He underwent LSC without complications and was discharged home on inotropic support with a weight loss of 49 pounds after 2 weeks.

**Results:** Several centers use body mass index (BMI) >35 kg/m² as a contraindication to proceeding with replacement therapies due to high risk of complications. Several studies showed bariatric surgery reduces the risk of heart failure development and reverses abnormalities in cardiac mass. LSG has been previously performed safely with successful progression to cardiac transplant listing and transplantation for patients with HF-CS and MO. To our knowledge, this is the first reported case of LSG in a patient with AL in CS supported with Impella CP combined with inotropes as a safe and feasible bridge to replacement therapies candidacy. More research is needed in order to best understand this vulnerable population.
ASAIO ELECTRONIC POSTER ABSTRACTS

EPCardiac21
The Effect of N-linked Deglycosylation on vWF and ADAMTS13 Structure and Function Under VAD-like Shear Stress
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Study: While ventricular assist devices (VADs) provide effective circulatory support in heart failure patients, the adverse effects include gastrointestinal (GI) bleeding and thrombosis. High molecular weight (HMW) von Willebrand Factor (vWF) is a multimeric blood circulating glycoprotein. HMW vWF has two critical roles in promoting platelet adhesion to damaged blood vessels and enhancing clot formation. vWF has twelve N-linked glycosylation sites and two of them are located at the A2 domain, a site for ADAMTS13 cleavage. Therefore, we hypothesised that N-linked deglycosylation of HMW vWF affects its interaction with ADAMTS13 under VAD-like shear stress.

Methods: His6-vWF or mCherry-ADAMTS13 expressing HEK293 cells were treated with tunicamycin for N-linked deglycosylation whereas the corresponding purified His6-tagged proteins were subjected to N-linked deglycosylation by PNGase F. These proteins were then added to human whole blood and exposed to VAD-like shear stress. The structure of deglycosylated vWF monomers and ADAMTS13 were then analysed by non-native immunoblotting. In addition, the effect of N-linked deglycosylation and shear stress on HMW vWF multimer integrity was analysed by native immunoblotting. Furthermore, the binding of deglycosylated vWF to ADAMTS13 was studied by an ELISA.

Results: Our preliminary results propose that N-linked deglycosylation could promote vWF interaction with ADAMTS13 under static and VAD-like shear stress. Therefore, this study of deglycosylation may provide useful information to define the structural properties of vWF. Also, the development of synthetic deglycosylated HMW vWF could be beneficial in treating patients with VAD-induced GI bleeding. However, to prevent potential thrombus-promoting events this vWF would require an enhanced susceptibility for ADAMTS13 breakdown. Further research is required to establish this effect and determine the N-linked glycosylation sites responsible for these changes.

EPCardiac22
Galectin-3 In Patients With Left Ventricular Assist Devices: A Prognostic Biomarker Of Post-implantation Outcomes
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Study: Galectin-3 is a novel biomarker that has been used to categorize HF patients by risk. Elevated levels are linked with poor outcomes and higher cardiovascular risk with values greater than 25.9 ng/mL associated with high risk. The relationship between Galectin-3 and outcomes in Left Ventricular Assist Device (LVAD) patients has not been well-explored.

Methods: From 2012 to 2016, 159 patients with heart failure at our institution had lab values collected for Galectin-3. Among them, 108 patients were implanted with an LVAD. Galectin-3 was collected for all patients prior to LVAD implant. Their clinical outcomes, including right ventricular failure (RVF), time on inotropes, need for right ventricular assist device (RVAD), length of intensive care unit (ICU) stay, and mortality were collected retrospectively.

Results: Patients who experienced RVF (n=42) had a higher mean Galectin-3 value compared to those who did not (n=66), with 33.75 ng/mL ± 18.4 compared to 25.76 ng/mL ± 10.46 (p=0.002). Those who received an RVAD (n=22) had higher Galectin-3 levels with mean 32.58 ng/mL ± 17.24 compared to those that did not (n=86) with mean 26.66 ng/mL ± 12.71 (p=0.138). Galectin-3 lab values were positively correlated with inotrope duration (r=0.223, p=0.026), and length of ICU stay (r=0.257, p=0.006). Galectin-3 levels in patients who died (n=49) were higher than in those who did not (n=59), with a mean of 29.18 ng/mL ± 15.45 compared to 26.26 ng/mL ± 12.29 (p=0.208).

These results show the Galectin-3 biomarker can be used as a predictor of post-LVAD implantation outcomes, elevated levels being associated with RVF, longer time on inotropes, increased length of ICU stay, and higher mortality.
Galectin-3: A Prognostic Biomarker Of Clinical Outcomes In Patients With Heart Failure
Ryan Hoang, None1, Jennifer Cruz, None1, Nabel Rasheed, BA1, Corinne Stonebraker, BA1, Sydney Lupo, None1, Mary Acosta, MD2, Colleen Lobuhn, APNP1, Sean Pinney, MD1, Valluvan Jeevanandam, MD2, Jonathan Grinstein, MD2; 1Section of Cardiac Surgery, The University of Chicago Medicine, Chicago, IL, USA, 2Section of Cardiology, The University of Chicago Medicine, Chicago, IL, USA

Study: Heart failure (HF) is associated with poor prognosis, with common end-stage treatments including LVAD implantation and heart transplantation. Galectin-3 is a novel biomarker, with elevated levels being linked to greater cardiovascular risk and poor outcomes in HF patients. We sought to further investigate the relationship between Galectin-3, pre-implant outcomes and mortality.

Methods: Between 2012 and 2016, 159 heart failure patients at our institution had Galectin-3 biomarker lab values collected. A retrospective study was performed investigating the clinical outcomes of these patients, looking at outcomes of LVAD implantation and heart transplantation, mortality, and the Intermacs score at the time of implant.

Results: In patients receiving an LVAD implant or heart transplant (n=107), the mean Galectin-3 lab value was 27.49 ng/mL ± 14.86, compared to 31.72 ng/mL ± 13.72 (p=0.077) in those with neither (n=52). Galectin-3 values were negatively correlated to the Intermacs score at time of LVAD implant or heart transplant (r=-0.307, p=0.001). Galectin-3 values were higher in patients who died (n=82) than in those who did not (n=77), with a mean of 31.09 ng/mL ± 15.87 compared to 26.55 ng/mL ± 12.78 (p=0.047).

In Vitro And Ex Vivo Assays Of Vascular Calcification
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Study: Vascular calcification (VC) is one major complication in patients with chronic kidney disease whereas a failed calcium and phosphate metabolism plays a crucial role. Since the mechanisms underlying VC have not been entirely revealed to date, the highly relevant studies aiming at the identification and characterization of the mediators/uremic toxins involved in VC are ongoing. The fact that many different protocols being used in the studies of vascular calcification processes complicates the comparison of study outcomes, composing systematic reviews, and meta-analyses. Moreover, the reproducibility of data is hampered, and the efficiency in calcification research through the lack of a standardized protocol is reduced. In this study, we developed a standardized operating protocol for in vitro and ex vivo approaches to aiming at the comparability of these studies.

Methods: Vascular smooth muscle cells (HAoSMCs) were used for in vitro experiments and aortas from Wistar rats were used for ex vivo experiments. The influence of the following conditions was studied in detail: phosphate and calcium concentrations in calcifying media; incubation time; fetal calf serum (FCS) concentration. The degree of calcification was estimated by quantification of calcium concentrations that were normalized to protein content (in vitro) or to the dry weight of the aortic ring (ex vivo). Additionally, the aortic rings were stained using the von Kossa method.

Results: We were able to demonstrate that the degree and the location of VC in vascular smooth muscle cells and aortic rings were highly dependent on the phosphate and CaCl₂ concentration in the medium as well as the incubation time. Furthermore, the VC was reduced upon increasing fetal calf serum concentration in the medium. The developed and validated final step-by-step protocol presented in the figure will help to standardize in vitro (A), and ex vivo (B) approaches to investigate the processes of medial vascular calcification.
EPCardiac25

Advanced Graphical User Interface For Continuous Flow MCS Devices
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Study: The Cleveland Clinic continuous-flow total artificial heart (CFTAH) uses an automatic speed control system to regulate the pump's output in response to hemodynamic changes. The system responds to changes in systemic vascular resistance (SVR) and can predict, detect and respond to pump suction. A user interface for the CFTAH, called the advanced pump controller interface (APCI), is being developed to manage and monitor the controller during in vitro and in vivo testing.

Methods: The APCI accurately estimates hemodynamic parameters, such as SVR and the pump's pressure gradients, by analyzing power consumption and the axial position of the pump rotor using regression equations and artificial neural networks. The data, calculations, and state of the controller are visualized by the APCI (Fig. 1). The interface makes it possible to fine tune the neural networks and calculation parameters during operation.

Results: The APCI and CFTAH controller system can model and estimate basic hemodynamic parameters and is capable of automatic speed control in initial testing. The APCI is also a prototype for a continuous patient monitor; a software tool that will be used by patients and physicians to monitor relative hemodynamic changes over time. Validating and improving accuracy and usefulness of the CFTAH control system will be a lengthy process, involving large sets of chronic in vivo data that cover a variety of dynamic situations, such as suction events and blockages proximal to the pump. The in vivo studies and in vitro validation with the APCI is ongoing.
EPCardiac26

Predictors Of Feasibility Of Ventricular Assist Device Explantation With Stable Myocardial Recovery In Chronic Non-ischemic Cardiomyopathy

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Michael Dande, MD, PhD4,
Roland Hetzer, MD, PhD5,
1Universitätsmedizin Berlin-Charité, Berlin, Germany,
2Charité Research Organization, Universitätsmedizin Berlin-Charité, Berlin, Germany,
3Hannover Medical School, Hannover, Germany,
4Cardio Centrum Berlin, Berlin, Germany.

Study: This meta-analysis aims to evaluate clinical parameters reflecting successful reverse remodeling and the viability of echocardiographic parameters as predictors of sustained recovery to determine VAD explantation feasibility.

Methods: PubMed was searched for VAD-implantation outcome studies in heart failure (HF) patients with non-ischemic cardiomyopathy. Inclusion criteria were echocardiographic data (pre-during, post-VAD implantation/explantation) with ≥one-year follow-up and myocardial recovery, HF recurrence or death as endpoints.

Results: Our meta-analysis encompasses 11 studies with 98 patients. Data on age at implantation, gender, pre-explantation LVEDD/LVEF, off-pump trial and pre-explantation stress tests were available in 83 patients. Additional data on HF duration, pre-explantation LV geometry (sphericity index, relative wall thickness) and reduced off-pump arterial diastolic pressure was known for 51 patients. Stepwise cox-regression in 51 patients demonstrated age at implantation (HR 1.094, p=0.002), HF duration (HR 1.438,p= 0.001) and sphericity index change (HR 1.541,p= 0.000) as significant risk factors for HF recurrence during VAD-weaning, while in 83 patients, pre-explantation LVEDD (HR 1.126, p=0.031) and LVEF (HR 0.080,p=0.007) were significant predictors (Fig.1) of myocardial recovery sustainment. Freedom from HF recurrence: 82%, 78%, 58% and 42% at 1,5,10 and 15 years, respectively. Post-weaning survival:100% and 80% at 30 days and 5 years respectively and 78% at 10-15 years. Risk factors: age at implantation (HR 1.098,p=0.004) and off-pump arterial diastolic pressure of 50 mmHg (HR 0.095,p=0.040). Neither gender (p=0.862) nor VAD-type (p=0.662) revealed statistical significance. Follow-up deaths were non-cardiac (infection, stroke).LV-geometry and functional off-pump stability may differentiate potential post-weaning clinical stability and HF recurrence.

EPCardiac27

Twenty-four-hour Normothermic Ex-Vivo Heart Perfusion Using Hemofiltration

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We show EVHP maintenance for 24h with HF toxin removal allows for preservation of myocardial function, improved tissue viability, decreased tissue edema, and less myocardial injury. These data suggest the possibility of prolonged heart survival using HF EVHP for future clinical translation.

Study: Normothermic ex-vivo heart perfusion (EVHP) for >24h is possible with both continuous paracorporeal plasma cross-circulation and continuous plasma exchange without paracorporeal support. We present a model of EVHP using continuous hemofiltration (HF) with myocardial viability up to 24h.

Methods: Hearts from 6-10kg piglets were procured after antegrade cardioplegia. Cannulae placed in the aorta, pulmonary artery, and left ventricle (LV) maintained the EVHP circuit. An LV pressure balloon allowed for hemodynamic monitoring. The circuit was primed with platelet- and leukocyte-reduced blood. The HF group (n=10) underwent EVHP with in-parallel HF (Prismaflex HF1000) at 1cc/h/g cardiac tissue and Filter Replacement Fluid (FRF), an isotonic electrolyte crystalloid, at equal rate to maintain circuit euvoolemia. The control (C) group (n=10) used EVHP alone. Groups were compared using student’s t-test and Fisher’s exact test.

Results: All HF vs 3 C hearts were viable at 24h (p=0.001). HF hearts had higher LV systolic pressures (63.5±7.5 mmHg vs 47.7±8.0 mmHg, p<0.001) and lower serum lactate (2.9±0.4 mmol/L vs 4.1±0.6 mmol/L, p<0.001) than C hearts. Heart weight gain at experiment end was lower in HF than C hearts (0.42±15.7% vs 11.42±7.4%, p=0.047). All HF vs 5 C hearts responded to epinephrine at experiment end (p=0.03). Histopathologic examination showed less extensive myocardial damage in HF vs C hearts.
Log Files Analysis Demonstrates Reduction In Flow In First Year Post Implantation Of Continuous Flow -left Ventricular Assist Device

Tani Kahlon, MD, Joel Graham, Master of Engineering, Jaimin Trivedi, MBBS, MPH, Christina Dunbar-Matos, DO, Mark Slaughter, MD; University of Louisville, Louisville, KY, USA

**Study:** Log files from HeartWare HVAD (Medtronic, Inc., Minneapolis, MN) device were analyzed for temporal trends in pump flow, a derived parameter that is inversely related to difference in inflow and outflow pressures, to investigate sustained shifts in hemodynamics due to long-term use of CF-LVAD devices.

**Methods:** Retrospectively compiled device parameter data was downloaded from all available controller log files for patients from 3/2013 through 09/2020 at a single center. Controller log data including flow (LPM), waveform peak and trough (LPM), speed (RPM), and power (W) were collected every 15 minutes and analyzed using LabVIEW software for the first year following implantation. Log files data was averaged for each day of available data. Flow parameters were indexed to BSA at time of implant. Log files were excluded if the day included a speed change, if power was outside of expected operation range, or less than 30 days of data was available.

**Results:** 12,405 controller log-days in 90 patients (138 +/- 80 days per patient) were included for analysis. Average and standard deviation parameters for indexed flow, peak, trough, speed, and power were 2.42 ± 0.37, 5.18 ± 0.65, 1.53 ± 0.40 L/min/m², 2726 ± 137 RPM, and 4.37 ± 0.78 W, respectively. Indexed flow decreased over one year following implant despite corresponding increase in pump speed in accordance with clinical standard of care. Significant decrease in flow index was observed at day 60 with continued reduction over the year, compared to baseline at 7 days (2.5 vs 2.7 L/min/m², p=0.008) while corresponding speed was significantly higher at these timepoints (2735 vs 2660 RPM, p=0.010). Conclusion: Decreasing requirements in flow with continued presence of CF-LVAD to reach perfusive hemodynamics has not previously been described. Further studies are needed to elucidate whether worsening RV adaptation, increasing aortic wall stiffness or myocardial remodeling are responsible for this phenomenon.

