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ASAIO JOURNAL

Top Cardiac

What if the Destination is Transplant? Outcomes of Destination Therapy Patients Who Were Transplanted

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Study: While healthcare payors may require destination therapy (DT) or bridge to transplant (BTT) assignment preimplant, that decision may not mirror a patient's final postimplant strategy. In the combined ENDURANCE/ENDURANCE Supplemental Trials (DT/DT2) of patients (pts) with DT HVAD System support, 13% eventually received heart transplant (HTx). We sought to characterize these DT pts who became transplant eligible after HVAD.
Methods: A post hoc analysis of the DT/DT2 Trials including all pts who underwent HTx after implantation compared baseline characteristics between the HTx and no-HTx cohorts. Time to HTx was compared to the HVAD BTT trials (ADVANCE and Continued Access Protocol).
Results: Of the 604 DT/DT2 HVAD pts, 80 (13%) underwent HTx. The HTx cohort was younger (53.6 ± 11.1 vs 65.2 ± 10.8, p <0.0001) with fewer Caucasians (60.0% vs 76.5%, p= 0.002) and less ischemic cardiomyopathy (42.5% vs 58.8%, p=0.008), atrial fibrillation (38.8% vs 54.4%, p=0.01), or prior sternotomy (18.8% vs 31.9%, p=0.02). Although the Intermacs Profiles were similar, the HTx cohort had longer 6-minute walk distances (135.0 ± 146.2 vs 102.1 ± 128.3 m, p=0.04). Most HTxs in DT/DT2 were categorized as elective (n=63, 79%). Of these, 44% of eligibility changes were due to modification of behavioral issues (compliance/substance abuse), followed by obesity (16%) and pulmonary hypertension (13%). Adverse events were the main indication for urgent HTx (n=17, 21%). Mean/median times to HTx were longer in DT/DT2 (608.9 /550.0 days) versus BTT/CAP (362.6/274.5 days).In this post-hoc analysis of the DT/DT2 trials, over 1 in 10 pts achieved transplant eligibility with subsequent HTx within approximately 3 years of HVAD support. Most transplants were elective and occurred after modification of behavioral or obesity exclusions. DT pts should be regularly reassessed for transplant eligibility and efforts to remediate modifiable contraindications should be ongoing after HVAD implant.

Top Bioengineering

In Silico, *In Vitro* and *In Vivo* Evaluation 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. The present study evaluated the hydraulic, hemodynamic and hemocompatibility performance of the device in silico, in vitro and in vivo.
Methods: Pump designs were analyzed and refined using computational fluid dynamics and fluid structure interactions (COMSOL Multiphysics). Hydraulic testing in a mock circulatory loop and hemolysis measurements in static and pulsatile conditions were then performed in vitro. Acute and chronic implants of the improved pumps were conducted in sheep.
Results: In vitro and in acute implants the device was operated in continuous, co-pulsation, counter-pulsation, and asynchronous pulsation modes. Sensorless detection of native systole was demonstrated for heart rates of 30-120 bpm. The pump successfully transitioned between operating points within one oscillation cycle (< 25 ms). In acute implants in sheep with induced heart failure, the pump generated pulse pressures >30 mmHg. The pump could generate average flow rates of 6+ LPM against physiologic pressure, and instantaneous flow rates >12 LPM during pulsatile operation. In chronic implants (N=5; 24-63 days) the pump demonstrated low hemolysis, <10 mg/dL for all implants after post-operative day 4, and an absence of significant thrombus. Conclusion: Long-term chronic animal studies of the CorWave LVAD validated the hemocompatibility and hemodynamic performance of the pump. The ability to restore physiologic pulsatility by sensorless synchronization with the native heart was demonstrated in acute pre-clinical implants.

Top Pediatric

HVAD Outcomes in the Advanced Cardiac Therapies Improving Outcomes Network (ACTION): An Initial Analysis

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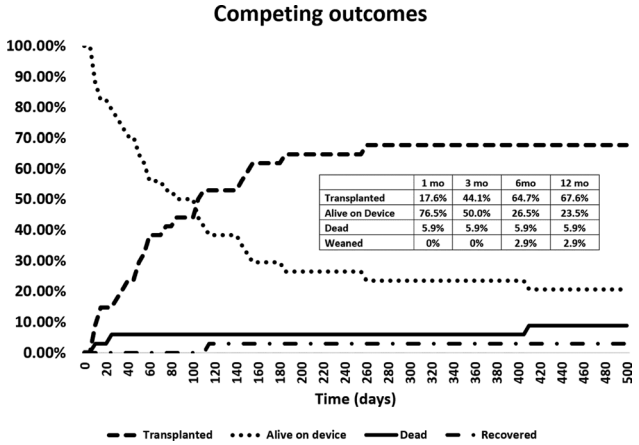
Study: ACTION (Advanced Cardiac Therapies Improving Outcomes Network) is the 1st pediatric ventricular assist device (VAD) quality improvement network (44 centers) with a goal of improving VAD outcomes. We aimed to describe ACTION's initial outcomes with the HeartWare HVAD.
Methods: Patients (pt) implanted with a HVAD and entered in the ACTION registry between 12/2012-12/2019 were analyzed. Descriptive and chi-square analyses were applied to pt characteristics and adverse events (AE). Competing outcomes analysis evaluated post-VAD survival.
Results: There were 34 pt implanted with a HVAD. Diagnosis (dx) was cardiomyopathy (CM) in 28 (82%) and congenital heart disease (CHD) in 8 (18%). There were 11 (32%) who had prior cardiac surgery. Median age (range) was 13.7 years (3.3-19.1), BSA was 1.4 m^2 (0.56-2.62), and weight was 49.1 Kg (12.8-135.3). The majority were bridge to transplant (TX) [n=23, 68%] and pt profile 2 (n=29, 54%). Mechanical ventilation and ECMO were required in 11(32%) and 5(15%), respectively. Post-VAD, there was a median of 76 (9-485) days on device, 17 (6 - 182) ICU days, and 27 (13 - 190) days until discharge (n=27) or transplant (TX; n=23). **Figure 1** shows post-VAD survival, which was 94% at 1-year post-VAD. Death on VAD was more likely with CHD (3/8 CHD vs 0/25 CM; p=0.005) and prior cardiac surgery (3/11 vs 0/23; p=0.009). AE included bleeding (n=4, 12%), stroke (n=1, 3%), extra-axial hemorrhage (n=2, 6%), driveline infection (n=3, 5%), right heart failure (n=3, 9%), and other (n=2, 6%). Anticoagulation included unfractionated (n=19, 56%) or Low molecular weight (n=2, 6%) heparin, bivalirudin (n=12, 35%), and warfarin (n=25, 74%). Aspirin was the only reported antiplatelet agent (n=32, 94%).



	1 mo	3 mo	6mo	12 mo
Transplanted	17.6%	44.1%	64.7%	67.6%
Alive on Device	76.5%	50.0%	26.5%	23.5%
Dead	5.9%	5.9%	5.9%	5.9%
Weaned	0%	0%	2.9%	2.9%

Conclusions: HVAD outcomes were excellent early in the ACTION experience, with 94% survival at 1 year. Only 3 deaths and one stroke were observed. AE were infrequent, but major bleeding was most common.

Top Nursing/Allied Health

Patient-Reported Issues Following LVAD Implantation Hospitalization

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Study: Despite the increasing attention in understanding the LVAD patient's health behaviors, the nature of the data of self-monitoring is understudied. This study examined the frequency and patterns of issues that emerged from a smartphone app used for LVAD self-monitoring and reporting at 1 and 3 months following hospital discharge.
Methods: An exploratory research design employed on the data provided by 18 (11 males and 7 females) patients with durable LVADs, mean age of 49.4 ± 15.8 years. Data generated by the patient's daily use of the smartphone app over 3 months (1,118 days) were extracted from the server. Next, data were coded and clustered according to issues related to LVAD parameters, equipment (e.g., alarms), self-care (e.g., dressing changes), signs/symptoms, among others. Descriptive statistics were used in analyzing data.
Results: Throughout the study, all patients reported at least one issue per day. The average number of issues per patient over 30 days at month 1 was 23.2 ± 6.9. Between months 1 and 3, the average number of issues per patient over 60 days was 40.0 ± 17.7 Commonly reported issues at month 1 were international normalization ratio (INR) [89%], edema (83%), equipment (78%), weights (72%), diastolic blood pressure (61%), shortness of breath (61%), driveline (58%), battery calibrations (56%), and dizziness (56%). With the addition of pulsatility index (50%), the following issues were still common between months 1 and 3: INR (94%), equipment (79%), weights (79%), driveline (61%), and edema (56%). In conclusion, despite the LVAD, heart failure symptoms are prevalent up to 3 months of post-hospital discharge. Also prevalent are issues related to LVAD equipment and pulsatility index. As expected, anticoagulation is a significant problem in LVADs. Large mechanistic studies are needed to validate our findings as well as designs of tailored health behavior interventions to maximize LVAD treatment outcomes.

Top Critical Care/ Anesthesiology/ Pathology

Causes of Mortality in Patients Undergoing Continuous-flow LVAD Implantation

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Study: Continuous-flow left ventricular assist devices (CF-LVADs) are widely used to treat end-stage heart failure. More than 50% of patients die within 5 years of CF-LVAD implantation. We were interested in determining the causes of mortality in this population.
Methods: In this retrospective study, we extracted data on patients who received a CF-LVAD as destination therapy or as a bridge to transplant at our institution. We excluded patients who underwent cardiac transplant after CF-LVAD implantation. Causes of death and the clinical course of death were analyzed.
Results: From Nov 2003 to Sept 2017, 372 patients underwent implantation of an axial-flow CF-LVAD [HeartMate II (HMII)] without subsequent cardiac transplant, and 263 eventually expired; 1/263 (0.38%) expired elsewhere (cause of death unknown). From May 2009 to February 2018, 198 patients underwent implantation of a centrifugal-flow CF-LVAD [Heartware (HW)] without subsequent transplant, and 86 died; 11/86 (12.7%) died elsewhere. The most common causes of mortality in HMII patients were infection (74/263, 28.1%), right heart failure (56/263, 21.3%), and neurological events (55/263, 20.9%). In HW patients, the most common causes of mortality were right heart failure (24/86, 27.9%), infection (16/86, 18.6%), and neurological events (12/86, 14.0%). (See Table). The clinical courses of death were similar for both HMII and HW patients: 31.2% and 44.2%, respectively, improved and then expired after an acute event, 28.3% and 20.9%, respectively, expired within 30 days of CF-LVAD implantation, and 21.6% and 7.0%, respectively, improved but then expired after a terminal decline. **Conclusions:** Patients who did not undergo cardiac transplant after CF-LVAD implantation died primarily from infection, right heart failure, and neurological events. Infection was a greater cause of mortality in HMII patients than in HW patients. The most common clinical course in both groups was an acute event that occurred after a period of recovery.

Causes of Death after CF-LVAD Implant

Cause of Death	HeartMate II (n=263)	HeartWare (n=86)
Infection	28.1%	18.6%
Right heart failure	21.3%	27.9%
Neurologic event	20.9%	14.0%
Arrhythmia	7.6%	5.8%
Muultiple system organ failure	7.2%	5.8%
Device malfunction	4.2%	10.5%
Intraoperative death	2.7%	1.2%
Gastrointestinal bleeding	0.0%	0.0%
Other	1.5%	3.5%

Top Pulmonary

***In Vitro* Performance of a Sulfobetaine Thromboresistant Coating in a Pump-lung Device**

R. A. Orizondo, *S. Ye, B. N. De, B. J. Frankowski, W. J. Federspiel, W. R. Wagner; University of Pittsburgh, Pittsburgh, PA.*

Study: To provide multiple types of respiratory support, including long-term bridge therapy, the Modular Extracorporeal Lung Assist System (ModELAS) is under development as a wearable pump-lung. In an effort to improve device thrombogenicity, we have previously developed a zwitterionic sulfobetaine (SB) coating and demonstrated positive results in a scaled-down setting. The objective here was to use in vitro methods to evaluate the performance of the SB coating implemented within a full-scale ModELAS.

Methods: A previously described SB coating was applied to all blood-contacting surfaces of the ModELAS integrated pump and polymethylpentene (PMP) fiber bundle (0.3 m^2) as well as attached tubing. Samples of the device housing, PMP bundle, and tubing were then removed for evaluation. Surface analysis was performed via X-ray photoelectron spectroscopy (XPS) to verify coating presence. Anti-fouling properties were assessed with acute exposure to whole ovine blood. Scanning electron microscopy (SEM) visualized platelet deposition on all samples. A lactate dehydrogenase assay was used to quantify platelet deposition on PMP samples. Lastly, potential effects of the coating on gas exchange were evaluated in vitro with bovine blood in accordance with ISO 7199.

Results: XPS analysis showed successful coating of all surface types as indicated via increased sulfur content. SEM images demonstrated markedly reduced platelet deposition for all SB-coated surfaces relative to uncoated surfaces. SB-coated PMP samples from the fiber bundle inlet, middle, and outlet exhibited an 85±11%, 87±6%, and 87±11% reduction in platelet deposition, respectively, relative to uncoated samples. CO_2 and oxygen transfer rates of SB-coated devices differed by less than 2% relative to uncoated devices. These results demonstrate the ability of the developed SB coating to improve thromboresistance within the ModELAS without inhibiting gas exchange.

BIO 1

A Structured Approach to The Design of Minimally Traumatic Continuous Flow Blood Pumps

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Study: Efficiency, durability, and clinical outcomes have improved with continuous flow left ventricular assist devices (cf-LVADs). However, patients supported with cf-LVADs still suffer from a high rate of hemostatic complications such as hemolysis, GI bleeding, pump thrombosis, and stroke. This study is to present a continuing effort on pursuing and designing a complication-free cf-LVAD from the Penn State College of Medicine.
Methods: The first generation (1st-G) minimally traumatic cf-LVAD that we developed (**Fig 1AB**) was further optimized by using our integrated design optimization platform (IDOP). Parametric design variables were set for the number of blades, front- (FA) and back angle (BA) of the rotor blade varying from 2 to 4, -25º to +25º, and -15º to +15º, respectively (**Fig 1A**) populating 20 random designs. *In-silico* hemolysis and thrombus susceptibility potential (TSP) were implemented as objectives. *In-vitro* hemolysis was evaluated at flow rates (Q) of 5-8 LPM and pressure heads (ΔP) of 80-90 mmHg (n=9). *In-vivo* thrombus resistance was evaluated in a 14 day calf study (89 kg) (**Fig 1C**). Upon euthanization, the pump was examined for wear and thrombosis.
Results: *In-vitro* normalized index of hemolysis in 1st-G was 0.0025±0.0034 mg/dl. *In-vivo* pump was run mostly at 4500 RPM providing Q~5 LPM and ΔP~80 mmHg. Necropsy revealed that the outlet anastomosis and graft were tight and clean, but small red adhesions (suspected thrombi) were observed from the outlet connector and a white adhesion at the volute joint crevice. Rotor was clean except for a 1mm diameter white adhesion on the outer surface (**Fig 1DE**). All organs looked normal except two renal infarcted regions (2x2x3 mm, 1.0x0.5x0.5 mm). Our 2nd-G optimization found the best design, i.e., a rotor possessing 3 blades, FA = -21.3º, and BA = -1.0º (**Fig 1F**) reducing hemolysis and TSP by 6% and 43%, respectively, at 5000 RPM, Q = 5 LPM generating ΔP = 87±6 mmHg. We are manufacturing the 2nd-G opt. rotor warranting *in-vitro* and *in-vivo* studies for validation.

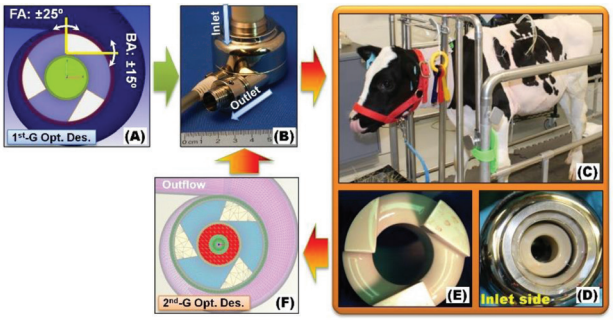

Fig 1. (A) 1st-G opt. design, (B) implant-ready pump, (C) calf model, (D) inlet side, and (E) blade side of the pump after explant, (F) 2nd-G opt. rotor.

BIO 2

Pathways to Medical Device Innovation: Academic Publication vs. Patent - "Chicken or the Egg?"

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Study: Medical Device development relies on advances in science, engineering, medicine and technology. Results of advances in all of these disciplines are codified for transmission of information in a range of sources, broadly categorized as either academic/trade publications versus intellectual property (patent) publication. It remains unknown what degree of advance is first published in open academic literature versus proprietary patent literature. We investigated that here, hypothesizing that a substantial degree of inventive knowledge appears first in one or the other domain.
Methods: Medical device relevant patent classes were chosen from the International Patent Classification system (10 classes). 1000 top-cited patents were analyzed and filtered for societal impact using the Derwent Innovation Index. Preceding and derivative patents, dissemination of the technology, and practical usability were taken into account. In parallel 10 "keyword strings" specific to each technology were generated. The inventor(s), assignee, invention topic, and identifying keyword strings were used to search the academic literature for publications related to the technology. The Web of Science was used for academic literature searches.
Results: The majority of impactful medical devices/technologies originated first as intellectual property (>70%). Of these, 45% were classified as cardiopulmonary devices, and 90% led to at least 120 derivative publications and patents. The remaining technologies (30%) were based on knowledge first originating in published academic works. These findings demonstrate that a distribution of discovery/information exists between publication sources. These data suggest the value and need to utilize both domains of information - intellectual property and academic publications, to better and more completely inform in the design of novel research studies; and for the development of medical devices and technologies.

BIO 3

Engineering and Production Challenges for Mechanical Circulatory Support Devices

A. R. Polakowski[1], *D. J. Horvath*[2], *B. D. Kuban*[1], *C. R. Flick*[1], *K. Fukamachi*[1], *J. H. Karimov*[1]; [1]*Cleveland Clinic, Cleveland, OH,* [2]*R1 Engineering, Cleveland, OH.*

Study: In the United States, 50,000 - 100,000 patients require heart transplants or mechanical circulatory support (MCS). The Cleveland Clinic device portfolio, which includes ventricular assist devices (VADs) and continuous-flow total artificial hearts (CFTAH), has been developed to address the need for MCS. Prototype blood pump components are tightly toleranced, whereas production components will need less stringent tolerancing to successfully achieve production quality standards. We report the engineering and manufacturing challenges when bringing a blood pump into full-scale production.

Methods: Techniques for metal casting and forging components in biocompatible materials, titanium (alloy Ti-6Al-4V) and zirconia (YTZP, yttria tetragonal zirconia polycrystal), have been explored in comparison to the traditional methodology of machining away 80 or 90% from a starting block of material. Inefficiencies in terms of time and overall effort for challenging machining processes have been investigated to minimize the use of costly materials. Physical seams (joints or interfaces between components) requiring minimization to reduce thrombosis were included in evaluation. Smaller devices for pediatric and infant patients require tighter envelopes, within which, motor manufacturers will develop stators that produce the required torque values, and are maximized for power efficiency.

Results: Design efforts to improve seams between components, which include step and gap reductions, have resulted in thrombosis prevention (Fig. 1-a). A complex machining feature (Fig. 1-b) and an oddly shaped part (Fig. 1-c) are shown, that when using traditional machining techniques require cost, time, and effort. A simple volume comparison between the finished component and the starting work piece yielded 90.5% scrap material (Fig. 1-d). Producing a cast part reduced scrap to less than 10%. Thus, limiting machining to only finishing operations significantly reduced part cost and fabrication time.

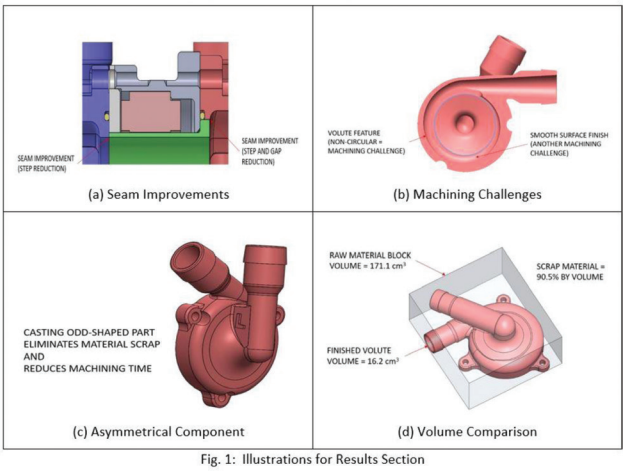

Fig. 1: Illustrations for Results Section

BIO 4

Rational Design of TEVG: The Process

N. A. Suárez V., *M. A. Rodriguez-Soto, A. Riveros C., J. C. Briceño; +Deparment of Biomedical Engineering, Universidad de los Andes, Bogotá D. C., Colombia.*

Study: Operation of vascular grafts under complex hemodynamic conditions (insufficient shear stress and mixed or pseudo-static flow) change the metabolic pathways of reendothelialization and regeneration of the vascular wall. Despite of recent approaches (including ours) in tissue engineered vascular grafts (TEVGs) design and manufacture; there is not an available TEVG ready for clinical use. Fully understanding the regeneration process is essential to design a methodology to produce grafts that reduce thrombogenesis and maintain long-term patency.
Methods: Actors in the regeneration process were identified and their response was evaluated in 3 phases upon implantation: Peri-implantation, early implantation and operation. A literature review was performed, and data was organized according to the actors interacting in the 3 phases under 3 levels of success. Phase 1: (i) foreign body reaction, (ii) thrombogenesis, and (iii) with reendothelialization potential. Phase 2: (i) fibrotic tissue impairing oxygen delivery, (ii) patent graft with stable hemodynamics without regeneration, and (iii) regeneration has started. Phase 3: (i) intimal hyperplasia, (ii) discontinuous regeneration, and (iii) physiological reendothelialization and SMCs proliferation rates.
Results: For Phase 1, failure or success of a vascular graft depends on the surface affinity and flow conditions to platelet activation factors. For phase 2, regeneration is guided by the switching of macrophage phenotype from M1 to M2 so that inflammatory response induces cell recruiting rather than fibrosis.

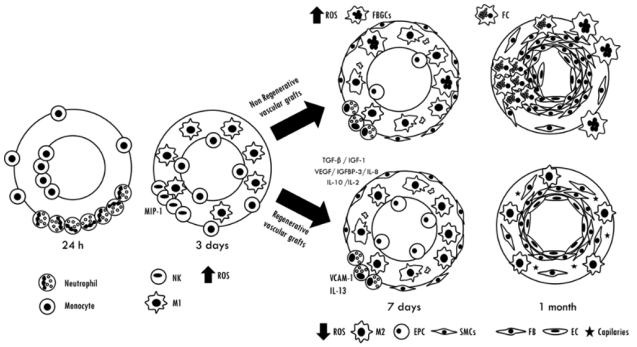

Figure 1: TEVG regneration

Long-term success depends on the graft's capacity to promote reendothelialization and expression of functional endothelium phenotype with active response to complex hemodynamic conditions and modulate smooth muscle cell proliferation and activity. As a result, a methodology oriented to design vascular graft in which these interactions are studied at early stages is proposed. It focuses on characterization of bulk material and surface interaction optimization.

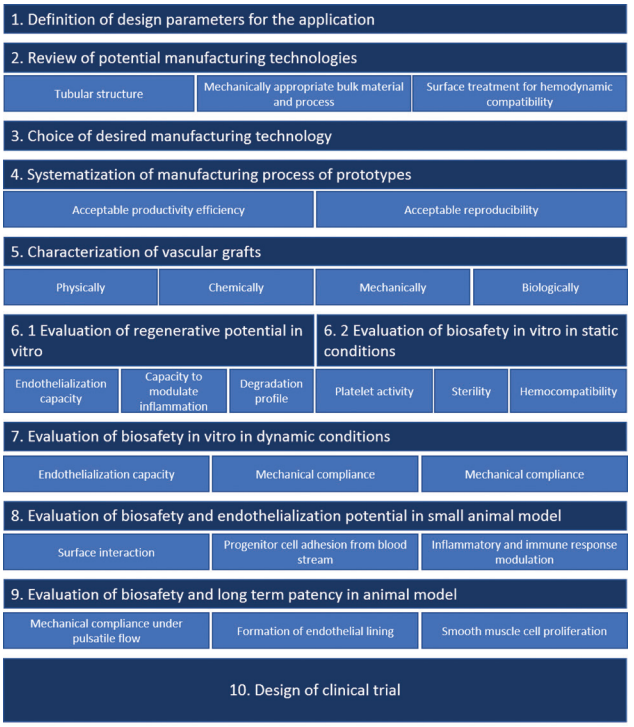

Figure 2: Design process of a TEVG

BIO 5

A New Portable Driver for NuPulseCV Chronic Counterpulsation Cardiac Support Device

A. Meyers, D. Ivers, P. DeDecker, G. Giridharan, **J. R. Woolley**, *S. Patel-Raman; NuPulseCV, Raleigh, NC.*

Study: The NuPulseCV (Raleigh, NC) Intravascular Ventricular Assist System (iVAS) is a minimally-invasive, long-term, portable counterpulsation device for heart failure treatment. An FDA-approved Feasibility Trial in over 70 patients demonstrated that the first-generation pneumatic driver (Gen1 NDU) provides effective counterpulsation while promoting rehabilitation and patient discharge. The Gen1 NDU was rated for only 90-days of use, expensive to build, noisy (> 60 dB), and required predictive pumping algorithms contraindicating implants in patients with atrial fibrillation. NuPulseCV is developing a smaller, lighter, cheaper, quieter and ergonomic second-generation driver (Gen2 NDU) for clinical introduction in a Pivotal Trial.

Methods: To reduce inflation/deflation time and increase durability, a more powerful motor was incorporated and the bellows travel distance was reduced from 33 mm to 12 mm. Electromechanical components (processors, circuit boards, valve manifolds) and internal software were developed to increase speed of response, and reduce weight and noise. Gen2 NDU incorporates Bluetooth and cellular network capability to upload operational information. The Gen2 NDU was designed to reduce manufacturing time and costs and incorporated human factors and ergonomics considerations.

Results: Benchtop testing demonstrated that the Gen2 NDU can support up to 160 bpm in 1:1 mode with real time pumping, and is quieter (< 46 dB). The Gen2 NDU is lighter (approximately 5 lbs), and cheaper to manufacture by over 30%. The anticipated durability is > 1 year. Human factor and ergonomics improvements in the Gen2 NDU include ergonomic carrying configurations, quieter operation, and an improved display and interface. Gen2 NDU improvements will result in enhanced hemodynamic support and patient experience, while expanding the patient population that could benefit from iVAS therapy.

BIO 6

Update on the Development of the Continuous-flow Total Artificial Heart and Advanced Pump Controller Interface

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Study: The continuous-flow total artificial heart (CFTAH) being developed at the Cleveland Clinic uses an automatic speed control system to regulate the pump's output in response to changes in the patient's hemodynamic conditions. The system responds to changes in vascular resistance, and can predict, detect and respond to pump suction. These features require accurate estimates of hemodynamic parameters, such as systemic vascular resistance, and the pump's pressure gradients. The CFTAH does this by analyzing power consumption, and the axial position of the pump's rotor with several regression equations and artificial neural networks.

Methods: 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. The APCI synchronizes the data from the motor controller, such as rotor position and current, with the data from the laboratory instrumentation, such as pressure and flow. This makes it possible to partially automate the process of fine tuning the neural networks and equation parameters.

Results: The APCI and CFTAH controller system can model and estimate basic hemodynamic parameters such as SVR (Fig. 1), 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. More *in vivo* and *in vitro* testing with the APCI is planned.

Fig 1. APCI window showing data from an *in vivo* experiment with open window selection menu.

BIO 7

Design of a VAD Alarm Sensing Device to Haptic Warning for Hearing Impaired Patients

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Study: The purpose of this study is to design a device to instantly wake up and notify hearing impaired patients who are supported with ventricular assist devices (VAD) of alarm notifications. Currently, VAD patients with hearing impairments rely on at-home assistive care, or a vibrating personal receiver to wake them up whenever a loud sound is detected. These receivers are not specifically designed for VAD support, have a delayed response time and they are prone to false detection from external noises. Our VAD alarm sensing device allows for instant notification and the dual sensor input design prevents false detection.
Methods: An Arduino Mini microcontroller was programmed to detect the alarm inputs and send a wireless signal through Radio Frequency Communication to a haptic wristband, which wakes up and notifies the patient. The device is intended to be situated next to or on the VAD pump controller. A Heartware (HVAD™) controller (Catalog no. 1403US, Medtronic) was used to assess the functionality of our device. The dual sensor input includes a microphone to detect VAD alarms, and a photoresistor to detect the VAD LED signal. A radio frequency signal is then sent to a haptic wristband built with haptic motors that pulses the patient awake.
Results: The device was able to detect alarms and activate the haptic wrist band within an average time of 0.25 seconds. The microphone was able to detect frequencies within the range of 20 Hz to 20 KHz. The battery capacity of our device (i.e. idle mode) lasted an average of 36 hours. This device has the potential to improve the quality of life of hearing-impaired patients with VADs by giving them the confidence of knowing that they will be alerted instantly, while not experiencing the stress of false alarms.

BIO 8

Further Steps Towards the Development of a Biohybrid Lung

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Study: The only curative therapy option for patients suffering from end stage lung diseases is lung transplantation, which is still associated with high risks. In order to provide an alternative treatment option, this project aims for the development of an implantable biohybrid lung (BL), based on hollow fibre membrane (HFM) technology used in extracorporeal membrane oxygenators (ECMO). Therefore, a crucial requirement to achieve long-lasting durability is the optimized bio- and haemocompatibility of all blood contacting surfaces, which can be achieved by endothelialisation.
Methods: In vitro test were carried out to compare the eligibility of Albumin/Heparin (A/H) and Fibronectin (FN) coated HFM to mediate the establishment of a viable, confluent and non-thrombogenic EC-monolayer. The activation status of seeded ECs was analysed in leukocyte- and thrombocyte adhesion assays. In order to assess the behaviour of the HFM-seeded ECs under workload conditions, i.e. fluid flow and oxidative stress exposure, experiments in a customized flow chamber were carried out. To identify a clinically relevant EC source, comparative studies including human cord blood derived endothelial cells (hCBECs,) induced pluripotent stem cell derived endothelial cells (iPSC-EC) and immunotolerable HLA-silenced hCBECs were conducted.
Results: A viable, confluent and physiologic monolayer, could be sustained under both, static and flow dynamic culture conditions. All tested EC types preserved their non-thrombogenic and non-inflammatory status on all tested HMF coatings. Exposure to relevant levels of hyperoxia or hypoxia did not affect the physiological function of the ECs. However, FN coated HFMs demonstrated an improved EC-monolayer resistance towards flow conditions. Summarizing, these results are the first promising steps towards the development of a BL. HLA-silenced ECs could be considered as suitable cell source, escaping the recipients immune response, while being used for sufficient endothelialisation of the FN coated HFM.

BIO 9

Electromagnetic Analysis of a Novel Motor for a Left Atrial Assist Device

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Study: We are developing a novel heart assist device designed to aid patients with heart failure with preserved ejection fraction (HFpEF). This device, the left atrial assist device (LAAD), is sewn into the mitral annulus and pumps blood from the left atrium into the left ventricle. In order to meet the demanding size and power requirements for the motor that drives the LAAD, we are developing a custom brushless, sensorless DC (BLSLDC) motor for the device. Also, since the LAAD utilizes a hydrodynamic bearing which must be balanced with the radial magnetic force of the motor, it was necessary to characterize the radial magnetic stiffness of the rotor-stator interaction. This characterization was done computationally using electromagnetic simulation.

Methods: JMAG Express software was used to design a BLSLDC motor with size, shape and power characteristics suitable for the LAAD device. ANSYS modeling and simulation software was then used to produce a 3D model (Figure 1) of the LAAD motor using the same parameters found in the design process. The model was then used to characterize the axial and radial magnetic stiffnesses of the rotor-stator interaction. It was also used to verify that there was no significant magnetic saturation in the stator laminations nor the rotor back-iron.

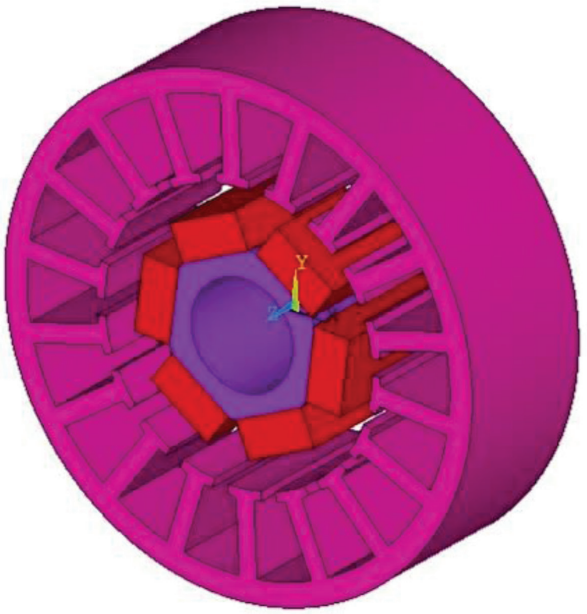

Figure 1. 3D model of LAAD motor generated in ANSYS for electromagnetic simulation

Results: The axial magnetic force versus axial rotor displacement was found to be nearly linear in the region of interest, with an average value of 12.1 N/inch. The radial magnetic force versus radial rotor offset from center of stator was also found to be nearly linear with an average value of 235.6 N/inch. Stator and rotor metal saturation was found to be negligible under the testing conditions. Computational fluid dynamic studies will now be performed to find the radial offset necessary to balance the fluid dynamic force and the radial magnetic force which will allow for stable pump operation.

BIO 10

Development of Structurally Reinforced and Biodegradable Vascular Graft with Small Diameter in a Porcine Model.

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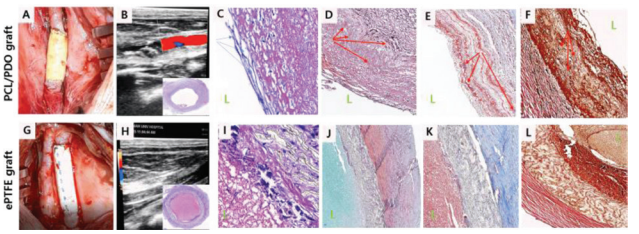
Study: There was no satisfactory improvement in short and long-term results in small diameter grafts, where most grafts failed due early thrombosis, aneurysmal dilation, atherosclerosis, and intima hyperplasia within the distal anastomosis. Herein, we studied an antithrombotic and small-diameter graft.

Methods: A total of 7 pigs (weight: 20-35kg) were used in this study. We made a 4mm graft with polycaprolactone (PCL) and polydioxanone (PDO) composite nanofiber via electro-spinning technique. We implanted simultaneously a commercially available expanded Polytetrafluoroethylene (e-PTFE) graft and our PCL/PDO graft into carotid arteries in pigs. An antiplatelet agent was administered only up to 3 days after implantation. Ultrasonographic examination was performed weekly to confirm the patency of the two grafts. After removal of grafts, we compared the biological compatibility of the two grafts by histologic staining and scanning electron microscope (SEM).

Results: Complications such as plasma leakage on the graft surface and significant bleeding from needle hole sites were not identified in the PCL/PDO graft immediately after implantation. On the ultrasonogram after 1 month of implantation, there was no blood flow in all e-PTFE grafts, but PCL/PDO grafts showed flow patency in 3 grafts (42.9%). PCL/PDO grafts were identified with extracellular matrix compositions (ECM) such as elastin, collagen, and glycosaminoglycan, but not in e-PTFE grafts.



BIO 11

New Biocompatible Polyphosphazene Biomaterials for Blood Contact Medical Devices

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Study: Biomaterial associated thrombosis and microbial infection limit the success of implanted devices. The quest to design and develop new materials with multiple functions including anti-thrombosis and antibacterial remains a high research priority. In this work, new polyphosphazenes, poly[bis(octafluoropentoxy) phosphazene] (OFP) and crosslinkable OFP (X-OFP), were synthesized and fabricated into surface textured films for use as blood contact medical materials.
Methods: New polyphosphazenes, poly[bis(octafluoropentoxy) phosphazene] (OFP) and crosslinkable OFP (X-OFP), were synthesized and fabricated into surface textured films for use as blood contact medical materials. Prior results demonstrated that new OFP polymer with fluorinate chemistry improved hemocompatibility with reductions in bacterial adhesion, platelet adhesion, and plasma coagulation, but lacked mechanical strength. To resolve this issue, crosslinkable allylphenoxy functional groups were introduced into P-N backbone of OFP for crosslinking under UV, which lead to improvements in mechanical properties. Polymer surfaces were textured with pillars of 500/500/600 nm.
Results: Surface texturing reduced surface contact area and reduced bacterial adhesion approximately 87%, 91%, 92% for S. epidermidis, S. aureus, and P. aeruginosa, respectively, compared to polyurethane MS/0.4. Assessment of biofilm formation demonstrated that no biofilms were observed on textured OFP/X-OFP surfaces over 7 days, while significant biofilms formed on polyurethane surfaces. Evaluations of hemocompatibility including plasma coagulation, platelet adhesion and activation, and red blood cell hemolysis demonstrate that OFP and X-OFPs have significantly lower responses than polyurethane biomaterials. Results suggest that new polyphosphazenes are promising biomaterials for blood contact medical devices that can potentially significantly decrease the risk of device-related thrombosis and infections.

BIO 12

Development of a Tissue Engineered ACL Using a Decellularized Pericardium

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Study: Anterior cruciate ligament (ACL) reconstruction with autologous ligament and replacement with artificial ligament are generally chosen when ruptured. However, several problems remained. Recently, decellularized tissues, which are prepared by the removal of cells from living tissues, are expected as candidate biomaterials because of high biocompatibility and functionality. Decellularized ACLs have been tried to apply as artificial ligaments. It was previously reported that the decellularized ACL showed good biocompatibility, while the cell infiltration into the interior was difficult. In this study, to solve this problem, we developed an artificial tissue-engineered ligament using a decellularized pericardium.
Methods: The porcine pericardium was treated with high hydrostatic pressure (HHP: 1000 MPa, 30 ºC) and then washed through a washing process. The HHP decellularized pericardium was subjected to HE staining and residual DNA quantification. C2C12 cells were seeded on the HHP decellularized pericardium, and the cell adhesion and proliferation were investigated. Subsequently, the re-cellularized decellularized pericardium was rolled cylindrically to prepare an artificial tissue-engineering ligament, and the mechanical property was measured.
Results: No cells were observed for the HHP decellularized pericardium, and the amount of residual DNA was decreased significantly. When the C2C12 cells were seeded on the HHP decellularized pericardium, the cells were aligned along with the fiber direction of the HHP decellularized pericardium (Fig 1). The re-cellularized pericardium was cylindrically rolled (Fig 2). The mechanical properties, ultimate tensile strength and elastic modulus, of the obtained cylindrical tissue were similar to that of human ACL. These results suggest that the tissue-engineered ligament-like tissue was successfully developed by the cylindrical formation of the re-cellularized decellularized pericardium.

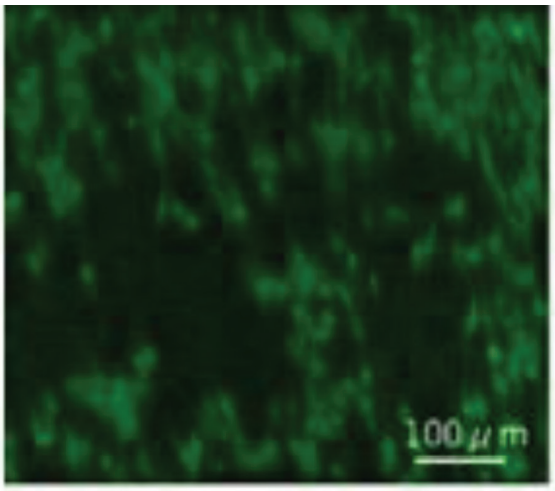

Fig. 1 Re-cellularization of the decellularized pericardium.

Fig. 2 Photograph of the tissue-engineered artificial ligament using decellularized pericardium

BIO 13

Rational Design of TEVG: Surface Modification

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Study: Despite the encouraging results in regenerative tissue engineered vascular grafts (TEVGs), their patency is lost under complex hemodynamic conditions where cells and blood components interact in non-physiological manner with the biomaterial. Here, we aimed at providing clues for the rational design of TEVGs modulating the surface-blood cell interaction.

Methods: Two TEVGs were tested: Decellularized arteries and tri-layered scaffolds made of oxidized Polycaprolactone. They were surface functionalized with polyethileneglycol (PEG), conjugated peptides (GRGDSP, SVVYGLR) and an organoselenium compound capable of releasing nitric oxide (NO).

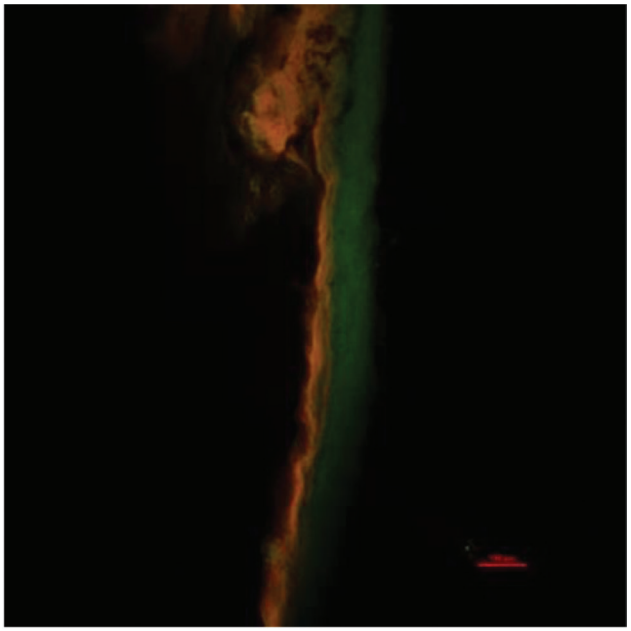

Figure 1: Confocal microscopy image from Alexa 555 stained PEG coating over decellularized artery

Functional groups were confirmed via Fourier Transform Infrared Spectroscopy (FTIR) and surface microstructure was imaged via scanning electron microscopy (SEM). Cytotoxicity was estimated from metabolic activity assay MTT. Hemolysis, platelet aggregation, adhesion and activation (LDH) tests were performed to evaluate hemocompatibility. Adhesion, spreading and proliferation of seeded endothelial cells (HUVECs) were estimated via immunofluorescence. NO release was quantified to assess endothelial function. qPCR was performed to conduct HUVECs expression profile of key genes.