Mechanical Circulatory Support For Biventricular Heart Failure Using Single And Dual Device Configuration

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**Study:** In patients with severe biventricular heart failure (HF) and cardiogenic shock, use of biventricular assist device (BVAD) can be a treatment of choice. We are developing advanced ventricular assist device (AVAD) and continuous-flow total artificial heart (CFTAH), with capability to support biventricular HF (BHF). The purpose of this initial in vitro study was to explore performance and regulation features that both systems could provide as BVAD.

**Methods:** The mock loop testing was conducted using two pulsatile ventricles for simulation (AB5000; Abiomed, Danvers, MA) of hemodynamic parameters within the BVAD-supported systolic HF cardiovascular system. The AVAD (Fig.1A) and CFTAH (Fig.1B) were used as BVAD (CFTAH: 3500 RPM: left AVAD: 3200 RPM; right AVAD: 2000 RPM) to get comparable systemic flow and pressure outputs. For BVAD using CFTAH and AVAD, the support was adjusted to maintain 4-5 L/min total systemic flow. Type of cannulation (atrial - AC; ventricular - VC; atrio-ventricular - AVC), degrees of valve closure has been evaluated.

**Results:** The BVAD performance was maintained for both CFTAH and (AVAD left and right support) within specified speed range of 2000 - 3500 RPM. Both device use configurations provided sufficient support for HF conditions, although demonstrated variability in tolerance to aortic and pulmonary valve regurgitation. Both devices demonstrated self-regulation, performance was demonstrated with the left (LAP) and right (RAP) atrial pressure difference (LAP-RAP) falling predominantly within the range of - 5 to 10 mm Hg in left and right heart failure conditions. BVAD speed, left and right, and total flow remained stable throughout the experiment. These initial bench evaluation demonstrated that use of the universal AVAD and CFTAH as BVAD supports cardiac output and arterial pressure in BHF. Each system demonstrated variability of features related to device control, physiologic response and system regulation.
EPCardiac30

Design Method Using Statistical Model To Predict Static Force Due To Rotor Eccentricity In A Hemolysis Assessment Platform

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Study: A hemolysis assessment platform (HAP) could reliably quantify blood trauma contribution from each component through iterative testing of LVAD designs. So the HAP does not confound hemolysis data, we proposed an enlarged gap motor coupled to a magnetic levitation (maglev) system. Characterization of the radial force generated by rotor-stator eccentricity is essential for maglev development. Since most experimental test systems have physical limitations, a method that can overcome those limitations to provide accurate results is valuable. In this study, we established a design method wherein empirical static forces are used to derive a statistical model to predict static force generated by motor eccentricity. The statistical model was then validated numerically.

Methods: The radial forces generated by a motor with variable rotor diameter were measured by a torque transducer mounted on a micrometer-driven stage in a static force test rig (FTR). Parabolic curves were generated to fit the force vs. rotor diameter data and used to extrapolate forces produced by 3 rotor diameters which exceeded the FTR limitations. The rotors were also modeled using finite element method in COMSOL 5.4 to compute the magnetic force generated by rotor-stator eccentricity.

Results: The static forces increase linearly with radial displacement (RD) numerically, whereas they increase linearly at small RD but gradually progress into parabolic curves at larger RD experimentally; this can be explained by rotor-shaft deflection in the (FTR). Since the numerical and experimental results matched at small RDs, we derived the statistical model from experimental data, which was then used for 3 rotor diameters (10.0, 9.5, 9.0 mm). The numerical and statistical static forces differed by ~5%, thereby validating the statistical model as a radial force prediction tool. Further development upon this method could include more geometric variables to accelerate the maglev system design process.
**EPCardiac31**

**Influence Of Motor Speed On Shear Stress For A Hemolysis Assessment Platform: A Computational Fluid Dynamics Approach**

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**Study:** We recently proposed a hemolysis assessment platform (HAP) that can be used to identify sources of blood damage in a left ventricular assist device (LVAD). Unlike conventional tests that evaluate the overall blood damage, this HAP was designed to quantify blood trauma contribution from individual components before building the complete LVAD. To eliminate the hemolysis induced by the HAP itself, we incorporated magnetic levitation bearings which maintain a large gap between the rotor and stator. In this study, we established a numerical model of the HAP motor gap to evaluate shear stress on the blood at different operating speeds.

**Methods:** We evaluated the HAP motor gap analytically and numerically at 4 motor speeds from 5,000-20,000 rpm with a 200 mL/min flow rate. Shear stress was estimated analytically before solving the unsteady Reynolds Averaged Navier-Stokes equations in Fluent 2020R1. A 1M element structured mesh was selected with time step 1.67E-5 s. Blood was defined as Newtonian.Boundary conditions were: uniform velocity inlet; constant pressure outlet; and no-slip walls. The k-ω SST model was selected for turbulence. Scalar shear stress (SSS) was calculated and the simulation ran until the averaged SSS was constant (~8,100 timesteps). The index of hemolysis (IH) was estimated from SSS and average time in the motor gap using a power law model.

**Results:** As the motor speed increased, the SSS increased from 5.43 Pa to 21.72 Pa analytically but increased from 7.11 Pa to 27.97 Pa numerically. Though the trends were similar, the numerical model estimated ~30% higher SSS than the analytical model, which can be explained by the presence of Taylor vortices. At 20,000 rpm, the IH was found to be 0.0055% whereas it was negligible at 5,000 rpm. This numerical model enables us to predict the hemolysis rate in the HAP motor gap at a given rotational speed. Furthermore, blood trauma will be analyzed at varied motor geometries and flow rates before HAP manufacture.

![Fig. 1. Hemolysis Assessment Platform schematic. Region inside dashed box was analyzed in the present study. The test region represents the individual LVAD component under investigation.](image)

![Fig. 2. Difference in shear stress in HAP motor gap with motor speed between numerical and analytical results (a) due to the presence of Taylor vortices (b).](image)

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**EPCardiac32**

**Transcatheter Treatment Of Twisted Outflow Graft Of HeartMate 3 Left Ventricular Assist Device**

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**Study:** Left ventricular assist device (LVAD) is a widespread option for patients with advanced heart failure (HF). One of the rare and potentially dangerous complication in the postoperative period is outflow graft (OG) twisting. We identified 3 cases of twisted OG (2.4%) occurring in 123 HeartMate 3 LVAD (Abbott, Chicago, IL, USA) implants before Outflow Graft Clip use. We report two unique cases of successful transcatheter treatment of twisted OG of HeartMate 3 LVAD.

**Methods:** OG twisting was diagnosed with comprehensive assessments including a clinical presentations, device parameters, laboratory data, transthoracic echocardiography (TTE) with ramp study and computed tomography angiography (CTA).

**Results:** Patient 1 was admitted to our center with low flow alarms (up to 0.6 lpm) with dizziness, dyspnea, weakness. Patient 2 was admitted as a follow-up. Laboratory studies revealed no signs of hemolysis. TTE-monitored ramp study was showed that LVAD pump speed increasing from 5000 RPM to 6000 RPM presented no any changes of the left ventricular end-diastolic internal diameter and pump flow. Patients underwent CTA that revealed OG twisting at the proximal part. Due to the high risk for redo surgery, multidisciplinary team decided to consider percutaneous intervention for treatment of twisted OG. Procedure was carried out under local anesthesia through the femoral artery. In first case balloon-expandable AndraStent 43 mm and CP Stent 45 mm on MaxiLD 14/40 dilatation balloon were implanted. After procedure the peak-to-peak gradient at twisted part was decreased from 136 to 5 mmHg. In second case we used three balloon-expandable stents on Atlas Gold 16/60 balloon. The peak-to-peak gradient was decreased from 42 to 22 mmHg. The patients were discharged 3 days later after procedure and remain stable to current date. Transcatheter treatment could be an alternative option to redo surgical procedure in high-risk patients and have been shown to be feasible and effective.
Higher Patient Compliance With CardioMEMSTM Is Associated With A Lower Rate Of Heart Failure-Related Admissions

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Study: Hospital admission rates for acute on chronic heart failure (HF) remain high despite modern advances. Wireless pulmonary artery pressure (PAP) monitoring systems allow for remote monitoring to facilitate early intervention and reduce admissions. While beneficial in reducing hospital admissions, no study has quantified the relationship between patient compliance and HF admission rate.

Methods: This was an IRB-approved retrospective cohort study of patients implanted with a CardioMEMSTM HF device (Abbott, Abbott Park, IL) between April 2016 and June 2020 at our institution. Daily PAP readings were extracted for all patients from date of implant to either death or June 19, 2020. Recording days were then grouped into 30-day intervals and compliance calculated as a percent of days with readings per days implanted. A logistic regression model using generalized estimating equations was fitted. PA pressures were recorded and correlated with hospital admissions.

Results: During the study period, 73 patients underwent CardioMEMSTM implant: 36 (49.3%) had HF with reduced ejection fraction (HFrEF) and 37 (50.7%) had HF with preserved ejection fraction (HFpEF). Mean follow up was 1.46±0.97 years. There was no significant difference in complications was fitted. PA pressures were recorded and correlated with hospital admissions. There was an associated 11% decrease in the odds of admission (OR 0.89 [0.82,0.96], p=0.003). There was no significant trend in systolic, diastolic, or mean PAP in the days prior to heart failure admission in either HFrEF or HFpEF. Increased compliance with daily CardioMEMSTM PAP readings may help decrease HF-related hospitalizations for those with chronic HF. It is possible that regularity in transmitting readings may be an indicator of adverse outcomes so identifying these patterns in the future may lead to earlier interventions.

New Noninvasive Method To Monitor Cardiac Recovery During VA ECMO*

Nikolai Krivitski, PhD, DSc; Transonic Systems Inc., Ithaca, NY, USA

Study: Early identification of heart recovery may shorten a patient’s time on VA ECMO, thus reducing complications and costs. Currently, there is no simple, noninvasive technology to continuously assess heart recovery. The aim of this study is to develop an operator independent monitoring system for the quantitative assessment of cardiac recovery in VA ECMO patients.

Methods: The blood flow of a centrifugal pump depends on the characteristics of the ECMO circuit and is influenced by the patient’s hemodynamics. In the order to evaluate this influence, an equivalent hydraulic electric model of VA ECMO connected to the patient was investigated. To solve the model’s equations the superposition theorem, and frequency analysis were used to address the issues related to multiple pressure sources and frequency dependent characteristics of the model. One of the model parameters that is sensitive to heart recovery was coefficient R%, which is the ratio of pulsatile component of arterial ECMO flow QECMO-p to average ECMO flow QECMO: R% = QECMO-p/QECMO*100% = CO_p/(P_PUMP/ZSYS - CO). Where CO and CO_p - average and pulsatile components of blood flow in the aorta that perfuses the organs, P_PUMP - pump pressure, ZSYS systemic vascular resistance. The flow data recorded by ELSA monitor (Transonic Systems Inc. USA) in 28 pediatric (n=95) and in 112 (n=512) adult patients was examined retrospectively.

Results: Most of the patients start VA ECMO with a small pulsatile component of less than 100 ml/min and with R% in the order of up to 5% (Table1). With heart recovery the pulsatile component significantly increased, while the average flow drops if the pump setting is not changed.

Conclusion. Continuous monitoring of the blood flow during VA ECMO allows quantitative assessment of the heart recovery. The next step is to validate the current methodology and to establish clinical thresholds of heart recovery.

<table>
<thead>
<tr>
<th>ECMO Blood Flow Average and Range</th>
<th>Patients</th>
<th>QECMO, ml/m</th>
<th>QECMO-p, ml/min</th>
<th>R%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pediatric</td>
<td>950 (130-1560)</td>
<td>100 (16-693)</td>
<td>17 (2.5-81)</td>
<td></td>
</tr>
<tr>
<td>Adults</td>
<td>3140 (840-5720)</td>
<td>380 (45-1875)</td>
<td>14 (2.2-78)</td>
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</tbody>
</table>

* - patent pending
ASAIO ELECTRONIC POSTER ABSTRACTS

EPCardiac35

Low Molecular Weight Heparin As An Effective Outpatient Treatment Of Early Ventricular Assist Device Thrombosis

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Study: Pump thrombosis is a devastating complication of ventricular assist devices (VAD). Treatment modalities include pump exchange and thrombolytic therapy. We aimed to evaluate the effectiveness and safety of treating early VAD thrombosis with low molecular weight heparin (LMWH) in an outpatient setting.

Methods: We reviewed 49 patients (pts) with a VAD followed in our program over 5 years and evaluated the treatment trigger (hemolysis markers and VAD parameters), efficacy [reduction in hemolysis markers, heart failure biomarkers (BNP) and VAD parameters] and complications of outpatient LMWH treatment for early VAD thrombosis.

Results: Pts were 55 years of age, 8% were women, 37% were INTERMACS 1&2 at implant with average support on VAD of 2.3 years. Early VAD thrombosis was identified in 6 patients (5 HeartWare HVAD and 1 HeartMate II) after median of 26 months of support. Eighty three percent of pts were diagnosed with early VAD thrombosis from elevated hemolysis markers [LDH 329 ± 82 U/L, plasma free hemoglobin (pfHb) 35.9 ± 19.4 mg/dL] and 17% from having elevated VAD powers (0.6 W over baseline) as identified through our remote monitoring program. All pts had therapeutic INR at time of thrombosis (INR 2.3 ± 0.2) and were continued on warfarin (INR goal 2.0-3.0). Pts were treated with consecutive courses of LMWH 40-60 mg BID for 3-5 days. Hemolysis markers improved (decreased over baseline: LDH 17.1 ± 17.7%, pfHb 72.6 ± 9.5%) for all pts, and BNP improved (decreased 20.8 ± 21.8% over baseline) for 67% of pts. VAD power (decreased 5.1 ± 3.6% over baseline) and flow improved or remained stable for all patients. The only complication was an episode of minor epistaxis that resolved within 48 hours. Conclusion: Use of LMWH in the outpatient setting can be an effective and safe treatment of early VAD thrombosis with improvement in hemolysis markers, heart failure biomarkers and VAD parameters.

EPCardiac36

Incidence Of Driveline Infections In Heartmate 3 Compared To Heartmate 2

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Study: Driveline infections (DLI) are a common complication and remain a major source of morbidity and mortality in patients with left ventricular assist devices (LVADs). This study compares DLI rates between the HeartMate II (HM2) and HeartMate 3 (HM3). The HM3 has a new modular driveline that facilitates simple replacement of the externalized portion.

Methods: This is a retrospective cohort study of patients from UC’s Advanced Heart Failure Clinic who have received an LVAD from 3/2011 - 8/2020. We obtained data by device, demographic data, risk factors for DLI, time until first DLI, pathogens, and treatment. We calculated the relative risk of DLI in the HM3 group compared to the HM2 group and compared mean days to DLI using a Mann-Whitney U Test.

Results: 75 patients received an LVAD between 2011-2020 at UCMMC. Two were excluded from the study due to loss to follow-up. 56 patients received the HM2 while 17 received the HM3. 5.4% of HM II patients developed a DLI by 3 months post implantation compared to 18% in the HM3 group. (Figure 1). The relative risk for HM3 patients developing DLI was 1.372 (CI .681 - 2.2381, p=.694) compared to HM2 patients. The mean time to DLI post implantation was 379.9 days in the HM2 group compared to 174.8 days in the HM3 group (Table 1). In our patient population DLI occurred earlier and more often in the HM3 group. A possible reason could be that the modular DL is heavier and more difficult to stabilize with an anchor. The use of a second anchor is often difficult for patients to handle. Further studies with a larger patient population are needed to confirm our results.

<table>
<thead>
<tr>
<th></th>
<th>HeartMate 2 n=56</th>
<th>HeartMate 3 n=17</th>
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</thead>
<tbody>
<tr>
<td>Median Age</td>
<td>53.5</td>
<td>53</td>
</tr>
<tr>
<td>Male %</td>
<td>78.6%</td>
<td>70.6</td>
</tr>
<tr>
<td>DLI % at 3 months</td>
<td>5.4</td>
<td>18</td>
</tr>
<tr>
<td>6 months</td>
<td>14.3</td>
<td>29</td>
</tr>
<tr>
<td>12 months</td>
<td>28.6</td>
<td>41</td>
</tr>
<tr>
<td>Mean Days to DLI</td>
<td>379.9*</td>
<td>174.8*</td>
</tr>
</tbody>
</table>

*p = .024
ASAIO ELECTRONIC POSTER ABSTRACTS

EPCardiac37

Ex Vivo Safety Testing Of Lvad Control Algorithms For Clinical Application
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Study: An algorithm for real-time physiological control of LVAD speed was developed. Before starting clinical use with real-time control, an environment for evaluation has to be created and tested. The presented work outlines ex vivo testing to prove feasibility and safety for clinical application of novel control algorithms for LVADs.

Methods: The Medtronic HVAD allows communication via a serial port. A microcontroller based environment (MicroLabBox, dSpace, Germany) was designed to interface with this port. A mechanical switch could be used to rapidly toggle between three sources of speed change commands sent to the controller: 1) Standard commands from the clinical monitor, 2) Speed commands from the dSpace box, and 3) A safety command for 2400 RPM pump speed, sent in case of unexpected, unsafe behavior. Outgoing waveform data from the controller was duplicated to both the clinical monitor and dSpace box. The final version of the setup was tested in three acute isolated-heart experiments. Manipulation of heart rate, preload, afterload and contractility tested stability and efficacy of the controller. Technical safety endpoints such as rate limits and absolute limits were defined, as well as physiological safety endpoints such as accurate detection of suction.

Results: Unexpected or unsafe speed changes were not observed. Out of 126 preload reduction maneuvers, 27 produced ventricular suction and 49 atrial suction. The algorithm was able to detect and react to 26 (96.3%) of the ventricular episodes and 31(63.3%) of the atrial episodes without any false positives. Technical safety endpoints such as minimum time between transmissions (1sec), amplitude (2000-3400 rpm) and rate of speed changes (200 rpm /10sec) were not violated and continuous datastream was ensured. The developed novel control algorithm demonstrated to be safe and it is currently used in an ongoing clinical study.

EPCardiac38

Using A VAD Outcomes Predictor Tool (VAD-OPT) Score To Predict Negative Outcomes: A Retrospective, Proof-of-Concept Study
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Study: The impacts of psychosocial risk factors on morbidity and mortality of patients with left ventricular assist devices (LVADs) are not well-defined. We developed a VAD Outcomes Predictor Tool (VAD-OPT) that included: distance to VAD center, language barriers, history of substance abuse, depression/anxiety, smoking, social supports, living situation, and quality of life.

Methods: We performed a retrospective chart review of consecutive patients with LVADs at our center in 2017-19. The above factors were scored from 1-3 (low risk to high risk) and were tabulated into a single VAD-OPT score. Descriptive statistics and regression modeling were performed with STATA 15.1.

Results: 118 patients were included with a mean age of 57 years. The median VAD-OPT score was 10 (IQR 9-12). There was no correlation of VAD-OPT score with mortality or major complications. Patients with higher VAD-OPT score tended to have a greater number of readmissions in the first year post-implant (α = 0.164, p=0.05), but the number of days spent readmitted was not different. Individual risk factors that comprise the VAD-OPT score were compared to number of readmissions and patient outcomes, however none was found to be statistically significant. In conclusion, although there was a slight association between the VAD-OPT score and number of readmissions in the first year, the VAD-OPT score and the individual psychosocial factors studies were not significantly associated with readmission or survival in a recent era of LVAD implants. Further work in a larger database is needed to validate the VAD-OPT score.
**EPCardiac39**

**The Effect Of Permissive Hypertension On Cerebral Perfusion During Treatment Of Embolic Stroke In LVAD Patients**

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**Study:** This study aims to investigate the effect of permissive hypertension, a deliberate raising of the Mean Arterial Pressure (MAP), on cerebral perfusion in LVAD patients, as treatment of embolic stroke.

**Methods:** A Lumped Parameter Model (LPM) of the entire human circulation that includes pulmonary and systemic circulation, as well as the four heart chambers, is modified to split the systemic circulation into the lower body and upper body. The upper circulation is subsequently split into the extracranial and intracranial vasculatures to study the perfusion in the brain as a function of MAP, peripheral and intracranial resistances. HVAD H-Q relationships are incorporated to model the instantaneous LVAD response. The impact of MAP values within a wide range, caused by changes in the systemic resistance, on intracranial flow rate is established. Increased resistance in the intracranial vasculature is then set to mimic a major embolic stroke, and its influence on cerebral perfusion is studied for a wide range of LVAD speeds, baseline MAPs, and systemic resistances.

**Results:** Flow to the intracranial vasculature significantly decreases when MAP is allowed to rise, at all LVAD speeds, consistent with the reduction in LVAD output for higher afterload. While at higher speeds, total cardiac output is higher and the fraction of total flow that goes to the brain is also higher than for lower speeds, the net intracranial flow rate always decreases with an increase in MAP. This remains true and is exaggerated when intracranial resistance is increased to model an embolic stroke. These results show how the increased sensitivity to afterload of third-generation LVADs, compared to the native heart, invalidates the paradigm that permissive hypertension can lead to an increase in cerebral perfusion. This study highlights the phenomenon that letting MAP increase in LVAD patients as a treatment of embolic stroke could negatively affect cerebral perfusion.

**EPCardiac40**

**Bicarbonate-based Purge Solution As A Bleeding Reduction Strategy In Patients On Impella Support**

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**Study:** The Impella Catheters require a heparin-containing purge solution to maintain proper pump function by reducing the risk of biomaterial deposition in the purge gaps. A bicarbonate-based purge solution (BBPS) has been proposed as an alternative to a heparin-based purge solution. We review performance in patients supported to date with a BBPS (heparin-induced thrombocytopenia patients were excluded from this analysis).

**Methods:** This review includes patients (n=26) supported using sodium bicarbonate (25 mEq/1L of D5W) in the purge from September 2020 to February 2021. These patients were supported with BBPS post-operatively where heparin in the purge was not desired or were transitioned to BBPS because of bleeding issues. Case data were collected from an internal database to develop the clinical narrative and cross-referenced against Impella Controller data logs to assess purge trends and pump function.

**Results:** All pumps were switched to BBPS in the purge if not started with BBPS (Figure 1A). The average time to initiating BBPS was 1.6 days (excluding n=3 outliers where time to switching was >15 days). The average duration of support with BBPS was 5 days and a maximum duration of 22 days (Figure 1B). Figure 1C shows clinical indications for use. Purge pressure and purge flow remained stable while on BBPS (Figure 1D). In conclusion, this preliminary experience suggests the feasibility of using BBPS to maintain purge patency, ensure pump motor reliability, reduce bleeding risk, and simplify anticoagulation management. Use of a BBPS may be a safe and effective alternative to heparin in the purge for patients in which heparin is contraindicated or not feasible. More patient experience and analysis are needed to evaluate how bicarbonate compares to heparin in the purge for all patients.

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**Figure 1:** (A) summary of purge anticoagulation at the beginning of the case, (B) duration of support with BBPS, (C) clinical indication of use (one case not specified), and (D) pump purge performance trends (n=5).
EPCardiac41
Bicarbonate Purge Solution To Support Impella Devices For Patients With Clinically Suspected Or Confirmed Heparin-induced Thrombocytopenia
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Study: The Impella catheter is a transvalvular, micro-axial left ventricular assist device that provides temporary mechanical circulatory support and requires a heparin-containing purge solution to reduce the risk of biomaterial deposition in the purge gaps and also maintain proper pump function. For patients with suspected or confirmed heparin-induced thrombocytopenia (HIT), direct thrombin inhibitors (DTI) have been proposed as an alternative to heparin in the purge, but have been associated with pump failure requiring temporary TPA in the purge solution to normalize pump function. In this report, we review HIT patients supported with a sodium bicarbonate-based purge solution (BBPS).

Methods: Patients with suspected or confirmed HIT on Impella support using sodium bicarbonate (25 mEq in 1L D5W solution) in the purge from September 2020 to January 2021 were reviewed. Case data were obtained from Impella Quality (IQ) database for those supported with a BBPS and clinically suspected or confirmed HIT. Purge pressures and purge flows were evaluated from the Automated Impella Controller (AIC).

Results: Ten patients were supported with a BBPS during this period. Impella support was begun either with no anticoagulant (n=5), DTI (n=2), or heparin (n=3) and then switched to BBPS. Impella run time using a BBPS ranged from 1-14 days; five pumps had a run time with a BBPS > 10 days (Figure 1). Systemic DTI use was used in five cases along with a BBPS. No purge pathway thrombosis or bleeding events were observed, along with no changes in purge flow or purge pressures observed. In conclusion, preliminary experience suggests the use of BBPS in the setting suspected or confirmed HIT patients supported with an Impella is safe and effective and may provide a useful therapeutic option for heparin intolerant patients. Future work should investigate mechanisms and purge reliability of BBPS in this setting.

Figure 1: (A) Clinical indication, and (B) Duration of use across different Impella purge types supported with bicarbonate in the purge.

EPCardiac42
Percutaneous Access Device For Preventing LVAD Driveline Infection
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Study: A durable left ventricular assist device (LVAD) requires long-term circulatory support capability, yet driveline infection (DLI) due to the percutaneous driveline access is an inevitable adverse event, which is one of the major causes of hospital readmission impeding the patient quality of life. Totally implantable system with a percutaneous energy transmission system may be an ultimate solution for this adverse event, but another potential approach historically attempted is a percutaneous access device (PAD).

Methods: PAD prototypes were fabricated for the in-vitro fitting tests, handling feasibility, and, in-vivo implantation tests. Control smooth surface (non-textured titanium surface), blasted rough surface, multiple sintered beads surface, and 3D-titanium sponge material was evaluated in tissue healing and integrity between skin-titanium interface. To identify the optimal animal model and chronic study protocol, working prototypes with sealed mechanism were designed based upon an anatomical fitting study (on the bovine study) and evaluated with goat and swine models (Mexican hairless and Göttingen mini pig) for chronic implantation. After termination, histopathology analysis was performed.

Results: Non-textured titanium surface developed poor tissue adhesion and developed epidermal down-growth. Titanium beads (spherical/asymmetrical) sintered surface establish better tissue ingrowth but inflammatory cell infiltration was sustained around the skin interface. Titanium sponge structure would develop stable skin and subcutaneous healing without the evidence of active inflammation and infection on the Göttingen minipig model up to 60 days chronics implantation. Histopathology study demonstrated tight tissue adhesion and micro vascularization. Skin button PAD may be a potential technology for preventing DLI by offering mechanical barriers for the driveline exit site avoiding bacterial invasion from the interface between the driveline and adjacent tissue.
Contraceptive Use On Ventricular Assist Device Therapy

Kristen Nelson McMillan, MD1, Sarah Kane, CPNP-AC2, Chelsea Kriesberg, CPNP-AC2, Viktoriya Kagan, APRN-BC3, Amber Truethart, MD, MS4, Sadia Haider, MD, MPH4, Laura Coyle, ARNP4, Sunil Pauwa, MD4, Toe Song, MD4, William Ravekes, MD5, Narutoshi Hibino, MD, PhD6, Luca Vricella, MD1, 1Pediatric cardiac critical care, Advocate Children’s Heart Institute, Oak Lawn, IL, USA, 2Advocate Children’s Heart Institute, Oak Lawn, IL, USA, 3University of Chicago, Chicago, IL, USA, 4Advocate Christ Hospital, Oak Lawn, IL, USA, 5Johns Hopkins University School of Medicine, Baltimore, MD, USA

Study: Recommendations regarding contraception in pediatric and adult patients on Ventricular Assist Device (VAD) support are sparse and may be center-specific.

Methods: We present a case involving a complication of necessary anticoagulation for VADs in females experiencing ovulation and results of a pilot survey evaluating local practice regarding contraception on VAD.

Results: A 15-year old female with dilated cardiomyopathy requiring left VAD implantation 16 months earlier presented with abdominal pain. She was on warfarin, aspirin and clopidogrel for her VAD. Imaging revealed ovarian torsion due to a ruptured hemorrhagic cyst. Gynecology performed a salpingo-oophorectomy following reversal of anticoagulation. Post-op, she was started on depo-provera to avoid estrogens and increase compliance. A pilot survey evaluating use of contraception on VAD therapy was subsequently developed by the study team via a modified Delphi method and disseminated to four local VAD program coordinators or directors. Results revealed pediatric and adult VAD programs have a significant portion of patients who are sexually active, but discussion of medical contraception is inconsistent. Most or all patients are on teratogenic medications, but consultation with gynecology is infrequent or non-existent. Some patients present with amenorrhea, such that discussion of contraception may be overlooked. All respondents reported that a tool to aid in gynecologic referral and/or medical contraception would be beneficial. While adult VAD recommendations include counseling regarding birth control and pregnancy prevention, there is no recommendation for method of contraception. No pediatric guidelines currently exist. Results from our pilot survey suggest that collaboration with gynecology to develop guidelines regarding contraceptive use in VAD patients is warranted. We now aim to disseminate the survey to additional pediatric and adult VAD programs to further define gaps and better inform guideline development.

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Missed Opportunities To Study The Association Of Female Sex With Aortic Insufficiency in LVAD Patients: A Systematic Assessment Of Observational And Preclinical Studies

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Study: Left ventricular assist device (LVAD) is associated to a 1-year survival of 80% but also to higher rates of deaths and re-hospitalizations, specifically in patients with aortic insufficiency (AI). Although it has been reported since 2004, the reason why female sex is a risk factor for AI in LVAD is still not well understood. Here we reviewed preclinical studies of LVAD and systematically assessed female representation in observational plus registry-based data of patients with LVAD.

Methods: EMBASE, MEDLINE, PubMed and CINAHL were searched for preclinical studies of LVAD carried since 2004. In addition, we retrieved clinical studies reporting on AI post LVAD.

Results: From 936 patient-related citations, 29 observational studies (2773 patients) showed comparable female representation (28.47% vs 22.2) to the INTERMACS interim report (10,603 patients between 2006-2016). Before resolution, inter rater agreement for study inclusion was 99.6% (κ=0.95). Incidence of de novo AI at 6 months varied from 5.5% to 68.8% using classical echocardiographic criteria. Out of 83 preclinical studies giving the number of animals used (including 52 with at least 5 animals), 71.1% did not mention the sex of the animal(s). Although more studies giving the number of animals used (including 52 with at least 5 animals), 71.1% did not mention the sex of the animal(s). Although more frequent in female patients post LVAD, current data from clinical and preclinical studies of LVAD are not specific enough to help further elucidate the relation between female sex and AI in LVAD.