Results: Surface functionalized TEVGs showed low cytotoxicity (<20%) and good hemocompatibility evidenced by low hemolysis (<5%), and platelet aggregation (<20%), adhesion (>1x105platelets/mm2) and activation. Functionalization promoted HUVECs cell adhesion, spreading and proliferation. A 2-fold increase in NO released by HUVECs seeded after 1 week suggested endothelial cell functionality.

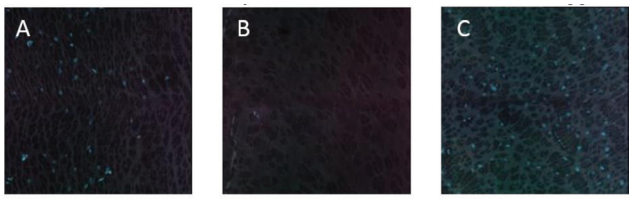

Figure 2: HUVECs cultured for 24h over (A) Untreated Surface (B)PEG treated Surface (C) Peptide coated surface

HUVECs expression profile corroborated that surface functionalization might cause induction or repression of key genes. The multifunctional surface modification here represents a suitable avenue to tailor TEVGs for the controlled surface-blood cell interaction. Future work will assess potential routes for inflammatory process modulation and the long-term performance of TEVGs.

BIO 14

Study of Cooperation Between the Heart and LVAD in Patients Undergoing Exercise Training

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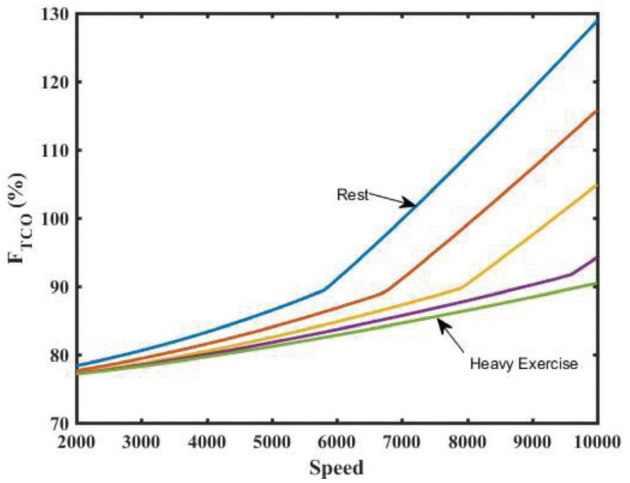
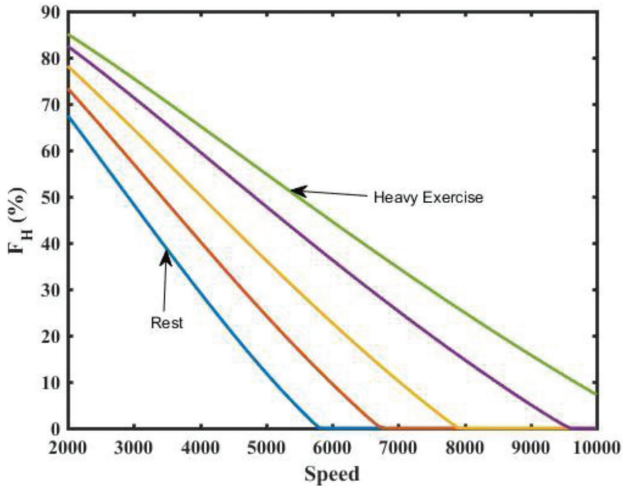
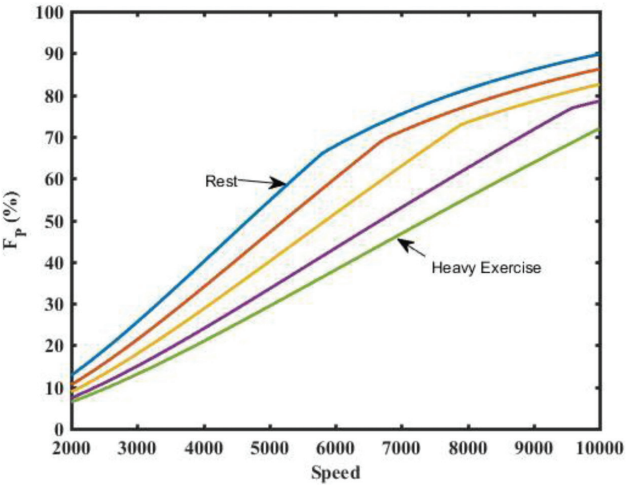
Study: Continuous flow LVADs operating at fixed speeds do not provide sufficient spontaneous increase in the pump flow to compensate for increased exercise demands. The inherent competition between the heart and the LVAD could be perceived as a cooperative mechanism which can be used as a basis to establish a control algorithm that can vary the speed of the LVAD to meet exercise demands. This study looks at fractional analysis of the blood flow between two paths, one through the aortic valve and the other through the pump, further classified flow due to the heart contraction as well as impeller speed.

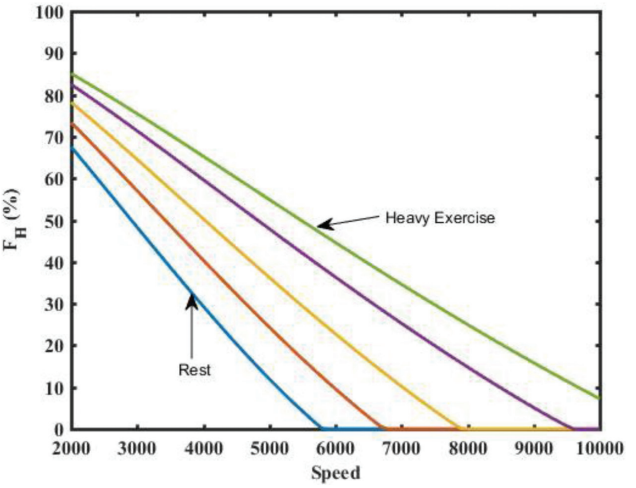
Methods: In our work, we use a validated mathematical model to analyze fractional blood flow through the aortic valve, F_H, and compute the relative total flow with respect to a healthy person undergoing similar exercise training, F_{TCO}. We also study the fractional flow through the pump pushed by the heart, F_{PH} and impeller, F_P. Initially, at constant speed and different levels of activity, various fractions are measured. Finally, the pump speed is changed in equal steps and the process is repeated.

Results: Our results indicate that the F_{TCO} does not satisfy the blood demand on exercise training. As the pump speed increases, the aortic valve shuts down permanently, and F_{TCO} changes significantly (Figure 1). However, when the aortic valve is shut, the pump operation can satisfy blood demand at different activity levels. Although F_H increases and F_P decreases with exercise (Figure 2a, b), the speed of the pump rises afterload, eventually closing the aortic valve i.e. F_H = 0 %. $F_{PH,}$ as expected, is higher at rest compared to heavy exercise (Figure 2c), however, it increases with speed until a maximum and drops when F_H = 0%. Therefore, $F_H + F_{PH} = 100\text{-}F_P$, which quantifies the cooperation. In conclusion, using the cooperative mechanism between the heart and pump, the blood flow to meet the demand of exercise training can be adjusted by varying the speed of the pump, which, in turn, varies the fractional contribution of the pump.









BIO 15

Real-Time Motion Capture with Computational Fluid Dynamic Analysis for Enhanced Ventricular Assist Device Implant Training

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Study: Ventricular assist device (VAD) inflow cannula malposition can lead to implant complications, especially in cases of complex pediatric pathology such as hypoplastic left heart syndrome (HLHS). While virtual fitting can supplement implant planning, this method lacks the tactile feedback needed for surgical training. Therefore, we envision a comprehensive approach to VAD implant training that combines kinesthetic, visual, and quantitative feedback using motion capture with computational fluid dynamic (CFD) analysis.

Methods: 3D-printed cannulas and HLHS hearts were registered with their virtual counterparts using tracking markers as shown in **Figure 1A**, enabling real-time motion capture of VAD placements. Cannulas were then physically implanted on either the diaphragmatic or apical surface of the heart. Resulting virtual configurations were analyzed using a laminar flow, non-Newtonian computational model and assessed for thrombogenic potential.

Results: Physical to virtual conversion of the implant configurations exhibits minimal alignment error with the ability to accurately position cannulas within a simulated environment (**Figure 1B-C**). CFD reveals regions of low-velocity, low strain rate fluid near the implantation site with varying residence times (**Figure 1D**). Overall, this method provides an enhanced training workflow that utilizes tactile and computational feedback to optimize VAD implant positioning within complex pediatric hearts.

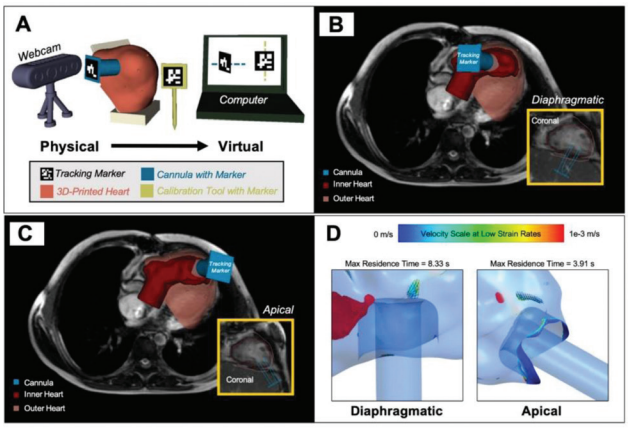

Figure 1: Physical to virtual model conversion using real-time motion capture obtained by tracking markers (**A**) is used to simulate diaphragmatic (**B**) *vs.* apical (**C**) inflow cannula positions within physical hearts. Computational analysis of the two configurations reveals regions of low-velocity, low strain rate fluid near the implantation site with varying residence times (**D**).

BIO 16

Total Artificial Heart Computational Fluid Dynamics Modeling - A Study on the Impact of Journal Bearing Nominal Clearance on the Potential for Blood Damage

M. Khelghatibana[1], *M. Yaksh*[2], *M. S. Goodin*[3], *D. J. Horvath*[4], *B. Kuban*[5], *A. R. Polakowski*[5], *C. Flick*[5], *J. H. Karimov*[5], *T. Miyamoto*[5], *K. Fukamachi*[5]; [1]*SimuTech Group, Montreal, QC, Canada,* [2]*Yaksh Magnetics Solutions, Lilburn, GA,* [3]*SimuTech Group, Hudson, OH,* [4]*R1 Engineering, Euclid, OH,* [5]*Cleveland Clinic, Cleveland, OH.*

Study: Cleveland Clinic's continuous-flow total artificial heart (CFTAH) is a double-ended centrifugal blood pump that has a single rotating assembly with an embedded magnet, which is axially and radially suspended by the balancing of magnetic and hydrodynamic forces. The journal bearing blood passage, which creates a narrow flow path connecting the left and right impellers, is a region found susceptible to blood damage. In this project, a series of coupled electromagnetic (EMAG)/computational fluid dynamics (CFD) analyses were performed to find an optimum nominal radial clearance that reduces the potential of blood damage in the journal bearing while satisfying the geometric design constraints imposed by the pump and motor configuration.

Methods: The CFD study was performed on the CFTAH100 design. This design replaces the CFTAH080 that was tested and found biocompatible in regards to the journal bearing and acceptable in terms of hydrodynamic performance. CFTAH100 has a similar bearing design with a lower radial magnetic stiffness due to an overall shorter magnet length. ANSYS Maxwell (ANSYS, Canonsburg, PA) was used to develop an EMAG model which determined the radial magnetic stiffness of the rotating assembly. Using the radial magnetic stiffness, moving mesh simulations using ANSYS CFX (ANSYS, Canonsburg, PA) were used to predict the magnetic/hydrodynamic force-balanced position of the rotor and investigate the influence of bearing clearance on rotor power and the main characteristics of the bearing blood flow.

Results: The EMAG/CFD coupled simulations showed that by increasing the nominal bearing clearance, rotor power, stator wall average shear stress and average blood residence time in journal bearing decreased while blood volume flow rate increased. The results were used to select a bearing design with the lowest potential for blood trauma which will be confirmed through upcoming *in vitro* and *in vivo* testing.

BIO 17

Characterization of The Hysteretic Behavior of a Pediatric Left Ventricular Assist Device

J. Valdovinos; *Electrical and Computer Engineering, California State University Northridge, Northridge, CA.*

Study: Pump characteristic curves are ubiquitous in the design of left ventricular assist devices (LVADs). These curves, which relate pressure head and volume flow rate, represent the steady-state response of the pump at a given operational point and load. However, the behavior of LVADs under physiologically dynamic conditions exhibits hysteresis which may elucidate clinically-relevant information regarding device-physiology interactions. This study aims to quantify this hysteresis loop for the Jarvik 2000 Child, a continuous flow pediatric LVAD.

Methods: A mock circulation representing the pediatric arterial circulation was developed to test the dynamic behavior of the Jarvik 2000 Child (Figure 1). The mock circulation consisted of a compliance chamber and a clamp as the resistive element. The atria consisted of an open-air tank with adjustable height for providing a variable preload. The ventricle was represented by a 30 cc Berlin Heart Excor pulsatile pump (Berlin Heart, Berlin, Germany) and was pneumatically powered by the Thoratec TLC-II Portable Driver (St. Jude Medical, Sylmar, CA). Pressure head was measured across the inlet and outlet of the LVAD using pressure transducers (AD Instruments, Colorado Springs, CO) and volumetric flow rate was measured using an ultrasonic flow probe (Transonic Systems Inc., Ithaca, NY).

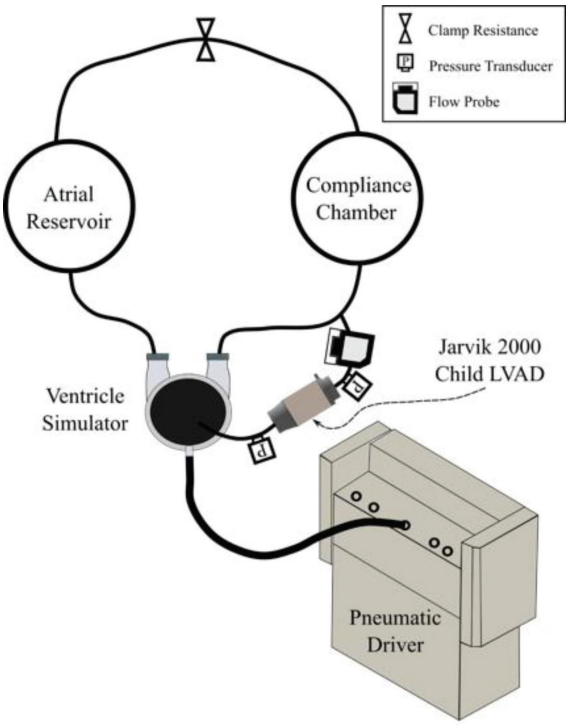

Figure 1. Experimental setup to derive the hysteretic behavior of a pediatric LVAD

Results: The pump characteristic curves were measured for operating speeds ranging from 10-18 kRPM and at various ventricular heart rates ranging from 50-100 BPM. Preloads were also varied from 2-20 mmHg. The area within the hysteresis loops were sensitive to ventricular heart rate for constant pump operational speeds and preloads. Hysteretic area was also sensitive to preload conditions for constant ventricular heart rate and pump operational speed. In addition, backwards volumetric flow was inversely related to operational pump speed. Overall, the results point to the possibility of extracting physiological information from LVAD dynamic behavior.

BIO 18

Prediction of Interventricular Septum Positioning During Left Ventricular Support

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Study: The implantation of left ventricular assist devices (LVADs) in heart failure patients is often complicated by arrhythmias as well as right ventricular failure (RVF) partially attributed to abnormal positioning of the interventricular septum (IVS). In the clinic, the pump speed is titrated to optimize device support using echocardiographic ultrasound (US) as the standard technique to monitor the positioning of the IVS. The goal of this study was to demonstrate the applicability of integrated US transducers in the cannula of the LVAD to measure the distance to the septum, and thus, monitor IVS positioning in real time.

Methods: We propose a distance-based predictor with three transducers and report its prediction error and robustness in detecting whether the IVS is shifted abnormally to the left ventricle, and whether the positioning can be measured continuously. The in vitro setting featured a test bench with four differently sized patient-specific silicone heart phantoms, derived from clinical data, at a range of distinct bi-ventricular volume states.

Results: The distance-based predictor of the IVS shift achieves an overall prediction error of less than 20% for all volume states and provides a continuous assessment of septum position for 99% of all cases. The prediction of the IVS shift is robust for a cannula rotation of ±20° and a cannula tilt of ±8°. The proposed intra-cardiac US measurement concept results in a viable predictor for an abnormal IVS positioning and represents a promising approach to continuously monitor the IVS in LVAD patients to prevent RVF, suction and inadequate ventricular unloading.

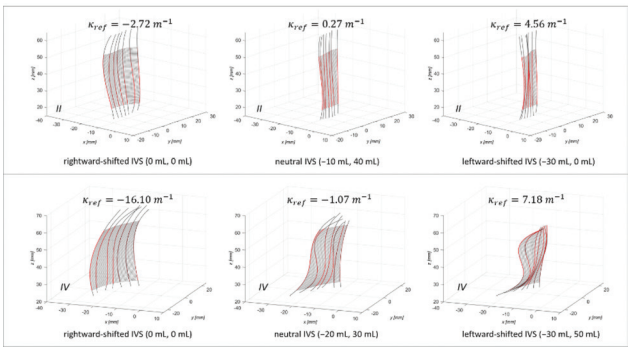


Figure 1. Visualization of interventricular septum (IVS) positioning. The septal wall of the heart phantoms *II* and *IV* are illustrated for three relative left ventricular and right ventricular volume changes (ΔLVV, ΔRVV).

BIO 19

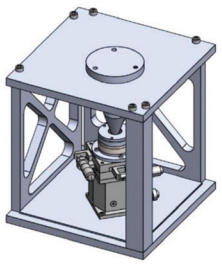
Static Force Evaluation of PM Rings for a Miniature Maglev System: Numerical and Experimental Approach

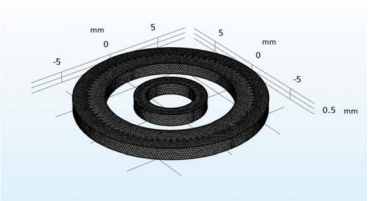
S. Karnik[1], P. Smith[2], **Y. Wang**[2]*, N. Kurita[3]; [1]University of Houston, Houston, TX, [2]Texas Heart Institute, Houston, TX, [3]Gunma University, Gunma, Japan.*

Study: In recent work, we proposed a blood shear stress device (BSSD) that features an exchangeable rotor to evaluate the hemocompatibility of each individual LVAD component. A computational fluid dynamics model was built to evaluate shear stresses in the BSSD drive motor. To improve hemocompatibility, we propose to levitate the rotor radially with passive permanent magnet (PM) ring bearing and axially with an active magnetically levitated bearing. This study examines the radial and axial stiffness produced by varied PM ring geometries.

Methods: A total of 27 geometries were evaluated numerically and experimentally. PM ring geometries included lengths 1, 2, 3 mm; stator outer diameters (OD) 16, 18, 20 mm; rotor ODs of 6, 8, 10 mm. A numerical model for the concentric arrangement of PM rings was simulated using COMSOL 5.4. The inner diameter of the outer PM ring and the inner PM ring were fixed at 10.7 mm and 4.0 mm respectively. The axial and the radial forces for each of the 27 geometries were calculated with the displacement of the inner PM ring in the axial and the radial direction. We designed to build a magnetic force test rig (MFTR) to evaluate the magnetic forces experimentally. Each geometry was tested twice by mounting the inner PM ring to a rigid shaft and the outer PM ring to a micrometer driven stage. The outer PM was positioned to record a range of axial and radial displacements.

Results: The trends found numerically were similar to those found experimentally. As the length increased, both the axial force/stiffness and radial force/stiffness increases by 5%. Stator OD had a little effect around 1%. Rotor OD had the greatest impact which caused an approximate increase of 35% in the radial stiffness and 20-30% increase in the axial stiffness. The average error between the numerical and experimental results is about 2.4% for axial stiffness and 0.6% for radial stiffness; therefore, the numerical model is validated experimentally.





BIO 20

Use of Intra-cardiac Cycle Delta Flow Delivery for a Constant Speed Microaxial Mechanical Circulatory Support Device to Assess Native Heart Recovery

R. Gandhi, *N. Roberts, C. Sheils, S. Bhavsar, S. Corbett, T. Siess; Abiomed, Danvers, MA.*

Study: The Impella 5.5 is effective in providing partial to full support for patients in acute heart failure to unload the heart targeting native heart recovery. There can be challenges in assessing when a patient has regained native cardiac function and is ready to wean. We hypothesized that an increase in the delta in flow within a cardiac cycle is indicative of native heart recovery for a given pump speed.

Methods: In vitro tests were completed using a mock circulatory loop in accordance with ASTM F 1841-97 (2005) to characterize flow across the full spectrum pressure range and through all commercially available pump speeds (Fig 1). Case data logs from patients supported by the Impella 5.5 with reported recovery at explant as identified by the Impella IQ database were obtained post explant. Data logs were evaluated for characteristic hydraulic performance in maximum, minimum, and mean flow at a constant pump rotational speed at specified time points during patient support including implantation, weaning, and pump explanation. Raw log data was analyzed using Labview, and data analyses were performed using Matlab and Minitab.

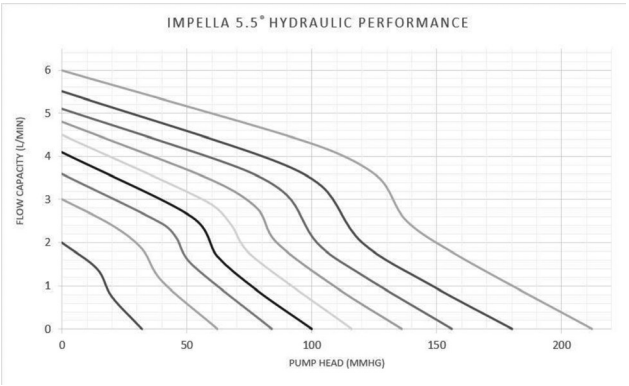


Fig 1. Impella 5.5 HQ Curve

Results: 15 patient cases identified as recovered with data logs collected were retrospectively analyzed. Duration of support to successful explant with native heart recovery ranged from 2 - 15 days. At a constant speed, the intra-cardiac cycle delta flow delivery (max - min flow) increased up to 0.3 L/min from the first 24 hours of support to the start of pump weaning and device explant.

Initial results demonstrated that an increase in delta flow delivery within a cardiac cycle was a directional indicator of recovery leading to a successful wean and device explant. Incorporation of trending the intra-cycle delta flow over the duration of patient support may provide insights on cardiac function and help inform patient management by allowing the physician to identify signals of native heart recovery.

BIO 21

A Novel, Non-invasive Metric for Assessment of Suction Prevalence Using HVAD Logfiles

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Study: Avoidance of suction conditions is a common management challenge of continuous flow devices. Volumetric suction may be associated with ventricular collapse, which when visualized on ECHO, is characterized by negative deflections in the flow waveform toward 0 L/min. The Medtronic HeartWare HVAD Controller calculates an estimated flow waveform at a rate of 50 Hz and stores operational trend data known as logfiles once every 15 minutes. An algorithm was developed for detecting suction in controller logfiles. The purpose of this study was to assess algorithm performance by characterizing sensitivity, false positive rate, and density correlation to waveforms.
Methods: High-resolution waveforms were collected continuously on 8 patients for at least 1 week. The presence of suction was determined by observing waveform morphology. Logfiles were evaluated using the suction detector algorithm and compared to waveforms. A cross-validation approach was utilized by splitting the waveform database into "development" and "validation" datasets. Only the development dataset was used in initial creation of the algorithm. The same algorithm parameters were then applied to the validation dataset. Validation data was blinded until tuning was complete on the development dataset.
Results: The results of the performance characterization are presented in Table 1.

Table 1. Results of Logfile Suction Characterization

	Number of Data Points (n)	Sensitivity	False Positives per 14-days
Development Dataset	9042	100%	0.149
Validation Dataset	18330	96.2%	0.146
Combined Dataset	27372	97.8%	0.147

Results suggest the algorithm detects suction with high sensitivity (97.8%) and low false positive rate (0.147 events per 14 days). Additionally, there is a high correlation of suction density (97.1%) comparing logfiles to waveform data, highlighting the utility of logfiles in assessing overall suction prevalence. This is a significant finding as logfiles are calculated continuously, thus allowing the clinician to retrospectively assess suction events occurring when the patient is not in clinic. Logfile analysis with suction detection and density metrics may provide supplementary data for patient optimization and clinical management.

BIO 22

Non Invasive Peripheral Tissue Perfusion Measurement in PatientsWith Continuous Flow Left Ventricular Assist Device Using Laser Speckle Flowgraphy

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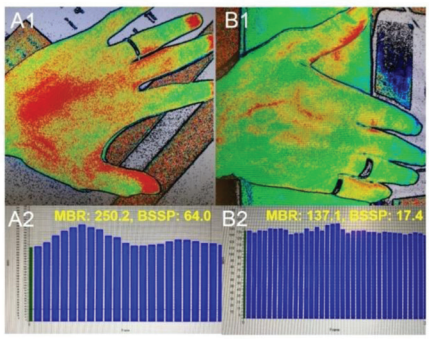
Study: It is common for Left Ventricular Assist Device (LVAD) patients to struggle with persistent right-sided heart failure (RHF), and the high readmission rate due to RHF remains a significant clinical issue. Laser speckle flowgraphy (LSFG) is a novel technology to measure tissue blood perfusion in a non-invasive fashion. We sought to utilize LSFG to monitor LVAD patients and to detect early signs of RHF.
Methods: Between 2008-2019, 515 patients underwent LVAD implantation at our institution. Among them, 89 patients received LSFG measurements. 20 healthy subjects served as control. Mean Blur Rate (MBR) and Beat Strength of Skin perfusion (BSSP) were obtained from the measurement data by LSFG. MBR indicates proportional blood flow relative to the velocity of erythrocytes, and BSSP is the difference of the MBRs in between the systolic and diastolic phase.
Results: LVAD baseline characteristic were (N=89): mean age 57.3±13.4 year-old, LVEF 18.9±6.4 %, LVEDD 68.6±9.9mm, CVP 12.9±6.5 mmHg, mean pulmonary artery pressure 38.1±10.3 mmHg, PCWP 24.9±9.0 mmHg, CO 3.8±1.1 L/min, CI 2.0±0.8 L/min/m^2, mean arterial pressure 90.6±11.6 mmHg. MBR was 190.1±57.3 in the LVAD group and 213.8±60.7 in the healthy group (p=0.1223). BSSP, which reflects pulse pressure, was less in the LVAD group compared with the healthy group (31.9±21.7 vs. 51.3±32.3, p= 0.0172). The results indicate that pulsatility related to peripheral tissue perfusion was less in the LVAD group than healthy group while mean blood flow was similar between two groups. In conclusion, it is feasible to measure peripheral tissue flows using LSFG in LVAD patients. The peripheral blood flow pattern obtained by LSFG in patients with LVADs was less pulsatile compared with that of the healthy subjects. Further study is necessary to determine whether LSFG can facilitate in the detection of early signs of right heart failure in LVAD patients.



Upper row: 2D color-coded map. (A1) Healthy control, (B1) LVAD patient.
Lower row: A synthesized pulse wave with heartbeat (time flame in the X axis、MBR in the Y axis). (A2) Healthy control, (B2) LVAD patient.

BIO 23

Cardiovascular Stent Hemocompatibility Assessment: Distinguishing Thrombogenicity vs. Hemolytic Potential *In Vitro*

K. R. Ammann[1], *M. Fang*[2], *T. Suekama*[2], *Y. Roka-Moiia*[3], *M. J. Slepian*[1], *S. Hossainy*[2]; [1]*Medicine, University of Arizona, Tucson, AZ,* [2]*Imperative Care, Inc., Campbell, CA,* [3]*Medicine, University or Arizona, Tucson, AZ.*

Study: Blood-surface interactions remain a vital component of cardiovascular device design. *In vitro* hemocompatibility testing is a critical step in the device development process, allowing for high throughput testing and decreased economic burden. However, there are many confounding factors during *in vitro* testing that can affect endpoints. Currently, a wide variety of techniques are employed for qualitative and quantitative hemocompatibility assessment of implantable devices including image- and colorimetric-based assays. In the present study we investigate both hemolytic and thrombogenic properties of clinically well-established blood-contacting devices (cardiovascular stents) in a closed flow loop. We hypothesize that utilizing basic *in vitro* methods, we can distinguish between the thrombogenicity and hemolytic potential of cardiovascular stents in relation to their geometry, surface composition, and blood flow rate exposure.
Methods: Stents of varying geometry and composition were loaded into silicone tubing (2.79 mm ID) and flushed with saline. Anti-coagulated (10% ACD) human whole blood was collected via venipuncture from a consenting healthy donor. Re-calcified whole blood was loaded into tubing and peristaltic pump (Ismatec® IPC 24) for 10 min run. Blood was aspirated for hemolysis testing and stents were prepared by lysing for lactate dehydrogenase (LDH) assay.
Results: Our results indicate geometry, surface composition, and flow rate can impact, to varying degrees, platelet adhesion and hemolysis. Varying stent strut geometry resulted in significantly different platelet adhesion ($p < 0.01$), but not hemolytic properties after blood exposure. Stent surface coatings led to increased hemolysis but similar platelet adhesion. Increasing flow rate (32 mL/min vs 8 mL/min) did not affect platelet adhesion on bare metal stents. Careful consideration should be taken when accounting for these factors during hemocompatibility testing.

BIO 24

Phosphatidylserine Expression on Microparticles Varies with Exposure Time to Shear

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Study: The purpose of this study was to characterize surface receptor expression on RBC MPs according to length of exposure to shear in microfluidics (MF) experiments and correlate the results to observations in mock flow loops with VADs.
Methods: RBCs from fresh human blood were washed, resuspended in isotonic solutions, passed through MF channels exposing cells to a shear rate of 100,000 s-1 for 0-15 msec, collected and incubated with RBC marker anti-Glycophorin A(CD235a) and either Annexin V, to indicate PS, or anti-human IgG Fc and analyzed by flow cytometry. For flow loop experiments, fresh human blood units were purchased from a local blood bank. The blood was circulated with either a Thoratec CentriMag or HeartMate II VAD. Samples were collected periodically, incubated with anti- CD235a and anti-human IgG and analyzed by flow cytometry.
Results: Annexin V on MPs increased significantly with a single shear exposure of 100,000 s-1 up to 15 msec. All samples showed significant Annexin V-MP binding with greater than 50% increase over controls at 15ms. This trend corresponded to increased MP production. A large fraction of MPs displayed bound IgG. In flow loops, we observed a four-fold and eight-fold increase sub-micron MP generation after 2 hours, respectively for the HeartMate II and CentriMag. In the HeartMate II, we saw a 57% increase in IgG-bound CD235a+ fragments (>1 micron), but no change in IgG-bound CD235a+ fragments for the CentriMag.
Conclusion: These experiments demonstrate the potential for MPs with Annexin V and IgG as markers to evaluate cellular trauma, and by extension the potential for adverse events, in VADs. Increased IgG binding in both MF channels and HeartMate II but not CentriMag suggests a mechanism related to pathological shear stress.

BIO 25

Intravital Imaging Reveals Drag-reducing Polymer Blood Additives Maintain Liver Microvessel Flow in SCD Mice Following Vaso-occlusive Stimulus

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Study: Sickle cell disease (SCD) is an inherited blood disorder affecting 100k+ individuals within the US and millions more worldwide. Under deoxygenated conditions, red blood cells become rigid and prone to hemolysis which creates a pro-inflammatory state causing severe vaso-occlusion resulting in tissue ischemia and pain. Previously, it has been shown that nanomolar concentrations of blood soluble drag-reducing polymers (DRPs) provide beneficial hemodynamic and hemorheological alterations to blood flow including enhanced microvascular perfusion and reduced vascular resistance. We hypothesized that the addition of DRPs in blood would reduce the degree of microvessel vaso-occlusion in transgenic SCD mice when provoked with a vaso-occlusive stimulus such as lipopolysaccharide (LPS).
Methods: Townes transgenic mice homozygous for SCD aged 2-4 months were given 0.1 µg/kg LPS along with an infusion of the DRP polyethylene oxide (PEO, Mw 4MDa) through the tail vein for a final concentration of 2.5 ppm. Control animals received LPS along with the same volume of a saline vehicle. Mice were anesthetized and ventilated, and the carotid artery cannulated for delivery of Ly6G green and Texas red dextran fluorescent dyes for visualization of neutrophils and blood plasma, respectively. The right lobe of the liver was surgically exposed, a custom liver viewing device secured via light vacuum, and multiphoton imaging performed. Similar experiments using transgenic trait mice (non-SCD) were also performed to determine baseline levels of vaso-occlusion.
Results: Mice receiving DRP maintain improved microvascular blood flow over multiple fields of view with fewer vaso-occlusions and stagnant areas as compared to control animals. DRP blood additives warrant further study as a potential treatment option to reduce the severity of vaso-occlusion in SCD patients.

BIO 26

VAD Derived Mechano-Acoustics Lead to Platelet Activation

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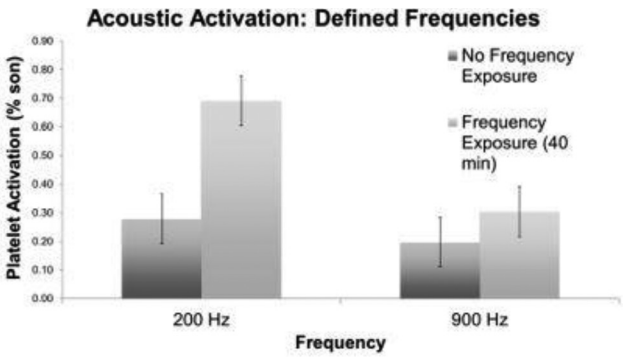
Study: Ventricular assist devices (VADs) continue to be plagued with platelet induced thromboembolic events. A leading factor of these events is the hyper-normal shear stress imparted by the continuous flow VADs. In previous studies, we have demonstrated that thrombus-associated alterations of flow and mass build-up impacts acoustic characteristics of VAD systems. In this study we examine the effects occluded and nonoccluded mechano-acoustic characteristics of VADs on platelet function in device thrombotic events.
Methods: An acoustic MEMS-based vibration sensor was placed on VAD housing of both heartMate II (HMII) and HeartWare (HW), with VADs incorporated into a mock circulation loop. Different occlusion levels were introduced (0%, 50%, 70%, 90%). The collected vibrational data was analyzed using acoustic spectral analysis. A tone at the median of frequency peaks range and a tone outside of the frequency peak range were used with an acoustic emulator to expose platelets. The platelets response was examined using by chromogenic platelet activity state assay.
Results: The frequency peak range remained between 100 and 300Hz throughout the different occlusion levels in both the HMII and HW. The median tone of 200 Hz used in exposing platelets was 40% more effective in activating platelets than a 900 Hz tone. Platelet activation due to these acoustic frequency peaks found in most commonly used VAD systems is a factor contributing to thrombin formation. Still there lacks a diagnostic/designing/modeling tool correlating the acoustic spectrum of a VAD to the level of platelet activation and subsequent thrombin formation.



BIO 27

Dynamics of Blood Flow and Hemostatic Abnormalities in Aortic Stenosis

C. Jhun[1], *R. K. Newswanger*[1], *J. P. Cysyk*[1], *S. Ponnaluri*[2], *B. Good*[2], *K. B. Manning*[2], *G. Rosenberg*[1]; [1]*Surgery, Penn State College of Medicine, Hershey, PA,* [2]*Biomedical Engineering, Penn State University, University Park, PA.*

Study: Supraphysiologic high shear stresses created in calcific aortic stenosis (AS) are known to cause hemostatic abnormalities, however, relating the complex blood flows over the severity of AS to hemostatic abnormalities is still lacking.
Methods: This study systematically characterized the blood flow in mild, moderate, and severe AS. A series of large eddy simulations (LES) validated by particle image velocimetry (PIV) were performed on physiologically representative AS models with a peak physiological flow condition of 18 LPM. Time-accurate velocity fields, transvalvular pressure gradient, and laminar viscous wall shear stress (WSS) and turbulent shear stress (RSS_{max}) were evaluated for each degree of severity.
Results: The peak velocities of mild, moderate, and severe AS were on the order of 2.0 m/s, 4.0 m/s, and 8.0 m/s, respectively (**Fig 1A**). Jet velocity in severe AS was highly skewed with extremely high velocity (as high as 8 m/s) and mainly traveled through the posterior aortic wall up to the aortic arch while still carrying a relatively high velocity (> 4 m/s). The mean laminar viscous wall shear stresses (WSS) for mild, moderate, and severe AS were on the order of 40 Pa, 100 Pa, and 180 Pa, respectively (**Fig 1B**). The RSS_{max} were on the order of 260 Pa, 490 Pa, and 2,500 Pa for mild, moderate, and severe AS, respectively (**Fig 1C**). This study may provide a link between altered flows in aortic stenosis and hemostatic abnormalities such as acquired von Willebrand syndrome and hemolysis, thus, help diagnosing and timing of the treatment.

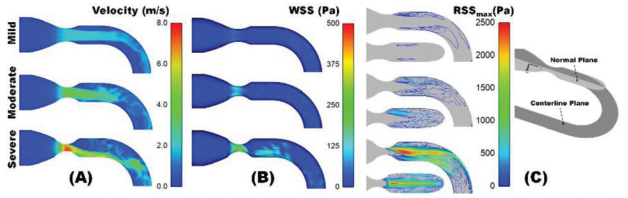


Fig 1. (A) Velocity, (B) wall shear stress, and (C) turbulent shear stress in mild, moderate and severe AS.

BIO 28

Impella 5.5® Versus Centrimag™: A Head-to-Head Comparison of Hemocompatibility of Ventricular Assist Devices *In Vitro*

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Study: Continued improvement of mechanical circulatory support design has led to the advance of increasingly effective, miniaturized catheter devices for large volume, rapid hemodynamic restoration. We examined the hemocompatibility of the new Impella 5.5® (Abiomed, Danvers, MA), in comparison to a reference device, the Centrimag™ (Abbott, Chicago, IL).
Methods: Domestic pigs (40 kg.) were heparinized (200 U/kg), blood was collected via sacrificial exsanguination and anticoagulated with citrate-phosphate-dextrose-adenine. For head-to-head device comparison, two identical mock loops were assembled (blood volume 750 ± 50 mL) into which either the Impella 5.5® or the Centrimag™ were inserted. Blood was recirculated for 4 hours at 37°C, operational flow 4.5 L/min, and pressure difference 60 & 350 mm Hg for Impella 5.5® & Centrimag™, respectively. Serial blood samples were collected to assess 1) free hemoglobin (Hb) using the Hemocue® Plasma Low system and colorimetric assay (Cayman Chem, Ann Arbor, MI), 2) lactate dehydrogenase activity using colorimetric assay (BioLegend Inc, San Diego, CA).
Results: The Impella 5.5® demonstrated a low level of hemolysis, with performance similar to the Centrimag, with both devices demonstrating a minor increase of free Hb following continued blood exposure to device-generated flows *in vitro*. For both devices, free Hb increased slowly over time reaching statistical significance after 1.5 hours (Figure 1A & B). Free Hb levels of Impella 5.5® showed good positive correlation with Centrimag™ as measured by Hemocue® (R^2= 0.953) and colorimetric assay (R^2 = 0.933). Lactate dehydrogenase activity for both devices remained equal to control levels over exposure time (Figure 1C). In a head-to-head comparison, the Impella 5.5® demonstrated acceptable and comparable hemocompatibility as compared to the Centrimag™ system. These data support the advance of design and utility of low profile, rapid access axial flow systems.

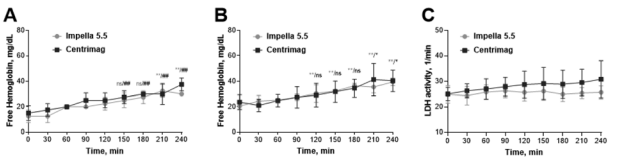


Figure 1. The effect of Impella 5.5® and Centrimag™ on hemolysis: A – free hemoglobin concentration measured by Hemocue® Plasma Low system, B – free hemoglobin concentration measured by colorimetric assay, C – lactate dehydrogenase activity in plasma (OD/min). Mean ± SD, n = 3, ANOVA: * - $p < 0.05$, ** - $p < 0.01$.