Feasibility Of Online Estimation Of Systemic Vascular Resistance Using On-board LVAD Signals

Suraj Pawar, Masters, Engineering1; Ethan Rapp, Masters, Engineering2; Jeff Gohean, PhD3; Erik Larson, PhD2; Richard Smalling, MD2; Raul Longoria, PhD1; 1The University of Texas at Austin, Austin, TX, USA, 2Windmill Cardiovascular Systems, Inc., Austin, TX, USA, 3Cardiology Division, UT Health-Houston, Houston, TX, USA

Study: A method for estimating systemic vascular resistance (SVR) of heart failure patients with an implanted left-ventricular device (LVAD) is presented. LVAD systems able to estimate flow rate and differential pressure can adopt this ad hoc approach to track changes in SVR without additional sensors. Model simulations and hybrid mock circulatory loop experiments (hMCL) are used to demonstrate the approach. These experiments use a cardiovascular system model with known physiological parameters, thereby allowing a basis for evaluating the accuracy of the algorithms.

Methods: To enable online implementation, a simplified two element Windkessel model is used to define an ad hoc SVR estimate in the form, $SVR_{est} = \left[ \sum (-\Delta P + PLVp) \Delta t \right] / \left( Cs(\Delta P_f - \Delta P_o) + \sum Qvad \Delta t \right)$, using available systemic compliance, Cs, and passive left ventricle pressure, PLVp, are systemic compliance, Cs, and passive left ventricle pressure, PLVp, are systemic compliance, Cs, and passive left ventricle pressure, PLVp, are initially tuned to match a known SVR in simulations or adjusted to a physiologically expected value in testing, without significant error if the ad hoc measurement is performed during diastole. LVADs able to synchronize with the cardiac cycle using ECG signals can ensure pumping occurs during diastole (counter-pulse mode) while SVR estimates are made. Fig 1 shows how the ad hoc measurement tracks the preset SVR value during a mock loop experiment.

Results: The proposed ad hoc measure can predict SVR with an accuracy of 4.7% (R^2 = 0.99) and 6% (R^2 = 0.83) during simulations and hMCL experiments, respectively. Fig 2 summarizes results for the latter case. The ad hoc measurement relies only on data provided by the LVAD system, and can be used for online and remote diagnostics of LVAD patients. Ongoing work is evaluating this method using data collected from acute animal experiments, allowing ad hoc measurements to be compared to SVR estimates based on the classical relation, $SVR = (MAP-CVP)/CO$, which relies on invasive measurements.
A Case Of Recurrent *Serratia Marcescens* Endocarditis In Native And Bioprosthetic Mitral Valves

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**Study:** *Serratia marcescens* is a known cause of native valve endocarditis (NVE). It is an uncommon cause of infectious endocarditis (IE), and can be challenging to treat. We describe a case of a recrudescence of *S. marcescens* IE in a bioprosthetic mitral valve 3 months after valve replacement surgery for NVE. We explore the challenges of treating *S. marcescens* in an intravenous drug use (IVDU) patient.

**Methods:** Clinical management of a 41 year old Caucasian female with an IVDU history who was diagnosed with *S. marcescens* NVE in December 2019, treated with antibiotics and mitral valve replacement but developed *S. marcescens* prosthetic valve endocarditis (PVE), was documented over the course of her multiple hospitalizations and compiled into a case report. We conducted a systematic search of PubMed, Sciedirect and Google scholar for articles on *S. marcescens* IE. We extracted and synthesized data on circumstances, treatment and patient outcomes and tabulated our findings to explore antibiotic resistance in the context of our patient. Our search included the following terms within the title, abstract and author keywords: “Serratia marcescens”, “infective endocarditis”, “recurrence”, “IVDU” and “prosthetic mitral valves”. We had no start date or country requirements and limited our search to papers in English. Our search included case reports, case series, original studies and letters of correspondence reporting small clinical studies.

**Results:** Following multiple courses of treatment including 6 weeks of Cefepime, mitral valve replacement and tricuspid annuloplasty with 4 weeks of Ciprofloxacin and Gentamicin post-MVR, 6 weeks inpatient treatment with Ciprofloxacin and Ertapenem and finally 6 weeks of oral Ciprofloxacin, the patient passed away. Our literature review explored *Serratia*s ability to affect left-sided heart valves, its virulence, antibiotic sensitivity and difficulty to treat in PVE in IVDU patients given the current opioid crisis.

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Potential Of Medical Management To Mitigate Suction In LVAD Patients

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**Study:** Ventricular suction can be due to multiple underlying pathophysiological conditions. Aim of this study is to analyze the potential of different therapeutic interventions to mitigate suction in different pathophysiological conditions.

**Methods:** A suction module (SM) consisting of a compliant latex tube was embedded in a cardiovascular hybrid (hydraulic-computational) simulator. The SM mimics the ventricular apex, it is connected on one side to a hydraulic chamber reproducing left ventricular flows, and on the other side to a HeartWare HVAD system (Medtronic). Starting from a patient profile with severe dilated cardiomyopathy, 4 different pathophysiological conditions leading to suction were simulated: hypovolemia (~900 mL), right ventricular failure (contractility -70%), vasodilation (8.3 Wood Units), and tachycardia (185 bpm). Once suction was obtained, different interventions (blood volume infusion (Vol+), right ventricular contractility increase, systemic vasoconstriction, heart rate increase, and pump speed reduction) were simulated and compared in terms of general hemodynamic.

**Results:** Each intervention elicited a different effect on the hemodynamic for every pathophysiological condition. Pump speed reduction mitigated suction but did not ameliorate the hemodynamic. Vol+ was the most efficient in mitigating suction and increasing the cardiac power. The measured cardiac powers in the conditions of hypovolemia, right ventricular failure, vasodilation and tachycardia when simulating Vol+ increased respectively by 38%, 25%, 42%, and 43%. In conclusion, VAD patient management should be carefully evaluated since suction is strictly related to the underlying physiological patient condition. Identifying the right therapeutic intervention can result in a better hemodynamic outcome than that obtained by simply decreasing the pump speed.

**Acknowledgements:** The study was supported by an FWO project 1SD0321N and by an internal KU Leuven C3 project C3/20/033
**EPCardiac49**

Real-time Visualization Of Thrombus Formation In An Extracorporeal Membrane Oxygenator Using Indocyanine Green Fluorescence

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**Study:** During extracorporeal membrane oxygenation, thrombi in a membrane oxygenator can cause embolisms and oxygenator performance deterioration. Hence, anticoagulation therapy is required, although it causes bleeding. Real-time thrombus visualization may be effective in preventing these complications. This study demonstrated a novel method to visualize thrombi in a membrane oxygenator using indocyanine green (ICG) fluorescence imaging.

**Methods:** ICG is a cyanine dye used in various medical fields. It binds to proteins in blood and is excited by 750-800-nm light and emits infrared light with a central wavelength of 840 nm. The ranges of absorption and excitation wavelengths are slightly affected by hemoglobin and water absorption. The high spectral sensitivity of the absorbed and exciting light enables to obtain blood information. Moreover, ICG can be repeatedly administered because of its half-life of 3-4 min. To verify the efficacy of ICG fluorescence, animal experiments were conducted in pigs equipped with an extracorporeal circuit comprising a centrifugal pump (CAPIOX SL) and oxygenator (QUADROX-i). ICG was administered hourly and observed using a dedicated optical detector (PDE-neo). The fluorescence images of the oxygenator were compared with eye observations before and after rinsing with regular saline.

**Results:** The figure shows ICG fluorescence images (A, B) and eye observations (C, D) of the oxygenator. The fluorescence image (B) revealed the thrombi as black areas in the oxygenator 8 h after initiation. The areas were similar to those detected by eye observation after rinsing with saline (D). ICG fluorescence imaging is feasible to visualize thrombus formation in a membrane oxygenator in real time. Thrombus visualization may lead to the prevention of complications and optimization of anticoagulant therapy in clinical situations and may be efficient in evaluating device antithrombogenicity at the research and development stage.

**EPCardiac50**

The Effects Of LVAD Pump Speed On Coronary Perfusion: Reanimated Heart Studies

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**Study:** Left ventricular assist devices (LVADs) are implanted in patients who require support to maintain adequate systemic perfusion. While pump flows and systemic perfusion have been studied clinically and preclinically, few studies have assessed the relative impact of LVAD settings on coronary blood flow, despite potential for future LVAD designs to use dynamic speed changes. This preliminary study was performed to assess the impacts of LVAD speed change on coronary perfusion with varied heart rates using a healthy reanimated swine heart model.

**Methods:** The Visible Heart laboratories has developed in vitro methodologies that preserve cardiovascular system behavior while simultaneously testing complex cardiac devices. One swine heart was reanimated via perfusion with a modified Krebs-Henseleit buffer; viscosity was 2.7 cP. Medtronic’s HeartWare HVAD was implanted, and temporary pacing leads were placed to control heart rate. Flow data was collected from the outflow graft and descending aorta for three heart rates (sinus rhythm, 100 BPM, and 120 BPM) for three pump speeds (2800, 3200, and 3600 RPM).

**Results:** Average coronary flow increased 14.2-16.1% (0.20-0.23 L/min) when pump speed increased from 2800 RPM to 3600 RPM, though pulsatility of coronary flow lessened as speed increased. Compared to pacing at 100 BPM, pacing at 120 BPM increased average coronary flow by 9.0-9.6% (0.05-0.14 L/min) for pump speeds 2800 and 3200 RPM, but had no impact for 3600 RPM. In the case presented, there was likely no clinically relevant impact to coronary flow with speed changes, but additional testing with a heart failure model and a wider range of pump speeds is needed for additional clarity.
EPCardiac51

Evaluation Of Four-Factor Prothrombin Complex Concentrate Use For Intracranial Hemorrhage In Patients With Durable Left Ventricular Assist Devices

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Study: The literature surrounding management of intracranial hemorrhage (ICH) in patients with left ventricular assist devices (LVAD) is limited, and safety and efficacy of using 4-factor prothrombin complex concentrate (4F-PCC) to reverse international normalized ratio (INR) in this cohort is not well known. The purpose of this evaluation is to describe an experience of using 4F-PCC for reversal of INR for ICH in patients with durable LVADs.

Methods: We performed a retrospective chart review of adult LVAD patients who received 4F-PCC for INR reversal for ICH. The 4F-PCC dosing at our institution is INR-based in concordance with the package insert recommendation. Demographic data, medication data, and clinical information within 90 days after reversal were recorded. The primary outcome was successful reversal of INR to less than 1.5.

Results: A total of 15 cases of ICH in LVAD patients in which 4F-PCC was administered were identified and reviewed. Of these patients, 14 (93.3%) received vitamin K at the time of reversal. The mean INR prior to reversal was 5.9 and 8 (53.3%) patients were successfully reversed after 4F-PCC. The mean 4F-PCC dose was 33.3 units/kg and the median time from head CT scan to initiation of 4F-PCC was 122 minutes (IQR 50-204). On repeat head CT after reversal, 6 (40%) patients had no change in the size of bleed while 9 (60%) patients had expansion of their bleed. In-hospital mortality was recorded in 8 (53.3%) patients, and of those who survived to discharge, 5 (71.4%) patients had neurologic deficits, 5 (71.4%) patients were alive at 3 months, and there were no incidences of thrombotic events. In conclusion, although INR was significantly lower in patients after receiving 4F-PCC, only 53.3% of patients were considered successfully reversed. Administration of 4F-PCC appears to be safe in regards to sparing LVAD patients from thrombotic events after reversal.

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<th>Table 1. Baseline Characteristics</th>
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EPCardiac52

Panel-reactive Antibody Results Prognosticate Mortality And Graft Survival After Heart Transplantation: A National Study Using The UNOS Database

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Study: Panel-reactive antibody (PRA) screening is routinely performed prior to heart transplantation (HTx) and is important for the measurement of sensitization. We assessed the use of PRA for risk stratification after HTx using the United Network for Organ Sharing (UNOS) Standard Transplant Analysis and Research Database.

Methods: We retrospectively reviewed heart transplants performed from January 2004 to September 2020. Multi-organ transplants and re-transplants were excluded from analysis. Most recent PRA Class I and Most Recent PRA Class II were used as other measures of PRA were missing in at least two-thirds of the sample. Patients were stratified into three groups: (1) No PRA (PRA% = 0), (2) Some PRA (PRA% >0 and <50), and (3) High PRA (PRA% >50). Survival curves were calculated using Kaplan-Meier analysis and compared by log-rank test and Cox proportional hazard model.

Results: A total of 41,537 patients were included in this study. When stratifying based on Most Recent PRA Class I, the Some PRA and High PRA groups had significantly worse survival (HR 1.14, 95% CI 1.1 - 1.2 and HR 1.24, 95% CI 1.1 - 1.4, respectively) and graft survival (HR 1.13, 95% CI 1.1 - 1.2 and HR 1.24, 95% CI 1.1 - 1.4, respectively) compared to the No PRA group (p <0.0001 for all). When using Most Recent PRA Class II, the Some PRA and High PRA groups similarly had worse survival (HR 1.14, 95% CI 1.1 - 1.2 and HR 1.24, 95% CI 1.1 - 1.4, respectively) and graft survival (HR 1.13, 95% CI 1.1 - 1.2 and HR 1.24, 95% CI 1.1 - 1.4, respectively) compared to the No PRA group (p <0.0001 for all). Our results suggest that PRA status is predictive of long-term outcomes post-transplant. Further, prospective studies should be conducted to investigate the utility of PRA for risk stratification, accounting for possible confounders.

Figure 1. Freedom from Epistaxis by INR at Discharge

EPCardiac53

Predictors Of Epistaxis In Patients With Left Ventricular Assist Devices

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Study: Patients with left ventricular assist devices (LVADs) are at a high risk for epistaxis due to the use of anticoagulation and the development of acquired von Willebrand syndrome (avWS). This adverse event is frequently recurrent and a common source of emergency department visits. We evaluated various risk factors for their potential to predict epistaxis occurrence after LVAD implantation.

Methods: We retrospectively reviewed 103 LVAD patients implanted at our center from 2015-2020. Various baseline characteristics were collected, including whether a patient’s INR at discharge and event were in therapeutic range (2-3). Univariate and subsequent multivariate analyses were conducted to determine independent predictors of epistaxis occurrence.

Results: In total, 33 (32%) patients developed epistaxis. Out of range INR at discharge (OR 4.13; 95% CI 1.75-10.14), fall implant (OR 3.5; 95% CI 1.05-12.7), and HeartWare HVAD usage (OR 2.56; 95% CI 1.07-6.27) were significant risk factors in univariate analyses (p <0.05 for all). In the multivariate analysis, out of range INR at discharge emerged as an independent predictor of epistaxis occurrence (OR 3.49; 95% CI 1.39-9.06; p = 0.009). In patients with epistaxis, INR at event did not significantly differ from INR at discharge (p = 0.3). 25 (76%) patients with epistaxis had recurrent events. Those who had an event ≤ 20 days post-implantation were at an increased risk for recurrence when adjusting for age (OR 12.56; 95% CI 1.59-295.5; p = 0.04). The lack of a significant change in INR from discharge to time of event suggests that INR at discharge may be useful for risk stratification regarding propensity for epistaxis. Particular attention should be given to patient who present with epistaxis ≤ 20 days post-implantation due to their increased likelihood of recurrence. Further multi-center studies should be conducted to corroborate these findings.
A Review Of Intra-aortic Balloon Pump Mortality And Morbidity In Randomized Controlled Trials

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Study: Intra-aortic balloon pump (IABP) applications have steadily decreased worldwide since the publication of the IABP SHOCK II Trial, which indicated that there was no significant benefit in post-operative mortality and morbidity indices for patients with acute myocardial infarction (AMI) complicated by cardiogenic shock (CS) when supported by IABPs. A systematic search of literature was performed to investigate whether these results were an outlier or consistent with other randomized controlled trials reported in literature.