BIO 29

Hemodynamic Evaluation of a New Pulsatile Blood Pump During Low Flow Cardiopulmonary Bypass Support

T. Miyamoto[1], *Y. Kado*[2], *J. H. Karimov*[2], *P. Grady*[3], *J. Nader*[4], *D. Vincent*[4], *S. Sale*[5], *K. Kvernebo*[6], *V. N. Tran*[6], *K. Fukamachi*[2]; [1]*Biomedical Engineering, Cleveland Clinic, Cleveland, OH,* [2]*Biomedical Engineering, Cleveland Clinic, Cleveland, OH,* [3]*Department of Thoracic and Cardiovascular Surgery, Cleveland Clinic, Cleveland, OH,* [4]*VentriFlo, Inc., Pelham, NH,* [5]*Department of Cardiothoracic Anesthesiology, Cleveland Clinic, Cleveland, OH,* [6]*Department of Cardio-thoracic Surgery, Oslo University Hospital, Oslo, Norway.*

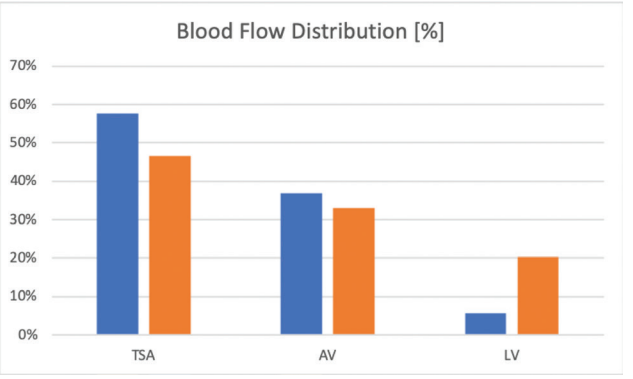
Study: The VentriFlo® True Pulse Pump (VentriFlo, Inc., Pelham, NH, USA) is a new pulsatile blood pump intended for use during short-term circulatory support including cardiopulmonary bypass (CPB). The purpose of this study was to evaluate the feasibility of the VentriFlo in a typical CPB circuit and compare it to a conventional centrifugal pump (ROTAFLOW, Getinge, Gothenberg, Sweden) in acute pig experiments.
Methods: Piglets (40-45 kg; *n*=14 were supported by CPB with the VentriFlo (n=9) or ROTAFLOW (n=5) for 6 hours. Both VentriFlo and ROTAFLOW circuits utilized standard CPB components. CPB was set to low flow (50 mL/kg/min), and no inotropic agent or vasoconstrictor was used during CPB support. We evaluated hemodynamics, blood chemistry, gas analysis, plasma hemoglobin, and microcirculation at the groin skin with computer-assisted video microscopy (Optilia, Sollentuna, Sweden).
Results: Piglets were successfully supported by CPB for 6 hours without any pump related complications in either group. The VentriFlo delivered an average stroke volume of 29.2 ± 4.8 mL. VentriFlo delivered significantly higher pulse pressure (29.1 ± 7.2 mm Hg vs 4.4 ± 7.0 mm Hg, $p<0.01$) as measured in the carotid artery, with mean aortic pressure and pump flow comparable with those in ROTAFLOW. In blood gas analysis, arterial pH was significantly lower after 5 hours support in VentriFlo group (7.30 ± 0.07 vs 7.43 ± 0.03, $p<0.01$), but there was no statistical difference in lactate concentration. There was no significant difference in plasma hemoglobin level in both groups after 6 hours of CPB support. In microcirculatory assessment, VentriFlo tended to keep normal capillary flow in groin skin, but it was not statistically significant. In conclusion, VentriFlo delivered significantly higher pulse pressure in the elastic arterial tree and showed lower arterial pH at 5 hour support compared to ROTAFLOW without hemolysis.*Design Mentor, Inc reincorporated as VentriFlo, Inc (a Delaware Corporation) in August 2019

BIO 30

Flow Distribution Analysis in Peripheral Versus Central Arterial Cannulation in VA-ECMO Support

G. Fragomeni[1], *M. Rossi*[2], *P. Fratto*[3], *G. Pisano*[3], *A. Covino*[4], *G. Catapano*[5]; [1]*Magna Graecia University, Catanzaro, Italy,* [2]*Grande Ospedale Metropolitano "Bianchi-Melacrino-Morelli", Reggio Calabria, Italy,* [3]*Grande Ospedale Metropolitano "Melacrino Morelli", Reggio Calabria, Italy,* [4]*Grande Ospedale Metropolitano "Melacrino-Morelli", Reggio Calabria, Italy,* [5]*Uiversità della Calabria, Rende, Italy.*

Study: The main purpose of ECMO cannulation is to provide the least traumatic, most durable and most simplified method for delivering the blood to and from the pump circuit. Arterial cannulation can be central, i.e. in the ascending aorta, or peripheral, i.e. in the common femoral artery. Apart from the opportunity to prefer one or the other depending on the clinical scenario (central cannulation for post cardiotomy syndrome or peripheral cannulation for myocarditis), it is not clear whether one site is superior to the other as for hemodynamic flow pattern and for distribution.
Methods: A computational approach was developed to carry out the investigation on a 3D patient-specific aorta model attained by angio CT scan by means of Computational Fluid Dynamics (CFD) simulations. Two different configurations, Central (CC) and peripheral (PC), were compared in order to analyze the changes in terms of both blood flow distribution and Shear Stress indexes. The same boundary conditions were imposed for both cases.
Results: The percentage of flow distribution was CC Vs PC case: 20% Vs 6% in the limb (LV); 33% Vs 37% in the Abdominal Vessels (AV); 47% Vs 58% in the three supra aortic vessels (TSA) - respectively (Fig. 1). The Wall Shear Stress was much higher in the PC Vs CC cannulation in every aortic region above the celiac trunk. The flow velocity stream lines showed a similar linear flow pattern in the TSA, but a much slower and turbulent flow in the ascending aorta in PC cannulation.Except for limb perfusion, where the CC cannulation is superior, both CC e CP configuration give effective abdominal and cerebral perfusion with a linear flow pattern. However, looking at the shear stress and flow turbulence, we had lower an more uniform stress wall imposed onto the aorta in the CC. These findings, together with a fast and linear flow recirculation in the ascending aorta, could account in a less thrombogenic configuration for the CC cannulation.

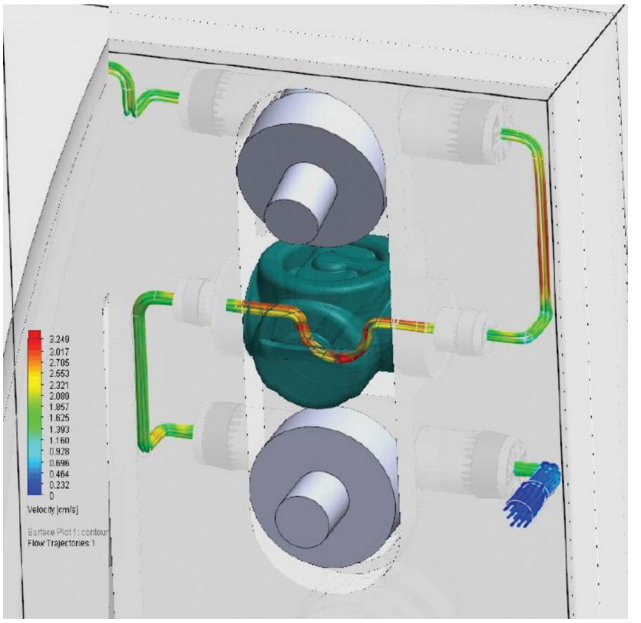


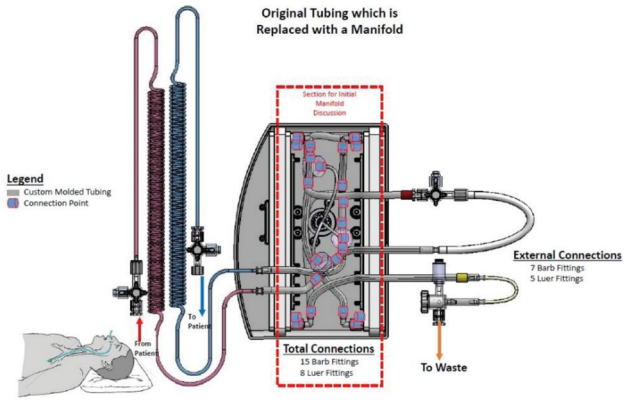
BIO 31

Manifolds - A Case Study for Improving Usability And Reducing Costs of Complex Disposables

M. Hill, *L. Lucke, D. Hansen, J. Jones; Minnetronix Medical, Saint Paul, MN.*

Study: Medical devices, for cardiac, pulmonary, or renal support, typically consist of reusable 'capital' equipment that interfaces with a sterilizable, single-use disposable that directly contacts the patient. The complexity of these multi-tube set disposables increases cost, and setup time for each treatment. This study focuses on methods and techniques to simplify these disposables with the use of sophisticated, integrated manifolds.
Methods: In this case study, various techniques, materials and production methods, were assessed for the feasibility of a new, innovative manifold solution for routing fluids to and from the patient as compared to the original complex tube set. Materials and assembly methods were assessed for their ease of use, cost, strength (I.e. for withstanding internal pressures), composition (needs to be sterilizable and biocompatible), and manufacturability. To aid in the analysis, dynamic modeling was leveraged to identify any routing and flow challenges.
Results: With additive manufacturing and the new materials available for use in such processes, the solution options for improving integration and reducing cost for sterilizable disposables are tremendous. The examination and analysis of materials and techniques for routing, measuring and sensing fluids using a manifold shows significant improvement to the usability of complex tube sets originally designed with barb and luer connections (**Fig 1**). Leveraging a sterilizable and biocompatible manifold solution (**Fig 2**) was shown to reduce manufacturing complexity resulting in the cost of the disposable being reduced by a factor of 2. This solution could be manufactured via an additive manufacturing or other printing processes for quicker time to market. Dynamic modeling results showed no statis or retrograde flow areas in the manifold solution.Original Design showing fluid routing with tubing and fittings:
Dynamic Modeling of Fluid Path:





BIO 32

"Digital Reflexes": Quantitation and Discrimination of Superficial Reflexes Via Stretchable Electronic Wearable Sensors

R. Slepian[1], *H. Swanson*[1], *K. Ammann*[2], *S. Miller-Gutierrez*[1], *S. Nye*[1], *B. Kaiser*[1], *A. Sweedo*[1], *B. Coull*[3], *M. Slepian*[1]; [1]*University of Arizona, Tucson, AZ,* [2]*Biomedical Engineering, University of Arizona, Tucson, AZ,* [3]*Neurology, University of Arizona, Tucson, AZ.*

Study: Superficial reflex determination is fundamental in neurology to assess upper vs lower motor neuron disorders. Reflex abnormality detection is of clinical value as changes may predate symptoms and signs of a given disorder. Deep tendon reflexes (DTRs), are presently assessed subjectively via limb/appendage movement and muscle contraction post hammer strike, on a 0 - 5 scale. This approach is limited due to: performer technique differences, subjective interpretation, and inconsistencies in serial assessment. We hypothesized that assessment of DTRs utilizing wearable sensors, able to assess limb/appendage 3D motion and muscle EMG, would provide a means of quantitation; as well as define motion and EMG "signatures" of a given reflex.

Methods: Stretchable electronic motion sensors (BioStamp, MC10), containing tri-axial accelerometers and EMG signal detection were applied to: 1. distal limb/appendage (to assess movement); 2. relevant muscle (EMG) and; 3. strike hammer (to coordinate strike time vs reflex response time and thus calculate reflex time lag). Triceps, Patellar and Achilles reflexes were assessed in healthy subjects (n=6); and subjects with diagnosed reflex abnormalities (n=4) (hyper- or hypo-reflexia), following standardized hammer strike.

Results: 1. For all reflexes tested, digital signal data of limb/appendage movement (x,y,z) and EMG was successfully obtained and analyzed. 2. Signals allowed quantitation of movement (dimension data), acceleration, muscle contraction and timing of events 3. Reproducibility of signals was observed for each individual 4. Each reflex yielded a characteristic motion signature (figure = Patellar). 5. Clear signal differences were detectable in subjects with neurologic disorders compared with controls. This new approach affords standardization, quantitation, signal discrimination, reduced inter-observer variability and serial assessment.

BIO 33

Impella 5.5 Ceramic Bearing System Reliability Assessment

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Study: We describe the bearing suspension system of the Impella 5.5, a minimally invasive, intravascular surgical heart pump. The Impella 5.5, delivered through an axillary artery or via the ascending aorta is intended for treatment of cardiogenic shock, cardiomyopathy and use during cardiac procedures. The motor comprises of an impeller, suspended between two ceramic sleeve bearings and having axial and radial range of motion. The bearing and shaft designs allow for through flow of heparin-containing glucose purge solution, which acts as a bearing lubricant and prevents blood ingress into the motor. The bearing geometry limits the rate of purge delivery, allowing for minimal systemic heparin delivery. The ceramic materials used are both robust and thermally conductive, allowing for long motor reliability and heat dissipation to enhance hemocompatibility.

Methods: In-vitro reliability testing was performed and device performance log data was analyzed. After study suspension, bearing surfaces were analyzed via surface profilometry. In addition to bench tests, early clinical experience was summarized.

Results: The cumulative run pump of n=183 pumps described was 7133 days, with the longest running in-vitro pumps suspended at 365 days, longest clinical case suspended at 164 days and average case at 12.5±19.8 days. As expected in axial bearing systems even after design optimization, minimal micron-scale bearing settling occurred in the first 24 hours of use. The overall bearing reliability of 80% with 80% confidence was demonstrated at 208 days.

BIO 34

Modulating Left Ventricular Assist Device Driveline Exit Site Biomechanics: A Systematic Approach to Achieving Percutaneous Implant Forgettability

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Study: Percutaneous drivelines limit left ventricular assist device (LVAD) patient activity and have a 19% infection rate. We developed a biomechanical exit site framework to study and address this issue.
Methods: We quantified 3 key drivers of morbidity and DLI risk: site trauma (tensile test), driveline tract disruption (max pullout force), and fluid/pathogen entry (dye penetration by spectrophotometric testing). With drivelines in porcine tissue (fig 1), we studied biomechanical properties of HeartMate drivelines and fresh porcine tissue via Instron and dye testing. We repeated tests with applications of 1 adhesive from each FDA-approved class. Data were t-tested with Bonferroni correction. We then embedded 3D-printed round-cap devices (fig 2) around the driveline with tissue anchors. These tested anchors' strain release and pullout force by varying: # of vertical anchors, # of radial anchors, anchor depth, and anchor-anchor angle. We then ran linear regression in R.
Results: Two adhesives (BioGlue and Dermabond) may reduce epithelial trauma by cushioning tissue from driveline, prevent driveline tugging if controller box drops (5N), and seal wounds. In device testing, only # of radial anchors correlated significantly with pullout force (B=0.66, p=0.0001), but all devices had higher pullout force than adhesives did. The biomechanical characterization of tissue-driveline interfaces, exit site biomaterials, and subcutaneous anchors enables further, systematic development of LVAD driveline exit site protection.

Figure 1. HeartMate driveline setup in fresh porcine abdominal tissue, connected to Instron tester. Angle from clear cylinder is derived from CT abdomen reconstructions of driveline tunneled tract length and angles.

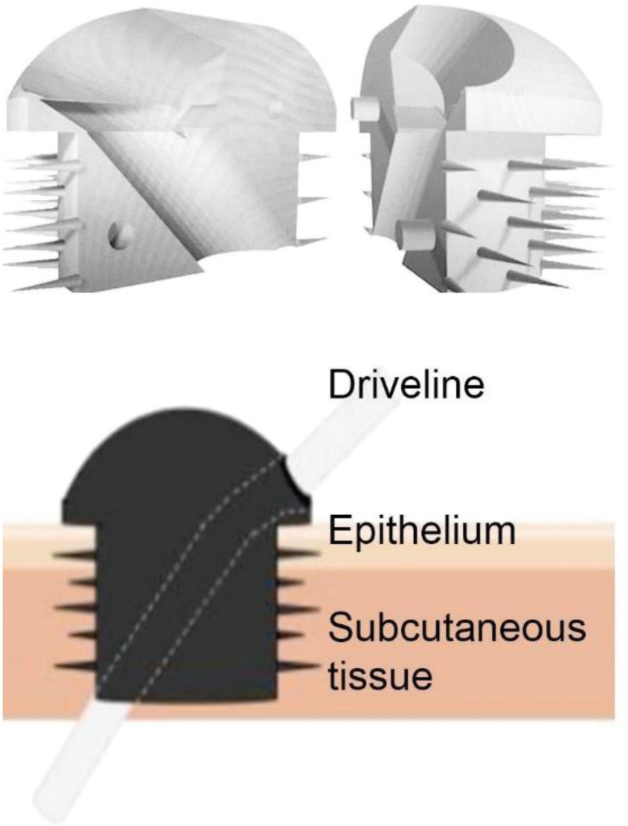

Figure 2. Computer-aided design and schematic of 3D-printed round-cap device surrounding driveline used to test effects of different distributions and numbers of tissue anchors on exit site biomechanics.

CAR 1

Quality Of Life Metrics In LVAD Patients After Hemocompatibility-related Adverse Events

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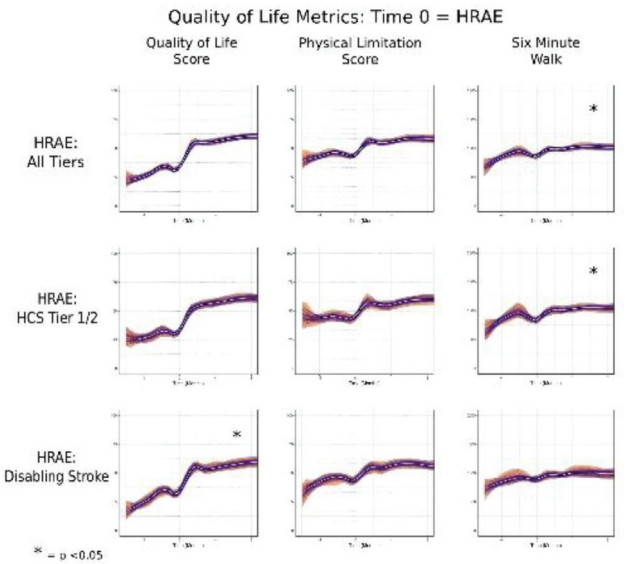
Study: Recent landmark trials demonstrate that hemocompatibility-related adverse events (HRAE) negatively influence patient survival. However, no large study has examined the impact of HRAEs on health-related quality of life (HRQOL) and functional outcomes following continuous flow left ventricular assist device implantation (CF-LVAD). Using the INTERMACS registry, we assessed the impact of HRAE events on HRQOL and hypothesized that HRAE's adversely impact HRQOL and functional outcomes.

Methods: INTERMACS database was queried to identify primary CF-LVAD patients from 2008 to 2015. HRAEs included stroke, non-surgical bleeding, hemolysis, and pump thrombosis and were identified as defined in the literature. HRAEs were stratified as Tier 1-2 and Tier 3-4 events. HRQOL metrics were assessed using the EuroQoL 5D (EQ-5D) and visual analog scale. To assess change over time, local polynomial regression curves modeling individual patients were superimposed into "spaghetti" plots. Friedman's test assessed predefined time points for each variable.

Results: The cohort consisted of 3509 primary CF-LVAD patients. Data were available on HRQOL and functional metric: (1) quality of life score, (2) physical limitation score, and (3) six-minute walk scores. Both HRQOL and functional metrics declined after experiencing an HRAE but recovered baseline levels or higher (Figure). Change in quality of life score was significant in the disabling stroke subset (p = 0.02) but not in the overall HRAE cohort (p=0.12). Change in six-minute walk test was significant in all HRAE patients (p=0.02) as well as HRAE tier 1-2 subset (p=0.01).

Conclusion:

The burden of HRAEs did not negatively impact quality of life. However, 6-minute walk test was decreased in all patients following disabling stroke. This may indicate that while objective measure of functional capacity is reduced, improvement of heart failure symptoms after LVAD coupled with optimal management following HRAE act to preserve enhanced quality of life.



CAR 2

Segmentation of Post-LVAD Patients by Characteristics Within 3-year Follow-up

F. Movahedi[1], *J. F. Antaki*[2]; [1]*Electrical and Computer Engineering, University of Pittsburgh, Pittsburgh, PA,* [2]*Meinig School of Biomedical Engineering, Cornell University, Ithaca, NY.*

Study: The rehospitalization (RHP) rate after LVAD bears significant cost and quality-of-life implications. This exploratory study aims to segment post-LVAD patients based on characteristics of RHP, specifically two metrics: *count* and *time of last RHP*.

Methods: This observational study included 37,865 recorded RHPs of 3-year follow up of 10,052 patients (median age of 50-59; 21% Female, 79% Male) after implant of a continuous-flow LVAD who had a least one RHP abstracted from the INTERMACS registry between 2006 to 2014. The *Minimum Description Length* method was used to bin the count of RHPs and time of last RHP that optimally differentiates patients by their final outcome within a 3-year period.

Results: Fig.1 shows the distribution of patients within a grid, segmented according to the aforementioned RHP *metrics*. Fig. 2 illustrates the corresponding proportions of the final outcomes of the patients within each bin in Fig. 1. The following points can be inferenced from these results: (1) 14% of all patients in this cohort had their last RHP after 30 months post-LVAD (see T5), with high survival probability (75%) regardless of the total number of RHPs - even those with >8 RHPs. (2) 61% of total patients experienced less than 4 RHPs with high probability of transplant (50%) for those with the last RHP during 3 to 14 months post-LVAD period (see C1.) (3) 51% of total patients had their last RHP by 14 months (See T1 and T2.) Fig. 2 shows that overall survival probability with the LVAD was inversely dependent on the time of last RHP; while transplant and death probabilities decreased. Overall, increased count of RHPs was associated with decreased probability of transplant. In summary, this analysis highlighted the effect of *the combination of* count of RHPs, and time of the last RHP on LVAD final outcome. For instance, patients who suffered from high number of RHPs, but spanning over 3 years exhibited surprisingly high survival probability.

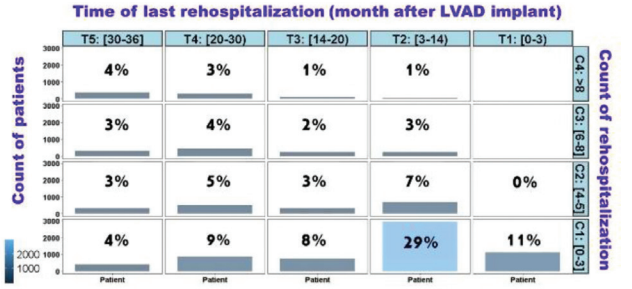


Fig.1: Distribution of patients within a grid, segmented according to count and time of last RHP (Percentage of total number of patients)

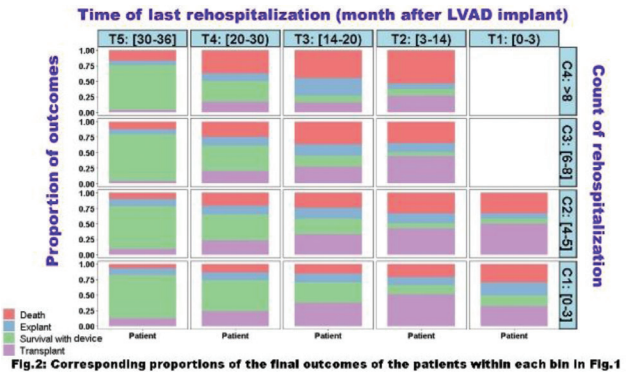


Fig.2: Corresponding proportions of the final outcomes of the patients within each bin in Fig.1

CAR 3

Central Cannulation for Mechanical Circulatory Support as Bridge to Heart Transplantation is Safe and Effective

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Study: Patients requiring temporary mechanical circulatory support (MCS) as bridge to heart transplantation (OHT) need adequate time for workup and end organ optimization, often at the expense of complications related to lower extremity cannulation and deconditioning from immobilization. We describe early clinical outcomes and challenges associated with a temporary MCS bridging strategy of central cannulation followed by chest closure, extubation, and mobilization.
Methods: We retrospectively reviewed all patients who underwent CentriMag ventricular assist device (VAD) as bridge to OHT candidacy from Oct 2018 to Dec 2019. All patients with LVAD had direct left ventricular apical cannulation with a tunneled 32Fr cannula for VAD inflow. Aortic outflow consisted of a tunneled cannula secured inside a Dacron graft attached to the ascending aorta. Right ventricular support consisted of either a percutaneously inserted dual lumen catheter or cannulation of the RA with a tunneled two-stage venous cannula and PA cannulation via the acute margin of the RV with a tunneled 24Fr cannula. Outcomes of interest included perioperative morbidity, mortality, and time to OHT.
Results: Eighteen patients underwent CentriMag VAD support with 11 successfully bridged to OHT (table 1). Survival 30-days post-transplant was 100%. Average time from CentriMag implantation to OHT listing was 30 days and average time to OHT after listing was 14. Of the transplanted patients, average time on the ventilator after CentriMag was 23 hours. Post VAD complications included exploration for bleeding in 7 patients and stroke in 6. There were no wound infections. Seven patients expired from multiorgan failure before they could be activated on the transplant list. MCS via central cannulation provides a means to adequately assess patients for OHT suitability, while improving mobilization and facilitating prehabilitation prior to OHT. Early outcomes suggest safety and feasibility of this strategy.

Table 1

Variables	BTD Group (n = 18)
Age (mean ± SD)	48 ± 12
Male sex (n,%)	18 (100%)
BMI (mean ± SD)	26.9 ± 6.6
Atrial Fibrillation (n,%)	8 (44.4%)
Hypertension (n,%)	7 (38.9%)
Coronary Artery Disease (n,%)	5 (27.8%)
Heart Failure Etiology	
Ischemic Cardiomyopathy (n,%)	4 (22.2%)
Dilated Cardiomyopathy (n,%)	11 (61.1%)
Restrictive Cardiomyopathy (n,%)	1 (5.6%)
Valvular Cardiomyopathy (n,%)	1 (5.6%)
Congenital Cardiomyopathy (n,%)	1 (5.6%)
Cerebrovascular Disease (n,%)	1 (5.6%)
Prior Stroke (n, %)	2 (11.1%)
Chronic Lung Disease (n,%)	0 (0%)
Prior Sternotomy (n,%)	6 (33.3%)
Chronic Kidney Disease (n,%)	6 (33.3%)
End-Stage Renal Disease (n,%)	4 (22.2%)
Right Ventricular Dysfunction (n,%)	
Mild (n,%)	7 (38.9%)
Moderate (n,%)	10 (55.6%)
Severe (n,%)	5 (27.8%)
Pre-CentriMag Mechanical Support Strategy (n,%)	7 (38.9%)
None (n,%)	11 (61.1%)
ECMO (n,%)	1 (5.6%)
Impella (n,%)	3 (16.7%)
IABP (n,%)	2 (11.1%)
Tandem (n,%)	3 (16.7%)
CentriMag Device	
BiVAD (n,%)	11 (61.1%)
LVAD (n,%)	3 (16.7%)
RVAD (n,%)	4 (22.2%)
Intraop KCentra Requirement During CentriMag Placement (n,%)	12 (66.7%)
Postoperative Transfusion Requirement After CentriMag (n,%)	6 (33.3%)
Hemorrhage Requiring Reoperation After CentriMag (n,%)	7 (38.9%)
Average Time to Extubation After CentriMag Among Transplanted Patients (mean ± SD)	23.4 ± 17.5 hours
Pump Thrombosis (n,%)	1 (5.6%)
Pump Exchange (n,%)	0 (0%)
Transient Ischemic Attack (n,%)	2 (11.1%)
Stroke (n,%)	6 (33.3%)
Surgical Wound Infection (n,%)	0 (0%)
Number of Patients Transplanted (n,%)	11 (61.1%)
Average Time from CentriMag to Transplant (mean ± SD)	30 ± 15 days
Average Time from Listing to Transplant (mean ± SD)	14 ± 10 days
Mortality on CentriMag while waiting for OHT Listing (n,%)	7 (38.9%)
Operative Mortality After OHT (n,%)	0 (0%)
30-day Mortality After OHT (n,%)	0 (0%)

CAR 4

Overestimation of Glycemic Control as Possible Etiology of Increased all-cause Mortality in Diabetic Patients with Left Ventricular Assist Device

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Study: Many studies have demonstrated worse post-left ventricular assist device (LVAD) outcomes in patients with diabetes mellitus (DM). We sought to determine whether DM is an independent predictor of mortality and to investigate the reliability of HbA1c testing after LVAD support.
Methods: We reviewed 128 sequential patients who underwent LVAD implantation at a single center between 1/2012 and 9/2018. DM patients were identified based on pre-LVAD clinical data. Baseline characteristics of DM and non-DM LVAD patients were compared using Mann-Whitney and Fisher exact tests. Survival analysis was performed using Kaplan-Meier (KM) plot. Estimated HbA1c (eHbA1c) was derived from average plasma glucose using a validated American Diabetes Association (ADA) formula and compared against measured HbA1c pre- and post-LVAD using Sign test of matched pairs.
Results: 64 patients (50%) had diagnosis of DM. Baseline characteristics of DM vs non-DM LVAD patients were similar for age (mean 55 years), gender (female 34%), bridge-to-transplant LVAD (51%), HeartWare LVAD use (72%), but different for ischemic heart failure (HF) etiology (55% vs 31%), BMI (31.2, 27.5-35.0 vs 26.3, 24.0-30.8 kg/m2). The duration of LVAD support 370 (183-595 days) and frequency of bridge-to-transplant (35%) was similar between groups, but DM patient death was higher (34% vs 13%, p=0.006). DM was associated with early mortality (Figure 1) and significant in both the unadjusted (HR 3.58, 95% CI 1.58-8.14, p=0.002) and adjusted models (HR 3.41, 95% CI 1.45-8.02, p=0.005; for age, gender, race, HF etiology, and BMI). Comparisons between HbA1c and eHbA1c were similar pre-LVAD (6.7, 6.3-8.1% vs 6.8, 6.1-8.3%, p=0.418),but different after LVAD support (6.0, 5.5-7.1% vs 6.7, 5.7-8.3%, p=0.006) as depicted in Figure 2.
Conclusions: Future studies should investigate whether favorable overestimation of glycemic control during LVAD support contributes to adverse outcomes.

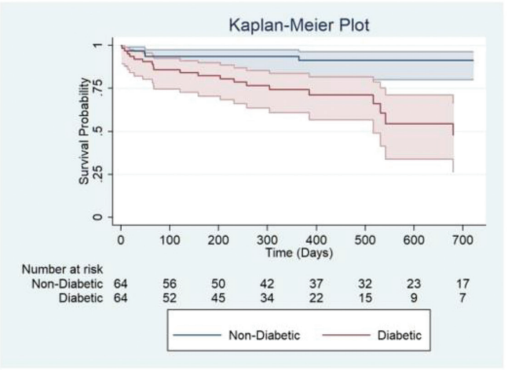

Figure 1: Two-year survival on LVAD support for patients with and without DM (p=0.001, log-rank test)

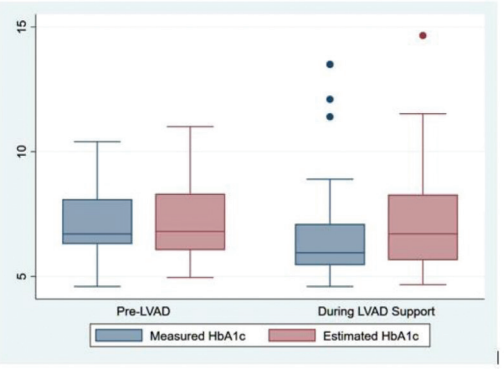

Figure 2. Comparison of measured and estimated HbA1c at pre-LVAD (p=0.418) and during LVAD support (p=0.006)

CAR 5

Time in Therapeutic Range Significantly Impacts Survival and Adverse Events in Destination Therapy Patients

G. P. Macaluso[1], *F. D. Pagani*[2], *M. S. Slaughter*[3], *C. A. Milano*[4], *E. D. Feller*[5], *A. J. Tatooles*[6], *J. G. Rogers*[7], *G. M. Wieselthaler*[8]; [1]*Cardiology, Advocate Christ Medical Center, Palos Park, IL,* [2]*Cardiac Surgery, University of Michigan Medical Center, Ann Arbor, MI,* [3]*Dept of Cardiovascular and Thoracic Surgery, Jewish Hospital University of Louisville, Louisville, KY,* [4]*Cardiac Surgery, Duke University Medical Center, Durham, NC,* [5]*Cardiology, University of Maryland Medical Center, Baltimore, MD,* [6]*Cardiovascular Surgery, Advocate Christ Medical Center, Palos Park, IL,* [7]*Cardiology, Duke University Medical Center, Durham, NC,* [8]*Cardiothoracic Surgery, Univeristy of Calif San Francisco Medical Center, San Francisco, CA.*

Study: To examine the effects of time in therapeutic range (TTR), defined as International Normalized Ratio (INR) 2.0-3.0, on adverse events and survival in patients receiving the HeartWare HVAD system for destination therapy.

Methods: HVAD patients enrolled in the ENDURANCE and ENDURANCE Supplemental trials who had >1 INR value recorded post-implant through 24 months were eligible (n=503). Patients were separated into 3 cohorts: Low TTR (10-39%, n=53), Moderate TTR (40-69%, n=225), and High TTR (≥ 70%, n=225). Differences in baseline characteristics, adverse events, and survival were analyzed.

Results: Compared to the Low TTR cohort, the High TTR cohort were more likely to be white (75.6% vs 56.6%, p=0.01), and have a higher ALT (35.9±42.3 vs 27.7±16.4, p=0.03), whereas the High and Moderate TTR cohorts were essentially similar. The High TTR cohort when compared to the Low TTR cohort had lower rates of gastrointestinal bleeding (GIB) (0.40 vs 1.29 events per patient year (EPPY), p<0.0001), hemorrhagic stroke (0.06 vs 0.20 EPPY, p<0.0004), ischemic stroke (0.14 vs 0.34 EPPY, p=0.0003), thrombus requiring exchange (0.01 vs 0.06 EPPY, p=0.03), renal dysfunction (0.06 vs 0.27 EPPY, p<0.0001), and right heart failure (RHF) (0.20 vs 0.45, p=0.0001). When compared to the Moderate cohort, the High TTR cohort had fewer GIB (0.40 vs 0.51 EPPY, p=0.04), thrombus requiring exchange (0.01 vs 0.04 EPPY, p=0.02). Two-year survival was significantly different between the 3 cohorts (High TTR: 74%, Moderate TTR: 71%, and Low TTR: 58%, (Log rank p=0.0007)) (Figure 1). Regression analysis demonstrates that the number of INRs is significantly correlated with TTR (p<0.0001). At 24 months, LVAD recipients with TTR>70% had lower rates of GI bleeding and pump exchange due to thrombus when compared to patients with TTR <70% and demonstrated superior survival with lower rates of stroke when compared to TTR <40%.

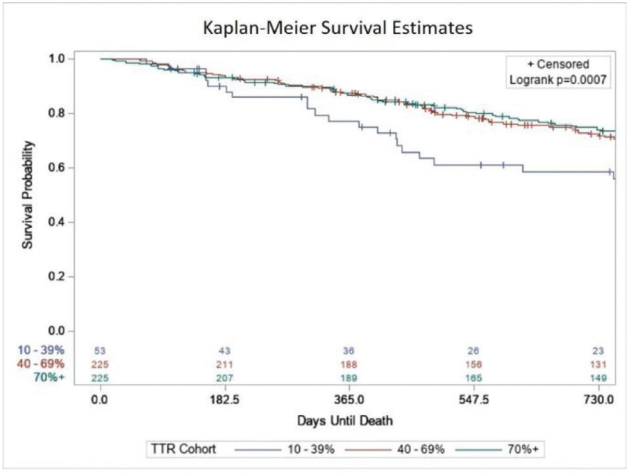

Figure 1: Kaplan-Meier Survival among Increased (>70%), Moderate (40-69%, and Low (<40%) Time in Therapeutic Range Cohorts.

CAR 6

5-year Outcomes in the Endurance and Endurance Supplemental Trials

C. Mahr[1], *L. T. Klein*[2], *J. J. Teuteberg*[3], *N. Mokadam*[4], *A. Tatooles*[5], *A. J. Sauer*[6]; [1]*Cardiology, University of Washington Medical Center, Seattle, WA,* [2]*Department of Medicine, Univeristy of Calif San Francisco Medical Center, San Francisco, CA,* [3]*Cardiology, Stanford University Medical Center, Stanford, CA,* [4]*Cardiac Surgery, Ohio State University Wexner Medical Center, Columbus, OH,* [5]*Cardiac Surgery, Advocate Christ Medical Center, Oak Lawn, IL,* [6]*Cardiology, University of Kansas Medical Center, Kansas City, KS.*

Study: To report the long-term outcomes in HVAD recipients who survived out to 5 years in the ENDURANCE and ENDURANCE Supplemental Destination Therapy trials.

Methods: All HVAD patients in the these trials were included. Baseline characteristics were compared between patients who were alive on the originally implanted device up to 5 years post-implant and those who were not. Additionally, adverse events and KM survival estimation were examined for those patients who survived to 5 years.

Results: At 5 years, of the 604 HVAD patients, 150 (24.8%) were alive on the originally implanted device and an additional 108 (17.9%) patients were transplanted or explanted for recovery. Patients still on original device were more likely to be women (28.0% vs 18.5%, p=0.02), less likely to be white (65.3% vs 77.3%, p=0.005), had less ischemic heart disease (47.3% vs 59.7%, p=0.01), shorter cardiopulmonary bypass time at implant (77.4 ± 35.7 vs 94.5 ± 46.2 min, p<0.0001), and shorter index ICU length of stay (9.3 ± 8.2 vs 12.3 ± 12.9 days, p=0.001). Major adverse event rates for the patients alive on original device up to 5 years were low with hemorrhagic stroke (CVA) at 0.08 events per patient year (EPPY), ischemic CVA 0.12 EPPY, and pump exchange for thrombus 0.04 EPPY. Overall survival estimates at 5 years is shown in Figure 1. In this post-hoc analysis of destination therapy patients implanted with HVAD, 42.7% of patients were either alive at 5-years on the original device, transplanted, or explanted for recovery, with a low adverse event profile.

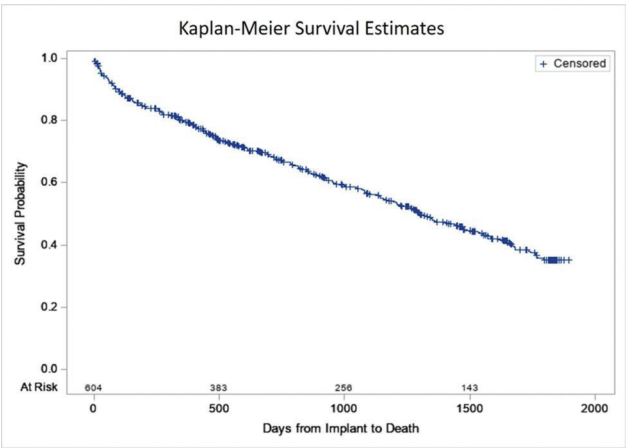

Figure 1: Kaplan-Meier survival estimates. Patients were censored at transplant, explant for recovery, device exchange, or did not have complete follow up at 5 years

CAR 7

First in Human Experience with the Second Heart Assist Device

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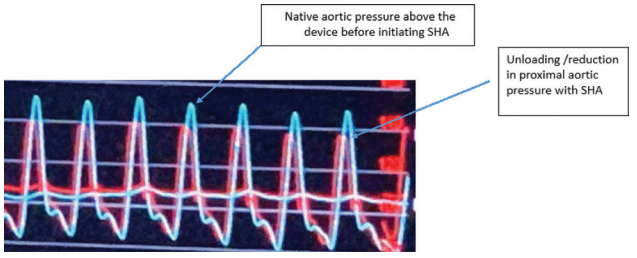
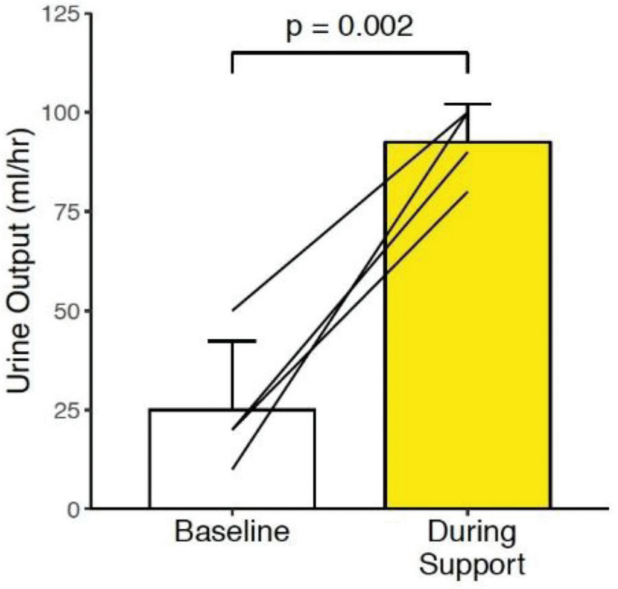
Study:
The Second Heart Assist Device is an impeller driven percutaneous temporary mechanical circulatory support device placed in the descending aorta that provides augmented pulsatile flow to the kidney and circulation. This First in Human study was designed to demonstrate the safety and feasibility of the device for support of patients undergoing high-risk percutaneous coronary intervention at a single center, Sanatorio Italiano, in Asuncion, Paraguay.
Methods: Four patients with reduced ejection fraction (30-40%) and complex coronary anatomy, underwent support with the Second Heart Assist device during elective PCI performed by radial approach.
Results: All patients had successful insertion of the SHA device via femoral access in less than two minutes. The pump was increased in speed to achieve a minimum of 10mmHg gradient across the pump, which averaged 8,500 RPMs (7,000-10,000). The duration of support was one hour in all patients. All patients had PCI of two vessels without complication or hemodynamic compromise. The device was removed percutaneously in all patients, and no patient experienced a serious Adverse Event. There was a four-fold average increase in urine output from baseline to end of support (mean 25 to 92.5 ml/min, and no increase in creatinine at discharge. (GFR data)





CAR 8

Device-Specific Adverse Event Profile May Favor Surgically Implanted Impella 5.0/LD

S. Chen[1], *D. Paone*[1], *L. Spellman*[2], *N. Ranganath*[1], *Z. Kon*[1], *N. Moazami*[1], *D. E. Smith, III*[1]; [1]*Cardiothoracic Surgery, New York University Langone Health, New York, NY,* [2]*Biochemistry, Barnard College, New York, NY.*

Study: The Impella (Abiomed, Danvers, MA) ventricular support system is a family of temporary mechanical circulatory support devices designed to treat patients with cardiogenic shock. These devices include the percutaneously implanted 2.5/CP and the surgically implanted 5.0/LD. Data to assess adverse outcomes and help guide decision-making between Impella CP and 5.0/LD devices is limited. The purpose of this study was to compare the characteristics and clinical outcomes between Impella CP and 5.0/LD at our institution.
Methods: From December 1, 2014 to October 31, 2019 a total of 117 patients underwent Impella implantation regardless of indication or device type. Of these, 82 patients were supported for greater than 24-hour duration. Baseline patient characteristics and outcomes were reviewed retrospectively. Groups were stratified based on either initial Impella CP or 5.0/LD placement and their clinical outcomes compared.
Results: Impella CP was implanted in 56 patients (median age: 60.5 years, male 71.4%) and Impella 5.0/LD (median age: 65.5 years, male 84.6%) were implanted in 26 patients. Regardless of the indication for Impella placement, 24 patients with Impella CP required additional mechanical support and were upgraded to either Impella 5.0/LD or extracorporeal membrane oxygenation (ECMO) (p=0.005). Patients with Impella CP had increased incidence of hemolysis defined as the presence of gross hematuria and elevated lactated dehydrogenase (Table 1). Patients with Impella 5.0/LD were more likely to survive from Impella and survive to discharge. Data from this study suggests that Impella 5.0/LD may have a more favorable device-specific adverse event profile compared to Impella CP.