Methods: Publications were drawn from the Scopus, PubMed and Web of Science databases and, in accordance with the PRISMA guidelines, weighed against inclusion and exclusion criteria. Sixteen publications were included in this analysis that reported both mortality and morbidity indices. Once data on the statistical significance of mortality and morbidity had been reported on, additional studies on device cost-effectiveness were viewed to determine the economic benefit of IABPs.

Results: A total of four studies included in this systematic review reported a significant decrease in short- and/or long-term mortality in patients randomized to receive IABP insertion, with one of these four trials reporting a significant decrease in short-term mortality (28 control mortalities vs 15 IABP, P < 0.05) for patients with complicating CS. Some improvements in patient morbidity indices were noted in a total of six studies (P < 0.05), with IABP found to stabilize patients intra- and post-operatively, with one study reporting improvements in both mortality and morbidity. One of the studies reporting morbidity benefits also noted a significant increase in minor bleeding associated with IABP insertion. Seven studies reported no results of statistical significance associated with IABP utilization. It can be determined that IABP insertion has ambiguous benefit on mortality and morbidity indices in critical AMI patients.
Seasonal Trends In Donor Heart Availability - An Analysis Of The UNOS Database

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Study: Despite the widespread belief that donor organ availability varies around holidays and with seasons, there is little empiric data supporting this long-held belief. Variations in donor heart availability may be of interest to patients and clinicians in determining transplant listing strategies, such as left ventricular assist device patients with 30 days of enhanced status time (EST). We sought to identify any meaningful differences in organ availability based on calendar trends.

Methods: The UNOS/OPTN registry was queried and data for all heart donations from October 1987 through March 2017 was abstracted and analyzed. Monthly heart donation rates were modeled using Poisson regression including month (categorical) and a spline term for year. Daily heart donation rates were modeled using cosinor Poisson regression, assuming a 12-month seasonal period. The holiday effect was assessed using conditional logistic regression.

Results: Seasonal plots suggest a significant, although modest, increase in organ availability during the summer months, except for region 1. The regions with the highest amplitude were region 7 (peak: July 20th, amplitude: 13.7%) and region 6 (peak: July 4th, amplitude: 11.1%). There was no significant difference in the odds of heart donation when comparing holidays vs. non-holidays using national data (odds ratio [95% CI]: 1.00 [0.97, 1.03], p = 0.99) or any regional subsets. There was no observable correlation between donor heart availability and holidays. However, a significant seasonality effect was observed with higher donation rates occurring during warmer months. These findings shed objective light on previously held anecdotal trends and may add another consideration to end-stage heart failure patients being evaluated for heart transplantation listing.

Platelet: Lymphocyte Ratio And Cardiac Recovery Post Left Ventricular Assist Device Placement

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Study: The platelet: lymphocyte ratio (PLR) is a novel prognostic marker is associated with poor outcome in heart failure. However, its significance & impact in patients with left ventricular assist devices (LVAD) has not been explored. We systematically investigated the impact of PLR on adverse events, recovery to explant, and all-cause mortality in this population over a 24-month period post LVAD implantation.

Methods: Study population of 177 patients received LVAD therapy between June 2011 and October 2018. No patients were excluded. PLR were divided into tertiles (<150; n=42, 150-300; n=84, and > 300; n=42) based on preoperative levels. Adverse outcomes were compared using Fishers exact test. The association between the PLR and 24-month mortality was examined via unadjusted and adjusted cox regression models. A Kaplan-Meir plot and log-rank statistics were used to compare survival across patient groups.

Results: The mean age across groups was 60 with up to 35% females. Patients with PLR > 300 had a greater use of intra-aortic balloon pump (30 and 21 vs. 34%, p<0.04) and ≥ two inotropes at admission (20 and 15.5 vs. 43%, p<0.05). This group also had a significantly lower baseline hematocrit (39.5 and 37.1 vs. 33.8, p<0.001). 24-month survival (Log-Rank p<0.29) and adverse events were equally distributed. There was no difference in mortality seen on either the unadjusted or adjusted modeling among tertiles [PLR 1 vs 2, HR 1.05 (0.50-2.22); p=0.73 and adjusted HR 1.05 (0.49-2.23); p=0.81] and [PLR 2 vs 3, HR 1.42 (0.66-3.04); p=0.39 and adjusted HR 1.34 (0.60-2.98); p<0.50]. However, recovery to explant of LVAD was seen in 14 patients with PLR 150-300 compared to only 1 and 2 patients in the 1st and 3rd tertiles respectively, p<0.02. PLR represents global burden of inflammatory and thrombosis cascades. A preoperative PLR ratio between 150-300 may help identify and target patients with maximal medical therapy to facilitate ventricular recovery.
EPCardiac58

In Vitro Evaluation Of A Newly Designed Bicuspid Pediatric Pulmonary Heart Valve
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Study: To evaluate the hemodynamics of a newly designed conduit with a bicuspid valve (figure) under the hydrodynamic conditions found in pediatric pulmonary circulation, in a simulation study.

Methods: The bicuspid polytetrafluoroethylene valves we developed are constructed from a cusp made of a 0.1-mm expanded polytetrafluoroethylene (ePTFE) sheet with a posterior central fixation of the free edge (Nunn et al. 2008) to provide a wide coaptation zone consisting of the cusp and a graft (figure). The new bicuspid valve also has a bulging sinus to reduce the regurgitant flow and a micro-pore on the cusp ensure the regurgitant flow for the prevention of thrombogenesis. We used a pediatric pulmonary mock circulation system consisting of a right ventricular chamber, a reservoir tank, and a resistor. We determined the hemodynamic characteristics of the ePTFE conduit along with those of the ePTFE tricuspid-valved conduit we use at our institute (14-mm dia.; the T conduit, n=3), the newly designed conduit (14-mm dia.) with a bicuspid valve (B conduit, n=3) and an ePTFE graft (22-mm dia.) with Magna EASE (19-mm dia.; M conduit, n=3). We used two pressure transducers and a ultrasonic flowmeter to measure the transvalvular pressure gradient and regurgitant flow ratio at heart rates (HR) of 100, 120 and 140/min.

Results: The transvalvular pressure gradients of the T, B, and M conduits were 13.0, 8.6, and 4.6 at HR100, 15.9, 9.6, and 8.1 at HR120, and 17.3, 11.2, and 9.2 at HR140, respectively. The transvalvular pressure gradient of the B conduit tended to be lower than that of the T conduit (p=0.218). The regurgitant flow ratios of the T, B, and M conduits were 18.1, 15.7, and 14.7 at HR100, 15.9, 14.5, and 14.7 at HR120, and 14.4, 13.7, and 14.8 at HR140, respectively. The regurgitant flow ratio of the B conduit tended to be lower than that of the T conduit (p=0.286) and equal to that of the M conduit.

EPCardiac59

Evaluating Long Term Outcomes Of Palliative Inotropes In End-stage Heart Failure Patients
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Study: Inotrope therapy is frequently used as a palliative option for patients with end stage heart failure who are not deemed candidates for durable advanced heart failure therapies. With the advent of improved medical therapy, early intervention, and the use of devices, the impact of inotropes on survival may be more significant than earlier reported. We aimed to evaluate the impact of palliative inotrope therapy on patient survival and outcomes over an extended period.

Methods: We retrospectively assessed 224 patients within our center with ACC/AHA stage D heart failure who were discharged with palliative inotrope therapy after January 1, 2010. Patients who underwent mechanical circulatory support (MCS) or those who underwent heart transplant were excluded. Statistical analysis was completed using univariable analysis in SAS software.

Results: Demographics, comorbidities, medications, and devices are listed in the Table. 86.6% of patients were discharged with milrinone and 21.4% on dobutamine. The average duration on therapy was 168 (53-387) days. Average number of hospitalizations within 2-years was 1 (0-3), and average number of clinic visits at 3, 6, and 12 months were 2 (0-3), 3 (0-6), and 4 (1-11), respectively. 4.5% of patients were found to have PICC line infections and 9.8% had new arrhythmias. 6-, 12-, and 24-month survival were 63.1%, 53.1%, and 41.9% respectively (see figure for product limit survival estimate). Palliative inotrope therapy shows modest survival benefit in conjunction with other advanced heart failure interventions.
Berlin Explantation In An Infant With Refractory Chaotic Tachycardia

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**Study:** Berlin Heart ventricular assist device (VAD) explanation in children is uncommon. There is limited data on selection of suitable candidates and systematic approach to pediatric VAD explanation. We report a case of VAD explant in an infant with tachycardia-induced cardiomyopathy (TIC).

**Methods:** A 3 month-old presented to the emergency department in cardiogenic shock. Heart rate on arrival was 250 beats/min and electrocardiogram revealed narrow complex tachycardia that was resistant to multiple antiarrhythmics. Echocardiogram (ECHO) showed severely dilated left ventricle (LV) with severely decreased function. Cardiac decompensation led to placement on veno-arterial extracorporeal membrane oxygenation and subsequent Berlin VAD implantation. He was listed for heart transplant as he continued to have refractory arrhythmias. While awaiting heart transplant, serial ECHOs showed recovery of LV function and VAD explanation was discussed. We followed our newly developed protocol that consisted of two phases. First trial-off was conducted with manual pumping of the VAD at 3/min with ECHO imaging. One week later, second trial-off in the catheterization suite with manual pumping at 3/min showed no differences in hemodynamics. Data obtained met our established criteria to undergo explant. Explant was performed the next day, after 142 days of VAD support. Patient was discharged two weeks later on triple antiarrhythmic regimen and was well when seen for follow up in our clinic.

**Results:** We established guidelines for trialing off VAD support to optimize screening and explant success in potential candidates. VAD explant is feasible in young infants.
**EPCardiac61**

**Successful Use Of VA-ECMO Without Systemic Anticoagulation In The Management Of Cardiac Arrest Secondary To Amniotic Fluid Embolism**

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**Study:** Amniotic fluid embolism (AFE) is a catastrophic complication of pregnancy, associated with cardiovascular collapse, respiratory failure, coagulopathy, and a high mortality rate. The use of venoarterial extracorporeal cardiopulmonary resuscitation (VA-ECMO) in the management of AFE remains controversial.

**Methods:** 29-year-old healthy G1P1 presented at 39+0 for elective induction of labor. She was given misoprostol and went into active labor, though started feeling presyncopal and fetal bradycardia was noted. She was taken for emergent Caesarean section and suffered profound peri-procedural hemorrhage and ultimately VT arrest. Bedside ultrasound was suggestive of acute cor pulmonale, and a presumptive diagnosis of AFE was made. Per hospital eCPR protocol, she was cannulated with VA-ECMO by an interventional cardiologist (via 17Fr femoral arterial and 23Fr femoral venous cannulas). Given her coagulopathy, no systemic anticoagulation was used at the time of cannulation or during ECMO support and a modified therapeutic hypothermia protocol was utilized. Her hemodynamics improved rapidly and she was decannulated within 48 hours, though she remained comatose. Brain imaging revealed scattered ischemic and hemorrhagic strokes, but no evidence of a significant anoxic injury. Supportive care was continued and she ultimately began to show neurologic and physical improvement and was discharged to rehab on hospital day 25 and home on day 29 with minimal deficits.

**Results:** Our case suggests the use of ECMO without systemic anticoagulation can be a successful strategy for hemodynamic support in patients with AFE.

**EPCardiac62**

**Thoracoabdominal Normothermic Perfusion In Donation After Circulatory Determined Death**

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**Study:** Donation after circulatory death (DCD) is emerging as an alternative pathway to traditional donation after brain death (DBD) in expanding the pool of cardiac allografts available for transplantation. Evidence suggest improved outcomes and decreased complication rate for abdominal organs transplanted after a short period of donor in-situ reperfusion compared to ultra-rapid recovery. Compared to ex-situ perfusion platform, it also enables a functional assessment of cardiac allografts before transplantation.

**Methods:** We describe our experience with both cardiopulmonary bypass (CPB) and veno-arterial extracorporeal membrane oxygenation (VA ECMO) in experimental as well as clinical setting of cardiac allograft recovery after a variable period of warm ischemia in donors after circulatory determined death. Technical aspects (cannulation technique, need for left ventricular vent), management considerations (anticoagulation, composition of a priming solution, physiologic targets on support and after weaning), logistical challenges (in-house versus distant procurements) of both techniques are described in detail.

**Results:** Based on our experience the use of CPB is superior to VA ECMO in DCD NRP organ recovery. The advantages of CPB are: better cardiac decompression during mechanical support, ability to return blood from the surgical field and lower cost. The strategies to overcome the shortcomings of VA ECMO are: left ventricular venting, donor transfusions with banked blood, using non-proprietary components of VA ECMO circuit. Conclusions: Employing various strategies to address limitations of VA ECMO in DCD NRP, this technique could be safely use in instances when CPB is not available.
**EPCardiac63**

Hemodynamic Effects Of Integrating Compliance In The Design Of An Artificial Lung: Assessment With A Hybrid Simulator

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**Study:** To assess the hemodynamic effects of an artificial lung (AL) with fiber-bundle-integrated compliance (RAS-Q® technology) implanted between pulmonary artery (PA) and left atrium (LA).

**Methods:** A hybrid cardiovascular simulator was used, including a model of atrial, ventricular, pulmonary and systemic circulation. The simulator was adapted to reproduce 4 pulmonary hypertension (PH) profiles: mild, moderate, severe and cardiogenic shock. A RAS-Q prototype was connected between the simulated PA and LA. For each profile, the hemodynamic effects of this prototype with and without integrated compliance were assessed in terms of pressures, flows and right ventricular (RV) volumes.

**Results:** Results are reported in the table and figure for the severe PH profile, as an example. The introduction of RAS-Q with disabled compliance led to an increase of arterial blood pressure and cardiac output in all PH profiles as well as a decrease in central venous pressure, peak RV pressure, end-diastolic volume, and pressure-volume area. Additionally, an increase in stroke work and RV power was observed in the severe PH and cardiogenic shock profiles. Enabling the integrated compliance in this RAS-Q prototype amplified these hemodynamic and ventricular energetic improvements even further, which came into their own in a severe PH status. In conclusion, RAS-Q technology exhibits a compliance integrated completely within the fiber bundle of an AL. This innovative RAS-Q prototype, when tested in a PA-LA configuration results in improved organ perfusion, RV unloading, and RV recovery for different stages of PH. The integrated compliance elicits more pronounced improvements compared to an equivalent AL without compliance. Our results support applying this strategy in the severe PH status before cardiogenic shock emerges.