Table 1. Baseline patient characteristics and clinical outcomes for patients placed on Impella support for >24 hour duration (total number (n) = 82 patients).

	Impella CP (n = 56)	Impella 5/LD (n = 26)	p-value
Recipient Characteristics			
Age (years)	60.50 [52.00-73.00]	65.5 [55.25-70.25]	0.788
Gender			0.272
Male	40 (71.4%)	22 (84.6%)	
Female	16 (28.6%)	4 (15.4%)	
Race			1.000
White	29 (51.8%)	13 (50.0%)	
Other	27 (48.2%)	13 (50.0%)	
Body mass index (BMI) ≥ 30 kg/m²	22 (39.3%)	7 (26.9%)	0.328
Indications for Impella			<0.0001
Acute decompensated heart failure (ADHF)	30 (53.6%)	4 (15.4%)	
Acute myocardial infarction cardiogenic shock (AMICS)	13 (23.2%)	2 (7.7%)	
High-risk electrophysiology (EP) procedure	1 (1.8%)	0 (0.0%)	
High-risk percutaneous coronary intervention (PCI) procedure	1 (1.8%)	0 (0.0%)	
Myocarditis	3 (5.4%)	0 (0.0%)	
Post-cardiac surgery	8 (14.3%)	20 (76.9%)	
Cannulation Site			<0.0001
Central	0 (0%)	18 (69.2%)	
L femoral	13 (23.2%)	1 (3.8%)	
R femoral	40 (71.4%)	0 (0.0%)	
R axillary	3 (5.4%)	7 (26.9%)	
Clinical Outcomes			
Upgraded to Extracorporeal Membrane Oxygenation (ECMO)	20 (35.7%)	3 (11.5%)	0.033
Upgraded to Impella 5/LD	7 (12.5%)	0 (0.0%)	0.091
Support Upgraded (ECMO or Impella 5/LD)	24 (42.9%)	3 (11.5%)	0.005
Impella Outcome			0.026
Death on Impella	17 (30.4%)	2 (7.7%)	
Survival from Impella	39 (69.6%)	24 (92.3%)	
Discharge Outcome			0.006
Survival to Discharge	29 (51.8%)	22 (84.6%)	
Non-survival to Discharge	27 (48.2%)	4 (15.4%)	
Creatinine ≥ 1.5mg/dL on Impella	34 (61.8%)	11 (42.3%)	0.150
Creatinine ≥ 2.0mg/dL on Impella	22 (40.0%)	8 (30.8%)	0.469
CRRT/HD	18 (32.1%)	7 (26.9%)	0.798
LDH ≥ 2 times upper limit of normal (i.e. ≥560 U/L)	36 (92.3%)	9 (47.4%)	<0.0001
Hematuria	26 (46.4%)	6 (23.1%)	0.005

CAR 9

Application and Outcomes of a Temporary Percutaneous Right Ventricular Assist Device Impella RP in Setting of Right Ventricular Failure

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Study: Right ventricular failure increases morbidity and mortality in post-operative cardiac surgical patients. Currently there are limited options for durable devices to support right ventricular failure. We describe our experiences and outcomes of using a temporary, percutaneous right ventricular assist device (Impella RP) to support right ventricular failure.
Methods: This is a single-center, retrospective review of consecutive patients who received the Impella RP device from August, 2015 to July, 2019. Patients' electronic records were thoroughly reviewed. The basic demographic information, duration of implantation, reason and setting for implantation, and patient outcomes data were collected and analyzed.
Results: During the study period, 11 patients received Impella RP as a temporary mechanical support for their right heart failure. The average age of the patients is 46 +/- 15 years. 91% are males. The mean length of implantation is 5.3 +/- 4.2 days, with a range from 0 to 14 days. Our survival rate is 72.7%. The majority of the survivors (88%) presented with complication from cardiomyopathy, and they either recovered, received a heart transplant, or a left ventricular assist device. Out of 3 mortalities, 2 patients died of complications after surgical pulmonary embolectomy for acute pulmonary embolism, and 1 patient died of bowel ischemia after mitral valve replacement. Of note, our survival outcomes improved during the second half of the study period (85.7% v.s. 50%) compared to the first 2 years of experience.
Conclusions: In patients with severe right heart failure that cannot be managed with medical means alone, a temporary percutaneous right ventricular assist device Impella RP is a viable option to improve patient survival. More experience in patient selection is also key in ensuring successful implant and subsequent recovery to explant.

CAR 10

Acute *In Vivo* Testing Of Realheart TAH In Sheep Model

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Study: The Realheart TAH is a new generation of total artificial hearts, which mimics the function and anatomy of the natural heart. It consists of two parts, the right and the left pump. Each pump consists of an atrium and a ventricle, and in between a movable valve-plane corresponding to the natural AV-plane. The valves correspond to the tricuspid and mitral valves. The cardiac output is regulated separately on the left and right side by changing the stroke length of the AV-plane movement. Both pumps are connected electrically and are beating synchronously, thus the cardiac output is regulated as well by changing the heart rate. All is controlled automatically. The aim of the study was to perform acute animal study to assess the anatomical fit and function of Realheart TAH in sheep and to assess the flow and control algorithm.
Methods: Twelve acute sheep operations were carried out during 2019. The sheep were female Belgian Milk Sheep and weighed between 80-95 kg. Through lateral thoracotomy, the ventricles of the natural heart were removed and the Realheart TAH was implanted into the chest cavity. The artificial atria of the Realheart TAH were connected to the natural atria of the sheep with new novel connector tools. The driveline was tunnelled dorsally through a separate small incision and connected to the control box.
Results: Realheart TAH fits well in a sheep and delivers physiological blood flows which varies depending on the needs of the animal. The left/right flow balance was maintained and the physiological parameters were adequate. The automatic control functioned successfully. The last animal was kept alive for 21 hours. No blood clots were found in post-mortem analysis.

CAR 11

Use of Virtual Reality as a Presurgical Planning Tool in LVAD Implantation

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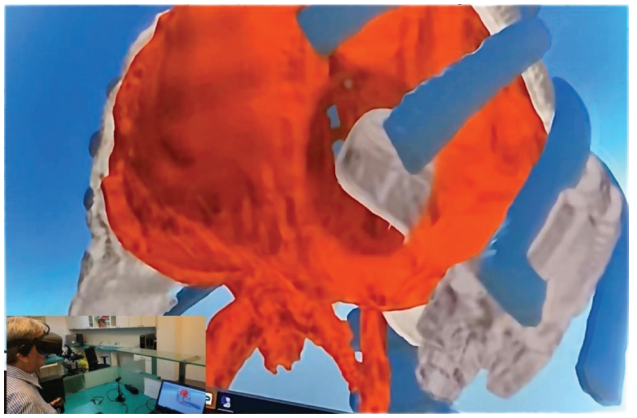
Study: A well positioned inflow cannula parallel to the septum and in line with the mitral valve is crucial for good outcomes in LVAD surgery. An improper position can lead to low flows and pump thrombosis. A ***pre surgical*** tool to aid in the perfect positioning of the inflow cannula can be useful during LVAD implantation to avoid complications especially in small built patients and in children where difficulties might be encountered in chest closure. We investigated the use of a virtual reality environment with wearable headsets and touch controllers in simulating an implant and aid in the ideal positioning of the LVAD.Also post implant CT scans have a lot of artefacts caused by the LVAD leading to difficulties in interpretation. Can this be improved by image processing?

Methods: Patient specific 3D images of heart, lungs and chest wall with the LVAD are generated by semi-automatic segmentation using 3D-Snake algorithm from preoperative contrast CT scans and imported into an interactive Virtual Reality environment created using UNITY engine enabling virtual implantation of the LVAD at the optimal site using Oculus touch controllers. Thresholding was used as a pre-segmentation mode with selected band limits and an optimal number of solid bubbles were seeded for the active contour initialization which evolves actively capturing the organs. The surgeon,wearing headsets, is able to visualise in 3D colour inside the ventricular cavity very clearly and implant the LVAD virtually in multiple sites in the ventricle and is then able to choose the optimal site for implantation.

The artifacts caused by the LVAD in post operative CT images were cleared by label editing in the ITK-Snap manually resulting in 3D images of great clarity.

Results: Virtual reality is a useful tool in surgical planning especially in small built patients leading to ideal inflow cannula positioning.Visualisation of implanted LVADS with enhanced clarity by removing artefacts in CT scans aids in postoperative decision making.



CAR 12

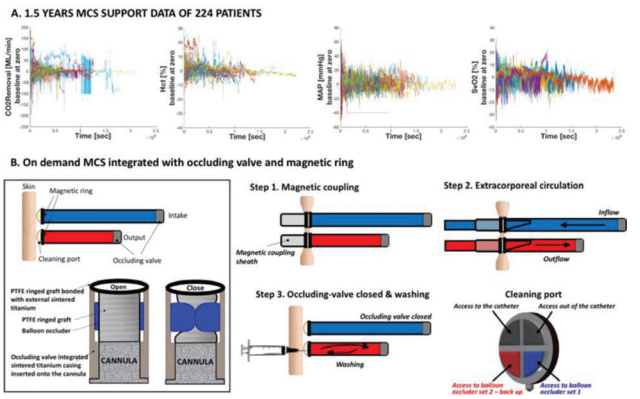
Automated Hypothermic Circulatory System for Deep Space Travel

J. Park, *P. Bonde; Yale School of Medicine, New Haven, CT.*

Study: Manned deep space travel requires a significant amount of mass reduction (up to 68%). The medical practice of therapeutic hypothermia has emerged as a promising solution as it profoundly decreases metabolic demand. However, nearly 40% of patients undergoing hypothermia develop ventricular fibrillation. An ideal scenario would be to have moderate hypothermia without affecting coagulation and enzyme cascades. We propose a novel application of mechanical circulatory system (MCS) that combines unique component with an innovative design which can facilitate periodic hypothermic hibernation.

Methods: First, we explored data from 224 patients who received MCS from January 2015 to August 2019 with moderate hypothermia to 34 to 35 degrees Celsius for safety and variability. Metabolic parameters such as CO2 removal, hematocrit (Hct), mean arterial pressure (MAP), and mixed venous oxygen saturation (SvO2) were examined and trended over the duration of support. Next, an occluding valve incorporated in inflow and outflow cannula was designed and prototyped which can isolate the MCS system from the in-vivo circulatory system and automates cleaning, maintenance, and servicing when still implanted within a human body, preventing complications such as infection or clot formation.

Results: Superimposed plots of each parameter for all patients demonstrate metabolic stability with minor fluctuations in MCS patients over a cumulative support period of 1.5 years (Fig 1A). Forty of these remained awake with normal diurnal variations in sleep patterns. Magnetically coupled connectors facilitate alignment and cannulation of MCS across a skin barrier (Fig 1B, Step 1 & 2). Once the target temperature is reached one can safely disconnect /discontinue MCS support (but with the ability to reinitiate if any arrhythmia takes place). When not in use automated cleaning via port placed beneath the skin is activated (Fig 1B, Step 3).



CAR 13

Early Enteral Feeding After VAD Implantation Is Associated With Reduced Rates of Gastrointestinal Bleeding

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Study: Gastrointestinal (GI) bleeding is a common adverse event affecting nearly 35% of all patients undergoing ventricular assist device (VAD) implantation, causing significant morbidity. A lack of enteral intake is associated with intestinal mucosal atrophy. The correlation between enteral feeding and GI bleeding is poorly studied in the VAD population. We hypothesize that early postoperative enteral nutrition (EEN) would be associated with reduced rates of gastrointestinal bleeding after VAD implantation.

Methods: Retrospective review of a single institution VAD database was performed for all patients between 2012-2019 (n=90). Exclusion criteria included a prior history of GI bleed or a lack of perioperative nutritional assessment. Patients were stratified by presence or absence of early (< 7 days) postoperative enteral nutrition. Primary outcome was presence of post-operative GI bleeding within 30 days. Secondary outcomes included patient survival, delayed GI bleed (>30 days), infection, stroke, and ICU lengths of stay.

Results: Post-operative EEN was initiated in 38.9% (n=35) of patients versus 61.1% (n=55) not receiving enteric nutrition. Baseline characteristics demonstrated similarity between EEN and non-EEN patients (Table 1). GI bleeding was present in significantly less proportion of EEN patients (5.00%, n=2) compared to the non-EEN cohort (21.82%, n=12; p = 0.037; Table 2). EEN was also associated with statistically shorter ICU lengths of stay (p<0.001) and index admission infectious complications (p<0.001). There was no difference between cohorts in survival or delayed onset GI bleeding (>30days post-implant). In conclusion, early initiation of EEN is associated with improved rates of early postoperative GI bleeding. Strong consideration should be given to instituting early enteric feeds in patients post-VAD implant.

Table 1 - Baseline Characteristics

	EEN	Non-EEN	p-value
Number	40	55	
Age	57.6 (47.7-66.8)	58.2 (45.6-65.4)	0.672
Female Sex	8 (20.00%)	13 (23.64%)	0.804
Ethnicity			0.399
White	27 (69.23%)	34 (61.82%)	
Black	11 (28.21%)	14 (25.45%)	
Other	1 (2.56%)	7 (12.72%)	
BMI	29.1 (24.0-33.5)	30.8 (24.8-34.7)	0.289
Moderate to Severe Malnutrition	10 (25.00%)	20 (36.36%)	0.271
INTERMACS			0.343
1	4 (11.11%)	13 (27.08%)	
2	19 (52.78%)	18 (37.50%)	
3	10 (27.78%)	12 (25.00%)	
4	3 (8.33%)	4 (8.33%)	
5	0 (0.00%)	1 (2.08%)	
Ischemic Etiology	16 (41.03%)	22 (40.74%)	0.302
Implant Indication			0.756
Bridge to Transplant	9 (22.50%)	14 (25.45%)	
Bridge to Decision	5 (12.50%)	9 (16.36%)	
Destination Therapy	25 (62.50%)	29 (52.73%)	
Recovery	1 (2.50%)	3 (5.45%)	
Pre-operative labs			
INR	1.2 (1.1-1.5)	1.3 (1.2-1.5)	0.177
Platelets	171 (135-213)	199 (130-228)	0.289
Lactate	1 (0.8-1.2)	0.8 (0.5-1.6)	0.434
Pre-operative anticoagulation	25 (62.50%)	37 (67.27%)	0.667
Intraoperative cardiopulmonary bypass time (min)	79 (59-90)	75.5 (54-123)	0.659
Concomitant cardiac procedure	11 (27.50%)	22 (40.00%)	0.276
Post-operative hypotension requiring vasopressors	33 (82.50%)	41 (74.55%)	0.455

Table 2 - Post-operative outcomes

	EEN	Non-EEN	p-value
GI Bleed			
Within 7 days	**2 (5.00%)**	**12 (21.82%)**	**0.037**
Within 90 days	5 (12.50%)	5 (9.09%)	0.738
Survival			
30 day	37 (92.50%)	45 (81.82%)	0.226
90 day	30 (75.00%)	33 (60.00%)	0.187
Index Hospitalization Outcomes			
ICU Length of stay	**6 (4-7)**	**11.5 (5-22)**	**<0.001**
Infectious complications	**8 (20.00%)**	**32 (58.18%)**	**<0.001**
Stroke	2 (5.00%)	8 (14.55%)	0.183

CAR 14

Functional Outcomes in Left Ventricular Assist Device Implantation via Left Lateral Thoracotomy with Outflow Cannula Anastomosis to the Descending Aorta

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Study: LVAD implantation with median sternotomy remains challenging in high-risk patients with previous sternotomy due to hostile anterior mediastinal anatomy, intact bypass grafts and preexisting prosthetic valves. Left lateral thoracotomy with outflow cannula anastomosis to the descending aorta provides an alternative method of implantation using a single incision while avoiding anterior mediastinal surgical planes. The aim of this study is to compare the functional outcomes of this technique with median sternotomy.

Methods: Patients who received HeartWare HVAD implantation in our institution between 2014-2019 were involved in the study. Collected data included cardiopulmonary exercise test (CPET) parameters (vO_2max, vE/vCO_2 slope, oxygen uptake efficiency slope), 6-minute walk test (6MWT) and quality of life (QoL: Minnesota Living with Heart Failure Questionnaire). Only patients with both pre- & post-implantation test results were included in the analysis. The effect of implantation technique on the improvement of test results following implantation was evaluated.

Results: From all implanted patients, 73 completed both pre- & post-implantation CPETs from which 59 had ascending aorta (sternotomy) and 14 had descending aorta (thoracotomy) anastomosis (Table 1). Among these, 60 and 29 patients also had 6MWT and QoL data respectively. Pre- and post-implantation CPETs were performed 62±12 days before and 215±17 days following implantation. The improvement in CPET, 6MWT and QoL parameters was not significantly different between the ascending and descending aorta anastomosis groups (Figure 2). In conclusion, this study found no statistically significant difference in the improvement of major functional outcomes between LVAD implantation via left lateral thoracotomy with outflow cannula anastomosis to descending aorta and implantation via sternotomy with outflow cannula anastomosis to ascending aorta.

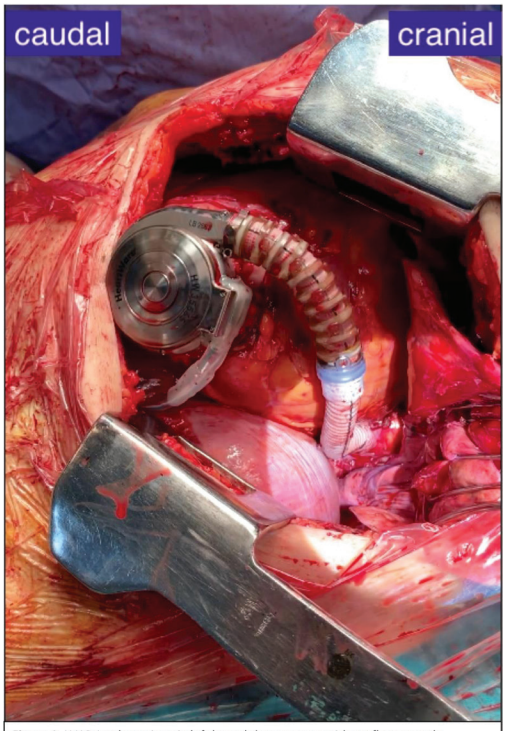

Figure 1. LVAD Implantation via left lateral thoracotomy with outflow cannula anastomosis to the descending aorta. Patient is placed in a 45° right decubitus position. The left lung is retracted while still ventilated.

Table 1. Pre-implantation characteristics of the ascending and descending aorta groups.

	Ascending aorta (n: 59)		Descending aorta (n: 14)		
Characteristic	**n (%)**	**Mean (±SEM)**	**n (%)**	**Mean (±SEM)**	**p-value[a]**
Age		50.08 (±1.58)		53.29 (±2.70)	.363
Gender					.059
Male	44 (74.6)		14 (100)		
Female	15 (25.4)		0		
BMI (kg/m²)		25.64 (±0.59)		28.12 (±1.25)	.071
Heart failure etiology					.000
Ischemic cardiomyopathy	15 (25.4)		13 (92.9)		
Non-ischemic dilated cardiomyopathy	44 (74.6)		1 (7.1)		
Previous sternotomy	7 (11.9)		14 (100)		.000
Hypertension	24 (40.7)		6 (42.9)		.999
Diabetes mellitus	14 (23.7)		7 (50)		.096
Cigarette smoking (pack years)		13.64 (±3.03)		16.43 (±4.64)	.676
COPD	6 (10.2)		2 (14.3)		.645
Intermacs profile					.439
1	3 (5.1)		0 (0)		
2	12 (20.3)		5 (35.7)		
3	20 (33.9)		4 (28.6)		
4	23 (39)		4 (28.6)		
5	1 (1.7)		1 (7.1)		
6	0 (0)		0 (0)		
7	0 (0)		0 (0)		
Creatinine (mg/dL)		1.31 (±0.14)		1.24 (±0.85)	.834
LVEDD (cm)		7.18 (±0.09)		6.84 (±0.22)	.136
LVEF (%)		19.97 (±0.34)		19.50 (±1.08)	.688
SPAP (mmHg)		50.89 (±1.80)		44.54 (±2.40)	.108
TAPSE (mm)		16.09 (±1.51)		14.14 (±1.10)	.531

[a]Student's t-test: Difference between ascending and descending aorta anastomosis groups.

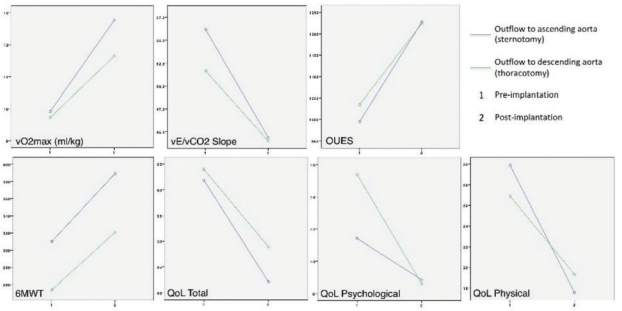

Figure 2. Effect of implantation technique on the improvement of CPET, 6MWT and QoL parameters.

	Pre-implantation		Post-implantation		p-value[a]
Cardiopulmonary exercise test	**Ascending Ao (n:56)**	**Descending Ao (n:14)**	**Ascending Ao (n:56)**	**Descending Ao (n:14)**	
vO_2max (ml/kg.min⁻¹)	9.91 (±0.35)	9.72 (±0.72)	12.77 (±0.47)	11.65 (±0.97)	.343
vE/vCO_2 slope	56.19 (±2.59)	51.66 (±5.31)	44.39 (±1.82)	44.01 (±3.74)	.521
OUES	994 (±55)	1034 (±113)	1227 (±59)	1224 (±121)	.748
6-minute walk test	**Ascending Ao (n:46)**	**Descending Ao (n:14)**	**Ascending Ao (n:46)**	**Descending Ao (n:14)**	
Distance (meters)	309 (±16)	253 (±30)	389 (±12)	320 (±22)	.720
Quality of life *(Minnesota Living with Heart Failure Questionnaire)*	**Ascending Ao (n:19)**	**Descending Ao (n:10)**	**Ascending Ao (n:19)**	**Descending Ao (n:10)**	
Total score	61.89 (±6.63)	64 (±9.15)	42.10 (±4.52)	48.90 (±6.23)	.715
Physical factor	29.89 (±2.80)	26.90 (±3.86)	17.53 (±2.01)	19.30 (±2.76)	.454
Psychological factor	11.42 (±1.94)	15.40 (±2.67)	8.84 (±1.45)	8.60 (±2)	.213

[a]Split-plot ANOVA: effect of anastomosis site on the improvement of the variable following implantation.
OUES: Oxygen uptake efficiency slope.
Results are provided as mean (±standard error of the mean).

CAR 15

Impact of Tricuspid Valve Repair at the Time of Left Ventricular Assist Device Implantation on Post-transplant Outcomes

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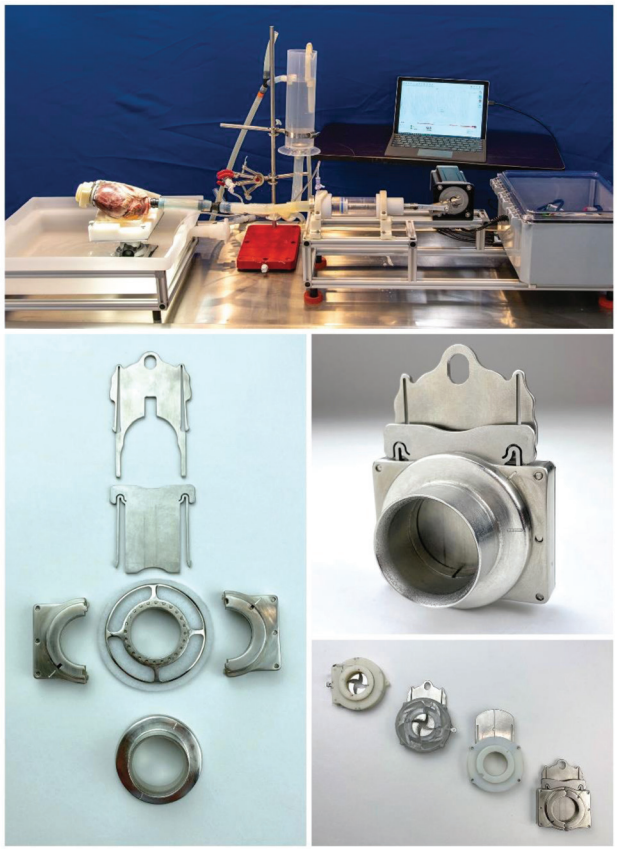
Study: Continuous-flow left ventricular assist devices (CF-LVADs) have become a standard of care for end-stage heart failure patients. Tricuspid valve repair (TVR) at the time of CF-LVAD implant is still controversial. We investigated the impact of TVR at the time of CF-LVAD implant on post-transplant outcomes.
Methods: Between January/2010 and June/2018, 100 underwent CF-LVAD implant and 20 CF-LVAD+TVR. Indication to perform TVR was preoperative tricuspid regurgitation (TR)≥moderate and was at the surgeon's discretion.
Results: Preoperative TR≥moderate was recognized in 41 patients (41%) in CF-LVAD and 19 (95%) in CF-LVAD+TVR (P<0.01). Mortality rates after CF-LVAD implant and CF-LVAD+TVR were 16% and 10%, respectively (P=0.49). There were no statistically significant differences regarding post-LVAD implant complications between groups. Fifty-two patients (52%) following CF-LVAD implant and 12 (60%) following CF-LVAD+TVR underwent heart transplantation (HTx) (P=0.51). Prior to HTx, 12 patients had moderate TR and 3 had severe in CF-LVAD (29%). Only 1 had severe TR in CF-LVAD+TVR (8%) (P=0.4). The right ventricular systolic pressure was 33±9 mmHg in CF-LVAD and 29±6 mmHg in CF-LVAD +TVR (P=0.10). Post-transplant hospital death was observed in 2 in CF-LVAD (4%) and 1 in CF-LVAD+TVR (8%) (P=0.10). There was no statistically significant difference regarding post-transplant survival (log-rank P=0.37). Three deaths in CF-LVAD versus 2 in CF-LVAD+TVR were observed at a mean follow-up of 4.2±3.1 years. There were 12 adverse events requiring readmission in CF-LVAD. However, no event was recorded in CF-LVAD+TVR (log-rank P=0.04). The latest creatinine, aspartate transaminase, alanine aminotransferase and total bilirubin levels were slightly lower in the CF-LVAD+TVR. Our data support the selected use of TVR at the time of CF-LVAD implant in transplant candidates. We postulate that TVR prevents hepatorenal congestion, resulting in fewer adverse events.

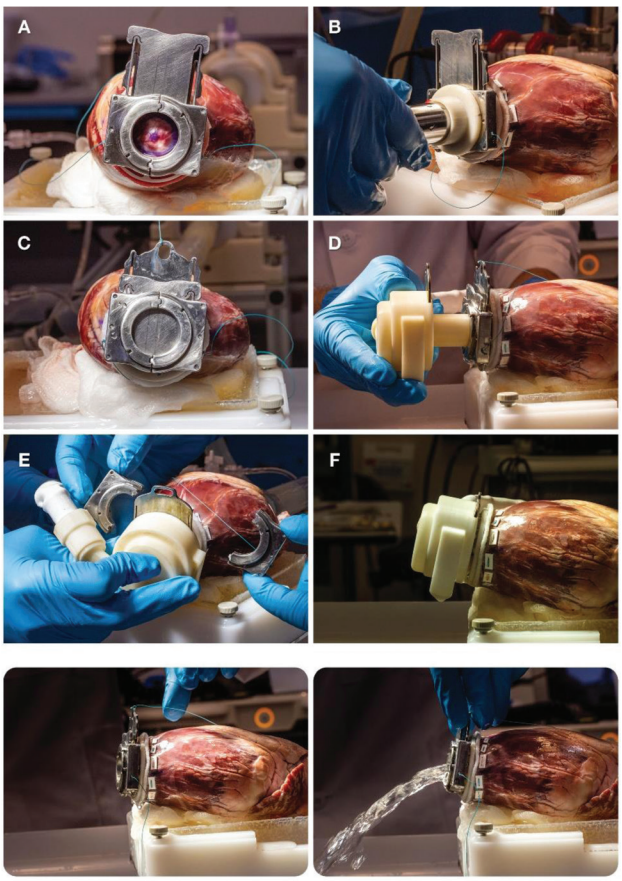


CAR 16

Exploring Temporary Valve Mechanisms to Facilitate Minimally Invasive Off-pump Left Ventricular Assist Device Implantation

H. Amirjamshidi[1], *J. S. Sauer*[2], *B. J. Boseck*[2], *C. J. Hand*[2], *B. Barrus*[1], *P. A. Knight*[1], *I. Gosev*[1]; [1]*Cardiac Surgery, University of Rochester Medical Center, Rochester, NY,* [2]*LSI SOLUTIONS, Victor, NY.*

Study: Improved technology and techniques can facilitate the utilization of a minimally invasive off-pump sternal sparing approach for left ventricular assist device (LVAD) implantation to help reduce morbidity and optimize outcomes in these critically ill patients. This study investigates the feasibility of using a novel temporary valve mechanism between an LVAD and its sewing cuff to enable more hemostatic and secure installation of the pump through a mini-thoracotomy on a simulated beating heart with circulating blood.
Methods: A new pulsatile ex-vivo porcine beating heart model was employed to investigate the ergonomics and hermetic security of LVAD placement into the saline pressurized left ventricles of 5 thawed porcine hearts. After suturing the inflow sewing cuff onto the apex, the valve housing clips onto the cuff's rim moving with heart's rhythm, coring occurs through the open valve, the core is removed and valve closed, the pump positioned and valve opened, the LVAD stem is partially inserted into apex, housing is split and removed, then the pump is fully advanced and clipped. Two valve prototypes with four radially moving occlusive panels and two versions with a single sliding door were assessed for saline leakage during simulated LVAD installation.
Results: The temporary valve provided excellent usability and hermetic security in this simulated pulsatile, pressurized porcine heart LVAD installation model. This technology can potentially reduce the risk of significant blood loss during open and minimally invasive off-pump LVAD implantation. These early feasibility results encourage further evaluation.



CAR 17

Outcomes of Medical Treatment for Early Detected Ventricular Assist Device Pump Thrombosis

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Study: Pump thrombosis (PT) is a devastating complication of ventricular assist devices (VAD) which, if detected early, can potentially be treated medically. We aimed to investigate if early detection and medical treatment can lead to successful outcomes.

Methods: We reviewed 180 consecutive patients (pts) implanted with HeartMate II (HM2) and HeartWare (HVAD) and evaluated PT incidence as events per patient year (EPPY), along with treatments used and their complications.

Results: Pts were 57 years of age, 15% women, 41% INTERMACS profiles 1 & 2 at implant with average support on VAD of 1.6 years. PT occurred in 7 HM2 pts (0.053 EPPY) and 8 HVAD pts (0.054 EPPY), at an average of 386 and 389 days post implant in HM2 and HVAD, respectively. The initial trigger for suspected PT was remotely transmitted power abnormalities without alarms in 87% of pts and abnormal routine laboratory LDH in 13% of pts. At the time of suspected PT, the mean INR was 2.2, mean LDH was 789 U/L and the power consumption was 30% higher in HM2 and 50% higher in HVAD pts compared to their baseline stable power consumption. All pts were treated with IV heparin (HM 2, mean 10.7 days; HVAD, mean 14.4 days) and some with tPA (HM2: 43%, average dose 77 mg; HVAD: 63%, average dose 52 mg) with normalization of power consumption and hemolysis markers in all pts. The initial treatment was associated with 3 episodes of minor bleeding and 1 minor stroke. PT reoccurred in 29% of HM2 pts (after mean 65 days) and 50% of HVAD pts (after mean 163 days), was treated with IV heparin and tPA and was complicated by 1 stroke, 1 VAD exchange and 1 death.

Conclusions: Early detection of PT using remote VAD data can lead to successful initial treatment with IV heparin and tPA with minor complications. A large proportion of pts have recurrent PT and subsequent treatments have a higher complication rate.

CAR 18

Maintaining Neurohormonal Blockade Prior to Long Term HVAD Implantation Across Intermacs Categories: An Analysis of the ENDURANCE DT and DT2 Studies

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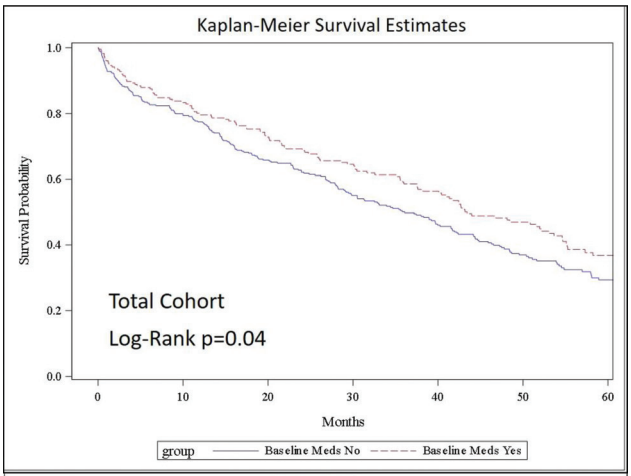
Study: Advanced heart failure teams must make decisions regarding the benefits of continuing neurohormonal blockade (NHB) in patients who require long term LVAD therapy. We sought to examine the effects of pre-implant NHB on morbidity and mortality after HeartWare HVAD System implantation as destination therapy.

Methods: All HVAD patients in the ENDURANCE and ENDURANCE Supplemental trials with baseline Intermacs score (n=601) were included. Patients were studied based on the presence of 2 or more neurohormonal blocking agents (NHB: Yes) (β-blockers, ACE-IARB, and mineralocorticoid antagonists) (n=224) *prior to implant* and those on one or less NHB agents (NHB: No) (n=377). The analyses in the overall cohort and stratified into Intermacs 1-2 and Intermacs 3-7 patients identified the impact of *baseline NHB* on adverse events and overall survival as the primary endpoints.

Results: Patients who were on or could tolerate NHB (37%) pre-implant had an increased baseline BMI (28.3±6.3 vs 27.3±5.6, p=0.05) and greater incidence of hypertension (76.8% vs 66.8%, p=0.01). The overall survival in the NHB group was significantly improved in long term follow-up (Figure 1) with 2- and 3-year Kaplan-Meier estimates of 69% vs 59%, and 62% vs 50% for the NHB and the no-NHB group respectively. There was no evidence for worsening survival in the stratified analysis of INTERMACS 1-2 patients and a trend for improved survival in the INTERMACS 3-7 patients (p=0.06). The NHB group demonstrated a lower event rate of sepsis (p=0.03) and requirement of an RVAD (p=0.03). Maintenance of neurohormonal blockade up to the pre-implant phase could have important benefits in patients undergoing long term continuous flow support with HVAD therapy. Future studies may resolve whether the benefits of pre-implant NHB in patients undergoing long term LVAD therapy are the result of a treatment effect or reflect the positive self-selection for tolerance of heart failure medications.



Patients at Risk

Time (Months)	0	12	24	36	48	60
NHB	**224**	**170**	**134**	**107**	**78**	**23**
no-NHB	**377**	**278**	**201**	**148**	**95**	**26**

Figure 1: Kaplan-Meier survival estimates

CAR 19

Restrictive vs. Non-restrictive Pathology in Donor-Recipient Size Mismatch: BMI Ratio is the Best Predictor in UNOS Database Analysis

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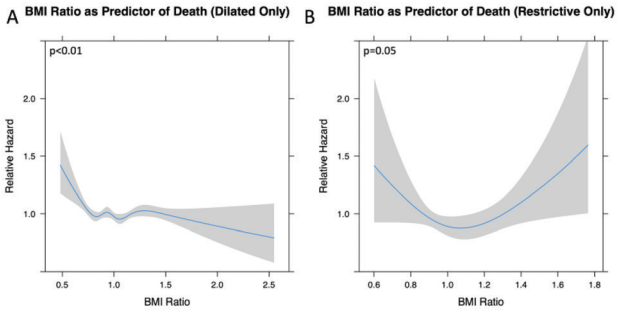
Study: There is no single established metric for donor-recipient size mismatch when evaluating donor hearts for transplantation. We sought to assess the performance of six commonly used size metrics to predict survival after heart transplant, accounting for restrictive vs. non-restrictive pathology.
Methods: The United Network for Organ Sharing registry was queried from 2000-2017 for all primary isolated heart transplants. Multiple imputation was performed for the missing data. Continuous nonlinear analysis was performed using restricted cubic splines to describe the commonly used size metrics and their association with survival. Statistically significant variables stratified to separately assess the performance for restrictive vs. non-restrictive pathology.
Results: 29,817 patients were identified. Height (p<0.01), predicted heart mass (PHM) (p<0.01, ideal body weight (IBW) (p<.01) and BMI ratios (p<0.01) were significantly associated with survival, while weight (p=0.18) and BSA ratios (p=0.11) were not. After stratifying the statistically significant size metrics, only BMI retained the significance for both restrictive (p=0.05) and non-restrictive (p<0.01) subsets. Visual inspection of the plots shows that in non-restrictive recipients, undersizing is penalized while oversizing is tolerated and may even appear to have some protective effect (Figure 1A). This is in contrast with restrictive recipients where both undersizing and oversizing comes at increased risk (Figure 1B).
Conclusion: Although ideal body weight, height, and predicted heart mass ratios demonstrate significant association with survival, BSA ratio appears to be the best metric when accounting for restrictive and non-restrictive subsets separately. Recipients with restrictive and non-restrictive pathology tolerate size mismatch differently and this has to be properly accounted for in donor-recipient size matching.



CAR 20

Risk of Hepatic Dysfunction After Left Ventricular Assist Device is Modulated by Markers of Right Ventricular Hemodynamics and Cardiopulmonary Bypass

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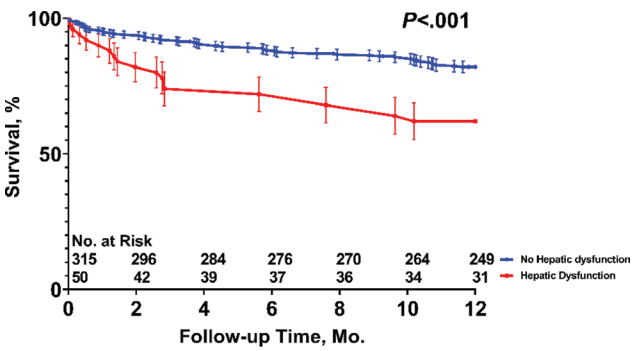
Study: Incident hepatic dysfunction (HD) after left ventricular assist device (LVAD) implantation has been previously associated with adverse outcomes, yet data on perioperative risk markers are sparse.
Methods: We retrospectively reviewed consecutive patients undergoing continuous-flow LVAD implant between 2007 and 2017 at a single institution. Perioperative variables were evaluated by univariate modeling and adjusted for false discovery rate. Variables most significantly associated with incident HD (INTERMACS definition) were evaluated using logistic regression and optimal cut-points were defined. One-year survival was evaluated using Kaplan-Meier analysis.
Results: We included 365 patients (79%M, mean age 59±13, 46% ischemic, and 63% destination therapy). Lower right ventricular stroke work index at the time of right heart catheterization (RVSWI), higher right atrial pressure six hours after right heart catheterization (RAP), longer cardiopulmonary bypass time (CPBT), and greater volume of intraoperative ultrafiltration (UF) were most strongly associated with incident HD (adjusted *P*<.01 for each), with good discrimination on multivariate regression (AUC 0.81, *P*<.0001). Initial RVSWI <460 mmHg*mL/m^2 (OR 4.6, 95% CI 2.3-9.4), 6-hour RAP ≥14 mmHg (OR 4.3, 95% CI 2.1-8.8,), UF >2.95L (OR 3.7, 95% CI 2.0-6.8), and CPBT >137 min (OR 3.3, 95% CI 1.8-6.2, *P*<.0001 for all) were highly associated with risk of HD. HD was associated with decreased one-year survival (*P*<0.001). RVSWI, RAP, CPBT, and UF were each associated with elevated risk of HD after LVAD implant. Optimization of right ventricular hemodynamics and minimizing CBPT and UF could potential reduce the risk of HD, but these observations require prospective validation.



CAR 21

Critical Plasma Dosing in Prolonged Normothermic *Ex Vivo* Heart Perfusion

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Study: Donor organ availability, placement, and ischemic time remain problems in cardiac transplant. Perfusion time can be extended from 6 to 72h using Normothermic Ex-Vivo Heart Perfusion (NEVHP) and continuous plasma exchange (1L/h) from a live paracorporeal animal. We aimed to determine the minimum dose of plasma needed to sustain adequate cardiac function and viability for 24h.

Methods: Seventeen ovine hearts were procured from healthy sheep and connected to a NEVHP circuit. Plasma exchange group (n=10) dosing rates were set at 0.2, 0.3, 0.4, 0.5, and 1.0 L/h. Controls (n=7) did not receive plasma exchange. Pre-determined perfusion parameters were followed, and hemodynamics were continuously recorded. NEVHP was terminated if end-point criteria were reached: mean left ventricle systolic pressure (LVSP) < 30mmHg, lactate > 7mmol/L, asystole, or 24h of NEVHP. At the end of NEVHP tissue was collected for histology.

Results: All plasma exchange hearts reached 24h while all controls failed before 24h (15.5±4.7h). The most common reason for failure was low LV pressures. At the end of perfusion, coronary resistance was higher in the plasma group than in the controls (0.53±0.2 v. 0.15±0.15mmHg/mL/min, p=0.0007). LVSP was also higher in the plasma group compared to controls (71.1±22.5 v. 42.8±32.7mmHg). Between specific plasma doses, there was no significant difference in mean LVSP, heart rate, serum lactate, oxygen consumption, and coronary resistance. Histology was similar in controls but showed elevated levels of myocardial hemorrhage at lower plasma doses compared to higher doses. These findings indicate that plasma exchange of 0.2L/h is sufficient to maintain endothelial integrity and adequate cardiac function during NEVHP.

CAR 22

Post-transplant Survival after Continuous-flow LVAD Implantation is Superior to Survival after Pulsatile-flow LVAD Implantation

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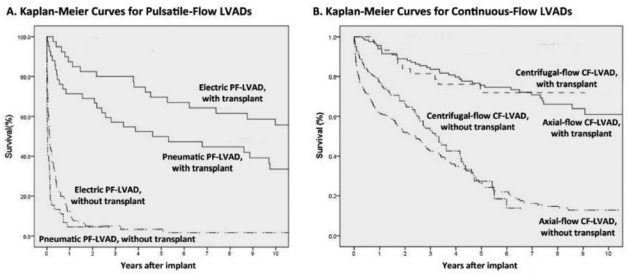
Study: Continuous-flow left ventricular assist devices (CF-LVADs) are the treatment of choice for mechanical support in heart failure, having supplanted pulsatile-flow (PF)-LVADs. Both CF-LVADs and PF LVADs have been used as bridge to transplant and destination therapies. We examined survival with/without subsequent orthotopic cardiac transplant for these devices.

Methods: We reviewed records from 730 centrifugal-flow CF-LVAD (May 2009 to February 2018), axial-flow CF-LVAD (November 2003 to September 2017), electric PF-LVAD (May 1991 to July 2010), and pneumatic PF-LVAD (January 1986 to July 2004) implantations at our institution. We calculated Kaplan-Meier survival curves for each device with and without subsequent transplant.

Results: Table 1 shows 5-year and 10-year survival outcomes. Figure 1 shows Kaplan-Meier survival curves for each device type, with and without subsequent cardiac transplant. Patients with a CF-LVAD who subsequently underwent transplant had significantly better survival than patients who had a PF-LVAD and subsequently underwent transplant (P<=0.05). **Conclusions:** Patients who had a CF-LVAD implanted but who did not undergo subsequent transplant had much better survival than patients who had a PF-LVAD and did not undergo subsequent transplantation. Patients who underwent CF-LVAD or electric PF-LVAD implantation and subsequently underwent orthotopic cardiac transplant had excellent survival, 70% or better, at 5 years. Ten-year survival also appears to be excellent, although the data is limited.

Kaplan-Meier survival outcomes

	With Subsequent Transplant		Without subsequent transplant		
	5-year survival n (%)	10-year survival n (%)	5-year survival n (%)	10-year survival n (%)	Lost to follow-up n (%)
Centrifugal-flow CF-LVAD (n=243)	175 (72)	N/A	67 (27.5)	N/A	19 (8.6
Axial-flow CF-LVAD (n=493)	373 (75.6)	301 (61.0)	133 (26.9)	64 (12.9)	62 (12.6)
Electric PF-LVAD (n=200)	139 (69.5)	111 (55.5)	31 (15.5)	17 (8.0)	12 (6.0)
Pneumatic PF-LVAD (n=87)	43 (49.4)	29 (33.3)	0 (0.0)	0 (0.0)	7 (8.0)

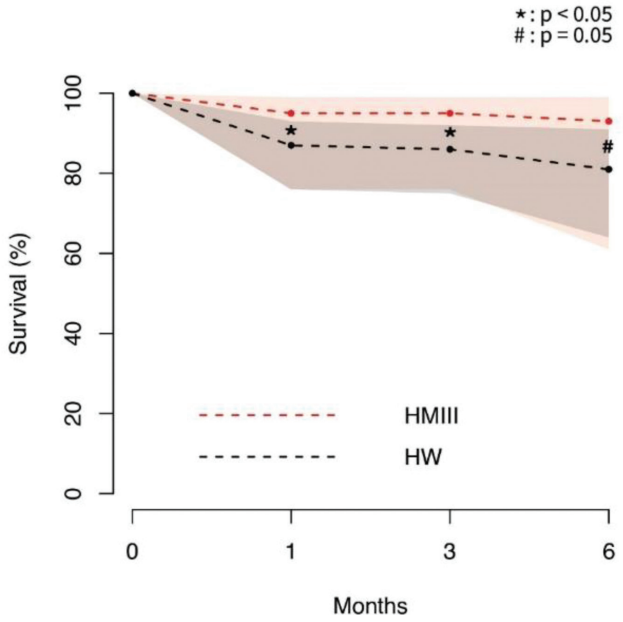


CAR 23

Continuous Flow LVAD Exchange to a Different Pump Model: Systematic Review and Meta-analysis of Outcomes

M. A. Austin[1], *T. J. O'Malley*[2], *M. N. Gadda*[3], *E. J. Maynes*[2], *R. J. Morris*[2], *M. K. Shah*[4], *P. R. Pirlamarla*[4], *R. J. Alvarez*[4], *J. W. Entwistle*[2], *H. T. Massey*[2], *V. Tchantchaleishvili*[2]; [1]*Sidney Kimmel Medical College, Thomas Jefferson University, Philadelphia, PA,* [2]*Cardiac Surgery, Thomas Jefferson University, Philadelphia, PA,* [3]*Drexel University College of Medicine, Drexel University, Philadelphia, PA,* [4]*Cardiology, Thomas Jefferson University, Philadelphia, PA.*

Study: Despite improved outcomes of modern continuous-flow left ventricular assist devices (CF-LVADs), device exchange is still needed for various indications. While the majority of CF-LVADs are exchanged to the same model, exchange to a different pump model is occasionally warranted. In this meta-analysis, we sought to consolidate the existing evidence to better elucidate the indications and outcomes in these cases.
Methods: A comprehensive search of Cochrane Controlled Trials Register, Ovid Medline, Cumulative Index of Nursing and Allied Health Literature and Scopus databases for adult patient cohorts who underwent CF-LVAD exchange to a different CF-LVAD model was performed. Study-level data from 10 studies comprising 98 patients were extracted and pooled for analysis.
Results: Mean patient age was 58 (95%CI: 48-65) and 81% were male. Indication for initial CF-LVAD was ischemic cardiomyopathy in 45% (34-57). Initial device was HeartMate II LVAD (HMII) in 93 (94.9%) and HeartWare HVAD (HW) in 5 (5.1%) patients. After mean CF-LVAD support time of 19.2 (15.6-21.6) months, exchange indications included thrombosis in 71% (43-89), infection in 21% (8-47) and device malfunction in 12% (7-21). HMII to HW exchange occurred in 53 (54.1%) patients, HMII to HeartMate III (HMIII) in 32 (32.7%), and HM II to either HW or HMIII in 13 (13.2%) patients. Postoperatively, right ventricular assist device was required in 16% (8-32). Overall, 20% (8-40) of patients experienced a stroke, while HW patients had a significantly higher stroke incidence than HMIII patients (HW: 22% (4-64) vs HMIII: 7% (0-90), p = 0.02). Overall 30-day mortality was 10% (6-17), while HW had a significantly worse 30-day mortality than HMIII (HW: 13% (7-24) vs HMIII: 5% (1-24), p = 0.03). Pooled stratified short-term survival over time is depicted in Figure 1.
Conclusion: Following device exchange from a different CF-LVAD model, HMIII is associated with decreased stroke and improved survival when compared to HW.

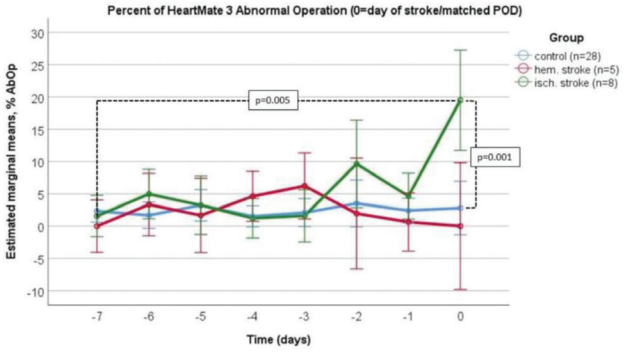


CAR 24

Assessment of Suction Events in HeartMate 3 LVAD Patients Using Logfiles - A Correlation to Neurological Dysfunction

T. Schlöglhofer[1], *A. Neumayer*[2], *F. Kaufmann*[3], *P. Aigner*[2], *M. Maw*[1], *C. Gross*[1], *E. V. Potapov*[3], *D. Wiedemann*[1], *F. Moscato*[2], *H. Schima*[1], *D. Zimpfer*[1]; [1]*Division of Cardiac Surgery, Center for Med. Physics and Biomed. Eng; LBI for Cardiovasc. Research, Medical University of Vienna, Vienna, Austria,* [2]*Center for Med. Physics and Biomed. Eng; LBI for Cardiovasc. Research, Medical University of Vienna, Vienna, Austria,* [3]*German Heart Center Berlin, Berlin, Germany.*

Study: Strokes are a frequent complication following LVAD implantation. The objective of this study was to determine a potential relationship between strokes and occurrence of suction events determined by HeartMate 3 (HM3) logfile analysis.
Methods: This retrospective, two-center study included 41 HM3 patients (Age: 59.2±12.0 yrs, female: 14%, BMI: 27.9±5.3kg/m2, iCMP/dilCMP/other: 57%/34%/9%) implanted at the Medical University of Vienna and German Heart Center Berlin between June 2014 and 2019. Of these patients, logfiles on the day of hemorrhagic (HS, n=5) or ischemic stroke (IS, n=8) as well as control patients (n=28) without any adverse events were included in the analysis. Abnormal operation (AbOp) (=suction occurrence) was determined using 5 features such as flow to PI morphology and occurrence of PI events. Ratio of normal operation vs. AbOp (due to suction) was analyzed 7 days preceding HS or IS and compared to the same period in the control group at matched times using a mixed-design ANOVA to investigate temporal changes in pump data.
Results: There was a significant difference between the 3 groups, F(2,38)=4.4, p=0.019, in AbOp and a significant interaction between time and group, F (6.8,129.9)=3.1, p=0.005. The interaction indicated that there was no significant difference in AbOp between the groups at baseline (p>0.87), further control and HS groups did not change over time, with an 8-day average of 2.5±4.8% and 2.3±6.7% respectively. However, the mean scores of AbOp increased significantly (p=0.005) over time from baseline (1.6±4.4%) vs. the day of IS (19.5±22.7%). This study indicates the utility of HM3 pump parameters and logfiles in assessing the overall number of suction and the potential correlation of these suction events with ischemic strokes.



CAR 25

Successful Ovine Heart Transplant after 24h Normothermic *Ex Vivo* Perfusion

W. Weir[1], **B. Schneider**[2]*, M. Hayes[2], M. Langley[2], M. Hoenerhoff[3], D. Drake[1], J. Toomasian[2], A. Rojas-Pena[2], G. Owens[4], R. Bartlett[2], J. Haft[1]; [1]Cardiac Surgery, University of Michigan, Ann Arbor, MI, [2]General Surgery, University of Michigan, Ann Arbor, MI, [3]Unit for Laboratory Animal Medicine, University of Michigan, Ann Arbor, MI, [4]Pediatrics, University of Michigan, Ann Arbor, MI.*

Study: Prolonged normothermic (37°C) ex-vivo heart perfusion (NEVHP) is possible for >24h with the addition of plasma cross-circulation from a live paracorporeal animal. To demonstrate adequate heart function and viability, we aimed to perfuse hearts for 24h followed by allotransplantation.

Methods: Two hearts from healthy sheep were procured and placed on a NEVHP circuit for 24h using a blood-derived perfusate and plasma cross-circulation (1L/h). Hearts were arrested with cardioplegia at the end of NEVHP and transplanted into healthy recipients using a bicaval technique with cardiopulmonary bypass (CPB) support. Ability to wean off CPB, intraoperative hemodynamics, and echocardiography were used to evaluate heart function for 4h. Animals were then euthanized for tissue analysis and histologic scoring.

Results: Hearts had an initial cold ischemic time (CIT) of 35 and 58min before NEVHP. Heart rate, left ventricular pressure, and serum lactate were within normal limits during NEVHP. Coronary vascular resistance was 0.3-0.5mmHg/mL/min per 100g myocardial tissue. The second CIT was 45 and 54min and average CPB time was 153±7min. Both recipients were successfully weaned off CPB and sustained normal left ventricular systolic function. Transplant A had a cumulative vasopressor index (CVI) = 4-7 and cardiac output (CO) = 2.5-3.5L/min. In Transplant B, CVI = 6-11 and CO = 1.5-2.5L/min. Both hearts demonstrated ejection fraction >50%. Histology showed slight elevation of myofiber degeneration and normal changes related to myocardial hemorrhages and interstitial edema. These findings suggest that NEVHP may shift the paradigm of cardiac preservation as it allows for longer preservation time and objective evaluation of organ function.

CAR 27

Platelet Membrane Fluidization via Exogenous Cholesterol Modulates Shear-Mediated Platelet Activation

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Study: Shear-mediated platelet activation (SMPA) is a prime driver of thrombosis in mechanical circulatory support (MCS). We previously demonstrated that: 1. anti-platelet agents are largely ineffective against SMPA and 2. modulation of platelet membrane fluidity (via DMSO) reduces SMPA. A "natural product" membrane fluidizing agent, as opposed to DMSO, would offer a safer, regulatory "friendly," path to a new therapeutic strategy. Cholesterol, a natural product and native cell membrane constituent, also alters cell membrane fluidity; and at low dose supplementally, un-oxidized, is safe and non-atherogenic. We hypothesized that uptake of exogenous cholesterol by platelets will modulate SMPA.
Methods: Human gel filtered platelets were incubated with Cholesterol (1 mM) + methyl-β-cyclodextrin (MBCD)(10 mM) to enhance uptake; or MBCD alone or untreated as comparators/controls; all for 30 min, 37°C. Platelets were then exposed to shear stress in a hemodynamic shearing device (70 dyn/cm^2 x 10 min). Platelet activation was assessed via thrombin generation assay (PAS) (as % sonication). Platelet aggregation was assessed via light aggregometry with thrombin agonist. Experiments are n= 6.
Results: Enrichment of platelets with exogenous cholesterol resulted in reduced SMPA (52%) vs. MBCD alone (68%) and untreated controls (73%). Cholesterol enrichment reduced SMPA by 27% overall (p<0.005). Enrichment of platelets with low dose, exogenous, unoxidized cholesterol holds promise as a natural product approach to developing a "mechanoceutical" strategy to limit SMPA in MCS patients.

CAR 28

Accuracy of Device Estimated Flow in Continuous Flow Ventricular Assist Device

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Study: Accurate noninvasive estimate of cardiac output can be useful in the management of patients with ventricular assist device (VAD). This study assesses the accuracy of VAD console estimated flow compared with invasive cardiac output by right heart catheterization (RHC).
Methods: In a longitudinal cohort of patients with HeartMate II (HM2), HeartWare HVAD (HW), and HeartMate 3 (HM3), invasive cardiac output by RHC was matched with device estimated flow recorded up to 4 hours apart. Echocardiographic assessment of aortic valve opening pattern was also retrieved. In patients with no or intermittent aortic valve opening, the accuracy of device estimated flow rate compared with Fick cardiac output was analyzed for correlation and agreement.
Results: A total of 197 pairs of device estimated flow and Fick cardiac output were identified in 115 unique VAD patients. Among these, 106 pairs were associated with no or intermittent aortic valve opening and used for subsequent analysis. Device estimated flow and Fick cardiac output had poor to moderate correlation (HM2: r 0.26, nonsignificant; HW: r 0.62, p-value < 0.01; HM3: r 0.74, p-value 0.02) (Figure 1). Using Bland-Altman plots, device estimated flow and Fick cardiac output (device - Fick vs. mean) had wide limits of agreements (95% confidence interval for HM2: -45% to +46%; HW: -52% to +36%; HM3: -43% to +21%) (Figure 2). In conclusion, VAD estimated flow rate is an imprecise measure of cardiac output and should not be relied upon for patient care.

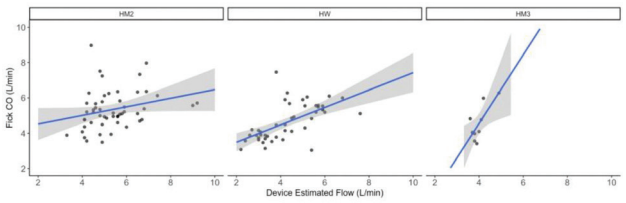

Figure 1. Overall correlation between Fick CO and device estimated flow. Shaded area represents 95% confidence interval of the linear regression lines. HM2: HeartMate II. HW: HeartWare HVAD. HM3: HeartMate 3.

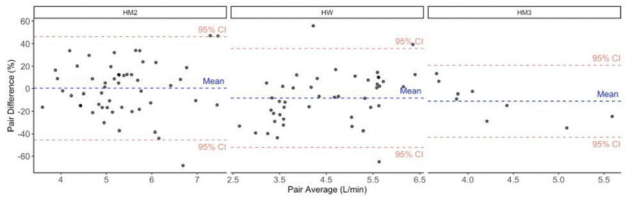

Figure 2. Bland-Altman plot assessing agreement between device estimated flow and Fick CO. HM2: HeartMate II. HW: HeartWare HVAD. HM3: HeartMate 3.

CAR 29

LVAD Speed and Map Management Optimization Through a Lumped Parameter Model Applied to a Large Patient Cohort

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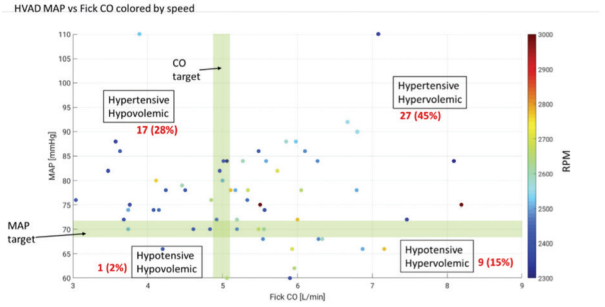
Study: This study demonstrates improvements in hemodynamic performance for a large patient cohort of VAD patients through optimizing LVAD speed and mean arterial pressure (MAP)

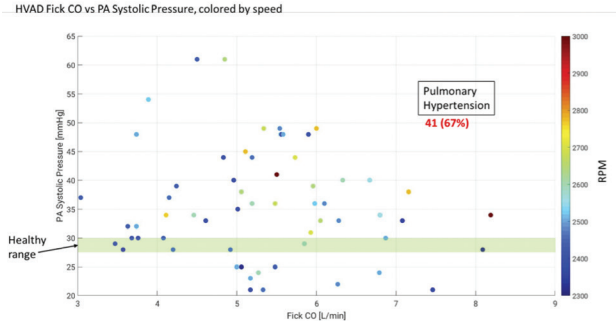
Methods: A computational hemodynamics lumped parameter model (HLPM) incorporates the systemic and pulmonary circulations, all cardiac chambers, intrinsic baroreflex, parallel circulatory pathways via the LVAD and the aortic valve and manufacturer-provided LVAD-specific H-Q relationship. The HLPM was tuned with patients' LVAD speed, MAP and cardiac catheterization-derived perfusion/pressure. Each patient was then optimized with the patient-specific HLPM to meet MAP and perfusion targets, and the complex pump-patient interaction analyzed to determine the impact of LVAD speed and patient MAP on hemodynamics

Results: 27 patients had high MAP and high perfusion values, based on right heart catheterization (Fick cardiac index), indicating inconsistencies between VAD displayed flow estimation and measured flow. The HLPM was tuned to each patient to represent the patient's complete circulation and LVAD, at the time of right heart catheterization. Each patient's hemodynamics were simulated at different MAP and LVAD speeds. In most of the 27 patients studied, when MAP was controlled to clinically recommended values in the model, perfusion greatly exceeded desirable values, unless LVAD speed was reduced at the same time. This coupled circulatory dynamical behavior indicates the risk of overloading the right heart due to excess LVAD speeds. The HLPM is able to predict how reducing the LVAD speed in conjunction with MAP management enabled optimization for each patient. LVAD speed adjustments that are not coupled to medical therapy to control MAP can be detrimental to long-term hemodynamics, causing supraphysiological total cardiac output that results in right ventricular failure. Thus, optimization of VAD speed and MAP using a model of the patient's vasculature can improve outcomes of LVAD support

(a) Patient data indicating 45% of patients overshooting both MAP and flow targets indicating the need for improved LVAD speed and MAP optimization



(b) Patient data indicating 67% of patients having elevated pulmonary artery pressures due to sub-optimal LVAD speeds and MAP management, which could potentially overload the pulmonary circulation



CAP 1

Correlation of Coagulations Tests in Adult Patients on ECMO

S. Mirzai, *R. Rose, A. Alund, V. Kagan, J. Okray, S. Creighton, K. Meehan, C. LaBuhn, A. Chinco, R. Piech, M. Meyer, A. Fonceva, D. Rodgers, P. Combs, T. Song; Section of Cardiac Surgery, University of Chicago Medicine, Chicago, IL.*

Study: Coagulopathy is a common complication of extracorporeal membrane oxygenation (ECMO) with many patients requiring aggressive transfusion of blood products to stabilize and maintain homeostasis. Thromboelastography (TEG) measures the efficiency of blood coagulation, including platelet function, clot strength, and fibrinolysis. This is in addition to measuring coagulation factor function which can be done by PTT and INR. Although PTT has been traditionally used to monitor coagulopathy in ECMO patients, we wanted to look at the correlation of TEG and INR with PTT values.
Methods: A retrospective chart review was performed on 64 patients who had recorded TEG values with corresponding PTT and INR reported +/- 2 hours from the time of TEG at a single academic institution in 2019. A total of 384 instances of lab data were analyzed in these patients. Transfusion requirements were also collected for each instance, including packed red blood cells (pRBCs), fresh frozen plasma (FFP), platelets, and cryoprecipitate, +/- 24 hours from the time of laboratory data. After checking for correlations between the laboratory tests and blood products, TEG alpha angle was found to correlate with PTT (p = <0.001) and cryoprecipitate (p = 0.001), TEG K time with PTT (p = 0.005) and cryoprecipitate (p = 0.005), and TEG R time with PTT (p = <0.001) and cryoprecipitate (p = 0.003). TEG maximum amplitude was found to correlate with INR (p = 0.003) along with pRBC (p = 0.003), FFP (p = 0.013), platelets (p = 0.025), and cryoprecipitate (p = <0.001). TEG lysis had no correlations.
Results: As expected, most TEG values correlated well with PTT, indicating TEG as a feasible option to monitor coagulopathy in ECMO patients. This was especially true with TEG maximum amplitude, an indicator of platelet function, which correlated well with transfusion of all blood products. This would further confirm ECMO as a cause of decreased platelet function which leads to more bleeding and transfusion requirements.

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	TEG_Max & PTT	285	-.077	.196
Pair 2	TEG_Max & INR	237	-.192	.003
Pair 3	TEG_Max & pRBC	253	-.185	.003
Pair 4	TEG_Max & FFP	121	-.225	.013
Pair 5	TEG_Max & PLT	128	-.198	.025
Pair 6	TEG_Max & CRYO	59	-.459	.000
Pair 7	TEG_Max & Volume	273	-.220	.000

Table 1. Correlation of TEG maximum amplitude with PTT, INR, and blood products.

CAP 2

Thromboelastography to Predict Transfusion Needs in Adults on ECMO

S. Mirzai, *R. Rose, A. Alund, V. Kagan, J. Okray, S. Creighton, K. Meehan, C. LaBuhn, A. Chinco, R. Piech, M. Meyer, A. Fonceva, D. Rodgers, P. Combs, T. Song; Section of Cardiac Surgery, University of Chicago Medicine, Chicago, IL.*

Study: Bleeding is a common complication of extracorporeal membrane oxygenation (ECMO), occurring in 29-33% of adult ECMO patients and resulting in significant morbidity and mortality. Thromboelastography (TEG) measures the integrity of the coagulation cascade from fibrin formation to clot lysis, including contribution by platelets. Although primarily used to assess heparin responsiveness in ECMO patients, we compared TEG to PTT and INR as a predictor of transfusion needs in these patients.
Methods: A retrospective chart review was performed on 64 patients who had recorded TEG values with corresponding PTT, INR, and platelet counts reported +/- 2 hours from the time of TEG at a single academic institution in 2019. A total of 384 instances of lab data were analyzed in these patients. Transfusion requirements were also collected for each instance, including packed red blood cells, fresh frozen plasma, platelets, and cryoprecipitate, +/- 24 hours from the time of laboratory data. The group was divided into two cohorts, bleeders (B) and non-bleeders (N). The bleeding group was those with greater than or equal to 1,500 mL pRBC requirement. Additionally, patients with platelet counts below 80,000/µl were considered thrombocytopenic.
Results: ECMO as a cause of platelet dysfunction in adults has been established in the literature with reduced platelet adhesion, activation, and aggregation. Several studies have also demonstrated decreased platelet counts while on ECMO. Our study demonstrates TEG maximum amplitude as a potential predictor of transfusion need for patients on ECMO (p = 0.006). Due to MA correlating with platelet function, this data could confirm platelet dysfunction as the primary cause of coagulopathy in patients with significant bleeding while undergoing ECMO treatment.

Paired Samples Test

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	TEG R_B – TEG R_N	2.93878	17.54559	2.50651	-2.10091	7.97846	1.172	48	.247
Pair 2	TEG K_B – TEG K_N	-.09980	6.52312	.93187	-1.97345	1.77386	-.107	48	.915
Pair 3	TEG Angle_B – TEG Angle_N	-5.11404	26.35204	3.65437	-12.45049	2.22242	-1.399	51	.168
Pair 4	TEG MA_B – TEG MA_N	-7.40686	18.33590	2.56754	-12.56392	-2.24981	-2.885	50	.006
Pair 5	TEG Lysis_B – TEG Lysis_N	1.50811	9.28970	1.52722	-1.58923	4.60545	.987	36	.330
Pair 6	PTT_B - PTT_N	8.124	43.386	8.677	-9.785	26.033	.936	24	.358
Pair 7	INR_B - INR_N	.10000	1.12559	.22976	-.37530	.57530	.435	23	.667

Table 1. Comparing TEG values, PTT, and INR as predictors of transfusion need in bleeding (B) and non-bleeding (N) patients on ECMO.

Paired Samples Correlations

	N	Correlation	Sig.	
Pair 1	TEG MA & Platelet count	150	.470	.000
Pair 2	TEG MA_Bleeder & Platelet count_Bleeder	31	.377	.036

Table 2. Correlation of TEG maximum amplitude (MA) to platelet count.

CAP 3

Personalized ECMO: A Case Report on Crafting Individualized Support

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Study: Historically, extracorporeal membrane oxygenation (ECMO) has been utilized in either a veno-arterial (VA) or veno-venous (VV) configuration. However, mechanical circulatory support (MCS) now can encompass a variety of different modes that can more specifically address a patient's underlying condition. In this case study, we demonstrate how six ECMO modes of support were utilized to support an evolving clinical picture in a single patient.

Methods: A 46-year-old male presented to an outside hospital with an acute myocardial infarction requiring aspiration thrombectomy from the Left Main Coronary Artery. He had multiple ventricular fibrillation arrests requiring defibrillation and Impella heart pump. He recovered and was transitioned to an intra-aortic balloon pump (IABP) but subsequently had a PEA arrest with hypoxia. Our institution was contacted for possible ECMO cannulation and transport. After on-site assessment by our ECMO team, VV ECMO cannulation to the left femoral vein and left internal jugular vein (IJV) was performed.

Results: Shortly after transfer to our institution, the patient developed vasoplegic shock. He was converted to V-AV ECMO with subsequent improvement in overall status. Despite initial improvement, he developed worsening lung function and hemodynamics. Thus, biventricular support was initiated after 3 days of V-AV ECMO to facilitate heart and lung recovery and mobilization, with a percutaneous OxyRVAD through the right IJV and minimally invasive LVAD through the LV apex. After 12 days, BiVAD support was converted to VV ECMO and IABP. However, he yet again suffered vasoplegic shock 3 days after VV ECMO conversion. He was converted back to VA ECMO using the left axillary artery with subsequent removal of the arterial cannula after 11 days. Following a total of 35 days requiring various modes of ECMO support, the patient was decannulated. He required a tracheostomy for ventilator dependence, and was eventually discharged to acute rehabilitation in stable condition.

CAP 4

Delirium During Veno-arterial Extracorporeal Membrane Oxygenation: Incidence and Associated Factors

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Study: Delirium is an acute disturbance in cognition that is associated with poor outcomes for intensive care patients. Data on delirium among patients on extracorporeal membrane oxygenation is limited.

Methods: In this single center study, we conducted a retrospective analysis on patients who received Veno-Arterial extracorporeal membrane oxygenation (VA-ECMO) between 2014 and 2018. Our primary outcome was to determine the incidence of delirium in VA-ECMO patients and associated factors. Patients were categorized in two groups based on whether delirium was present or absent during admission, using the Confusion Assessment Method. We reviewed parameters that might be associated with delirium, including Survival after Veno-Arterial Ecmo (SAVE) score, length of stay, ECMO indication, time on ECMO, infection, antibiotics administration, Impella use, cardiopulmonary resuscitation (CPR), requirement of renal replacement therapy (RRT), pulmonary embolism (PE), or blood transfusion.

Results: We analyzed 105 patients who received ECMO, 62 (59%) patients were assessed for delirium and 12 (19.4%) experienced delirium. In the remaining 43 patients, the occurrence of delirium was undetermined due to poor neurologic exam or profound hemodynamic instability. Of patients analyzed, 8 (66.7%) were male, 11 (91.7%) were white, and 9 (75%) had infection necessitating antibiotics. The presence of delirium was associated with lower SAVE scores (6.80 vs 5.87, p=0.018). There was no difference between the two groups in age, length of stay, ECMO indication, time on ECMO, infection, antibiotics administration, Impella use, requirement of RRT, MELD score, PE, CPR, or blood transfusion. **Conclusion**: In this retrospective study, ECMO patients with delirium were found to have lower SAVE scores. Prospective studies with a larger sample size are warranted to better identify the incidence of delirium and contributing factors in patients receiving VA-ECMO for cardiogenic shock.

Factors showing no difference among the delirium-present vs delirium-absent groups

	Delirium	No delirium	p-value
Age (years)	55 ± 14	58 ± 13	0.46
Length of stay (days)	35 ± 17	27 ± 28	0.32
Time on ECMO (days)	6.60 ± 3.09	7.11 ± 5.43	0.75
Lactate	6.95 ± 4.64	7.16 ± 4.75	0.88
pH	7.32 ± 0.13	7.30 ± 0.14	0.65

CAP 5

ECMO Blood Phototherapy to Treat Carbon Monoxide Poisoning

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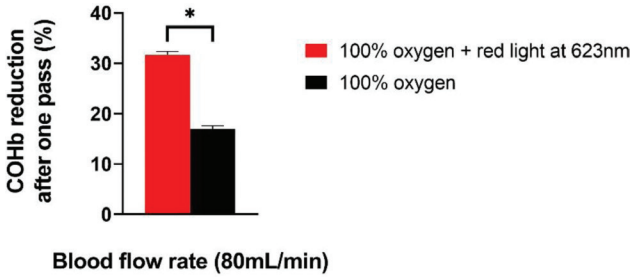
Study: CO poisoning is a leading cause of poison-related deaths in the United States. CO binds to hemoglobin, displaces oxygen and reduces oxygen delivery. Standard treatment involves administration of oxygen. When CO poisoning is associated with lung injury due to smoke inhalation, burns or trauma, treatment by breathing oxygen becomes less effective. Visible light is known to dissociate CO from hemoglobin without affecting oxygen binding. In a rat model of CO poisoning, with or without concomitant acute lung injury, extracorporeal circulation of blood through a newly developed membrane oxygenator, combined with phototherapy at 632 nm ("mini" CO photo-remover) significantly improved the rate of CO removal and survival of CO-poisoned animals.

The objective of this study was to develop a larger ("maxi") CO photo-remover that can be used to treat patients with CO poisoning and ARDS.

Methods: The maxi CO photo-remover was tested using an in vitro model of CO poisoning, with human blood passing through the device at a flow rate of 80 ml/min. The membrane was illuminated with 40 LEDs at a wavelength of 623nm and an irradiance of 13.6W/cm^2.

Results: We modified the mini CO photo-remover by increasing the dimensions of the polypropylene membrane (from 6cm x 6cm to 14cm x 14cm) and the number of layers (from 8 to 15). The gas exchange area was increased from 0.05m^2 to 0.6m^2 and the priming volume increased from 4ml to 60ml. After a single pass of CO-poisoned blood through the maxi CO photo-remover (with 100% oxygen but without phototherapy) the COHb concentration was reduced by 17%. Application of photo-therapy to the maxi CO-photo remover produced a 32% decrease in COHb after a single pass through the device.

The new, maxi CO photo-remover has a blood flow rate that is 10 times higher than that of the original device. To further increase the blood flow rate, without altering the efficiency of CO removal, several maxi CO photo-removers will be connected in parallel. Future studies will test the device in a large animal model of CO poisoning.



CAP 7

Cannulation Related Complications in Obese Patients on Adult Veno-arterial and Veno-Venous Extracorporeal Membrane Oxygenation (ECMO)

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Study: Placement of ECMO in obese patients has been challenging, however cannulation risk in obese patients has not been clearly investigated. We therefore investigated ECMO cannulation complications in obese patients on both VA and VV ECMO.
Methods: Data was reviewed from an IRB-approved, prospectively maintained adult ECMO database from 2010-2019. Patients were stratified by body mass index (BMI) (normal weight, NW [BMI 18.5-24.9], overweight [BMI 25-29.9], class 1 [BMI 30-34.9], class 2 [BMI 35- 39.9], class 3 [BMI >40]), and peripherally cannulated veno-arterial (VA) and veno-venous (VV) ECMO. Combined ECMO cannulation complications and survival data was retrospectively analyzed. Patients with central cannulation were excluded from this study. Multivariable and binary logistic regression analyses were performed to test for associations between BMI and ECMO outcomes and to adjust for potential confounders.
Results: There were 234 patients, 157 VA ECMO patients [44 (29%) NW, 52 (33%) overweight, 36 (23%) class I, 12 (8%) class II, and 11 (7.0 %) class III] and 77 VV ECMO patients [14 (18%) NW, 14 (18%) overweight, 16 (21%) class I, 11 (14%) class II, and 22 (29%) class III]. There were significantly more cannulation site bleeds in VA Class III (55%) patients compared to VA NW patients (15%) p=0.009. There was no significant difference in cannulation site bleeding between BMI groups for VV ECMO. There was no difference in 30-day mortality, ECMO survival for all BMI groups in both VA and VV ECMO.Peripheral VA cannulation of obese patients with BMI > 35 have increased risk of groin catheter site bleeding, although survivals are similar in selected obese patient

CAP 8

Distal Perfusion Catheters in ECMO: Do Bigger Cannulas Save More Legs?

S. Mirzai, *J. Okray, R. Rose, U. A. Siddiqi, V. Kagan, S. Creighton, K. Meehan, C. LaBuhn, A. Chinco, R. Piech, M. Meyer, A. Fonceva, D. Rodgers, P. Combs, T. Song; Section of Cardiac Surgery, University of Chicago Medicine, Chicago, IL.*

Study: Femoral veno-arterial (VA) extracorporeal membrane oxygenation (ECMO) is a rapidly deployable form of extracorporeal life support. However, it has potential complications such as lower limb ischemia requiring fasciotomy or amputation in 10% and 2-10% of patients, respectively. Despite distal perfusion catheters (DPCs) having become an established method of maintaining limb viability with VA ECMO, there has been a paucity in the literature regarding ideal DPC size.
Methods: A retrospective chart review was performed on 59 patients who underwent VA ECMO with DPC placement at a single academic institution between 2018 and 2019. Limb perfusion data collected included limb assessment, near-infrared reflectance spectroscopy (NIRS) skeletal muscle oxygen saturation (StO2) at 24 hours post-DPC cannulation (+/- 4 hours), and occurrence of limb complications. In addition to DPC size, factors such as BMI/BSA, comorbidities, ECMO device type, outflow cannula size, and ECMO flow at 4 and 24 hours were collected and analyzed.
Results: Amongst our patients, 14 were cannulated with a 6F DPC (mean StO2 of 71.4 ± 4.6%), 5 with 7F (StO2 78.0 ± 6.1%), 26 with 8F (StO2 72.4 ± 14.0%), and 14 with 9F (StO2 80.1 ± 9.5%). Larger DPC size was found to be positively correlated with better perfusion in terms of StO2. In patients with limb complications, 2 were cannulated with a 6F DPC, 4 with 8F, and 1 with 9F. Neither DPC size nor StO2 was found to be a predictor of limb complications. Therefore, although larger DPC size did not decrease limb complications, the higher StO2 seen does suggest better limb perfusion. Larger studies need to be undertaken to assess the correlation between DPC size and complication rates specifically.

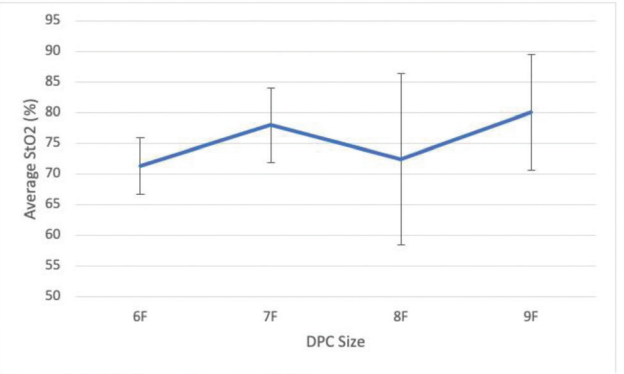

Figure 1. DPC size and average StO2.

CAP 9

Utilization of Extracorporeal Life Support for Diffuse Alveolar Damage: A Systematic Review

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Study: Modern extracorporeal life support (ECLS) technology has been successfully utilized to treat diffuse alveolar damage (DAD); however, reports in the literature remain scarce. We sought to pool existing evidence to better characterize ECLS use in these patients.
Methods: An electronic search was conducted to identify all studies in the English literature reporting the use of ECLS for DAD. Thirty-two articles consisting of 38 patients were selected, and patient-level data were analyzed.
Results: Median patient age was 36 [IQR: 27, 48] years, and majority (63.2%) were female. Most common etiological factors included granulomatosis with polyangiitis (8/38, 21.1%), systemic lupus erythematosus (8/38, 21.1%), Goodpasture's syndrome (4/38, 10.5%) and microscopic polyangiitis (4/38, 10.5%). Immunologic markers included ANCA in 15/38 (39.5%), ANA in 6/38 (15.8%) and anti-GBM antibodies in 4/38 (10.5%). Diffuse alveolar hemorrhage (DAH) was present in 32/38 (84.2%) of DAD cases. ECLS strategies included veno-venous (VV-ECLS) in 28/38 (73.7%), veno-arterial (VA-ECLS) in 5/38 (13.2%) and one case of right-ventricular assist device with oxygenator (RVAD-ECLS). Heparin was utilized in 18/38 (47.4%) cases with no difference between DAH versus no DAH (p=0.46) or VA- versus VV-ECLS (p=1). Median duration of ECLS was 10 [5, 14] days. Pre- versus post-ECLS comparison of blood gases showed improvement in median PaO2 (49 [45, 59] mmHg versus 80 [70, 99] mmHg, p<0.001), PaO2:FiO2 ratio (48.2 [41.4, 54.8] vs 182.0 [149.4, 212.2], p<0.01) and pulse oximetry values (76% [72, 80] versus 96% [94, 97], p=0.086). Thirty-six of 38 (94.7%) survived to decannulation while 30-day mortality was 10.5% (4/38) with no differences between VA- and VV-ECLS (p=1 and p=0.94, respectively).
Conclusions: DAD occurs in a younger, predominantly female population, and tends to be associated with systemic autoimmune processes. ECLS, independent of its type, appears to result in favorable short-term survival.

CAP 10

Use of Extra-Corporeal Membrane Oxygenation in Blunt Traumatic Injury Patients with Acute Respiratory Distress Syndrome

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Study: Blunt traumatic injury is often associated pulmonary contusion which may lead to acute respiratory distress syndrome (ARDS). Some cases of ARDS may require circulatory support in form of extra-corporeal membrane oxygenation (ECMO). We describe here a series of trauma patients requiring ECMO support and their hospital outcomes.
Methods: A single center ECMO data was evaluated between years 2016 and 2019 to identify trauma patients supported with ECMO. Patient demographic information, trauma etiology, ECMO information and outcome information were collected and evaluated. Basic descriptive statics were used to analyze the data.
Results: A total of 7 patients (all male, aged 32.1+/-8.7 years) had blunt traumatic injury which led to pulmonary contusion and subsequent ARDS. Of the 7 patients, 5 (71%) received veno-venous (VV) ECMO and 2 received veno-arterial (VA) ECMO. The mean ECMO support duration was 13.2+/-6.5 days (median 17 days) and 6 patients were successfully weaned. Overall 2 (29%) out of the 7 patients died, 1 after weaning and 1 could not be weaned and both had required VA ECMO. Patient of who died after weaning developed septic shock whereas the other patient had massive pre-ECMO pulmonary embolism and stroke ultimately leading to brain death. The median post-ECMO hospital stay was 40 days. Although, all patients had some degree of blood loss anemia they were started on heparin; 2 continued on heparin, 1 had resistance and switched to argatroban and in 4 patients' heparin was discontinued due to follow-up bleeding event (ECMO support continued).
Conclusion: Trauma patients with pulmonary contusion and ARDS can be successfully supported by ECMO and have acceptable hospital survival despite limitations and challenges in managing anti-coagulation therapies. Patients requiring VA ECMO support maybe at increased risk of adverse outcomes.

Patient Demographic	Support Type	ECMO Support (Days)	HeparinStatus	Hospital Survival
24y M	VV ECMO	17	Withheld	Yes
40y M	VV ECMO	18	Continued	Yes
19y M	VV ECMO	17	Continued	Yes
35y M	VV ECMO	20	Resistance	Yes
27y M	VA ECMO	16	Withheld	No
40y M	VV ECMO	6	Withheld	Yes
40y M	VA ECMO	3	Withheld	No

CAP 11

Peripheral ECMO Survivors and Common Peroneal Nerve Palsy in the Absence of Limb Ischemia: The Unreported Sequela?

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Study: We have observed common peroneal (CPN) palsy, or "foot drop," in the absence of limb ischemia. This chronic entity in peripheral extracorporeal membrane oxygenation (ECMO) survivors is associated with significant morbidity.