<table>
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<th>Hemodynamics</th>
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**EPCardiac64**

Assessing The Effect Of Blockage On Blood Flow In A Heart-lung Machine (ECMO) Using A Computational Hemodynamic Model

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**Study:** Clot formation within the ECMO (heart-lung machine) circuit is a common complication and the current methods for monitoring for such blockages have limitations. It is hypothesized that the flow in a small shunt tube in the ECMO circuit (through which a small amount of blood flow is redirected to the pump and used for blood access) will be affected by oxygenator clotting or other obstructions in the veno arterial ECMO (VA-ECMO) circuit. The goal of this study is to test the hypothesis that blood flow rates in the shunt could be used to monitor for circuit obstructions using a computational model of the VA-ECMO system.

**Methods:** A computational hemodynamic lumped parameter model (CHLPM) representing the blood flow within both the VA-ECMO circuit and native cardiovascular system (including both right and left heart, systemic and pulmonary circulations) was used for a comprehensive hemodynamic parametric analysis. The pressures and flow rates at several critical locations (ECMO pump, oxygenator inlet and outlet etc.) along the ECMO-patient circuit were investigated for various levels of ECMO support (2 - 5 L/min). Several degrees of obstructions within the oxygenator and inlet and outlet cannulas were simulated, and the flow in the shunt was monitored in each case to assess its sensitivity to circuit obstructions.

**Results:** We simulated a range of oxygenator blockages (from 10% - 50%), and demonstrated that shunt flow increased linearly with increasing oxygenator obstruction for each ECMO flow rate tested. Similar correlations were established between shunt flow and inflow / outflow cannula blockage. The findings are consistent with our hypothesis, indicating the sensitivity of the blood flow rate in the shunt as a hemodynamic predictor of VA-ECMO circuit obstructions. Further, the CHLPM simulated realistic flows in the ECMO circuit and hence can be used for further interrogation of other aspects of the ECMO circuit such as oxygenator, cannula, and pump characteristics.

![Figure 1](image-url)
Continuum Model Simulation Of VWF Unfolding In A Cross-slot Extensional Flow Microchannel
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Study: von Willebrand Factor (vWF) has been established as the primary mediator of high-shear thrombosis. Bleeding events in LVAD patients have been linked to the loss of large-molecular-weight vWF. Both vWF binding to collagen/platelets and its mechanoenzymatic cleavage are preceded by the unfolding of collapsed vWF chains. Therefore, it is essential to account for the state of these multimers in modeling thrombosis or vWF degradation. This study isolates the vWF component of our multi-constituent model of thrombosis and examines vWF subjected to planar extensional flow. The model predicts vWF unfolding in response to extensional flow kinematics with literature-derived unfolding thresholds.

Methods: The flow was simulated in a cross-slot microfluidic channel by Alves (2008) where the geometry was optimized to obtain a homogeneous elongation rate around the stagnation point spanning the orthogonal flow axes. vWF was modeled as two interconvertible scalar species representing its two conformational states: collapsed, vWF\(_{c}\), and stretched, vWF\(_{s}\). The inlet BCs and domain initial concentrations were prescribed as \([vWF_c]=1000\, \text{nmol/m}^3\) and \([vWF_s]=0\). vWF collapsed-to-stretched transition takes place if the local flow type parameter and Weissenberg number (Wi) exceed the critical values for unfolding.

Results: The cross-slot geometry and the simulated flow field are shown in Figure 1(A). The device creates near-perfect extensional kinematics along the flow axes and in the region surrounding the central stagnation point. Flow type \(\lambda = 1\) corresponds to purely extensional kinematics, 0 is simple shear, and -1 is pure rotation. Wi is scaled by the square root of flow type and induces vWF unfolding in the extension-dominated regions. The resulting concentration of the stretched vWF\(_s\), shown in Figure 1(C), peaks along the outflow axis and resembles a typical polymer birefringent strand produced in cross-slot extensional rheometers.

Mechanical Circulatory Support As A Bridge To Transplant Candidacy: When Does It Work?
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Study: Durable mechanical circulatory support (dMCS) devices can be offered as a bridge-to-transplant (BTT) strategy for candidates awaiting a donor heart, or as a bridge-to-candidacy (BTC) strategy for candidates with contraindications to transplant listing, including pulmonary hypertension (BTC-PH), morbid obesity (BTC-Obes), social issues (BTC-Soc), or chronic illness (BTC-Illness). In a BTC strategy, the dMCS device would provide time to allow resolution of the medical or social contraindications to transplant listing so that patients may ultimately undergo transplantation. The purpose of this study was to compare the outcomes of patients who underwent dMCS as a BTC strategy by induction to those who underwent dMCS as BTT. An understanding of the trajectory of BTC patients could guide future triage of advanced heart-failure patients who are not candidates for transplantation.

Methods: We performed a retrospective review of hospital medical records and identified all patients who underwent dMCS implantation as either BTT (206 patients) or BTC (114 patients) from January 1st, 2010 through March 31, 2020. Clinical characteristics and post-transplant outcomes were compared.

Results: There was no significant difference in mortality between BTC patients and BTT patients. Compared with the BTT group, significantly more patients in the BTC-PH group were transplanted (81% vs 63%, p<0.05) and significantly fewer patients in the BTC-Obes group (44%, p<0.05) and BTC-Soc group (39%, p<0.05) were transplanted. Additionally, the readmission rate was higher for those in the BTC-Obes (3.42 vs 1.88, p<0.05), BTC-Soc (6.04, p<0.05), and BTC-Illness (3.93, p<0.05) groups. Overall, BTC patients generally had poorer post-dMCS trajectories than BTT patients. Centers should not be dissuaded from pursuing a BTC strategy for qualified patients; however, careful consideration of potential adverse outcomes as part of a shared decision-making strategy is necessary.
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Platelet Receptor Glycoprotein Shedding In Patients Supported By Left Ventricular Assist Device: A Comparison Between HeartMate 3 And HeartWare HVAD Recipients

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Study: This study quantified and compared temporal changes in platelet-receptor-glycoprotein (PRG) shedding in two current generation continuous-flow left ventricular assist device (CF-LVAD) recipients. We also identified and compared short-term postoperative bleeding complications in those patients.

Methods: We enrolled 24 subjects into three groups; (i) non-heart failure control group (n=8), heart failure patients undergoing (ii) HeartMate3 (HM3) (n=8) and (iii) HeartWare HVAD (n=8) implantation. PRG shedding was measured for GPIbα (vWF receptor), GPVI (collagen receptor) and GPIIbIIIa (fibrinogen receptor). PRG shedding was quantified pre-implant (baseline) and weekly for 4 weeks post-implant in platelet free plasma samples. Patients were evaluated for any bleeding events within 4 weeks post-implant.

Results: At baseline, no significant differences in PRG shedding were observed between the non-heart failure controls, HM3 and HVAD patients (Fig.1A-C). Interestingly, the two patients with higher baseline PRG shedding were the only ones to experience post-operative bleeding. The patient implanted with the HVAD bled on POD 13 and the HM3 patient bled on POD 25 (Fig.1A-C). PRG shedding of GPIbα and GPVI increased at 1 week post-implant, but subsequently returned to baseline by 4 weeks in both types of CF-LVAD recipients. HVAD showed significantly higher shedding at 2 weeks post-implant compared to HM3 (Fig.1D-E). The GPIIbIIIa receptor shedding was similar for both HM3 and HVAD recipients (Fig.1F). Patients with higher baseline PRG shedding may be more susceptible to postoperative bleeding, and based on these results, device selection may be particularly important considering the extent of GPIbα and GPVI shedding in the HVAD compared to the HM3.

Figure 2. Estimated cumulative incidence of death (Figure 2A) and transplant (Figure 2B) as a competing risk between D and C subgroups.

Figure 2A

Figure 2B

Figure 2C

Figure 2D

Figure 2E

Figure 2F
Midterm Outcomes Of Orthotopic Heart Transplantation Versus Left Ventricular Assist Device In Patients 70 Years And Older
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Study: The optimal treatment of end stage heart failure for elderly patients remains challenging. This study compares survival, complications and readmissions after orthotopic heart transplant (OHT) versus left ventricular assist device (LVAD) implantation in patients 70 years and older.

Methods: In a high-volume single center, we retrospectively evaluated all consecutive 70 years and older patients with end stage heart failure who underwent OHT or LVAD between February 2010 to May 2020 (n=119). In our study 88 patients (73.9%) underwent OHT, and 31 patients (26.1%) underwent LVAD implantation. Our primary endpoint was survival over a three-year period. Secondary end points included incidence of early (30 days) and late (>30 days) post-operative adverse events which included gastrointestinal (GI) bleeding, stroke, right ventricular failure, infection, renal failure, length of hospital stay and hospital readmissions.

Results: The LVAD group was significantly older, median age 74 years (interquartile range (IQR) 72 - 77) compared to the OHT group, median age 71 years (IQR 70 - 73), (p <0.0001). The OHT patients had shorter length of hospital stay, 11 (IQR 9-16) vs 30 (IQR 23-50) days, (p<0.0001). Early adverse events including infection, 5.7% (n=5) vs 13.3% (n=4); stroke, 5.7% (n=5) vs 6.6% (n=2); and renal failure requiring permanent dialysis 1.2% (n=1) vs 3.7% (n=1); were not significantly different between OHT and LVAD groups, respectively. The OHT patients had lower incidence of late infection, 12% (n=10) vs 42.3% (n=11); GI-bleeding, 3.6% (n=3) vs 8.2% (n=9); RV failure, 0% vs 13.3% (n=4) and freedom from hospital readmission (66% vs 42%), (p<0.05). Overall survival at 3 years was 83% (95% CI (73.6-90.2)) in the OHT group vs 60% (95% CI (40-76.1)) in the LVAD group, (p<0.01). Conclusion: As the population of patients 70 years and older with heart failure continues to grow, age should not be the sole criteria for exclusion for consideration of transplantation.

Outcome Of Percutaneous Hearmate3 Deactivation A Single Center Experience
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Study: To spotlight the role of percutaneous LVAD deactivation as a safe procedure after myocardial recovery in advanced heart failure patients, aiming to minimize the surgical risks of explantation. The HeartMate3 left ventricular assist device (Abbott, Chicago, IL) is designed to provide circulatory support with enhanced hemocompatibility for patients with advanced heart failure. Most VADs are used as a bridge to heart transplantation, however, in certain cases, myocardial function recovers and VADs can be explanted after the patient is weaned. While surgical explantation remained the gold standard, minimally invasive percutaneous deactivation has been described as a successful alternative. Within this study, we present our experience, one year outcomes, and adverse events of the percutaneous LVAD deactivation.

Methods: We conducted a retrospective review of the data of six consecutive patients underwent percutaneous LVAD deactivation.

Results: Six patients were enrolled into the study, with all of them completing at least six months after HM3 deactivation. No technical complications were documented. No strokes were observed within the study and the ejection fraction was improving. The mean follow up duration was 12.3±5.5 months and survival rate was 100%.

Conclusion: Percutaneous HM3 deactivation appears to be a safe alternative to surgical explanation as the survival after the procedure was 100% and no events, especially thromboembolic ones, occurred.
Comparing Postoperative Outcomes Between The Heartware HVAD And The HeartMate 3

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Study: Postoperative complications including stroke remain a leading cause of morbidity and mortality in patients supported with long term left ventricular assist devices (LVADs). Though the HeartMate 3 (HM3) and HeartWare HVAD (HVAD) are the most technologically advanced LVADs currently available, there is relatively little data comparing clinical outcomes for these devices. The present analysis seeks to describe clinical outcomes in a contemporary, non-clinical trial cohort of HM3 and HVAD patients.

Methods: This is a single center, non-randomized retrospective study which includes patients implanted with either a HVAD (n=41) or HM3 (n=36) during 2019 with a minimum follow-up of 1 year, concluding 12/31/2020. The primary endpoints were postoperative stroke, infection, arrhythmia, and hemolysis. The secondary endpoint was 1-year postoperative stroke-free survival.

Results: The rate of preoperative stroke or TIA was 24.4% in the HVAD group and 22.2% in the HM3 group, p=.082. There were no significant differences between preoperative clinical and demographic variables between the groups, with select parameters provided in Table 1. 30-day survival was 97% in the HVAD group and 100% in the HM3 group, p=1.0. There were no hemolysis episodes in the HM3 patients, compared to 0.94 events per patient year (EPPY) in the HVAD patients, p<0.001. Stroke occurred at a rate of 0.72 EPPY in the HVAD group and 0.32 EPPY in the HM3 group, p<0.001. Infection occurred at a rate of 1.23 EPPY in the HVAD group and 0.66 EPPY in the HM3, p<.001. Arrhythmia occurred at a rate of 1.69 EPPY in the HVAD and 0.90 in the HM3 group, p=0.001. Kaplan-Meier analysis indicated significantly improved stroke-free survival in the HM3 group, p<0.001 (Figure 1). Conclusions: Our study describes a predominantly destination therapy cohort with excellent early survival. There were higher rates of stroke, infection, arrhythmia, and hemolysis as well as reduced 1-year stroke-free survival in the HVAD group compared to HM3.
Impact Of LVAD Outflow Cannula Configurations On Blood Flow Characteristic - A Computational Study
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Study: Our current understanding of flow through the circulatory system in patients with left ventricular assist device (LVAD) remains incompletely understood. Here we investigate the impact of outflow cannula configurations on the aortic flow with an LVAD using a computational fluid dynamics (CFD), which allow for analysis of flow in the cardiovascular system.

Methods: A 3D anatomical model of the aorta with outflow cannula was reconstructed from multi-slice CT images in a patient supported by an LVAD. Using a lumped-parameter computational model of the patient’s circulatory system, including performance (HQ) curve of a HeartMate3, a patient-specific LVAD outflow was estimated and applied as inflow condition of 3D CFD analysis with the anatomical model. In total, 12 variations of the outflow cannula were included: 3 insertion points (original insertion point and its 2 cm proximal/distal locations), 2 cannula diameters (14 mm and 10 mm), and 2 insertion angles (45 and 90 degrees). CFD simulations were conducted to characterize the flow patterns.

Results: Maximum velocities in the aorta was 2.22±0.15 m/s (10 mm cannula) vs 1.12±0.10 m/s (14 mm cannula). This resulted in 56% larger blood volume exposed to abnormal shear rate (>1000 s⁻¹) for 10 mm cannula, compared to 14 mm cannula (0.97±0.38 ml vs 0.62±0.08 ml). The location of the insertion point defines the flow patterns in the aorta, and some combinations of the cannula configuration offers a unique benefit; 10 mm cannula inserted at low ascending aorta with 90-degree insertion produced a healthier ESS in the aortic root (1.38 Pa vs 0.38±0.17 Pa for all the other cases). The results suggests that a “sweet spot” of cannula configuration is possible and CFD could identify the ideal configuration for each individual patient.

EVAHEART 2 Left Ventricular Assist System With The Double-cuff Tipless Inflow Cannula Is Promising For Prevention Of Thromboembolic Events: Case Report
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Study: A 34-year-old man with fulminant myocarditis leading to asystole had received paracorporeal biventricular support for 4 months, and then he had undergone implantation of an EVAHEART 2 left ventricular assist system with the double-cuff tipless inflow cannula, not protruding into the left ventricle, and concomitant total cavopulmonary connection as an alternative right heart assist. His heart had remained in asystole during the entire support. Approximately 2 years after EVAHEART 2 implantation, he underwent heart transplantation. This is the first report of explanting the EVAHEART 2 with the double-cuff tipless inflow cannula. The purpose of this study is to verify the clinical efficacy of the double-cuff tipless inflow cannula.