Methods: We reviewed charts of 238 patients who were placed on femoral-femoral veno-arterial (VA) ECMO between July 2014 - July 2019. Inclusion criteria included documentation of foot drop, or physical therapy notes demonstrating anterior tibialis strength of 0/5 or 1/5, with the inability to dorsiflex the foot. All patients who expired prior to discharge or had limb ischemia, stroke, or gross bilateral lower extremity weakness were excluded. Patients on ECMO for under 1 hour were also excluded.

Results: We identified 159 VA ECMO patients who met inclusion criteria and 12 (7.5%) of those developed CPN palsy. No patients on VV ECMO support developed CPN palsy. No significant differences in ECMO duration were found between the patients who developed CPN palsy and the patients without it. Five patients (35%) with CPN palsy had diabetes mellitus. Peripheral vascular disease was noted in patients with foot drop. At the time of discharge, five patients were non-ambulatory, and five patients required an AFO (ankle foot orthosis) and assistive device for safe and efficient gait. Ten of the 12 patients required an in-patient rehabilitation center after discharge. Conclusion: CPN palsy has been identified as a chronic complication of peripherally cannulated VA ECMO survivors and has a high incidence in our population. CPN palsy in patients with VA ECMO cannulation leads to significant debility requiring extensive physical therapy and rehabilitation, thereby affecting the patient's quality of life. Further prospective trials are needed to identify possible risk factors of CPN and methods to reduce this debilitating complication of VA ECMO.

NURS 1

Substance Abuse and Left Ventricular Assist Devices: Does History Matter?

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Study: Active substance abuse is detrimental to patients supported with left ventricular assist device (LVAD). We reported previously the short-term post LVAD outcome of patients with history (hx) of substance abuse. In this study we are reporting the long term outcomes of post LVAD and post heart transplant in patients who were supported with LVAD.
Methods: The UTAH Artificial Heart program database was queried for history of alcohol, tobacco and illicit drug use for patients who were implanted with a continuous flow LVAD from 01/2013 - 12/2019. The history of alcohol use was categorized as non-drinkers, social drinkers, and heavy drinkers based on The National Institute on Drug Abuse (NIDA) criteria. Kaplan Meier survival analyses were performed with on each of these subgroups and log rank was done to determine significance.
Results: 105 patients were included in the study, 63 had a history of use of at least one substance and 42 were non-users. There was no difference in 2 and 4 years survivals post LVAD and heart transplantation between the two groups (p=0.085) (Figure 1, 2). Likewise, there was no survival difference based on history of tobacco use (Figure 3). However, patients with history of heavy alcohol use had lower 4 year survival (38.3%) compared to non-drinkers (68.7%) p=0.015 (Figure 4). Our study showed the history of substance use does not impact the survival after LVAD, except for history of heavy alcohol use. This data can be used to increase the availability of LVADs for patients who may have had a history of substance abuse. Referring these patients with history of substance abuse to counseling programs pre and post LVAD might help mitigate the potential for adverse outcomes.

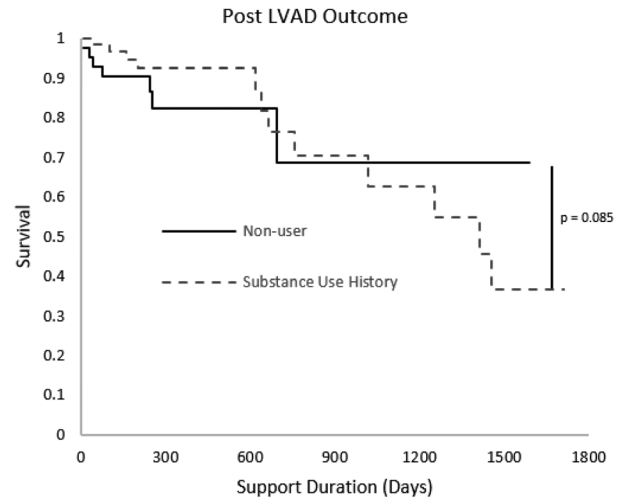


Figure 1.

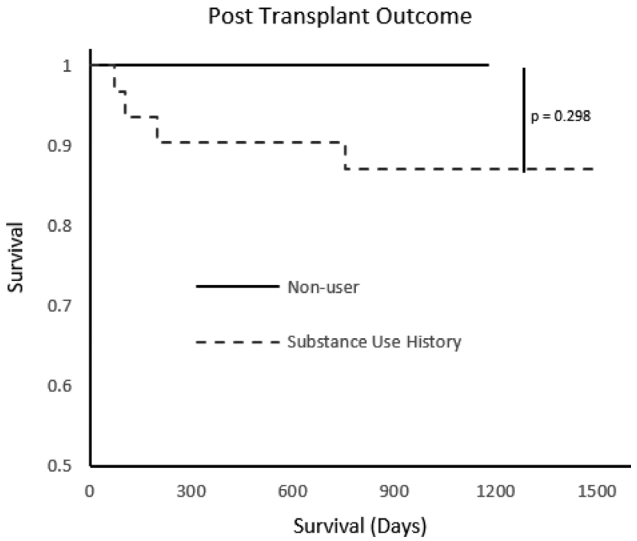


Figure 2.

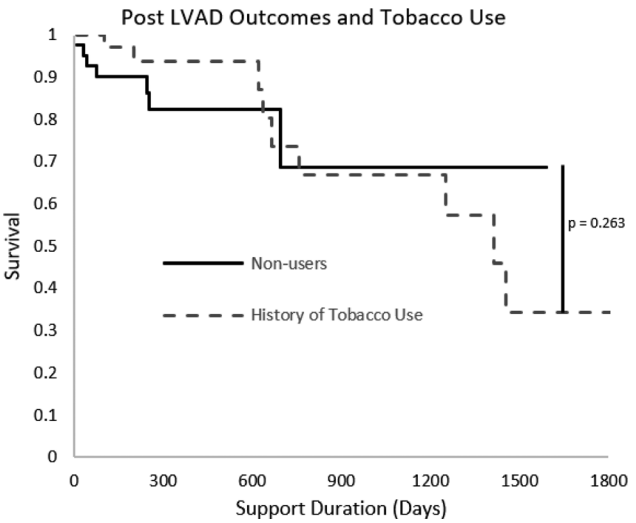


Figure 3.

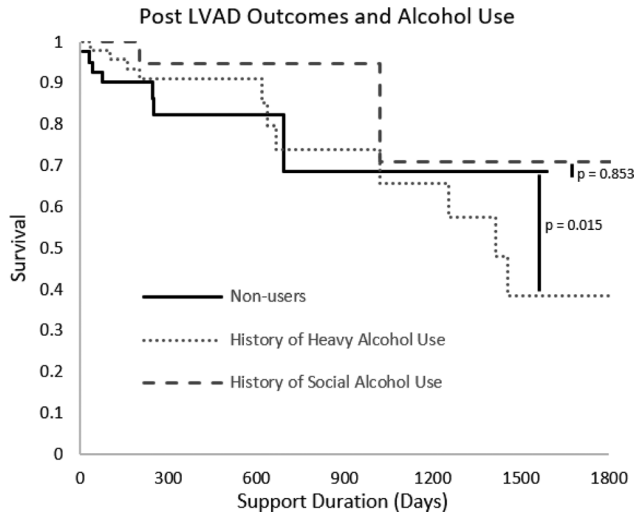


Figure 4.

NURS 3

The Journey Home: A Single Center Snapshot of VAD Patients' Dying Experience

U. A. Siddiqi, *P. S. Combs, C. Staub, A. Fonceva, D. Rodgers, C. Stonebraker, C. LaBuhn, K. Meehan, J. Okray, S. Creighton, V. Kagan, A. Chinco, V. Jeevanandam; Section of Cardiac Surgery, University of Chicago Medicine, Chicago, IL.*

Study: Recent data shows that the home is the most common place of death in the United States, for the first time in more than fifty years. Furthermore, 80% of Americans would prefer to die at home. We assessed this trend in our center's population of patients with ventricular assist devices (VADs).
Methods: We retrospectively reviewed medical records from 244 patients implanted between 2006 and 2019 at our center using Electronic Medical Records (EMR). We analyzed: 1) location of death, 2) cause of death, and 3) length of survival using IBM SPSS Statistics 26.
Results: Of the 244 VAD patients implanted between 2006 and 2019, 78 patients (31.97%) died. The median age at implant for these patients was 59 years. The mean and median survival times for deceased patients were 358.34 days and 179 days, respectively. Most of the patients (58; 74.36%) died in the hospital, and only 10 patients (12.82%) died at home. The other 11 (14.10%) patients died in either a Long Term Care facility (7; 8.97%), out of hospital (2; 2.56%), or in rehab (1; 1.28%). Cardiac causes were responsible for the most deaths (30; 37.97%), followed by infection (22; 27.85%), and neurological causes (14; 17.72%). GI bleeding, hemorrhagic shock, sepsis, and failure to thrive were responsible for 2 deaths (2.53%) each, while lung cancer, organ failure, pump thrombosis, and withdrawal of support each caused 1 death (1.27%). Although most Americans would prefer dying at home, we found that our VAD patients died mostly at the hospital. Our results suggest that VAD programs may need to be more cognizant of the patient's wishes regarding end-of-life care. Frank discussion between the patient and their VAD team along with detailed documentation may promote medical decisions in accordance with patients' wishes.

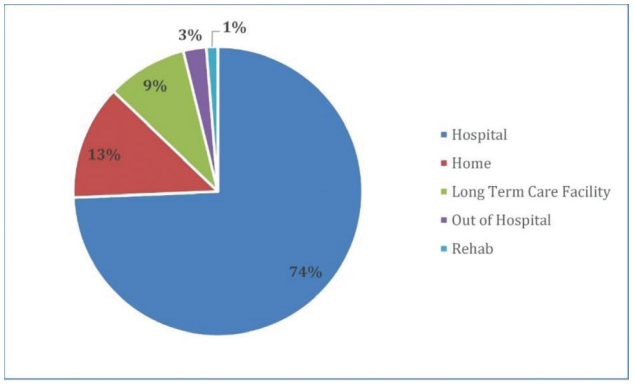


Figure 1: Location of Death

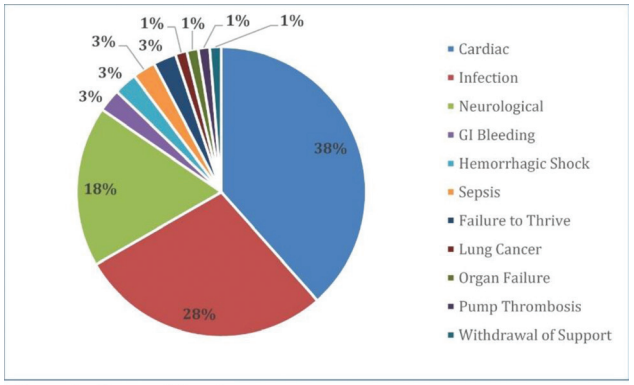


Figure 2: Cause of Death

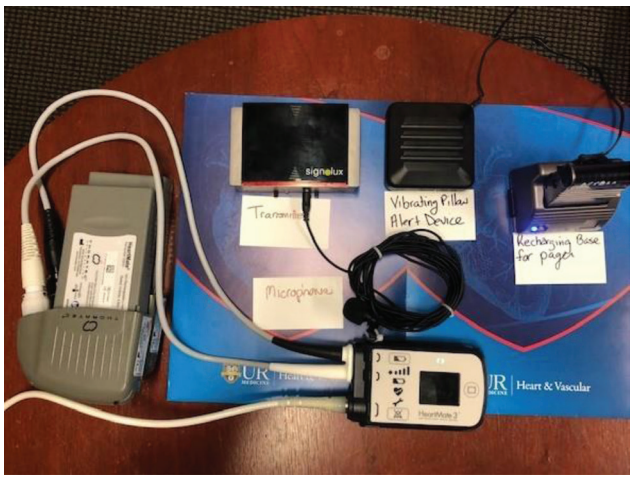
NURS 4

Alarm Management in the Deaf HeartMate 3 Patient

C. Cheyne[1], *C. Black*[1], *B. Dengler*[2], *M. Loftis*[2], *K. Nelson*[1], *P. Canne*[3], *E. Storozynsky*[4], *I. Gosev*[5]; [1]*VAD Program, University of Rochester Medical Center, Rochester, NY,* [2]*Bioclinical Engineering, University of Rochester Medical Center, Rochester, NY,* [3]*Social Work, University of Rochester Medical Center, Rochester, NY,* [4]*Cardiology, University of Rochester Medical Center, Rochester, NY,* [5]*Cardiac Surgery, University of Rochester Medical Center, Rochester, NY.*

Study: The Abbott HeartMate 3™ (HM3) LVAD system utilizes visual messaging and auditory alarms to notify patients of advisory and hazard alarms. Abbott does not provide adaptation to the HM3 alarm messaging for use in the deaf population. To date, there is no FDA approved alerting system for use with the HM3. We report our experience coordinating a safe discharge for a deaf HM3 patient.

Methods: The majority of alert systems provide visual or tactile vibration alerts intended for use in the home (ie: smoke detector). As our HM3 patient and caregiver are both deaf, it was paramount to find a *portable* alerting system. The Signolux alert system used successfully with a HM3 patient in Austria transmits on 868 MHz which is not available in the US. It is however available in North America on the 915 MHz frequency. After review by the hospital frequency allocation board, permission was granted to use this band temporarily to test the Signolux system. The Signolux system consists of a battery operated transmitter, vibrating pager and vibrating pad. The transmitter includes an acoustic sensor, 1 meter long connection lead and adjustable sensitivity knob. The sensor is placed near the HM3 controller tone emitter. Once an alarm sound is detected, the transmitter triggers the pager to vibrate and alert the patient. If the patient is sleeping, the vibrating pad alerts the patient to an alarm.Coordinators tested the equipment, adjusted the sensitivity knob and found it to reliably detect the HM3 tones on demo equipment and with the patient. However, we did make securement modifications to the sensitivity knob to ensure it did not accidentally adjust. Patient was taught to immediately look at controller and check connections each time a vibration was felt.



Results: The Signolux System was found to reliably detect and alert the patient to HM3 controller tones. The patient was successfully taught on the system and discharged home. Further investigation should focus on finding a portable LVAD specific alarm detection system for use in the deaf population.

NURS 5

Ground Troops: Exploration of Bedside Nursing Care in Patients with VADs

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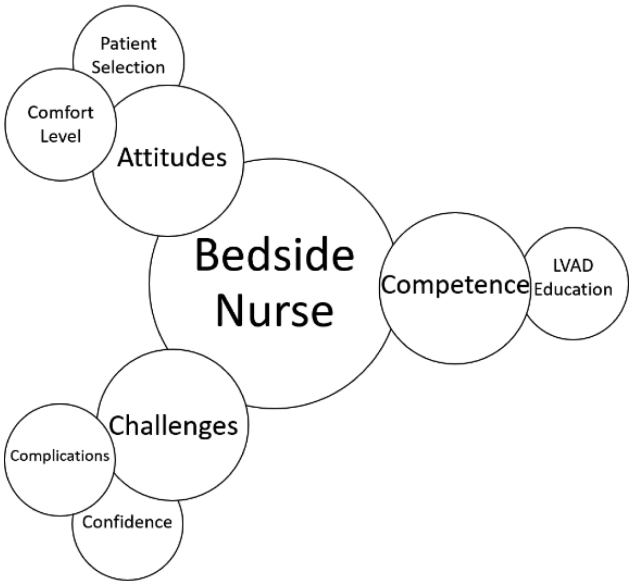
Study: Despite rapidly growing and evolving VAD technology, the bedside RNs caring for hospitalized patients with VADs remains understudied. This study aimed at exploring VAD care competence, attitudes, and challenges among the cardiac care unit (CCU) and progressive care unit (PCU) RNs in the US.

Methods: We employed an exploratory, descriptive research design using the data (n=70 bedside RNs) from a parent study where informed consent and surveys were administered online. We extracted survey data consisting of: (1) an 8-item, 0 to 10 rating scale (e.g., 0=not competent at all to 10=extremely competent) and (2) a one-item open-ended question consistent with the study aim. Demographics and survey data were analyzed with SPSS 23.0. Content analytic procedures aided by Nvivo 10 qualitative software were used.

Results: The bedside RNs were predominantly female (93%) with baccalaureate degrees or higher (84%) employed in university hospitals (57%) in the Northeast (21%) and Midwest (33%) regions of the US. Mean scores across competence and attitude domains range from 6.15 to 9.03. CCU RNs reported significantly higher knowledge, overall competence, and confidence than the PCU RNs; respective mean scores range from 7.94 to 8.11 vs. 6.15 to 7.6, p-values <.05. Themes that emerged from written responses included the following: (1) competence is dependent upon VAD care education/training; (2) care of VAD patients and their families is challenging; (3) negative attitudes exist toward the VAD candidate selection process; and (4) a low comfort level in caring for the VAD population is an identified perception (Figure 1).

We uncovered discrepancies in the perceived competence of CCU and PCU RNs caring for the highly vulnerable VAD population nationwide. Negativity of bedside RNs situated in the context of the demanding and challenging needs of VAD patients and their families are of particular concern.



NURS 6

VAD Social Workers: A National Self-Reflective Survey

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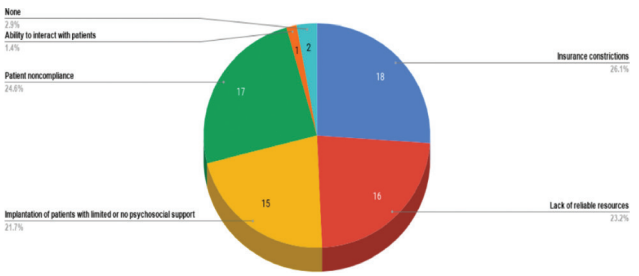
Study: Ventricular Assist Device (VAD) Social Workers (SWs) are becoming increasingly integrated into VAD care teams by playing a significant role in the psychosocial aspects of patient care. However, the contributions and methods of VAD SWs are relatively undefined. This study reports on the results of a first-of-its-kind survey of VAD SWs that ascertains the VAD SW's views of their own work, as well as their perception of the role the position fills on the VAD care team.

Methods: A survey was created using Survey Monkey® and sent to 35 VAD SWs in the United States by the ICCAC Social Worker Workforce. The survey consisted of 20 multiple-choice questions.

Results: We received 31 SW survey responses (89%). During patient selection meetings, 55% of SWs presented partial assessments rather than full assessments. Additionally, only 6% reported using a formal tool to assess caregivers before implant. Nearly all SWs (97%) followed the patient post-implant until the end of therapy. Regarding substance use, the majority of SWs (65%) stated they did not use a formal assessment tool. Insurance constrictions were the most common barrier to performing their role (26%) (Figure 1). Nearly all SWs (94%) felt that the VAD team utilized them as a resource and most SWs (81%) felt valued by their program. The data indicates VAD teams across centers commonly utilize VAD SWs, however the methods and roles of the VAD SW have large variability. Further studies should be conducted to shed light on the role of VAD SWs, specifically regarding the methods and responsibilities of these SWs between centers and the opinion other personnel have of the VAD SWs.



NURS 7

Acute and Durable Support is all The Same; Including the MCS Coordinator in the ICU

V. Kagan, *R. Rose, J. Okray, K. Meehan, S. Creighton, C. LaBuhn, R. Williamson, P. Combs, V. Jeevanandam, T. Song; Cardiac Surgery, University of Chicago Medicine, Chicago, IL.*

Study: As the use of acute mechanical circulatory support increases, so does the demand for a multi-disciplinary approach. Traditionally, patients with durable left ventricular assist devices (LVADs) are managed by VAD coordinators along with a care team including heart failure cardiology, cardiac surgery and any consulting specialties. Our institution expanded the role of the VAD coordinator to a Mechanical Circulatory Support (MCS) Coordinator to encompass the management of any patient on acute support such as extracorporeal membrane oxygenation (ECMO). We sought to evaluate survival before and after the implementation of the MCS Coordinator in the Cardiothoracic ICU.

Methods: A chart review was performed on patients who were placed on acute MCS from December 2018 to September 2019 at a large volume academic medical center. Patients were separated into two groups, before the MCS Coordinator role was implemented (Dec 2018-April 2019) and after (May 2019-October 2019).

Results: Total of 94 patients were supported on ECMO. In the Pre MCS coordinator group, 7 patients were placed on veno-veno (VV) ECMO and 38 patients were placed on veno-arterial (VA) ECMO. In the post MCS Coordinator group, 12 patients were placed on VV ECMO and 38 patients were placed on VA ECMO.

Incorporating an MCS Coordinator to manage both durable and acute mechanical support can improve patient survival. There is a trend toward statistical significance and clinical significance is clearly seen yet a longer follow up time is needed. Evaluating length of stay and complications of MCS after the implementation of the MCS Coordinator can further demonstrate the benefit of this evolving role.

	Pre MCS Coordinator Group N= 45	Post MCS Coordinator Group N= 49
Average Age	53	53.6
Gender	18 (40%) female	14 (28%) female
Hx Cardiac Arrest	33 (73%)	18 (37 %)
Greater than 2 pressers or inotropes	15 patients (33%)	13 patients (27%)
Pump run (days)	10.5 days	15 days
Length of stay (pump to discharge)	19 days	44 days
Total VV patients	7	12
Total VA patients	38	38
Survival VV ECMO	3/7 (43%)	7/12 (58%)
Survival VA ECMO	18/38 (47%)	23/38 (60%)
Overall Survival to discharge	21 (46%) patients	30 (61%) patients

NURS 8

Hypercoagulable Work-up for Predicting Adverse Events after Mechanical Circulatory Support (MCS)

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Study: MCS is a therapeutic option for end-stage heart failure patients. However, hematologic adverse events may be seen with current MCS devices. A hypercoagulable work up on all patients being evaluated for MCS device was implemented at Cedars Sinai Medical Center with the aim to identify patients with hypercoagulable risk factors.

Methods: Medical records from January 2016- December 2018 were retrospectively reviewed with IRB approval. A total of 120 patients were reviewed for demographics, hypercoagulable panel (lupus anticoagulant, protein C/S, antithrombin III, and von Willebrand factor multimeric analysis), chest CT scan, carotid Duplex scan, baseline thromboelastogram, prior temporary circulatory support (TCS), warfarin genotyping, adverse clotting and/or bleeding events. Chi-square and Fisher's Exact statistical tests were used to compare groups.

Results: 58/120 (48.3%) patients had at least 1 hematological adverse event and 62/120 (51.7%) patients had no hematological adverse events. In the adverse event group, 11/58 (19.0%) were identified as clotters, 42/58 (72.4%) as bleeders, and 5/58 (8.6%) had both events. There were no statistically significant differences across the groups in terms of race, age, gender, patient medical history (diabetes, dyslipidemia, hypertension, history of atherosclerotic cardiovascular disease [ASCVD]), family with a history of ASCVD, or prior TCS devices. There was a trend (p-value 0.07) toward an increased adverse event in patients with low antithrombin III and those with low protein C (p-value 0.07). There was a significantly higher adverse event rate in patients with an abnormal carotid Duplex scan (p-value <0.01) and there was a trend (p-value 0.078) toward an increased adverse event in patients with an abnormal chest CT scan. The nature of hematologic adverse outcome post-device implantation is likely multifactorial. Low ATIII / low protein C showed a trend toward increased adverse events. Further studies are required.

PEDS 1

Rest and Recovery? A Single Center Pediatric Experience with Myocardial Recovery on LVAD Support

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Study: Myocardial recovery is possible in end-stage heart failure (HF) with mechanical unloading, though pediatric reports are sparse. We describe our pediatric center's experience in assessment of myocardial recovery and explant of durable LVADs in children.
Methods: A retrospective chart review at a single institution.
Results: A total of 119 durable VADs were implanted at our institution over a 20-year period. Seven patients on durable VAD (HeartWare = 5, Heartmate II = 1, Berlin EXCOR = 1) demonstrated sufficient recovery for explant. Assessment of myocardial recovery was performed using serial echocardiographic measurements of chamber size and left ventricular systolic function, brain natriuretic peptide levels, and 6-minute walk tests if able at baseline and on reduced VAD speed. Most patients (4/7, 57%) also underwent hemodynamic assessment by cardiac catheterization with wean of LVAD speed to minimal settings. Median duration of support prior to explant was 257 days (range of 18 to 482 days). There were no deaths after explant. Four out of 7 remain explanted and without transplant. These 4 patients all demonstrated recovery of ventricular function (EF> 45%) within the first 100 days after LVAD implant that was sustained over their LVAD course. One patient (case #4) had recurrence of HF symptoms, with worsening function; the remaining 3 patients are asymptomatic at last follow up (median duration of follow up 4.6 years). Three patients demonstrated worsening HF after explant: 2 required LVAD re-implantation (average time to re-implant 161 days) with 1 of these 2 subsequently undergoing transplantation; 1 additional patient underwent transplantation.
Conclusion: Myocardial recovery is possible for pediatric patients on LVAD support. Early recovery of ventricular function (<100 days) with sustained improvement may predict patients with highest likelihood of durable recovery.

	Case	Age at Implant (years)	Sex	Weight at Implant (kg)	Cardiac Diagnosis	VAD Type	INTERMACS Profile at Implant	Length of Support (days)	Time Until EF >45% After LVAD Implant (days)	Reimplant (Yes/No)	Transplant (Yes/No)
No Re-Implant or Transplant Following Explant	1	14	Male	55.8	Septic myocarditis	HeartMate II	2	176	66	No	No
	2	14	Female	44.3	Chemotherapy-induced cardiomyopathy	HeartWare	2	372	94	No	No
	3	9	Male	24	Dilated cardiomyopathy	HeartWare	1	98	62	No	No
	4	7	Female	20.6	Chemotherapy-induced cardiomyopathy	HeartWare	2	257	88	No	No
Re-Implant or Transplant Following Explant	5	12	Female	32	Dilated cardiomyopathy	HeartWare	2	393	15*	Yes	Yes
	6	7	Female	21.2	Pacemaker cardiomyopathy	HeartWare	2	482	207*	Yes	No
	7	1	Male	8.5	Dilated Cardiomyopathy	Berlin EXCOR	1	18	9	No	Yes

*Ejection fraction (EF) not sustained >45 after implant

PEDS 2

Hemodynamic Characteristics of Children Supported with Ventricular Assist Devices

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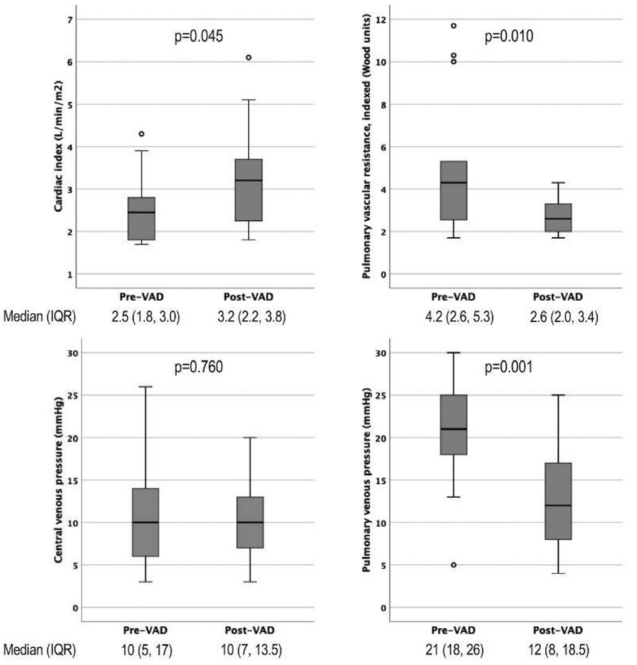
Study: Ventricular assist devices (VADs) are increasingly being used to support children with end-stage heart failure. The hemodynamic impact of VAD therapy in pediatric patients is unknown. We sought to describe the hemodynamics of children on VAD support, and to compare hemodynamics before and after VAD implant.
Methods: A single center retrospective review was conducted of all patients < 21 years of age who underwent cardiac catheterization while on VAD support between 2014-2019. Central venous pressure (CVP), pulmonary capillary wedge pressure (PCWP), cardiac index (CI), and indexed pulmonary vascular resistance (PVRi) were extracted from the medical record. Catheterization data within 90 days prior to VAD implant were also collected, if performed. Descriptive statistics were performed and hemodynamic data were compared amongst subgroups and pre- and post-implant.
Results: Among 40 patients analyzed, median age was 11 years; 58% had cardiomyopathy (CM) and 40% had congenital heart disease (CHD). 80% were successfully bridged to transplant, 18% died on VAD support. From catheterization data after a median 49.5 days (IQR 19.5, 101.8) of VAD support, median CI was 3.4 (2.4, 4.1) L/min/m2, CVP 11 (7, 15) mmHg, PCWP 10 (7, 16) mmHg, and PVRi 2.5 (2, 3.2) mmHg/L/min/m2. Overall, 87% had normal cardiac output (CI ≥ 2.2 L/min/m^2), 72% had PCWP ≤ 15 mmHg, and 60% had CVP ≤ 12 mmHg. Compared to CM patients, those with CHD had higher CI [4.0 (3.4, 4.5) vs. 3.0 (2.2, 3.5), p=0.001] and CVP [13 (10, 18) vs. 7.5 (5.3, 13.8), p=0.017], and lower PVRi [2.2 (1.7, 2.5) vs. 2.9 (2.3, 3.6), p=0.002], but no difference in PCWP [10 (7.3, 15.8) vs. 10 (5, 17), p=0.789]. Among 17 patients with a pre-VAD catheterization, post-VAD PWCP and PVRi were significantly lower and CI was higher, while there was no difference in CVP (Figure). In children, VADs can effectively augment cardiac output and decompress the systemic ventricle, resulting in decreased pulmonary venous congestion, but have less of an effect on CVP.



PEDS 3

Effect of a Bivalirudin-based Anticoagulation Protocol on Stroke Rate in Pediatric Patients Maintained on Ventricular Assist Devices, A Single-Center Study

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Study: Ventricular assist device (VAD)-associated stroke remains a considerable risk for morbidity and mortality in the Pediatric VAD population. In this study, we examine the impact of a Bivalirudin-based anticoagulation protocol on stroke rate in Pediatric VAD patients in a single center.
Methods: We performed a retrospective chart review of all patients on VADs from 2009-2019 in a single center over two eras: Era 1 (2009-2016) and Era 2 (2017-2019). For extracorporeal devices, an anticoagulation protocol using heparin/enoxaparin, or warfarin, along with aspirin with or without dipyridamole was used in Era 1 and a bivalirudin/aspirin protocol with or without dipyridamole was used in Era 2. A warfarin/aspirin protocol for intracorporeal devices was used in both eras. A Fisher's exact test was used to compare stroke rates across eras and across devices.
Results: A total of 95 VADs were placed in 90 patients during the study period. Number of devices placed was (Era 1 vs Era 2): Berlin Heart (BH) 30 vs 11, CentriMag (CM) 24 vs 7, and HeartWare (HVAD) 16 vs 7. There was no significant difference in stroke rate between BH and CM in Era 1 (33% vs 25%, $p = 0.56$). There was a significant decrease in stroke rate in patients on BH in Era 1 vs Era 2 (33% vs 0%, $p < 0.05$) without a significant change in stroke rate in patients on CM (25% vs 43%, $p = 0.38$). There was a significant difference in stroke rate between CM and BH in Era 2 (43% vs 0%, $p < 0.05$). Stroke rate in patients on HVAD remained low in Era 1 and Era 2 (6.25% and 0%) and was not significantly different in the two eras. Transition to a Bivalirudin-based anticoagulation protocol resulted in a significant reduction in stroke in patients supported on the Berlin Heart. A similar effect was not seen on patients supported on CentriMag. Optimizing anticoagulation in these patients will be essential in reducing morbidity and mortality and may influence choice of device for long term support in smaller patients.

PEDS 4

Little Patients, Big Victories: Outcomes from Three Decades of Infant Heart Transplantation

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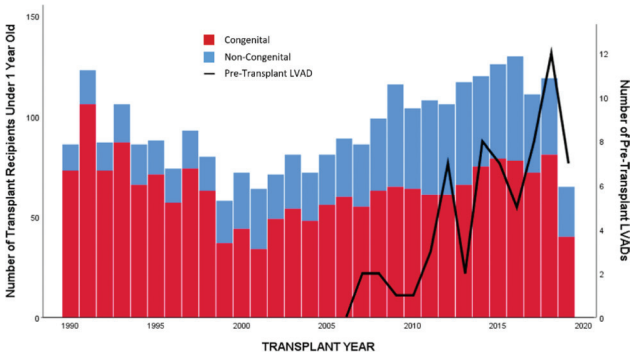
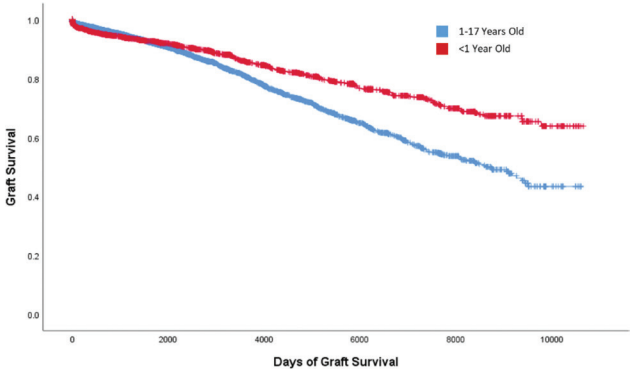
Study: Heart transplantation in pediatric patients, especially neonates and infants, has rapidly evolved over the last three decades as protocols for treating congenital heart disease have changed and Ventricular Assist Devices (VADs) have become more common. We sought to determine trends and differential outcomes among these patients.
Methods: All data collected was obtained from the UNOS Transplant Database and OPTN Data web app. Patients with multiple organs transplanted and/or patients' second transplants were excluded. Comparisons were made between an infant group (<1 year old) and a pediatric group (1-17 years old) who underwent heart transplantation between 1/1990 and 6/2019. Patients were censored during analysis to adjust for date of transplant.
Results: Despite a small increase of donor hearts recovered annually from 1990-2018 (1.59x), pediatric heart transplants have increased 2.6x during the same time interval. Pre-transplant VAD use in this population has rapidly increased in the last decade, from 16 in 2010 to a peak of 55 in 2017. Infant heart transplantation decreased throughout the 1990s, reaching a low in 1999 (n=58). However, infant transplantation has continued to increase since, with VADs slowly becoming utilized in this population. Overall survival of heart transplantation patients since 1990 has differed between infant and pediatric patients ($p=.053$). Long-term survival is better among infant patients, with overall survival becoming greater for infants than pediatric patients at about 7.5 years post-transplant and thereafter. Long-term graft survival in infants is also superior to the general pediatric population ($p<.001$). Graft survival remains similar between the two groups for the first 4.5 years post-transplant, and then quickly diverges with improved graft survival among infant recipients. In summary, infant heart transplants are increasing with positive results alongside increased usage of VADs.





PEDS 5

Total Cardiac Volume Ratio, Unlike Donor-recipient Weight Ratio, Correlates with Pediatric Heart Transplant Survival

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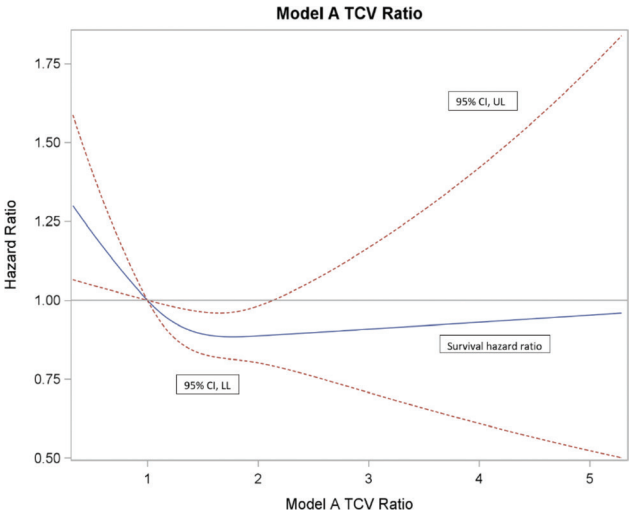
Study: Donor-recipient weight ratio (DRWR) is used to match donor hearts as a good fit for the potential recipient. However, DRWR does not correlate with outcomes, particularly for ratios >1. Due to this unknown, there is significant variability in listing practice and a significant number of donor refusals for size mismatch. This study investigates if predicted total cardiac volume (pTCV) is a better measurement by which to determine the donor pool for a pediatric heart transplant (HTx) recipient by assessing its association with post-HTx survival compared to DRWR.

Methods: The United Network for Organ Sharing (UNOS) was used to identify pediatric patients (<18yo) who received a primary HTx from 1989 to March 2019. Cases with available weight, height, age and gender were included. TCV of both recipient and donor hearts were predicted using an imaging-validated model of normal subjects and donor-to-recipient pTCV ratio was obtained. The values: <0.7, 0.7-1.8, and >1.8 were used as size ratio ranges. The ratio of 0.7-1.8 was defined as an optimal range based on previous literature. Survival analysis and hazard ratio plots were performed.

Results: 8577 patients were identified. Survival analysis shows that undersized hearts have the worst survival across both DRWR and pTCV ratio. pTCV ratio as a continuous variable is significantly associated with survival (hazard ratio=0.9; p = 0.02) (fig. 1), however, DRWR does not correlate with survival (p=0.19). pTCV ratio identified 10% more potential donors than DRWR in the optimal range (0.7-1.8) (91.4% vs 81.8%; p<0.001). In conclusion, unlike our present system of listing by weight ranges, pTCV ratio is associated with survival. TCV-estimated matching may be a more reliable tool in pediatric HTx listing and with widespread use and validation, could allow for more efficient organ size matching, standardization of donor size ranges, and reduction in donor refusal for size mismatch.



PEDS 6

Automated Chest Compression Device Assisted Extracorporeal Cardiopulmonary Resuscitation Cannulation in Pediatric Patients - A Simulation Study

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Study: Surgical neck cannulation for pediatric extracorporeal cardiopulmonary resuscitation (ECPR) requires multiple interruptions of manual chest compressions to facilitate the procedure. Effective uninterrupted CPR is essential to prevent neurological injury. We hypothesized that an automated chest compression device can be used to provide effective and uninterrupted chest compressions during pediatric neck ECPR cannulation. The feasibility of surgically cannulating the right carotid artery and right internal jugular vein in an infant during ongoing automated chest compressions was tested in a simulation study.

Methods: A working prototype of a pediatric chest compression device (Figure 1) was designed to provide automated chest compressions on an infant CPR mannequin at the rate of 120 compressions/minute. A feedback device attached to the mannequin was used to monitor the effectiveness of CPR. A synthetic artery, vein along with carotid sheath and skin was utilized to simulate surgical neck exploration. An automated chest compression device assisted ECPR simulation was conducted in the cardiac intensive care unit.

Results: Three ECPR simulations were conducted during which vessel sparing cannulation of the right internal carotid artery and right internal jugular vein was performed during ongoing mechanical chest compressions (Figure 2). The entire procedure was successfully completed without the need to interrupt chest compressions. Sterility of surgical field could be easily maintained at all times.

In a simulated environment, pediatric ECPR neck cannulation with uninterrupted chest compressions may be accomplished using an automated chest compression device. The strategy of automated chest compression device assisted ECPR cannulation requires further study and could potentially reduce the neurological complications of ECPR.

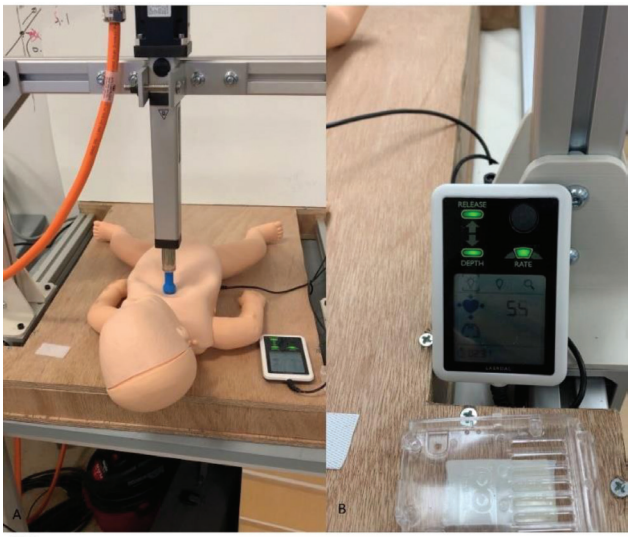

Figure 1
A. Basic working prototype of an automated pediatric chest compression device.
B. Feedback device attached to the mannequin to assess adequacy of chest compressions

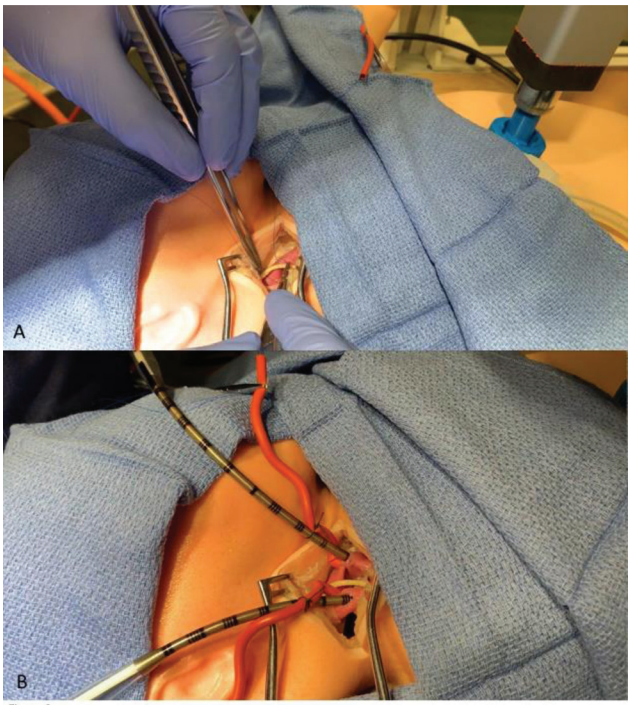

Figure 2.
A.Ongoing automated chest compression device assisted ECPR simulation.
B.Vessel sparing cannulation of right carotid artery and right internal jugular vein .

PEDS 7

Chronic *In Vivo* Results of the Miniaturized Fontan Circulation Assist Device

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Study: We have miniaturized and optimized the first implantable rotary blood pump to provide long term right heart support for patients who have failing Fontan circulation. The objective of this study was to evaluate the miniaturized Fontan Circulation Assist Device (mini-FCAD) in 30-day animal studies.

Methods: The mini-FCAD was implanted in adult, 80-90 kg Dorset sheep via a right thoracotomy (n=5). While on cardiopulmonary bypass, the SVC and IVC were completely separated from the RA and anastomosed end-to-end to the pump inlet cannulae. The outlet cannula was anastomosed end-to-side to the PA. Pump flow was initiated and increased as bypass flow was simultaneously weaned and discontinued. Pressure monitoring lines were placed on the SVC, IVC, PA, and LA and brought out separately through the posterior chest wall. Postoperatively, unfractionated heparin was given to maintain thromboelastography (TEG) R times of 2x normal resulting in minimal heparin activity as measured by anti-Xa assay (< 0.23 IU/ml). At the conclusion of the study, the animal was euthanized and the pump was removed and examined for wear and thrombosis.

Results: The first two studies were terminated on Day 0 and Day 4 due to complications. In the final three studies the animals remained healthy and were electively terminated at 30 ± 2 days. As shown in the table, pump flow was 5-7 lpm and physiologic pressures were normal. There was no evidence of hemolysis, end organ or pulmonary dysfunction, thrombo-embolic events, nor thermal damage to the surrounding tissue. Explanted devices from the three successful studies were free of thrombi except for thin fibrin rings occasionally at the pump-graft junctions.

Summary: The mini-FCAD was successfully tested *in* vivo as a right heart replacement device demonstrating adequate circulatory support and normal physiologic pulmonary and venous pressures.

	Implant 003	Implant 004	Implant 005
Days	29	28	31
Pump speed [rpm]	4090 ± 60	4440 ± 220	4900 ± 130
Flow estimate [lpm]	5.6 ± 0.5	6.6 ± 0.6	6.3 ± 0.4
AoP [mmHg]	94 ± 11	92 ± 11	108 ± 11
LAP [mmHg]	10 ± 11	4 ± 9	15 ± 7
PAP [mmHg]	14 ± 12	18 ± 9	28 ± 9
IVC [mmHg]	3 ± 10	11 ± 10	18 ±9
SVC [mmHg]	10 ± 9	9 ± 11	17 ± 10

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Initial *In Vivo* Evaluation of the Ension Portable Cardiopulmonary Support System (pCAS)

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Study: Study: Ension, Inc has developed a unique magnetic levitation (maglev) motor system for ECLS applications which eliminated permanent magnets from the motor rotor. This motor is integrated into the disposable pump-oxygenator of Ension's pCAS. Following extensive *in vitro* testing, two acute porcine and two 3-day chronic bovine studies were conducted to assess the basic *in vivo* performance of the maglev pCAS pump-oxygenator.

Methods: Methods: Acute piglet studies focused on pCAS performance in an animal model size (10-12 Kg) representative of the relevant pediatric population (V-A Cannulae 10 and 8 Fr). Chronic calf experiments focused on extended performance and biocompatibility (V-A Cannulae 21 and 17 Fr; one animal de-cannulated immediately post-op).

Results: Results: The pCAS delivered a nominal flow rate of 800 ml/min in the acute piglet studies and up to or in excess of 1 Lpm in the chronic calf studies. Biocompatibility was assessed via standard gross measurement of red cell, white cell, and platelet consumption as well as post-explant light and SEM microscopy of device surfaces and results from gross necropsy. The acute studies demonstrated sufficient levitation control. Over the course of the 3-day calf *in vivo* study, the pump speed was maintained at 1300 rpm with excellent levitation control and a blood flowrate in the range of 0.8 - 1.0 Lpm varying only during postural changes (ACT nominally 200 secs). Hemolysis remained acceptable low (an average of 6.8 g/dl) throughout the experiment. During necropsy, no gross embolism in any organs nor any evidence of inflammation, fibrosis, and thrombo-embolism in end organs was observed. Similarly, the maglev-based pump assembly was free of any gross deposition. These *in vivo* tests confirmed the maglev-based pCAS pump-oxygenator performed equal to or better than the previous blood bearing-based version of the pCAS pump-oxygenator on the basis of functionality and basic biocompatibility acceptance criteria. [Supported by NHLBI 1R41HL134455]

PEDS 9

Novel Centrifugal Impeller Design for a Maglev Pediatric Cardiac Assist Pump

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Study: Due to the limited availability of pediatric MCS devices, clinicians often turn to large, complex, and expensive adult devices with associated risk of significant adverse events. To address this unmet clinical need, we are developing a low cost, universal magnetically levitated extracorporeal pump with interchangeable pump heads for short-term pediatric support. An impeller has been developed using design constraints (⌀ ≤ 1", priming volume ≤ 15mL, up to 3.5 L/min flow at 150 mmHg) and classical pump theory.
Methods: Hydrodynamic performance (flows, pressures) and mechanical properties (torques, forces) of the pediatric pump were investigated. The design was characterized at multiple pump speeds (500-6000 RPM) using computational fluid dynamic (CFD) software (SolidWorks Flow Simulator), and transient, time-dependent simulations calculated by the sliding mesh method. The design was also empirically tested in a mock flow loop primed with blood analogue solution (37 C) using an SLA printed impeller/pump with a shaft driven by a permanent magnet motor with variable power supply and a laser-based tachometer. Flow, pressure, impeller rotational speed, motor voltage, and current were recorded over the range of pump speeds.
Results: Computational analyses predict the impeller may achieve 0.50 L/min at 30 mmHg, 2.0 L/min at 87mmHg, and 3.5 L/min at 210 mmHg during low, medium and high support conditions (2000, 4000, 6000 RPM), which was confirmed empirically. Pressure-flow curves (HQ) characterizing prototype pump performance are presented in Figure 1. Hydraulic torque (resistance to impeller rotation) as high as 15.6 mNm was observed. CFD analysis and bench testing confirmed the pediatric impeller exceeded design requirements. Force and torque data will be used to design the magnetic motor to power the pump. Future development will also focus on adult and pulmonary applications to achieve the goal of developing a single, universal system.

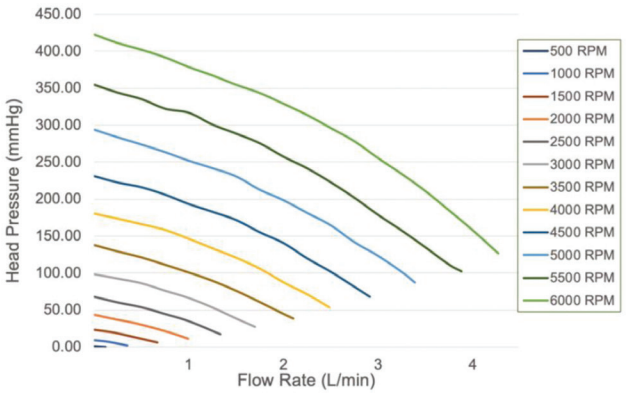

Figure 1. Pressure Flow (HQ) curves produced by the pediatric impeller for variable pumps speeds (500 – 6000RPM).

PEDS 10

Development of a Minimally Invasive Pediatric Chronic Counterpulsation Cardiac Support Device (PediPulse)

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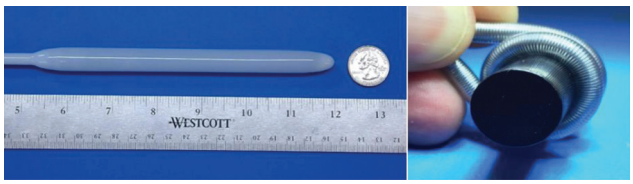
Study: Pediatric heart failure is a major health care burden for which minimally invasive, long-term mechanical circulatory support (MCS) is critically needed. Current MCS options in children are severely limited and requires invasive implantation, with high adverse event rates (28% 6-month mortality, greater than 40% bleeding, and greater than 30% stroke rates). To overcome these limitations, NuPulseCV (Raleigh, NC) is developing a minimally-invasive chronic implantable counterpulsation device (PediPulse) for pediatric support in patients over 10 years of age.
Methods: The PediPulse system has been developed for superficial implantation without the need to enter the chest and enables complete patient mobility. The PediPulse leverages pump and driver technologies developed for the adult NuPulseCV intravascular assist system (iVAS) that has been successfully implanted in over 70 patients.
Results: The PediPulse system components developed include a 22-ml and a 28-ml blood pump with a 3.3 mm diameter, reinforced driveline that is kink resistant (Figure 1: PediPulse blood pump (left) and driveline (right)). The blood pump is sized to be placed in the descending aorta through the subclavian artery for patients over 10 years of age. Benchtop testing demonstrated that the pump can be actuated in 1:1 support mode for native heart rates of up to 160 bpm by a small, portable pneumatic driver through a percutaneous air-line. The pump can be triggered by the patient's ECG via subcutaneous or skin leads.The PediPulse system fulfills a critical clinical need in pediatric patients with cardiac dysfunction. Subclavian artery to aortic placement avoids complications associated with repeat sternotomies and may be beneficial for some patients with complex congenital heart malformations. The safety, biocompatibility, and reliability of the PediPulse system is anticipated to be identical to the adult iVAS system that is currently undergoing clinical trials.



PEDS 11

Durable Implantable Non-obstructive Venous Assist Device for Support of Fontan Circulation

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Study: The Fontan circulation presents special challenges in providing mechanical circulatory support. We aimed at developing a high redundancy non-obstructive mechanical assist device intended to replace the interposition graft used for Fontans, which in case of pump failure reverts to an unassisted Fontan.
Methods: Solid and cored axial flow impellers, sized to match the diameter of the venous flow path, supported on partial arc journal bearings and driven through magnetic coupling were used to optimize impeller design, which were further refined using Computational Fluid Dynamics (CFD). Improved performance and low blood shear stresses were demonstrated by CFD studies. A demonstrator pump prototype was built and used to test performance.
Results: Threshold performance criteria were: hydraulic performance (flow≥3L/min with pressure≥15mmHg), static pressure drop (≤ 3mmHg for flow up to 3L/min), hemolysis no greater than other pediatric continuous flow devices, and long-term durability. CFD studies were used to design impellers to satisfy the first two criteria. An impeller test fixture was used to evaluate rapid-prototype impellers to support and validate the CFD studies and to allow detailed design analysis and sizing of the other demonstrator design elements. The demonstrator pump met required hydraulic performance and static pressure drop criteria. Lower but still fully acceptable performance with lower static pressure drops (<1mmHg at 4L passive flow) was obtained with cored impeller design(Figure 1A-G). A titanium prototype built duplicates the hydraulic performance. Conclusions: A high redundancy venous assist device meets threshold criteria needed for mechanical support of Fontan circulation. The device when substituted for a Fontan conduit would act as a propulsive conduit, and a passive conduit when not in use. A similar device in the SVC or by itself in a reconfigured Fontan with a single pulmonary artery inflow would allow assistance of the entire venous circuit.

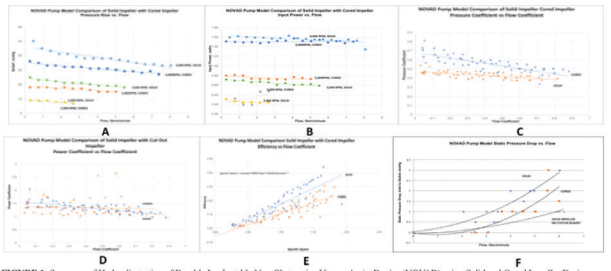

FIGURE 1: Summary of Hydraulic testing of Durable Implantable Non-Obstructive Venous Assist Device (NOVAD) using Solid and Cored Impeller Designs

A Comparison of Pressure Rise vs. Flow at various pump speeds (rotations per min/RPM) for pumps with solid and cored impeller designs; B. Comparison of Input Power vs. Flow at various pump speeds (rotations per min/RPM) for pumps with solid and cored impeller designs; C. Comparison of Pressure Coefficient vs. Flow coefficient for pumps with solid and cored impeller designs; D. Comparison of Power Coefficient vs. Flow coefficient for pumps with solid and cored impeller designs; E. Comparison of Efficiency vs. Flow coefficient for pumps with solid and cored impeller designs; F. Static Pressure Drop vs Flow for pumps with solid and cored impeller designs

PEDS 12

Study Of Hemodynamics Within The Penn State Failing Fontan Blood Pump

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Study: An estimated 1,000 Fontan procedures are performed annually in the US, allowing venous blood to flow directly into the pulmonary arteries. With surgical improvements, Fontan survival has increased to over 85% at 20 years post-op and mortality has shifted into adulthood due to "Fontan failure". To address these patients, Penn State University is developing a blood pump for long-term mechanical support. The goal of this study is to investigate hemodynamics within the pump using experimental and computational methods to minimize thrombotic and hemolytic risks.
Methods: An experimental flow loop was constructed with an acrylic Fontan pump model to collect particle image velocimetry (PIV) data. Three pump operating conditions with varying flow rates and rotational speeds were studied. Computational simulations were also performed using OpenFOAM to model the same pump geometry, boundary conditions, and fluid properties. To capture the flow patterns caused by the pump's impeller, transient simulations with sliding boundaries were used along with a k-ω SST turbulence model. To estimate hemolysis, a power-law model was incorporated into the CFD solver.
Results: PIV data were collected at three operating conditions and showed nearly axisymmetric inlet flows and outlet flows that skewed toward the outer wall with a cutwater separation region. CFD simulations were first performed using a blood analog fluid for validation. Further simulations used blood properties to determine device performance in vivo. CFD simulations also allowed for regions unattainable using PIV to be analyzed. Peak velocities of 6.8 m/s were observed at the rotor edges with low wall-shear rate regions between the rotor blades.

PEDS 13

High Molecular Weight Multimer Loss is Associated with Increased Bleeding in Pediatric Patients on Continuous Flow Left Ventricular Assist Device Support

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Study: Acquired Von Willebrand syndrome, a common finding in patients on continuous flow ventricular assist devices (CFVAD), is defined as high molecular weight multimer (HMWM) ≤10%. Our goal was to investigate if the degree of HMWM loss was associated with increased bleeding events in pediatric patients on CFVAD.

Methods: Patients <21 yrs on CFVAD at our center from 1/2016 to 11/2019 and at least one multimer study during support were included. Bleeding episodes within 2 months of multimer testing were analyzed. Major bleeding was defined using PEDIMACS' definition in addition to intracranial hemorrhage (ICH). Minor bleeding was any other form of bleeding.

Results: Thirty four patients met inclusion criteria; 61% were male and 22% had congenital heart disease. Median age at CFVAD implant was 12 yrs (IQR 8,16) with a median duration of support of 385 days (IQR 160, 684). There were 69 multimer tests of which 37 tests (54%) had HMWM ≤10%. Three multimer tests were normal. Median time of testing from implant was 191 days (IQR 49, 503). Longer duration of CFVAD support was not associated with HMWM loss (p=0.4). There were 16 major bleeding episodes in 15 patients (15/34, 44%); 6 ICH, 4 gastrointestinal, 5 mediastinal, and 1 retroperitoneal. Half (8/16) of the major bleeding episodes were associated with supratherapeutic anticoagulation. There were 93 minor bleeding episodes in 25 patients (25/34, 73%). Three patients had no bleeding events. Patients with major bleeding had lower median HMWM (8% vs 11%, p= 0.005). On multivariable regression analysis, lower median HMWM remained associated with major bleeding (p= 0.005, OR 1.4, 95% CI 1.1-1.75). There was no association of HMWM loss with minor bleeding (p=0.9). These data suggest an increased risk of major bleeding with more HMWM loss on CFVAD. Minor bleeding was not associated with multimer loss. Multimer testing can supplement routine anticoagulation markers to assess for risk of major bleeding.

PULM 1

Improved Multi-constituent Model of Thrombus Deposition in a Micro-Scale Oxygenator Fiber Bundle

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Study: Thrombosis in blood oxygenators is more rapid than most other blood-wetted devices, leading to failure within days to weeks and attendant mortality and morbidity. To enable numerical design of oxygenators with reduced thrombosis, this study introduced two improvements to our previously published thrombosis model that reflect oxygenators' unique, low velocity, high surface area conditions. This includes adding direct, surface-induced coagulation cascade activation by incorporating a surface thrombin flux with a developing fibrin mesh.
Methods: The model treats blood as an incompressible, Newtonian fluid composed of a mixture of plasma, platelets, red blood cells, and a developing, porous thrombus phase. The flow field is modeled using the Navier-Stokes equations. The transport and conversion of platelets and platelet agonists are defined by a series of convection-diffusion equations. In this study, a computational domain containing two gas exchange fibers served as a representative 2D cross-section of an oxygenator fiber bundle. To investigate the role of surface coagulation cascade activation, surface thrombin flux (10^{-11}-10^{-13} nmol/μm^{2}s) and the development of a growing fibrin mesh were added to the fiber surfaces and simulated for 10 min. Results for the original and updated model were compared to experimental fibrin deposition and platelet adhesion from human blood.
Results: The original model predicted platelet deposition exclusively to the upstream face of the fiber, with increased thrombin concentrations localized near the aggregated, deposited platelets (Fig 1A, 1B). This contrasts with experimental results, showing a fibrin network trailing the fibers (Fig 2). The revised model shows thrombin extending downstream of the fiber with corresponding fibrin formation (Fig 1D, 1C). This encouraging result motivates further model development, including determining the ideal thrombin flux and platelet binding to the fibrin mesh.

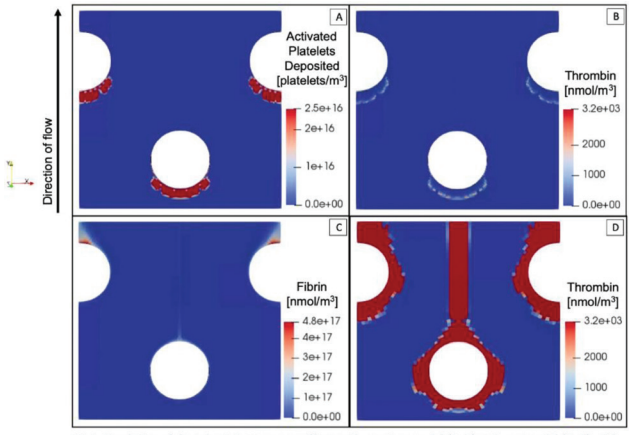

Fig 1. Simulation of thrombosis in oxygenator fibers with previous model (A, B) and new model (C, D), with 20 cm/min velocity at the inlet after 10 min.

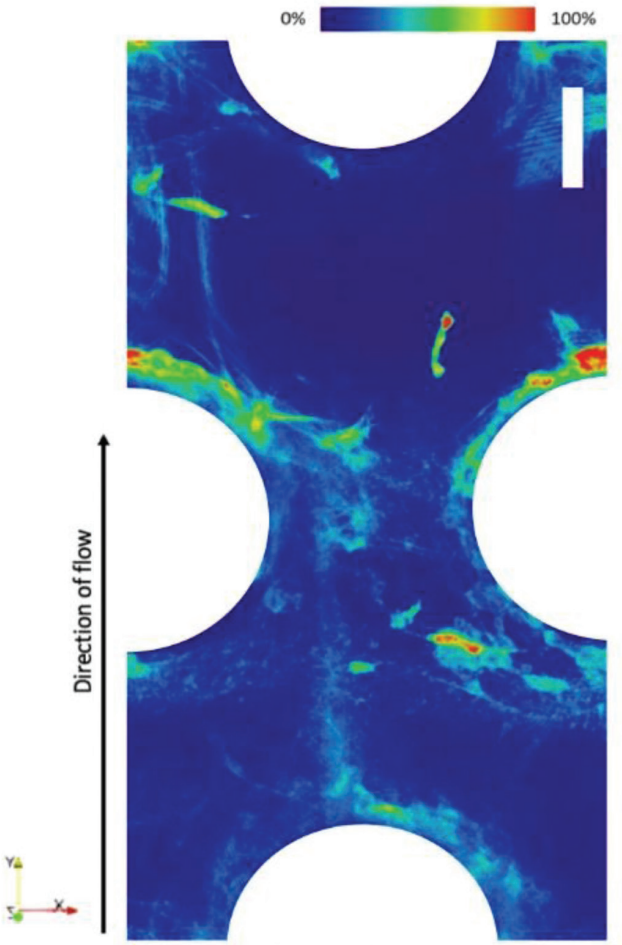

Fig 2. Probability of fibrin deposition in human blood experiments; 200 μm scale bar.

PULM 2

Vascular Anatomy Modulates Perfusion in Peripheral Extracorporeal Membrane Oxygenation Support

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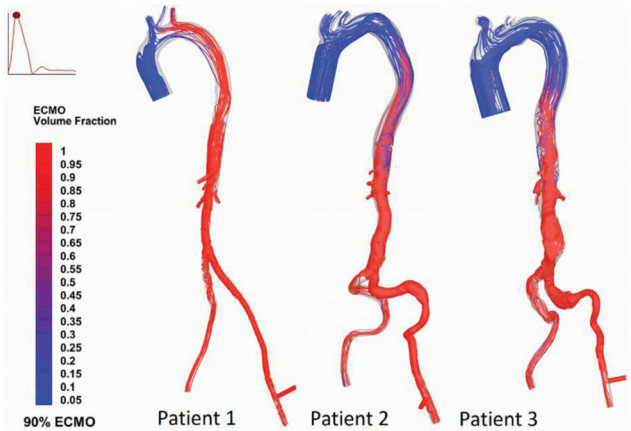
Study: Extracorporeal membrane oxygenation (ECMO) is a vital therapy in the support of cardiogenic shock patients despite limited understanding of how patient-specific characteristics affect end-organ perfusion
Methods: Patient-specific geometries were reconstructed with a range of peripheral vasculature tortuosity and employed computational models to investigate the ECMO-failing heart circulation as a function of varying the level of ECMO support (from 50% to 75% to 90% of total systemic perfusion) to simulate severity of heart failure. A lumped-parameter model was employed to determine dynamic boundary conditions at different outlets, and defined a morphology parameter, distance factor metric (DFM), to quantitatively measure the vasculature tortuosity. Hemodynamic features, stress metrics, and end-organ perfusion were analysed and compared in different patient-specific anatomies (patient 1: low, patient 2: medium, and patient 3: high tortuosity)
Results: Vascular morphology and cannulation location play a critical role in shifting the mixing cloud where ECMO-derived continuous flow collides with pulsatile flow from the failing heart. Patients with highly tortuous and elongated peripheral branches have elevated risk of hypoxia in the setting of lung disease even with higher volume of ECMO support. For identical ECMO support level, proximal arteries in a patient with highly tortuous anatomy (i.e. Patient 3) receive 23% less ECMO-oxygenated blood compared to a patient with less tortuous anatomy (patients 1) with the potential for increased risk of cerebral hypoxia. Our findings highlight the value of computational tools to scrutinize circulatory support systems and motivate the need for systematic studies to improve understanding of the clinical impact of cannulation strategies and their interplay with subject anatomy to predict end-organ malperfusion



PULM 3

Computational Modeling of Blood Damage and Mass Transport in a Membrane-Based Microfluidic Device

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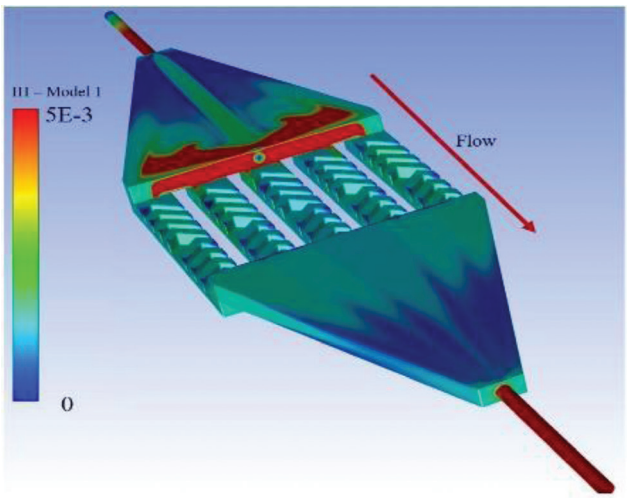
Study: Microfluidic membrane-based devices, such as dialyzers and oxygenators, could benefit from a numerical model that considers both blood damage and mass transport. These devices are an important step towards completely portable dialyzers and oxygenators, which could reduce patient complications and mortality rates. Recent manufacturing improvements have led to selective membranes that are so permeable that the mass transport is limited by the transport within the laminar flow. Geometrical mixing elements can disturb the flow and allow increase overall transport, but these features may also impose additional stresses. A robust numerical model of mass transport of physiologically relevant molecules (oxygen/urea) and blood damage was developed to study this tradeoff.
Methods: In-house developed User Defined Functions are used to model mass transport and blood damage are including in ANSYS Fluent, which solves these and fluid motion. As an application of this model, two devices are designed: a control device and a device with herringbone features. The membrane is modeled as an infinitely thin surface through which diffusion occurs based on the calculated permeability. This transport model is validated against 1D analytical solutions. The blood damage model is based on a power law model (blood damage is a function of shear stress and exposure time) and coefficients of several groups are used to generate eighteen Eulerian damage models. Flow is simulated and the resulting blood damage and diffusion are compared. Devices are fabricated and experimental hemolysis results are compared to simulation prediction.
Results: The herringbones are shown to disrupt the boundary layer and improve transport (~30%) at the membrane surface. Damage predicted by the models ranges several orders of magnitude. All hemolysis models predict a marginal increase (5-13%) in damage from the herringbone geometry. The increase of transport and damage are expected due to the flow disturbances.



PULM 4

Evaluation of the Pulmonary Artery Flow with an Ultrasonic Flowmeter in Native Lungs on Pulmonary Artery-Left Atrium Extracorporeal Membrane Oxygenation Support

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Study: Extended extracorporeal membrane oxygenation (ECMO) support has been extensively used for recovery from severe respiratory failure or as a bridge to lung transplantation (BTLT). ECMO devices used for long-term support require better membrane durability and biocompatibility to avoid thrombotic and bleeding complications, device dysfunctions, and hemolysis. Pulmonary artery (PA)-left atrium (LA) ECMO is used as BTLT, but little is known about its potential complications, such as decreased native lung (NL) blood flow resulting in NL ischemia, an immunocompromised status. The aim of this study was to evaluate the effects of decreased pulmonary blood flow on NLs by using a large animal model of PA-LA ECMO.

Methods: Healthy female goats, weighing 47-51 kg, were enrolled in this study. The PA-LA paracorporeal circuit was established with composite cannulas sutured to the PA trunk and LA appendage. A membrane oxygenator and pump (Emersave®, Terumo Corp., Japan) were used for the PA-LA system. Ultrasonic flowmeters were attached to the PA trunk, proximal to the sutured site, and to the PA-LA circuit, which enabled monitoring of the ratio of the NL-to-circuit blood flow. The damage to NLs was evaluated macroscopically after autopsy. We studied the goats who were maintained for at least 1 week on the ECMO support.

Results: Four goats were included in the study. The mean PA flow was 4.38 ± 0.53 L/min, and mean PA pressure was 19.00 ± 1.73 mmHg. The flow to the membrane oxygenator was maintained at approximately 2 L/min, and mean ECMO duration was 23.8 ± 15.2 days (range: 7-48 days). Two goats, who were on long-term ECMO supports for 24 and 48 days, developed diffuse lung congestion and pulmonary hematoma, respectively. Our model seemed useful to evaluate the optimal blood flow ratio in long-term PA-LA support settings used either for recovery of the diseased lungs or as BTLT.

PULM 5

A Novel Device for Blood Oxygenation Using Virtual-Wall Channels Structured from Vertically Aligned Carbon Nanotubes

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Study: Extra-corporeal life support devices utilize microporous hollow-fiber membranes for blood oxygenation and CO_2 removal. While membrane oxygenators are highly efficient for short and mid-term use, the large pressure gradient and turbulent flow require anticoagulation and cause damage to blood components and thrombosis. We herein present a novel technology for blood oxygenation using virtual-wall channels (VWC) manufactured using Nanotechnology.

Methods: Using nanotechnology a novel oxygenator was built consisting of a "forest" of superhydrophobic Vertically Aligned Carbon Nanotubes (VACNT) having diameter in the nano range and positioned 200-300nm apart. The forest has 50-100 micron "clearings" that form 2 mm long "virtual channels" (VC), through which blood flows (figure 1). The gas molecules fill the space between the VACNT such that there is direct blood-gas contact at the circumference of the VCs, allowing efficient gas exchange by diffusion. Proof of concept experiments were performed in minipigs weighting 3.1 to 20 kg. Extra-corporeal circulation experiments in both ECMO and CPB configurations were used with blood flow rates of 100-1500 cc/min for a duration of 3 - 6 hours.

Results: O_2 transfer was 44-60 ml/l/min, and CO_2 removal was 52-60 ml/L/min. The blood flow driving pressure gradients were stable in the range of 6 - 12 mmHg, i.e. in the range generated by the right ventricle. One animal was weaned from the extracorporeal circulation and nursed to full recovery.

Conclusions: Virtual-wall based oxygenators introduce a novel concept enabling efficient blood gas exchange and very low gradients across the oxygenator, which reduce insult to blood constituents and reduces thrombogenicity. This technology has the potential to present efficient short and long-term support for patients having cardiac and respiratory failure, including respiratory assist devices and artificial lung.

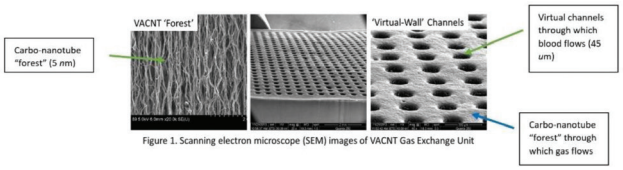


Figure 1. Scanning electron microscope (SEM) images of VACNT Gas Exchange Unit

PULM 6

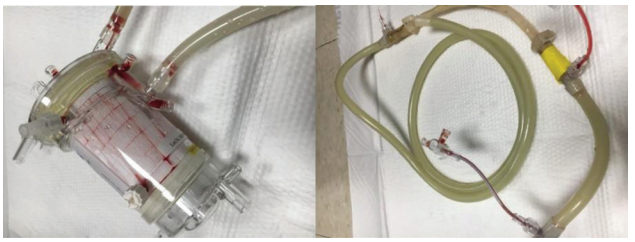
The Artificial Placenta without Heparin: Nitric-Oxide Surface Anticoagulation (NOSA)

B. P. Fallon[1], *T. Major*[1], *G. Lautner*[2], *S. L. Harvey*[1], *M. W. Langley*[1], *M. M. Jeakle*[1], *T. Fegan*[1], *O. Lautner-Csorba*[2], *A. Rojas-Pena*[1], *M. E. Meyerhoff*[2], *G. B. Mychaliska*[3]; [1]*Department of Surgery, University of Michigan Medical School, Ann Arbor, MI,* [2]*Department of Chemistry, University of Michigan Medical School, Ann Arbor, MI,* [3]*Section of Pediatric Surgery, University of Michigan Medical School, Ann Arbor, MI.*

Study: Development of an artificial placenta (AP) holds great promise to improve outcomes in premature newborns. Clinical application of an AP will require eliminating heparin to mitigate the risk of intracranial hemorrhage among these vulnerable patients. We present the first series of animals supported on the AP without heparin using the nitric oxide (NO) surface anticoagulation (NOSA) system.

Methods: We used a 118-day fetal lamb model, which approximates the lung development of a human fetus at 24 weeks gestation. Lambs were cannulated in the umbilical vein (reinfusion) and jugular vein (drainage). Flow was adjusted to maintain target fetal blood gas values. The circuits of the NOSA group (n=4) were coated with diazeniumdiolated dibutylhexanediamine (DBHD-N_2O_2) and argatroban and NO was blended into the sweep gas at 100 ppm. They received no systemic anticoagulation. The control group (n=6) received a heparin infusion with a non-coated circuit. Groups were compared using the Mann-Whitney U test.

Results: All animals were supported by the AP for at least 7 days with similar hemodynamics and gas exchange. Activated clotting time was lower in the NOSA group than the control group (189 vs. 257, $p<0.001$). There was no difference in platelet count (191 vs. 153, $p=0.15$) or platelet activation, measured by P-selectin expression (737 vs. 753 mean fluorescence intensity (MFI), $p=0.85$) between the groups. The NOSA group had less activation of monocytes (654 vs. 1278 MFI, $p=0.002$) and granulocytes (666 vs. 1292 MFI, $p=0.008$), measured by CD11b expression. There were no thrombotic complications in the NOSA group; one oxygenator in the control group was changed for clotting. Figure 1 shows a typical oxygenator and circuit from the NOSA group, demonstrating negligible clot burden. These data suggest that the NOSA system can eliminate the need for systemic heparin in the AP without an increase in thrombotic complications. The NOSA system has the potential to be used in all forms of extracorporeal circulation.



PULM 7

Advancing Towards 3D Printed Microfluidic Artificial Lungs: Characterization of a Photopolymerizable PDMS Resin

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Study: Microfluidic artificial lungs (µALs) have exhibited excellent gas exchange efficiency and biomimetic flow paths, but current fabrication methods require time-consuming manual steps, and limit designs to 2D. 3D printing of µALs via stereolithography would address these drawbacks, but sufficient feature resolution has not been demonstrated in a gas permeable resin. This work for the first time seeks to use a commercially available 3D printer and a custom PDMS resin to build microfluidic channels and membranes suitable for constructing microfluidic artificial lungs (< 100 µm feature size).

Methods: Custom PDMS resins were developed and 3D printed with an Asiga MAX X UV27 (XY resolution: 27 µm; Z resolution: 1 µm). Test structures consisting of arrays of microchannels and membranes were printed to assess feature resolution.

Results: Two custom resins exhibit resolutions 10x smaller than the highest performing, commercially available resin used with this printer (Fig. 1) and ~2X smaller than previous PDMS resins. Printed test structures exhibited 60 µm channels with 20 µm membranes that were clear of uncured resin (Fig. 2) This represents a ~4X decrease in feature size compared to previous work using PDMS resins. Next, a full µAL will be fabricated using this custom resin.

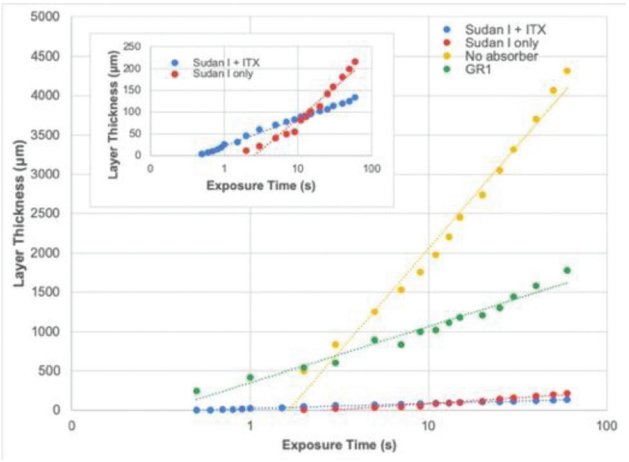

Fig. 1. Presence of the UV absorbers, Sudan I and ITX, improve resolution 10-fold compared to the commercially available GR1 and absorber free PDMS formulation. GR1 is a high-resolution resin specifically sold for use with the Asiga MAX 385nm series.

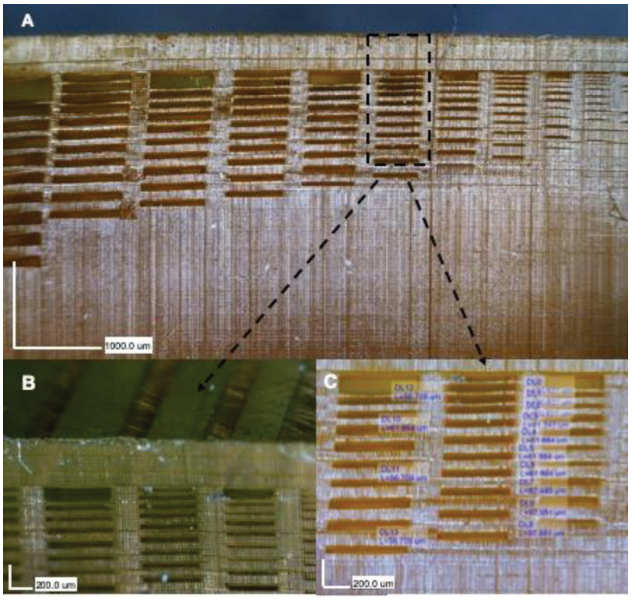

Fig. 2. Test structure with microchannels of varying heights and membrane thicknesses to characterize resolution (A). Channels identified in A are successfully cleared of uncured polymer (B) exposing 58 ± 3 µm channels with membranes as thin as 20um (C).

PULM 8

Toward a Sweep Gas Controller to Automatically Regulate CO_2 Removal In Wearable Artificial Lungs (WALs)

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Study: WALs could greatly improve the quality of life of the many patients with end stage lung disease who are not candidates for lung transplant. Several WAL systems are currently being developed, but none can automatically adjust CO_2 removal in response to changes in patient activity. We have shown that all metabolically produced CO_2 can be removed using 20% of cardiac output and that sweep gas flow rate dramatically impacts CO_2 removal. We have previously developed a large, prototype benchtop system that automatically adjusted CO_2 removal in an artificial lung by servo regulating the sweep gas. This current work seeks to develop a robust and compact CO_2-based sweep gas servo-regulation system suitable for future battery-powered WALs.
Methods: A proportional-integral-derivative (PID) feedback controller is used to meet a target exhaust CO_2 level by changing sweep flow and implemented using an embedded TI Hercules microcontroller, a centrifugal air pump, a Sensirion mass ow sensor and a CO2Meter infrared CO_2 sensor (Figure 1). The graphical user interface was designed on a custom touchscreen using QML/JavaScript. A desiccant was used to protect the sensor from exhaust gas condensate. The system was tested for 6 hr with a Novalung iLA oxygenator and anticoagulated bovine blood.

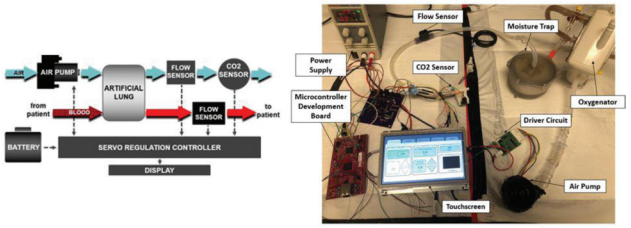

Figure 1: Control architecture (left) & system components (right).

Results: Inlet blood pCO_2 was varied to mimic changes in patient activity (Figure 2; blue triangles a-d represent simulated changes) for blood flow rates between 0.25 and 1.5 L/min. The PID automatically adjusted the sweep gas flow to rapidly (<1 min) meet target exhaust CO_2. Blood pCO_2 was decreased from 36-90 mmHg (inlet) to 29-46 mmHg (outlet) for a target exhaust CO_2 level of 20 mmHg. Condensate was managed and did not affect the CO_2 sensor. The servo regulator was successful in adjusting to changing blood CO_2 levels while consuming < 3.5W of power, representing the first step towards a WAL that responds to the metabolic needs of the patient.

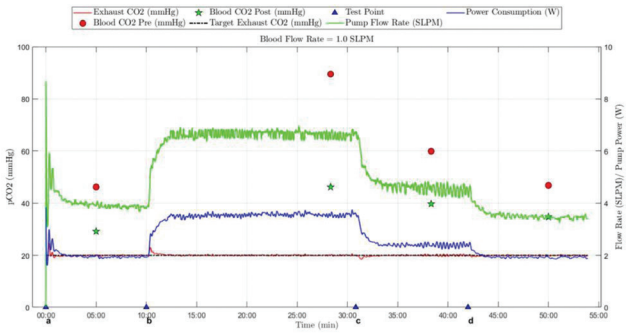

Figure 2: *In vitro* results . Blue triangles on the x-axis represent simulated changes in patient activity via adjusting inlet blood pCO2 levels.

PULM 9

A Heparin-Free Surface Coating for Extracorporeal Life Support Using a Nitric Oxide Catalyst

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Study: Modern extracorporeal life support (ECLS) devices are constructed with heparin and albumin surface coatings to prevent thrombosis; however, these coatings alone do not prevent clotting, requiring systemic anticoagulation. An alternative strategy is a nitric oxide (NO)-generating surface coating to prevent thrombosis, as NO has antiplatelet properties. We assessed a NO-catalyzing coating (CuBTTri) during 7hrs blood circulation *ex vivo*. We hypothesized that CuBTTri maintains circuit patency with reduced supplemental heparin administration versus standard circuits.
Methods: CuBTTri was applied to ¼ in ID tubing and 19 Fr dual-lumen catheters assembled into ECLS circuits (n = 4) using pediatric oxygenators compatible with CardioHELP (Maquet; Rastatt, DE). Heparin Bioline® (n = 2) and albumin Softline® (n = 2) circuits were controls (CTRL group). 1 L porcine blood was divided and circulated (500 mL/min) through CTRL and CuBTTri. Heparin was administered to ACT of 120-150sec. Blood was collected at baseline, 3h and 6h to assess coagulation (PT, aPTT, antithrombin III, D-dimer, TEG, free hemoglobin), platelet count/function (p-selectin platelets; impedance aggregation), CBC, lactate and methemoglobin. At 7h, circuits were dissected and fixed for scanning electron microscopy. A mixed model with repeated measures and Tukey adjustment was used to assess group differences (two-sided test; sig p<0.05).
Results: Heparin administration was similar with no significant thrombosis. No group difference in coagulation, platelet count/function, CBC, lactate or methemoglobin was observed. In CuBTTri, TEG clot strength (MA) and PT were significantly reduced at 6h vs baseline (-6% MA; -10% PT). In CTRLs, lactate and D-dimer were elevated at 6h vs baseline (+36% lactate, +46% D-dimer). While no clinically appreciable difference was observed, CuBTTri did not elicit untoward effects and may be a safe alternative to heparin coatings when warranted (e.g. heparin-induced thrombocytopenia).

PULM 10

Novel Flushed Bearing Design Mitigates Thrombus Formation *In Vivo* **And** *In Silico*

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Study: The Modular Extracorporeal Lung Assist System (ModELAS) consists of an integrated centrifugal pump and a cylindrical stacked fiber bundle (0.65 m^2). The rotor of the centrifugal pump is supported by upper and lower ball-and-cup bearings. Early *in vivo* studies in 40 - 60 kg sheep (n=3) resulted in the consistent occurrence (100% of experiments) of problematic large thrombi forming at the lower bearing. The purpose of the current study was to evaluate the efficacy of a novel flushed bearing design.