Methods: We reviewed his clinical course during the support, assessed the inflow position by image examinations, and macroscopically investigated around the left ventricular inflow ostium of the excised heart during heart transplantation.

Results: There was no thromboembolic and cardiac events and pump malfunction. Computed tomography showed no malposition of the inflow cannula and pump body. Left ventricular cavity of the excised heart showed smooth inflow ostium with appropriate intimal formation and neither pannus formation nor wedge thrombus formation. This finding, which had been previously shown in animal study, suggested the validity of the double-cuff tipless inflow cannula in a long-term clinical situation. This unique inflow cannula is promising for reduction of thromboembolic events and may contribute to more stable long-term patient management.
Fractal Eyes V2.0 - Visual Natural Language Processing Of Medical Images For Enhanced Value
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Study: Platelet activation (PA) is central in thrombosis which continues to limit cardiovascular therapeutic devices. Understanding mechanisms of PA, and the time course and natural history PA are vital in efforts to modulate thrombosis. To assist this research effort we developed a neural-network based platform for the qualitative analysis of platelets in varying phases of PA.

Methods: The Fractal Eyes system extracts feature data from scanning EM including: platelet area, perimeter, eccentricity, color density differences, light intensity, and approximate pixel length and width as it maps to an image. The system consists of four subsystems: Graphical User Interface (image selection and summary of results), Image Pre-Processing (voxel creation/image normalization), Image Classification (via pre-trained convolutional neural network model trained on non-activated platelets and activated platelets), and Feature Extraction.

Results: Fractal Eyes effectively can calculate platelet center, pixel area and perimeter, and determine and eccentricity with major and minor axis lengths as seen in Fig. 1. Another example of what the feature extraction subsystem can calculate for a non-activated platelet and activated platelets is in Fig. 2. This figure is displaying the data calculated from the subsystem, which can be seen in Fig. 1 and is an example for how the data will be displayed to the user in the Graphical User Interface. Current development of the Image Classification subsystem has yielded acceptable model accuracy in terms of the validation process of the model training for binary classification of SEM images of non-activated platelets and activated platelets. The results of the binary classification training can be seen in Fig. 3. At the current moment of the writing of this abstract, the image dataset for training a model on the different phases of PA are in the process of being cultivated and tested. It is planned that a working model will completed before the final presentation.
In Vitro Investigation Of The Effect Of Pulsatility Modes On Left Ventricular Hemodynamics In Third Generation LVads

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Study: The aim of this study is to investigate the effect of pulsatility modes on the hemodynamics in the Left Ventricle (LV).

Methods: A patient-specific LV silicone model is implanted with a transparent cannula connected to a third generation LVAD. The LV/LVAD test rig is connected to a flow loop, with accurate control of pre- and after load, and peripheral resistance. An index of refraction-matched working fluid is connected to a flow loop, with accurate control of pre- and after load, and its viscosity is matched to that of blood to achieve complete dynamics similarity with the clinical problem. We measure the intraventricular flow velocity via time-resolved stereo Particle Image Velocimetry (PIV). The influence of the timing between the LVAD speed modulation and the ventricle filling cycle (preload) is characterized to understand if keeping all conditions constant, measurements were repeated with the LVAD pulsatility triggering at 4 phases related to the peak intraventricular pressure (IVP): minimum/maximum IVP, and in the middle of the increasing and decreasing pressure stages.

Results: For every LVAD speed, the LV flow field shows stagnation and recirculation areas, especially between the cannula and the apex, and in the LVOT. Keeping the average LVAD flow rate constant (4.5L/min), the timing between the oscillatory IVP (systole-diastole) and the onset of LVAD pulsatility induces large variations in the instantaneous flowrate and also strongly impacts flow patterns in the LV. This parametric study shows that the effectiveness of LVAD speed modulation strongly depends on physiological parameters, such as the native LV contractility (preload) and the peripheral resistance (afterload), and that this dependency is sensitive to the operating rpm of the pump. Optimization of LVAD pulsatility mode (rpm lowering/raising values, duration and timing) needs to consider these parameters globally to reduce thrombogenicity of LVAD therapy and improve long-term outcomes for patients.

A Higher Sensitivity Mini-loop Hemolysis Model For Ventricular Assist Devices

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Study: Pre-clinical hemolysis assessment of ventricular assist devices (VAD) is a requirement to demonstrate safety before clinical studies. Testing guidelines are standardized in ASTM-F1841, but for the latest generation of VADs, like the HVAD, the ASTM method detects a low blood trauma signal-to-noise ratio (SNR) which is insufficient to evaluate future design changes and improvements. Hence, the goal of this study was to develop a hemolysis test method with a higher signal sensitivity.

Methods: Mini-loop modifications from the ASTM model include removal of blood reservoir (500 to 60mL volume reduction); decreased test time and sampling (6 to 2 hrs); and more blood passes through the pump [4/5 to 8 liters per minute (LPM)]. Mini-loop test feasibility was evaluated with ten HVAD devices in 68 tests using citrated bovine blood from 14 donors for two use cases: nominal (4LPM, 100mmHg; n=26) and accelerated (8LPM, 100mmHg; n=38). Delta plasma free hemoglobin (PfHb) was the measured difference before pump start and at 2 hrs. Delta PfHb, normalized index of hemolysis (NIH), and PfHb SNR (µ/σ) were compared to previously collected HVAD ASTM data (2LPM, 100mmHg; n=47 in 12 heparinized bovine donors).

Results: Delta PfHb is similar between 4LPM mini-loop and 5LPM ASTM (33 vs 35 mg/dl). A 7-fold increase was observed (220 vs 33 mg/dl) between the 8LPM and 4LPM mini-loops (Figure 1). NIH results in the 4LPM mini-loop was reduced compared to 5LPM ASTM (0.0027 vs 0.0068) though NIH was higher in the 8LPM mini-loop (0.0092). SNR of Delta PfHb was reduced compared to 5LPM AST (0.0027 vs 0.0068) between the 8LPM and 4LPM mini-loops (Figure 1). NIH results in the 8LPM mini-loop compared to 5LPM ASTM (4.3 vs 2.3).

Conclusion: This work shows the feasibility of evaluating hemolysis of VADs using the mini-loop model. The mini-loop model has a higher signal-to-noise ratio than the ASTM method, which is advantageous for evaluating minor changes to the VAD system such as controller, algorithm, or pump design improvements.

![Figure 1](image-url)
Left Atrial Appendage Occlusion To Reduce Thromboembolic Risk With Left Ventricular Assist Devices: A Simulation Study

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Study: Thromboembolic events and consequently stroke are devastating complications of left ventricular assist devices (LVADs) therapy. Atrial fibrillation (AF) is a common comorbidity in LVAD patients and has been identified as a risk factor for stroke as blood stasis inside the left atrial appendage (LAA) can be a major source of thrombosis. Previous clinical studies suggest that LAA occlusion (LAOO) may prevent thromboembolism in LVAD patients, however its impact on blood flow dynamics has not been established. Therefore, this study aims to investigate the effect of LAA occlusion on thrombosis-related parameter using Computation Fluid Dynamics (CFD) simulation.

Methods: Left ventricular and atrial models of an LVAD patient with AF were obtained from computed tomography. Hemodynamic data were generated by a lumped parameter model for full support condition with a total cardiac output of 5 L/min (LVAD flow: 3.6-7.6 L/min) and stroke volume of 35 mL. The hemodynamics were applied for two pulsatile CFD simulations with moving walls over 6 cardiac cycles (CC) comparing LAAO to the LAA situation. Stagnation regions (mean velocity <5mm/s), wall shear stress (WSS), and blood washout applying a virtual-ink technique were evaluated.

Results: The ventricular flow patterns were similar for both simulations, however, LAAO leads to +8% higher mean velocity within the atrium. An increase of +13% WSS at the atrial wall was observed with LAAO leading to decrease of atrial stagnation volume by -35%. After 6 CC, 100% of blood was cleared from the atrium with LAAO compared to only 91% clearance for the atrium with LAA. In CFD simulations significant stagnation volumes in the LAA where identified in LVAD patients with AF. Blood stagnation in the LAA and low WSS are potential sources for thrombus formation which might be resolved by LAA occlusion. This significantly reduced the thrombus-related flow parameters and might also lowers the risk of thromboembolic events from the appendage.

Outcomes In Significant Mitral Regurgitation After Left Ventricular Assist Device Implantation

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Study: Significant mitral regurgitation (MR) after the placement of a continuous-flow left ventricular assist device (LVAD) is associated with pulmonary hypertension, right ventricular failure, and mortality in small studies. We completed a large cohort study to determine the impact of MR on LVAD patients over an extended follow-up period (mean = 1.96 years).

Methods: A retrospective review of LVAD recipients from January 2012 to March 2020 at a single tertiary institution was completed. Severity of MR was determined by echocardiography report. Tiers of MR included moderate (mMR), moderate-to-severe (msMR), and severe (sMR). Echocardiographic parameters and survival status outcomes were collected.

Results: 413 patients received a LVAD; 55 were excluded from the final analysis (15 received biventricular support and 40 had inadequate imaging). Of the patients analyzed, 86.3% (309/358) had less than mMIR. In the 49 patients with significant MR, 22 patients (44.9%) had mMR, 16 (32.6%) had msMR, and 11 (22.4%) had sMR. Compared with mMR and msMR, the sMR group had a larger LVIDD (6.5 ± 1.5, 6.8 ± 1.1, 8.0 ± 1.9 cm, respectively) and a higher RVSP (29 ± 9.4, 38 ± 9.5, 42 ± 19 mmHg, respectively); however, neither reached statistical significance (p= 0.09 and p = 0.14, respectively). There was no significant difference in mortality among patients with msMR/sMR compared with the all cohort (HR 1.24±0.43, CI 0.62-2.4, p=0.18) even when patients who underwent heart transplant were excluded (HR 1.21±0.43, CI 0.6-2.4, p=0.19) (Figure1). Conclusion: Tiered, significant MR post-LVAD may be associated with a larger LVIDD & increased RVSP, but there is no significant difference in mortality, regardless of MR severity.
ASAIO ELECTRONIC POSTER ABSTRACTS

EPCardiac78

Hemodynamics Of Impella Support: A Computational Patient-specific Model Of Therapy For Cardiogenic Shock

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Study: Though percutaneous ventricular assist devices (PVAD) such as the Impella increasingly provide circulatory support, understanding of their hemodynamic impact remains limited.

Methods: A patient-specific computational model of aorta flow with Impella support was developed. Physiologically validated aortic waveforms were used for virtual implantation of catheter, impeller, and surrounding cage. Total perfusion was set to 5 LPM while varying relative heart failure with progressively reduced native flow including fraction of Impella CP flow: 0 (baseline, without Impella), 30, and 70%. Dynamic boundary conditions at aortic outlets were assigned considering lumped-parameter models. Hemodynamic patterns were captured solving for the turbulent flow and quantifiable features including velocity, turbulent kinetic energy, shear stress metrics, and vital organs perfusion.

Results: Aortic flow during Impella support demonstrated greater vorticity and turbulent energy with increasing PVAD support. End-organ perfusion was maintained in all scenarios even when flow became less pulsatile with increasing impella contribution. Impella-induced flow alterations increased shear stress within the ascending aorta commensurate with that reported for other circulatory support devices. Our results illuminate the unique potential of computational approaches for mechanistic understanding and risk stratification of mechanical support therapies and demonstrated flow and perfusion patterns with support under different heart failure states.

Figure 1 (A) Schematics of the aorta model and impella design, (B) Computational mesh, (C) Turbulent kinetic energy, and (D) wall shear stress (WSS) at peak systole in different scenarios.

EPCardiac79

Simultaneous Protek Duo RVAD And Impella LVAD For Hemodynamic Support In Cardiogenic Shock

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Study: Mortality from cardiogenic shock (CS) remains high. Veno-arterial extracorporeal membrane oxygenation (VA-ECMO) is commonly used for biventricular support in CS, but is associated with increased complications. We reported our single center’s experience with simultaneous Protek Duo RVAD and Impella LVAD (perc-BiVAD) to treat CS.

Methods: We performed a retrospective study of patients receiving perc-BiVAD for CS in 4/20-12/20. Patients’ outcomes were reported. Vasoactive-inotropic score (VIS) was the total dose of all vasoactive and inotropic medications the patient received within the hour before, and 24 hours after perc-BiVAD implant. Comparison was made with Wilcoxon signed-rank test. P < 0.05 was considered statistically significant.

Results: Five consecutive patients received perc-BiVAD. Mean age was 65 ± 7 years. Mean support duration was 15 ± 10 days. Mean VIS in four patients decreased from 16 ± 9 at implant to 8 ± 8 mcg/kg/min post-implant (p = 0.06, Figure) (pre-implant VIS unavailable in one patient). Etiologies of CS were: stress cardiomyopathy (n = 1), acute heart failure (n = 2), and cardiac arrest (n = 2). One patient was on VA-ECMO then converted to perc-BiVAD, while the rest received perc-biVAD as first-line therapy. Four patients had axillary Impella 5.5 placement, allowing early ambulation; one had Impella CP. In four patients, perc-BiVAD was removed due to myocardial recovery. Survival to discharge was 80%. One patient died of sepsis while on device support. There was no stroke or device-related infection. One patient had gastrointestinal bleeding, and another had insertion site hematoma. In conclusion, simultaneous Protek Duo RVAD and Impella LVAD allows direct left ventricular unloading, reduction of venous congestion from right heart failure, patient’s mobilization, and less inotropic use. This is a viable and safe option for timely hemodynamic support to treat patients with CS.
**EPCardiac80**

**Long-term Outcomes Of Porcine Bioprosthesis Replacement In The Aortic Position With Concomitant Mitral Valve Repair**

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**Study:** Aortic valve disease with concomitant mitral regurgitation is clinically relevant, especially in the era of transcatheter interventions involving aortic and mitral valves. However, a lack of data regarding combined or multiple-valvular disease has led to the absence of clear evidence-based recommendations. This study retrospectively evaluated long-term outcomes after stented porcine aortic valve bioprosthesis (Mosaic, Medtronic Inc.) replacement in the aortic position with concomitant mitral valve repair/plasty (MVP).

**Methods:** We focused on the subgroup of patients at 10 centers in Japan as part of the Mosaic valve long-term multicenter study (J-MOVE), which constituted a large, retrospective, multicenter clinical study.

**Results:** From 1999 to 2014, 157 patients (median (interquartile range) age, 75 (70-79) years; 47% women) underwent aortic valve replacement using the Mosaic bioprosthesis with concomitant MVP (AVR+MVP) and 1,045 patients (median (interquartile range) age, 76 (70-80) years; 54% women) underwent aortic valve replacement (AVR alone) using the Mosaic bioprosthesis. Five-year overall survival rates were 81.5±4.1% for AVR+MVP and 85.1±1.4% for AVR alone; 10-year overall survival rates were 75.2±5.7% for AVR+MVP and 75.1±2.6% for AVR alone. Cox proportional hazards analysis showed no significant difference in survival rates between AVR+MVP and AVR alone (hazard ratio: 0.87, 95% confidence interval: 0.54-1.40, P=0.576), shown in Figure 1. Among female patients with mild-to-moderate to mitral regurgitation who were not receiving dialysis, those who underwent AVR+MVP, were aged >75 years (Figure 2A), and had preoperative left ventricular ejection fraction 30%-75% (Figure 2B) tended to have lower mortality risk than those who underwent AVR alone.

**Conclusions:** The J-MOVE cohort showed satisfactory long-term outcomes of AVR+MVP.

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**Figure 1. Kaplan-Meier curves for comparison of overall survival rate between patients in the AVR+MVP group and those in the AVR alone group**

**Figure 2. Relative risks for AVR+MVP compared with AVR alone**
Surface Coatings For Rotary Ventricular Assist Devices: A Systematic Review

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Study: Rotary ventricular assist devices (VADs) are frequently used to provide mechanical circulatory support to patients suffering from end-stage heart failure. These devices (especially their pump impeller and housing components) have stringent requirements on wear resistance and haemocompatibility. Various surface coatings have been investigated to improve the wear resistance and/or haemocompatibility of these devices. Durability (retention ability on the substrate) of coatings is also of great importance. The aim of the present systematic review was to build a comprehensive understanding of surface coatings utilised in rotary VADs and provide insights on potential future research directions.

Methods: A Boolean search for peer-reviewed studies was conducted in databases Web of Science, Scopus, PubMed and ScienceDirect. A preferred reporting items for systematic reviews and meta-analyses (PRISMA) process was followed for selecting relevant papers for analysis. Included articles were reviewed to identify the wear properties, durability and haemocompatibility of coatings.

Results: A total of 45 out of 527 publications were included for analysis. Eighteen coatings were reported to improve the wear resistance and/or haemocompatibility of rotary VADs. Six ceramic coatings like diamond-like carbon (DLC), BioMedFlex (BMF), titanium nitride (TiN) and ultrananocrystalline diamond (UNCD®) were both wear-resistant and haemocompatible coatings. The other 12 coatings were haemocompatible (only) coatings like heparin, methacryloyloxyethyl phosphorylcholine (MPC), sintered titanium microspheres and endothelial cells. The most widely investigated coatings were MPC, heparin and DLC, accounting for 24.4%, 20% and 17.8% of publications. Ninety-three percent of studies focused on haemocompatibility, while only 4% of studies focused on wear properties and 13% of studies investigated durability, indicating that investigation on wear properties and durability is needed in future work.
ASAIO ELECTRONIC POSTER ABSTRACTS

**EPCovid1**

**Survival Of Pregnant COVID-19 Patient After Prolonged Use Of VV ECMO**

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**Study:** The mortality rate in patients with coronavirus disease 2019 (COVID-19) requiring mechanical ventilation is high, however, veno-venous extracorporeal membrane oxygenation (VV ECMO) may serve as a successful rescue therapy for some patients. To date, there are limited case series reporting the impact of COVID-19 on pregnant women who require prolonged VV ECMO. Here we describe the survival of a pregnant COVID-19 patient who had a successful C-section preterm delivery before subsequent intubation and placement on VV ECMO.

**Methods:** The patient is a 42-year-old female who presented with a history of dyspnea and fever at 27 weeks 3 days gestation. She tested positive for COVID-19 and presented to the intensive care unit for hypoxic respiratory failure. Due to fetal decompensation and persistent hypoxia, the patient underwent a high-risk C-section at only 28 weeks. She continued to have respiratory failure requiring mechanical ventilation, paralysis, and proning. The patient was ultimately placed on VV ECMO with inflow cannulation to the left internal jugular vein and outflow to the right internal jugular vein.

**Results:** The patient’s post ECMO course included sepsis, DVTs requiring anticoagulation, and development of an acute bleed from the brachial artery that led to hemorrhagic shock. She required blood transfusions, medical management with pressers and antibiotics, and received a tracheostomy while on ECMO. Following a total of 37 days on ECMO support, the patient was successfully decannulated and discharged home in stable condition.

**EPCovid2**

**The Shortcomings Of Tocilizumab In COVID-19**

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**Study:** IL-6 blockers have gained the spotlight for their benefits in treating coronavirus disease (COVID-19) induced cytokine release syndrome (CRS). Tocilizumab, sarilumab, and siltuximab are being investigated in numerous clinical trials for their efficacy in preventing ICU admission, mechanical ventilation, and ultimately death. While several case series, and case reports claim favorable outcomes with the drug, the first phase III clinical trial results for tocilizumab (COVACTA) failed to meet primary and secondary target endpoints. We hypothesize some reasons that might have contributed to this outcome.

**Methods:** A qualitative review was performed on PubMed to screen for case reports, case series, and cross-sectional studies involving the off-label use of tocilizumab to treat COVID-19 from March to October 2020. We analyzed the study design and results described in each article to hypothesize why more recent findings have been contradictory to earlier statements.

**Results:** We found that an inadequate understanding of the pathophysiology behind COVID-19 cytokine storm, particularly with regards to IL-6, inconsistencies in the time of administration and dosing, the use of adjunctive therapies, and an element of reporting bias were plausible reasons for tocilizumab’s failure in latest clinical trials. The NIH COVID-19 treatment guidelines and IDSA recommendations both discourage the off-label use of tocilizumab outside of clinical trial settings. Although several studies have reported remarkable results with tocilizumab, it would be advisable to wait for further results from other clinical trials before reaching a verdict.
EPCovid3
Can Hb-based Oxygen Carriers (HBOC) Be Used In COVID-19 Treatment?
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Study: The main clinical manifestation of severe COVID-19 is hypoxemia that fulfills the criteria of acute respiratory distress syndrome (ARDS). The "cytokine storm" driven in large part by reactive oxygen species (ROS) during an excessive immune response to SARS-CoV-2 infection leads to ARDS aggravation and multi-organ failure (MOF). Other complications include massive endothelial dysfunction and widespread coagulopathy. Despite all efforts there is no effective therapy available yet. The efficacy of vaccines could be threatened by viral mutations. Since HBOCs are intended to reverse hypoxemia, this study examined their hypothetical therapeutic potential for COVID-19.

Methods: There are several types of HBOCs under development: human, bovine or worm Hb-based; cross-linked, conjugated, polymerized or encapsulated; low or high oxygen affinity (P50); oxygenated or carbonyl -bovine or worm Hb-based; cross-linked, conjugated, polymerized or encapsulated; low or high oxygen affinity (P50); oxygenated or carbonyl.

Results: HBOCs with low P50 can yield insufficient oxygen delivery and with high P50 will be unable to be properly oxygenated. CO-HBOCs can deepen hypoxemia. HBOCs with uncontrolled redox potential will be a source of ROS/ferryl Hb, thus augmenting "cytokine storm," endothelial injury and MOF. HBOCs not catabolized physiologically will lead to iron overload, increasing susceptibility to bacterial infections.

Conclusions: It seems that only oxygenated HBOCs with moderate P50, controlled redox chemistry and anti-inflammatory properties, without procoagulant activity and catabolized physiologically could be considered for future studies to establish their therapeutic value in COVID-19.

EPCovid4
It’s Easy To Miss Mis-a: A Case Series Of Multi-inflammatory Syndrome In Adults Associated With Sars-Cov-2 Infection And Cardiogenic Shock Managed With Mechanical Circulatory Support
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Study: Hyperinflammatory syndrome with multi-system organ involvement has been identified in adults diagnosed with COVID-19 infection. Paralleling a disease in children similar to Kawasaki, it has been aptly titled multi-inflammatory syndrome in adult (MIS-A). We present two cases of MIS-A leading to profound inflammation and cardiogenic shock successfully managed with mechanical circulatory support (MCS).

Methods: Patient 1 and 2 were admitted with elevated inflammatory markers, severe left ventricular systolic dysfunction and vasopoplegia. This quickly progressed to mixed shock with a cardiogenic component leading to multi-organ failure necessitating initiation of multiple vasopressors and inotropes. Despite escalating doses of parenteral support, the patients continued to decline from a hemodynamic and metabolic perspective. Demographics, laboratory findings, imaging results, treatment and outcomes are summarized in Table 1.

Results: Patient 1 underwent intra-aortic balloon pump placement and Patient 2 required VA-ECMO and axillary Impella placement. Both were treated with high dose steroids with significant improvement in inflammatory markers and clinical status. MCS was eventually weaned and decannulated with recovery in left ventricular function and favorable outcomes despite critical illness in both cases. MIS-A is characterized by elevated inflammatory markers, multi-organ involvement, cardiac dysfunction and shock. It remains a challenging entity to diagnose as little is understood about this hyperinflammatory syndrome, which has precluded standardization of treatment. We present two cases of MIS-A associated with cardiogenic shock successfully treated with MCS, confirming feasibility of using MCS to support this patient cohort through severe illness.
EPCovid5
Mitigating Bleeding Risk In COVID-19 Infected Patients Undergoing Extracorporeal Membranous Oxygenator Support. A Focus On Fibrinogen
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Study: Different fibrinogen management approaches for COVID-19 patients on extracorporeal membranous oxygenation (ECMO) support are compared in two patients. Observations of measured levels and blood transfusion requirements are reported.
Methods: Case #1. A 25-year-old obese, asthmatic male progressed to septic shock requiring two courses of ECMO support. The fibrinogen replacement threshold for this patient was 100 mg/dL. The patient’s fibrinogen level prior to ECMO cannulation was 808 mg/dL, and fell to a low of 184 mg/dL by Day 7 of the first ECMO course. The patient’s anticoagulation regimen consisted of heparin infusion at an average rate of 17 units/kg/hr for a goal anti Xa level of 0.15-0.3 IU/mL until he developed a large chest wall hematoma requiring multiple packed red blood cell (pRBC) transfusions. The patient was eventually extubated and discharged.
Results: 3 units of pRBC’s through her 20-day ECMO course.
Case #2. A 25-year-old post-partum female also developed septic shock requiring ECMO support. This patient’s fibrinogen replacement threshold was set at 250 mg/dL initially. Anticoagulation was initiated with heparin infusion then was changed to bivalirudin with a low of 184 mg/dL by Day 7 of the first ECMO course. The patient's fibrinogen level prior to ECMO cannulation was 808 mg/dL, and fell to a low of 184 mg/dL by Day 7 of the first ECMO course. The patient’s anticoagulation regimen consisted of heparin infusion at an average rate of 17 units/kg/hr for a goal anti Xa level of 0.15-0.3 IU/mL until he developed a large chest wall hematoma requiring multiple packed red blood cell (pRBC) transfusions. The patient was eventually extubated and discharged.
Results: 14 units of pRBC’s and was noted to have had both an internal jugular vein thrombus and pulmonary embolism during his 13 days of ECMO. Patient #2 received 12 units of cryoprecipitate and 3 units of pRBC’s through her 20-day ECMO course.

EPNursing1
Results Of Responding To A Responsive LVAD Patient With A Prolonged Pump-off Event: A Case Study
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Study: We discuss the case of a HeartMate II patient whose LVAD was off for 4.5 hours before being restarted.
Methods: Our elderly patient frequently admitted for concern for dementia. Psychiatry, neurology, PT and OT were consulted regarding his memory deficits (especially regarding power management of the LVAD.) The patient’s caregiver often noted LVAD alarms due to power cable disconnections. Device interrogations yielded “no external power” alarms, causing the VAD coordinators to counsel the caregiver about the need for 24/7 supervision, which could not be arranged. On the day of the event, the caregiver found the patient drowsy, confused, and disconnected from the LVAD’s external power. There were no visual or audible alarms. His caregiver promptly reconnected the controller to power and noted the green “pump running” symbol to illuminate, and the pump to restart. She immediately called the LVAD clinic.
Results: The patient regained mentation when the LVAD restarted, and he suffered no ill effects from his prolonged pump stoppage. Head CT done at a local ER was unremarkable. Pump function remained normal and free of alarms. Abbott logfiles were obtained, showing the controller utilized the emergency backup battery for 75 minutes until deplletion. The logfile timestamp and caregiver arrival time at the home, proved the HMI pump to be off for 4.5 hours. This incident highlighted the need for ongoing emergency response education. A formal algorithm was created to address emergency situations with the intent to review the content yearly. This caregiver remains actively engaged, checking in several times per day via phone. She also installed a robust camera system which allows for intercom communication 24/7. This case highlights a favorable outcome, with little evidence supporting repeatability in subsequent or similar cases. Beyond the need for robust emergency management education, the team gained valuable clinical experience, and ideas for aiding in providing 24/7 care, even from afar.
EPNursing2

Enhancing Communication To Prevent LVAD Early Readmissions Post-acute Care
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Study: Hospital readmissions remain a significant obstacle for patients supported with durable left ventricular assist devices (LVADs). Our team identified an increase in readmissions of LVAD patients discharged to acute inpatient rehabilitation following hospitalization. We sought to determine if an enhanced LVAD team communication plan with our acute inpatient rehab quality partners would reduce unplanned 30 and 60 day hospital readmissions.

Methods: A retrospective analysis of patients implanted with durable left ventricular assist devices between January 1st 2019 and January 1st 2021 discharged to acute inpatient rehab was performed. Unplanned readmissions within 30 and 60 days of discharge were analyzed. The implementation of our enhanced communication plan began January 1st 2020. This consisted of weekly emails from the acute inpatient rehab updating the LVAD team on medication changes, lab results, LVAD related issues, and updated discharge medication lists with plan when patients were discharged from the rehab to ensure timely follow up at the LVAD center.

Results: In 2019 and 2020, 14 and 12 patients were discharged to acute inpatient rehab, respectively. Prior to the communication implementation plan, the initial 30-day hospital readmission rate was 43% (n=6/14) and two additional patients were admitted within 60 days, with a 60 day readmission rate of 57% (n=8/14). After the initiation of the communication plan, hospital readmission rate decreased to 16% at 30 days (n=2) and one patient was admitted within 60 days (n=3/12). Utilizing an enhanced inter-center communication plan ensures safe and effective transition of care and can potentially decrease unplanned hospital readmissions. Further investigation is required to explore reasons for unplanned readmissions in order to prevent them. Furthermore, a similar implementation plan can be applied to non LVAD patients to reduce readmissions and enhance transitions of care from acute hospitalizations.

EPNursing3

Implementation Of An LVAD Educator To Improve Quality Outcomes
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Study: Left Ventricular Assist Devices (LVAD) is a growing form of therapy for patients with advanced heart failure. While LVAD patient volumes grow, the need for additional education both for the patients and hospitals has grown. The implementation of dedicated LVAD educators into LVAD programs can be beneficial for program quality indicators as well as patient outcomes.

Methods: Left Ventricular Assist Devices (LVAD) is a growing form of therapy for patients with advanced heart failure. While LVAD patient volumes grow, the need for additional education both for the patients and hospitals has grown. The implementation of dedicated LVAD educators into LVAD programs can be beneficial for program quality indicators as well as patient outcomes.

Results: The implementation of a dedicated LVAD educator occurred January of 2018. Outcome results were evaluated for 2017 prior to the educator and 2018 after implantation of the educator. The volumes for 2017 and 2018 were similar at 47 and 63 respectively. Outcomes evaluated included median length of stay from implant of LVAD to discharge from hospital which decreased from 20.5 days to 18.9 days. Driveline infections rates decreased from 23.81% to 17.71%. Unplanned readmissions decreased from 3.53% to 2.91% and one year survival between the two groups remained comparable at 93.74% and 92.81%. Acuity of the patients was comparable in both groups and programmatic staffing remained unchanged otherwise.
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