Methods: The region around the lower bearing was redesigned to incorporate a novel recessed space that is passively flushed by centrifugally energized blood. The thrombogenic characteristics of the original versus new lower bearing designs were evaluated using the CFD-based thrombosis model being developed at Cornell University. ModELAS devices with the modified flushed bearing concept were tested *in vivo* with heparin anticoagulation.

Results: CFD studies demonstrated that concentrations of plasma free hemoglobin and other biochemical agonists (ADP, TxA2, thrombin) are significantly reduced in the flushed bearing. Five 30-day animal studies with the modified ModELAS produced three thrombus-free devices, one device failure due to ingestion of a large thrombus, and one device with lower bearing thrombus that was attributed to anomalous pump operation. A sixth study is ongoing with no apparent thrombus issues after 21 days. *In silico* studies are ongoing to identify features of the lower bearing that can be further improved to reduce its thrombogenecity potential.

PULM 11

Cross-circulation for Multivisceral Support and Extracorporeal Liver Perfusion

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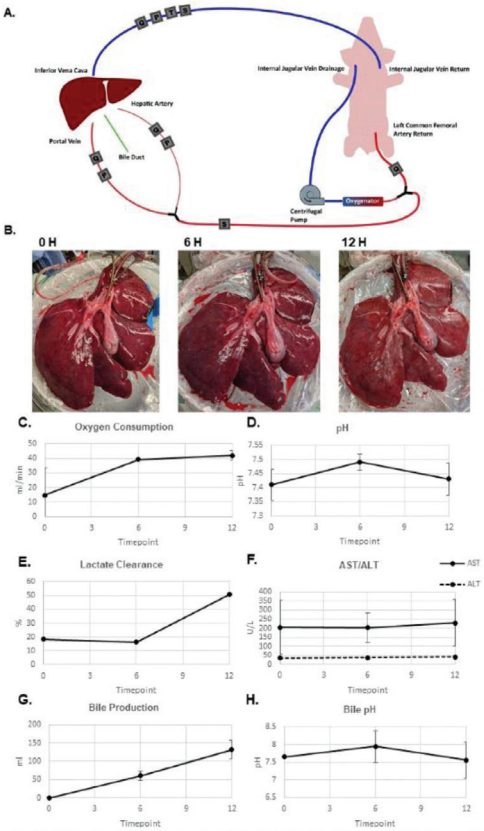
Study: Combined heart-liver transplantation is a complex life-saving procedure necessitating cardiopulmonary bypass and occasionally extracorporeal membrane oxygenation (ECMO) to ensure graft and recipient survival. Liver machine perfusion platforms are limited by non-physiologic conditions lacking metabolic and neurohumoral regulation of other body organs. An organ support platform providing hemodynamic support after heart transplantation as well as normothermic extracorporeal liver perfusion may facilitate subsequent liver transplantation and optimize early graft function. Here, we present a clinically relevant large animal model of veno-arterial-venous (VAV) liver cross-circulation.

Methods: Livers were procured from healthy domestic swine (n=2; 67 ± 2 kg) and cannulated through the portal vein, hepatic artery, inferior vena cava, and bile duct. Recipient swine were cannulated for peripheral VAV ECMO via bilateral internal jugular veins and left common femoral artery. Cross-circulation of whole blood between extracorporeal livers and anesthetized recipient swine ensued for 12 hours (Fig. 1A). Extracorporeal liver function, structural integrity, and recipient safety were assessed.

Results: Recipient swine remained hemodynamically stable throughout 12 hours of cross-circulation without vasopressor support (HR: 86 ±13 bpm; SBP: 95 ±24 mmHg; pH 7.44 ±0.05). Gross imaging revealed maintenance of global hepatic structure and uniform perfusion (Fig. 1B). Liver weight remained stable (0H: 1.85 kg; 12H: 1.75 kg). Biochemical data demonstrated maintenance of physiologic liver function (Fig. 1C-H). Maintenance of liver metabolic activity was demonstrated by increasing alkaline bile production (11 ml/hr, pH 7.56-7.94), hepatic oxygen consumption (0H: 15 mlO_2/min, 12H: 42 mlO_2/min), and lactate clearance (Fig. 1C-H). A cross-circulation platform providing simultaneous heart and liver support may facilitate multivisceral transplantation.



Q, flow probe; P, pressure transducer; T, temperature probe; S, oxygen saturation probe

PULM 12

Noninvasive Quantities Assessment of Lung Function In VV-ECMO Patients

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Study: Lungs recovery is a major goal of VV ECMO therapy. The arterial saturation (**SaO^2**) does not offer a reliable diagnostic means as it is subject of cardiac output (**CO**), ECMO flow (**Q^{ECMO}**) and unknown value of venous saturation. The aim of this study is to develop a simple noninvasive method to quantitively assess lung oxygenation function in VV ECMO patients.
Methods: Consider that there are two flows passing lungs: first flow **Q^{EFF}** from oxygenator with ~100% saturated blood and second flow is (**CO - Q^{EFF}**) that is the flow of the remaining venous blood (RVB) that did not pass the oxygenator. The saturation of RVB may change while passing partially working lungs to **S^LO^2**. (In reality the lungs act on the mixture of both sources of blood, but this provides a useful abstraction for analysis). The recovery of lungs can be judged by how close post lung oxygenation **(S^LO^2)** of the RVB is to 100%. The mass balance equation for saturations will be: **$CO*SaO^2=Q^{EFF}*100\%+(CO-Q^{EFF})*S^LO^2$ Eq.1** Where **$Q^{EFF}=Q^{ECMO}*(1-R\%/100)$** adjusted for recirculation **R%**. The values of **SaO^2**, **R%** and **Q^{ECMO}** can be measured. If CO is also known then the post lung saturation **S^LO^2** of RVB can be calculated. Clinical protocol. 17 adult patients were included in the retrospective study. **SaO^2** was measured by fingertip oximeter, recirculation and CO [1] were measured by the ELSA monitor (Transonic Systems Inc. USA). CO was also recorded by FloTrac Vigileo (Edwards Life Sciences, USA).
Results: Total 50 CO sessions were examined (Table):

Cardiac output and calculated oxygen saturation after lungs by ELSA and Vigileo.

Monitor	CO mean ± SD (range) l/min	CI mean ± SD (range) l/min/m^2	S_LO_2 mean ± SD (range)%
ELSA	5.11 ± 1.31 (2.74 - 10.4)	2.96 ± 0.90 (1.67 - 6.22)	71 ± 12 (41 - 90)
Vigileo	6.91 ± 2.23 (4.10 - 14.9)	3.88 ± 1.47 (2.08 - 10.2)	86 ± 37 (-158 - + 110)

Note, that often oxygen saturation after lungs produced by Vigileo is obviously erroneous being sometimes negative or larger than 100%. This tells that the value of CO reported by Vigileo appears to not hold with the mass balance equation Eq.1.

Conclusion. Knowledge of CO during VV ECMO gives opportunity to calculate post lung saturation of venous blood that didn't pass the oxygenator, thus quantitatively assessing lung function. Periodic observation of this parameter may help evaluate lung recovery. [1] *ASAIO JOURNAL*, *65*(Suppl1), pp 126.

PULM 13

New Venous-Arterialvenous ECMO Circuit Configuration for the Management of Differential Hypoxia

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Study: The implant of ECMO by peripheral arterial-venous femoral cannulation exposes the patient to the risk of differential hypoxia when severe pulmonary dysfunction is present. In this case, a solution is represented by the conversion to the venous-arterialvenous configuration (V-AV). In this configuration the regulation of the arterial-venous support flow (A-V) with respect to the venous-venous (V-V) one is challenging. We propose a configuration of ECMO V-AV with insertion on the circuit of two centrifugal pumps for adequate flows regulation.
Methods: 8 patients (6 men and 2 women;) who previously underwent peripheral VA-ECMO in our centre were switched to V-AV ECMO because the Harlequin Syndrome was diagnosed. The proposed assembled circuit for V-AV support consisted of a right femoral venous inflow line, the main pump, called master, which provided the total output flow (total flow - TF) partialized through a Y branch to the femoral artery reinfusion line (femoral flow FF) and to the internal jugular vein reinfusion line (jugular flow JF). Another centrifugal pump, called slave, was inserted on the reinfusion line in the jugular vein to modify the JF. According to this configuration, the JF can be easily adapted to the clinical conditions paying attention that the FF results from the difference between TF and JF.
Results: Mean duration of V-AV ECMO support was 5.3±1.4 days. In seven patients (87.5%) as the cardiac function recovered totally the A-V support was removed and V-V support was maintained. After 13.5±2.7 the pulmonary function recovered and V-V support was removed too. One patient (12,5%) was switched to VA ECMO because an improvement in the pulmonary function happened whereas the cardiac function recovered completely after other 10 days of support. The use of a secondary centrifugal pump to regulate the JF provides different advantages when a V-AV configuration ECMO is used: 1) V-V ECMO flow easily adapted to the clinical condition of the patient; 2) Separate weaning allowed.

PULM 14

Novel Left Atrial Cannulation Technique for Attachment of Artificial Lung

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Study: The artificial lung (AL) has the potential to provide support for recovery or transplantation in children with acute and chronic respiratory failure. Left atrial access is necessary for low-gradient, pumpless systems, such as the MLung; however, cannulating the thin, fragile left atrium (LA) for long-term support is fraught with complications. Here, we describe a novel approach for LA cannulation.

Methods: The LA and pulmonary artery (PA) were exposed through a left anterior thoracotomy. Device inflow was created using an end-to-side anastomosis between the PA and a 10-mm ringed polytetrafluoroethylene (PTFE) graft. A 28-Fr venous cannula was inserted through the graft to the level of the anastomosis. Outflow was established through the LA. Using 5-0 polypropylene with pledgets, two concentric purse-string sutures were placed in the dome of the LA (**Fig. 1a**). An atriotomy was performed and a 28-Fr venous cannula was inserted (**Fig. 1b**). A 10-mm PTFE graft was passed over the cannula and circumferentially secured to the dome of the LA and the pledgets. The graft was secured to the cannula with silk ties (**Fig. 1c**).

Results: The procedure was successful in four sheep (12-20 kg). The mean flow through the MLung was 821.3±241.9 mL/min, equal to 44.1±14.2 % of cardiac output. Average pressure drop across the device was 4.9±3.7 mmHg. Two survived for 7 days; 1 died at 48 hours from unrelated complications. There were no anastomotic complications. This method of LA cannulation is safe and effective. It achieves optimal flow in a low-resistance, pumpless AL.

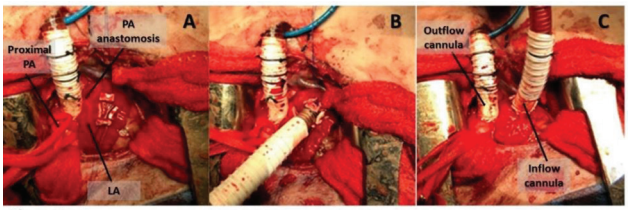

Figure 1 a-c

PULM 15

Indwelling Central Venous Catheters Drive Bacteremia in Patients Supported on ECMO

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Study: Bacteremia is a lethal complication in patients supported with extracorporeal membrane oxygenation (ECMO). It is common in patients with veno-venous (VV) ECMO since these patients are supported for longer durations. Since these patients have concurrent indwelling central venous catheters (CVC), it remains unknown whether the ECMO circuit, CVC, or both, contribute to the development of bacteremia. Here, we evaluated the microbiological characteristics and risk factors associated with bacteremia in patients receiving VV ECMO.

Methods: A single institution veno-venous (VV) ECMO study with consecutive patients with ARDS from 2016 through 2019. In all patients (n=61), at the time of VV ECMO decannulation, ECMO catheters and the circuit oxygenator were aseptically collected and analyzed for microorganisms.

Results: New bacteremia was diagnosed in 15 (20.3%) patients. None of the ECMO catheters or oxygenator fluid were found to be culture positive. Development of bacteremia increased mortality by 3-folds. Bacteremia was also associated with higher incidence of acute kidney injury and gastrointestinal bleeding (64.3% vs 8.5%, p<0.01, 20.0% vs 8.5%, p=0.04). Bacteremia increased with CVC use of over 8 days. Indeed, bacteremia was significantly lowered when CVC were exchanged by day 8 compared to patients who had line exchanges at later points (14.6% vs 45%, p=0.02). Median length of central line use in the infection-negative and infection-positive group were 6.3±5.0 and 9.4±5.1, respectively (p=0.04). Bacteremia is a lethal complication in patients receiving ECMO support. Indwelling CVC, not the ECMO circuitry, is the likely contributor for bacteremia. Exchanging CVC by day 8 can reduce the incidence of bacteremia.

Table 1. Baseline Characteristics of Patients with CVC exchange Before and After 8 days

Variable	<8 Days (n=40)	>8 Days (n=21)	*P* value
Support days	8.6 ± 14.7	26.9 ± 21.5	0.001
Age, years	46.3 ± 15.1	51.1 ± 17.6	0.29
BMI, kg/m2	28.8 ± 14.6	30.7 ± 10.6	0.56
BSA, m2	1.9 ± 0.5	1.9 ± 0.3	1.00
RESP Score	0.6 ± 3	-0.4 ± 2.6	0.18
Laboratory			
Hemoglobin, g/dL	11.2 ± 3.7	10 ± 1.8	0.09
WBC, 1,000/mm3	13.3 ± 6.5	16.2 ± 10.2	0.24
Platelets, 1,000/mm3	212.6 ± 116.9	217.3 ± 113.1	0.88
Sodium, mEq/L	138.3 ± 35.3	135.8 ± 10.5	0.68
Creatinine, mg/dL	1.7 ± 0.9	1.5 ± 2.2	0.69
BUN, mg/dL	31.3 ± 23.2	25.5 ± 18	0.28
AST, U/L	91.8 ± 222.1	37.8 ± 26.8	0.13
ALT, U/L	71.6 ± 196.3	33.4 ± 17.8	0.23
Total bilirubin, mg/dL	1.1 ± 1.7	3.2 ± 9.4	0.31
Albumin, g/dL	3.0 ± 0.8	2.7 ± 0.6	0.10
PT	14.1 ± 4.5	17.5 ± 11	0.18
INR	1.3 ± 0.4	1.6 ± 1	0.19
PTT	35.3 ± 11.1	36.6 ± 13.5	0.71
ABG (at cannulation)			
pH	7.3 ± 1.9	7.3 ± 0.1	1.00
PaCO2	56.1 ± 28.2	56.4 ± 23.2	0.96
PaO2	111.7 ± 53.9	91.7 ± 66	0.24
HCO3	25.5 ± 9.2	28.2 ± 6.8	0.20
Lactate	4.2 ± 3.1	2.5 ± 2.3	0.02

PULM 16

Discordance Between PTT and Anti-Xa Monitoring of Heparin Anticoagulation in MCS

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Study: It is unclear whether partial thromboplastin time (PTT) or anti-factor Xa (Anti-Xa) is a more accurate assay in monitoring unfractionated heparin anticoagulation in mechanical circulatory support (MCS) patients. This study investigates the pattern and predictors of discordance in simultaneously measured PTT/Anti-Xa pairs in patients supported by MCS devices.

Methods: PTT and Anti-Xa were simultaneously measured in all MCS patients between years 2016 and 2019 at a tertiary academic medical center. Patient demographics, device type, and 15 other laboratory variables were also collected (Table 1). Therapeutic PTT and Anti-Xa levels were defined as 60-100 seconds and 0.3-0.7 IU/mL, respectively, and concordance is defined as the two assays being both subtherapeutic, therapeutic, or supratherapeutic. Basic descriptive statistics were performed for discordance pattern. To identify predictors of discordance, a multivariate regression analysis using generalized estimating equation was applied.

Results: 19,834 pairs of simultaneously measured PTT/Anti-Xa were collected from 742 patients. Seven MCS device types were represented consisting of 187 Intraaortic Balloon Pump (IABP), 170 Impella, 133 Extracorporeal Life Support (ECLS), 117 HeartWare HVAD, 78 HeartMate II (HM2), 39 HeartMate 3 (HM3), and 18 Total Artifical Heart (TAH) devices. PTT and Anti-Xa were concordant for 33.8% of paired observations and discordant for 66.2% (PTT > AntiXa 63.8%; PTT < AntiXa 2.4%) of paired observations (Figure 1). In a multivariate regression analysis comparing concordance vs discordance (PTT > Anti-Xa), higher values of hemoglobin, haptoglobin, platelets, and albumin were associated with concordance, whereas Asian race, and higher values of International Normalized Ratio (INR) and total protein were associated with discordance (Table 1). Discordance pattern was similar among the three durable ventricular assist devices (HVAD, HM2, and HM3).

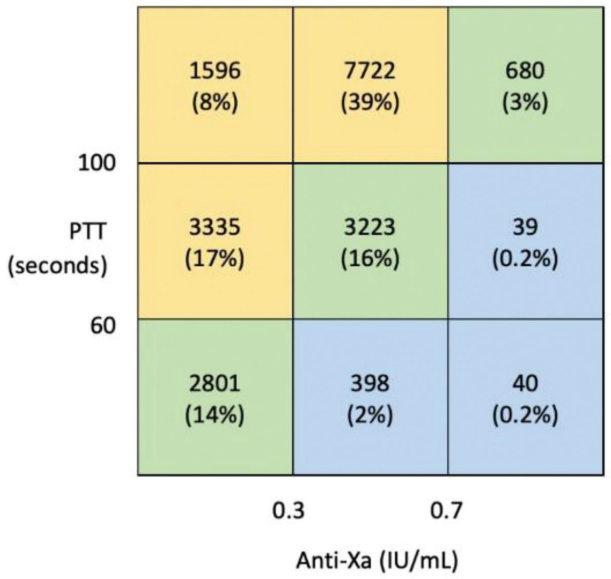

Figure 1. Concordance/discordance pattern of simultaneously measured PTT and Anti-Xa pairs in MCS patients.

Variable	Mean	S.D.	Odds Ratio of Concordance (95% CI)	P-value
Age (years)	55.65	15.79	0.94 (0.84-1.07)	0.347
Sex - Female			1.00	Ref
- Male			1.17 (0.87-1.58)	0.298
Race - White			1.00	Ref
- Black			1.24 (0.80-1.93)	0.341
- Asian			**0.54 (0.35-0.85)**	**0.008**
- Other			1.18 (0.80-1.74)	0.417
INR	**1.56**	**0.51**	**0.54 (0.46-0.64)**	**<0.001**
Hemoglobin (g/dL)	**9.01**	**1.79**	**1.36 (1.19-1.54)**	**<0.001**
Platelet (10^3/mL)	**169.56**	**96.16**	**1.37 (1.17-1.59)**	**<0.001**
Creatinine (mg/dL)	1.64	1.29	0.98 (0.88-1.09)	0.741
AST (units/L)	277.95	1320.26	1.12 (0.95-1.31)	0.175
ALT (units/L)	175.79	701.43	0.97 (0.84-1.12)	0.636
Total Bilirubin (mg/dL)	1.83	3.13	0.88 (0.75-1.03)	0.118
Albumin (g/dL)	**2.96**	**0.56**	**1.28 (1.05-1.57)**	**0.015**
Total Protein (g/dL)	**5.68**	**1.05**	**0.73 (0.59-0.89)**	**0.002**
HS-CRP (mg/L)	122.21	93.35	0.94 (0.83-1.07)	0.343
LDH (units/L)	799.41	1828.90	1.03 (0.93-1.14)	0.553
Haptoglobin (mg/dL)	**91.55**	**77.73**	**1.26 (1.10-1.45)**	**0.001**
Device - ECLS			1.00	Ref
- HM2			**0.53 (0.31-0.89)**	**0.017**
- HM3			**0.45 (0.23-0.85)**	**0.014**
- HW			**0.43 (0.26-0.70)**	**0.001**
- IABP			0.79 (0.49-1.26)	0.314
- Impella			1.49 (1.00-2.22)	0.052
- TAH			0.76 (0.36-1.60)	0.467

Table 1. Multivariate GEE model for concordance vs discordance (PTT > Anti-Xa pattern). Odds ratios are in the direction of concordance and for 1 S.D. from the mean for continuous variables.

PULM 17

Extracorporeal Life Support for Central Airway Surgery: A Systematic Review

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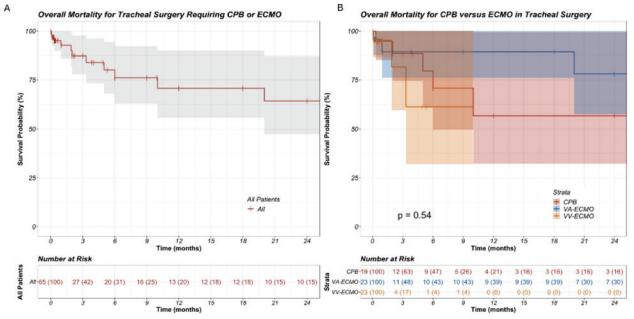
Study: Malignancies and other lesions requiring surgery on major airways can pose a complex problem to perioperative central airway management. Adjuncts to advanced ventilation strategies have included cardiopulmonary bypass (CPB), veno-arterial (VA-ECLS) or veno-venous extracorporeal life support (VV-ECLS). We performed a systematic review to assess the existing evidence utilizing these strategies.
Methods: An electronic search was conducted to identify all studies in the English literature reporting the use of any form of ECLS during central airway surgery. 44 studies consisting of 78 patients were selected, and patient-level data were analyzed.
Results: Median patient age was 50 [IQR: 35-58] and 59% (46/78) were male. Indications for surgery, included central airway or mediastinal cancer in 57.7% (45/78), lesion or injury in 15.4% (12/78), and stenosis in 12.8% (10/78). Location of the tracheal lesion included the lower third in 39% (16/41) and the middle third in 36.6% (15/41), with 24.4% (10/41) in the upper third and 19.5% (8/41) at the carina. Support was initiated pre-operatively in 9.86% (7/71) and at the time of induction in 55.3% (42/76). It was most commonly used at the time of tracheal resection / repair [93.2% (68/73)], intubation of the tracheal stump [94.4% (68/72)], and re-anastomosis [94.2% (65/69)]. 13.7% (10/73) patients were supported post-operatively. Most commonly performed surgery was tracheal repair or resection in 70.3% (52/74). Median hospital stay was 12 [8, 25] days, and in-hospital mortality was 7.9% (6/76). There was no significant difference in survival between the three groups (p = 0.54). Kaplan-Meier survival curves are demonstrated for overall (Figure 1A) and stratified survival (Figure 1B).
Conclusions: Central airway surgery, even when assisted with various forms of ECLS, carries rather significant short-term mortality, reflecting the complexity of this pathology.



PULM 18

Moderate Hypothermia is Effective in Mitigating Warm Ischemic Injury in Donor Lung Allografts

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Study: During implantation of donor lung allografts, there is a mandatory period of warm ischemia. We sought to evaluate the effect of moderate hypothermia on lung performance using a small-animal model of ex-vivo lung perfusion (EVLP).
Methods: Heart-lung blocs from Lewis rats (250-400 g) were procured following heparinization and cold flush. Control (hypothermic) conditions (n=5) were subsequently stored for 1 hour at 4 °C. Normothermic and moderate hypothermic conditions (n=5) were stored for 30 minutes at 37 °C and room temperature (approximately 20 °C), respectively. Lungs were then evaluated with EVLP (IPL-2 Isolated Perfused Lung System, Harvard Apparatus, Holliston, MA) using a 3-hour, closed-atrium protocol. Pulmonary arterial (PA) pressure, left atrial (LA) pressure, tracheal pressure, and dynamic compliance were monitored. PaO_2 to FiO_2 ratio (P:F) was assessed on the hour after 5 minutes of ventilation at FiO_2 100%.
Results: Normothermic conditions exhibited lower compliance than hypothermic and moderate hypothermic samples throughout EVLP (0.137 vs 0.319 vs 0.374 mL/cmH_2O at 3 hours; $p < 0.001$). Normothermic grafts also demonstrated higher tracheal pressures (13.4 vs 8.6 vs 8.9 cmH_2O at 3 hours, $p < 0.001$). All LA and PA pressures remained within a physiologic range, though moderate-hypothermia grafts exhibited lower PA pressures at later timepoints (17.9 vs 17.6 vs 12.4 cmH_2O at 3 hours, $p = 0.006$). P:F values for hypothermic and moderate hypothermic conditions remained excellent, while normothermic values diminished by 3 hours (416 vs 437 vs 308, $p < 0.001$). Analysis of variance (ANOVA) was utilized to compare metrics across groups.
Conclusion: Moderate hypothermia mitigates warm ischemic injury in lung allografts as assessed by performance metrics during EVLP. The use of cardiopulmonary bypass with moderate hypothermia during implantation may be of clinical utility in minimizing warm ischemic injury.

PULM 19

Effect of Hematocrit and Plasma Protein Concentration on Co_2 Removal in Artificial Lungs

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Study: Extracorporeal CO_2 removal has the potential to benefit two important patient populations, patients with acute respiratory distress syndrome (ARDS) and those with acute exacerbations of COPD (aeCOPD). In ARDS patients $ECCO_2R$ may allow the use of lung protective mechanical ventilation and in the aeCOPD population it may prevent the need for invasive mechanical ventilation altogether. As the investigation of $ECCO_2R$ clinically rises, all factors that influence the CO_2 removal rate in $ECCO_2R$ should be well understood. While many factors have been explored, some have not. In this study we explored in- vitro the effect of hematocrit (HCT) and presence of plasma proteins on CO_2 removal in $ECCO_2R$.
Methods: Bovine blood was diluted with saline or plasma to HCT levels ranging from 33% to 8%. In vitro CO_2 removal was evaluated in our ambulatory artificial lung according to ISO standards at a blood flowrate of 500 ml/min, a flowrate that provides therapeutic $ECCO_2R$ in our device.
Results: CO_2 removal rate (vCO_2) decreased linearly by 42% and 32% in saline and plasma respectively from a HCT of 33% to 8%. The difference in vCO_2 in plasma versus saline was not statistically significant. The effect of HCT on vCO_2 is hypothesized, as is the case in the native lung, to be due to the release of fewer Bohr protons, a decreased buffering capacity of blood due to lack of red blood cells (RBC), and a reduced flux of bicarbonate ion across the RBC membrane. Thus, the HCT of blood should be accounted for when assessing the CO2 removal rate in $ECCO_2R$.

PULM 20

Membrane Scrambling Induced by MCS-Related Shear Stress is not Associated with Platelet Apoptosis

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Study: Mechanical circulatory support (MCS) while efficient in restoration of patient hemodynamics remains limited by the coagulopathy associated with thrombotic and bleeding events. Shear-mediated alterations of platelet function is a major driver of the MCS-related coagulopathy. We hypothesize that shear stress promotes platelet intrinsic apoptosis via dysfunction of their mitochondria and caspase 3 activation.
Methods: Human platelets were exposed to shear stress in a hemodynamic shearing device. Alternatively, platelets were sonicated to promote high-extent mechanical activation. Platelets were stained with fluorescein-congugated anti-CD41, mitochondrial probe $DiOC_6(3)$, annexin V detecting phosphatidylserine externalization (PSE), or caspase-3 inhibitor DEVD-FMK. Platelet fluorescence was quantified by flow cytometry.
Results: Platelet exposure to shear stress and sonication resulted in significant dissipation of mitochondrial membrane potential ($\Delta\Psi m$) and prominent PSE. Thus, the number of platelets accumulated $DiOC_6(3)$ was largely decreased following 50 & 70 dyn/cm^2 shear and sonication (Fig. 1A). Similarly, annexin V binding increased dose-dependently with the increase of shear stress (Fig. 1B). No significant caspase 3 activation was detected following platelet exposure to shear stress. Yet, sonication induced more than 2-fold increase of platelets expressing activated caspase 3 (Fig. 1C).
Conclusion. While both shear stress and sonication induce platelet $\Delta\Psi m$ dissipation and PSE, only platelet sonication results in notable activation of caspase 3, a major executor and definitive indicator of platelet apoptosis. Thus, we concluded that platelet membrane scrambling induced by MCS-related low and intermediate shear stress is not associated with platelet apoptosis. Alternative mechanisms of PSE, e.g. Ca^{2+}-mediated lipid translocation or mechanical alteration of lipid bilayer symmetry due to shear exposure, should be further considered.

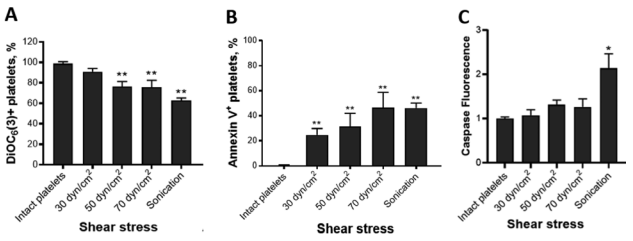

Figure 1. Platelet exposure to low and intermediate shear stress induces dissipation of mitochondrial membrane potential (ΔΨm) and augmentation of phosphatidylserine externalization (PSE), while no caspase 3 activation occurred. In contrast, sonication induced typical proapoptotic phenotype with decrease of ΔΨm, notable PSE and caspase 3 activation: A – the number of platelets accumulating mitochondrial probe $DiOC_6(3)$ indicating intact ΔΨm, B – the number of platelets binding annexin V detecting PSE, C – fluorescence intensity of FITC-DEVD-FMK positive platelets indicating caspase 3 activation. Mean ± SD, n = 6-8, ANOVA: * - $p < 0.05$, ** - $p < 0.01$.

PULM 21

Studies on Mechanisms of Anti-Inflammatory Activity of Heparin- And Hyaluronan Surface Coatings Targeting NF-κB Signalling Pathway

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Study: Biomaterial can cause inflammation. Monocytes represent key players at implantation site, where they differentiate to macrophages secreting pro-inflammatory cytokines, which synthesis is dependent on nuclear transcription factor-κB (NF-κB) signaling pathways. Glycosaminoglycans (GAGs) like heparin (Hep) and high molecular weight hyaluronic acid (HMWHA) possess a valuable anti-inflammatory potential related to inhibition of NF-κB signaling and transcription.
Methods: GAG were covalently immobilized or physically adsorbed as multilayer system using layer-by-layer (LbL) technique. The surface topography and wetting properties were characterized by scanning electron microscopy (SEM) and water contact angle (WCA) measurements. Macrophages were used to examine the anti-inflammatory potential in terms of adhesion and formation of multinucleated giant cells (MNGCs). Western blotting (WB) was applied to study NF-κB activation. The association and uptake of Fluorescein isothiocyanate (FITC)-labelled-GAG were studied by immunofluorescence (IF) microscopy and flow cytometry.
Results: WCA showed increased wettability of GAG-coated surfaces, which depicts the successful immobilization of Hep and HA. The multilayer coatings reduced macrophage adhesion and MNGCs formation more than covalently-bound in comparison to positive controls. IF staining as well as the flow cytometry indicated that FITC-labelled GAG associated with macrophages. Studies with WB and IF staining of p65 showed also effects on NF-κB signaling pathway related to inhibition of macrophage activation by GAG. The anti-inflammatory mechanism of GAG is based on suppressing of NF-κB transcription factor together with increased wettability of substrata with GAG. Overall, both immobilization techniques indicate anti-inflammatory activity of Hep, which is of great interest and potential to modulate inflammatory responses of implant materials.

PULM 22

Cellular and Molecular Effects of Carbon Monoxide-bound Hemoglobin-based Oxygen Carriers (HBOCs)

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Study: The initial application of carbon monoxide (CO) in the manufacturing of HBOCs was related to pasteurization of unmodified (U) Hb; since CO-Hb is resistant against heating. Nowadays the use of CO expanded into CO-HBOCs that may act as CO-releasing molecules. Although some CO-HBOCs show promise in the treatment of ischemic stroke and TBI, little is know about their molecular and cellular effects. CO is a signaling molecule possessing vasodilatory, anti-oxidant, anti-inflammatory and neuroprotective properties. On the contrary, oxygenated (O_2)-UHb and O_2-HBOCs, for the most part, have the opposite effects.
Methods: This ex-vivo study investigated the impact of UHb and Hb polymerized with glutaraldehyde (GLUTHb) in O_2- and CO-forms on human astrocytes (ASTs) and brain capillary endothelial cells (BECs) (Clonetics, Walkersville, MD). Using established and previously reported methods, ASTs, after incubation with these Hb solutions (in a concentration of 1 g/dL), were evaluated for hypoxia inducible factors (HIF)-1 & 2 alpha stabilization, vascular endothelial growth factor (VEGF) and erythropoietin (EPO) expression, nuclear factor (NF)-kappa activation and TNF-alpha synthesis; and BECs for expression of adhesion molecules (ICAM-1, VCAM).
Results: Both O_2-UHb and O_2-GLUTHb induced complete degradation of HIF-1 & 2 alpha, inhibited synthesis of VEGF and EPO, and mediated inflammatory responses of ASTs. These Hb solutions increased expression of adhesion molecules by BECs. CO-UHb and CO-GLUTHb prevented degradation of HIF-1 & 2 alpha and increased basal production of VEGF and EPO. However, these Hbs were unable to fully inhibit NF-kappa B activation and suppress TNF-alpha synthesis by ASTs, and expression of ICAM-1 and VCAM by BECs.
Conclusions: These results indicate that Hbs-liganded with CO have a significant effect on HIF-1 & 2 alpha stabilization and production of neuroprotective VEGF and EPO by ASTs; however were unable to prevent NF-kappa B induction in ASTs and BECs.

PULM 23

Repetitive Mechanostimulation of Platelets Alters Regional Membrane Stiffness and its Distribution

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Study: Shear-Mediated Platelet Activation (SMPA) is a prime driver of thrombosis in Mechanical Circulatory Support (MCS). We have previously shown that *overall* platelet stiffness is a determinant of SMPA. It remains unknown if mechanical activation alters *regional* platelet stiffness. Regional stiffness may play an important role in activation via preferential force transduction in localized membrane "hot-spots." In this study we mechanically stimulate platelet regions by atomic force microscopy (AFM) tip and examine changes in regional platelet stiffness to better understand stress distribution as a function of mechanical force exposure.
Methods: Gel filtered platelets adhered to mica were serially imaged (over 2 hr) on a Multimode AFM (Bruker). Height and stiffness maps were derived from force-volume (FV) curves sampled across a raster-scanned image (maximum peak force: 0.4-0.6 nN). FV curves were fitted to the Hertzian model and its Dimitriadis finite-thickness correction to obtain elastic moduli. Radial stiffness distributions were evaluated with respect to a selected origin.
Results: Adhered platelets exhibited either constant-height or "fried egg" shapes. Increasing force accumulation led to elevated "pseudonuclei" in constant-height platelets which later merged into a single elevated region. Concurrently, stiffness redistributed such that peripheral regions stiffened and increased in area, while the central elevated region softened, increased in height, and decreased in area. Our results suggest that even highly activated platelets are capable of adapting their morphology and stiffness in response to external mechanical stresses. Minimizing the soft area may be a mechanism to reduce stress-induced deformation. As elevated stiffness is expected to promote force transduction, these morphological changes could decrease damage at the expense of sensitivity to physical force. Stiffness modulation may therefore be a viable strategy for reducing SMPA.

REN 1

Tributary Venous Access, Blood Access without Intimal Damage

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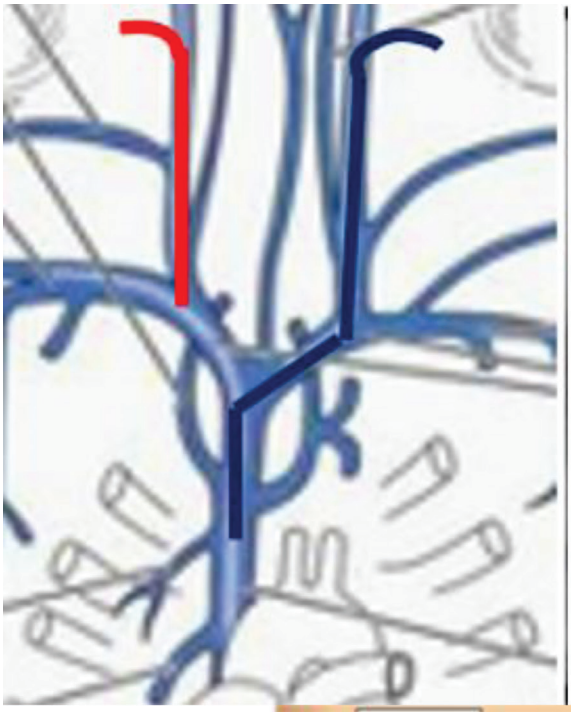
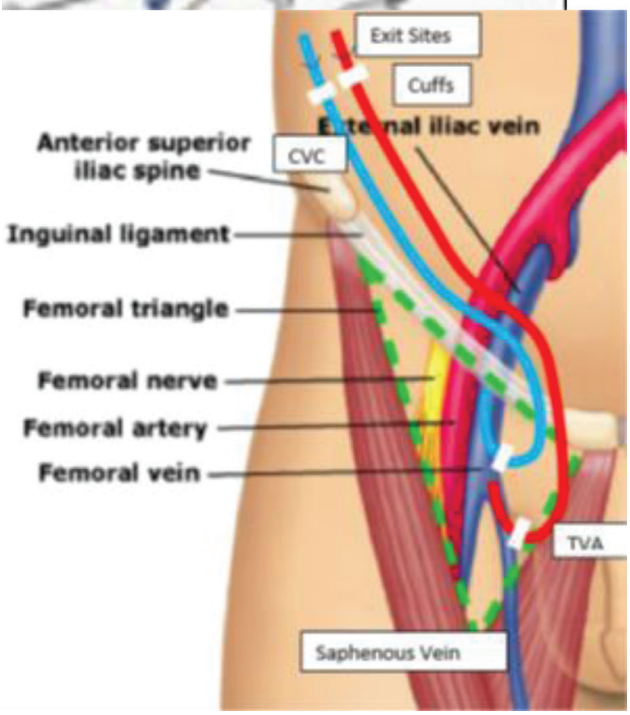
Study: The venous intima is a single layer of delicate endothelial cells. Irritation of intima by central venous catheters (CVC) leads to fibrous sheathing, stenosis of central veins, and diminution of the blood flow removal rate. However, if a catheter were connected "end to side" to a vein, with the tip barely entering the vein, blood removal would be possible without damage to the intima. We performed preliminary testing of this concept in four normal sheep.

Methods: Under general anesthesia, 5 mm OD cylindrical silicone catheters (TVA) were placed into the jugular vein and advanced until the tip just entered the brachio-cephalic vein, as shown by angiography. A 5 mm diameter CVC of standard design was placed through the opposite jugular vein and the tip advanced into the superior vena cava (Figure 1). Both catheters had movable Dacron cuffs for fixation just outside the vein and in the subcutaneous tissue, and were tunneled to skin exit sites. Sheep were recovered from anesthesia and blood outflow rate was measured under controlled negative pressure (-40 mm Hg) 3 times weekly for 3 weeks.

Results: Blood outflow rate in awake and standing sheep was 180-240 ml/min for the TVA, and statistically the same as when drawing blood from the CVC. Blood infusion rate was also similar for the TVA and CVC. Postmortem dissection of the central veins indicated intimal damage to the SVC and jugular veins from the tip and body of the CVC, but no damage in the jugular or brachiocephalic vein from the TVA. In humans a TVA placed through the saphenous vein with tip protruding 1-2 mm into the femoral vein should provide adequate blood removal rate for chronic hemodialysis (250 to 400 ml/min), without damage to the venous intima. A silicone CVC placed into the femoral vein above the TVA could provide simultaneous blood return (Figure 2). For single-access dialysis applications, TVA alone would suffice.





REN 2

A Pilot Study to Measure Distensibility Using an Open-Source Software

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Study: Arteriovenous fistulas (AVF) are the preferred access for hemodialysis. Yet, they often fail to mature. Doppler ultrasound has been employed for enhancing the preoperative examination of the patient prior to AVF construction. Blood vessel distensibility may be useful in predicting fistula maturation. This pilot study reports on the feasibility of measuring distensibility using conventional ultrasound data and an open-source ultrasound software program that our group developed based on ultrasound speckle tracking.
Methods: 27 subjects scheduled for AVF surgery were enrolled in the study. Demographics and clinical data were collected. Ultrasound scanning of the brachial and radial artery were performed. Conventional digital imaging and communications in medicine (DICOM) format data were collected from the ultrasound exam. The distensibility of arteries were computed from the DICOM data using our open-source software to track the frame to frame displacement of user selected pixels located at the near and far field edge of the vessel wall. Exploratory relationship between baseline brachial and radial artery distensibility is presented using scatter plot for numerical variables and boxplots for categorical variables.
Results: Of the total 27 patients, there were 27 males, 21 had history of diabetes, 26 had hypertension. The distensibility of the brachial artery is more than the radial artery. Patients with diabetes have lower distensibility in the brachial and radial artery than those without diabetes. Patients with peripheral vascular disease (PVD) have lower distensibility in the radial artery than those without PVD. The distensibility of the brachial or the radial artery does not vary by intake of calcium channel blockers, ACEi/ARB blocker or beta blockers. Statistically significant relationship is observed between distensibility of the radial artery and systolic and pulse pressures.

REN 3

Factors Influencing Variation in Vascular Distensibility Measurements by Ultrasound Speckle Tracking: Measurements by Ultrasound Speckle Tracking

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Study: Vascular ultrasound measurements may be useful in predicting fistula maturation, which is essential for hemodialysis in patients with end-stage renal disease (ESRD). Our group developed a novel open source ultrasound software program that measures distensibility using conventional ultrasound Digital Imaging and Communications in Medicine (DICOM) data. In this pilot study, we evaluated the inter-user variability in measured arterial wall distensibility based on user's initial selection of points on top and bottom of vessel wall.
Methods: Ten subjects scheduled for arteriovenous fistula (AVF) surgery were enrolled in the study. Ultrasound scanning of the brachial/radial arteries were performed. To implement the ultrasound software program on the DICOM data obtained from scanning, ten users were prompted to select two points of interest at the top and bottom of the arterial vessel wall in each subject. These points were tracked using the Kanade-Lucas-Tomasi (KLT) speckle-tracking algorithm over the stack of images in the DICOM cine loops of the ten subjects. The distensibility of the vessel wall was calculated from a graph of the change of vessel diameter over time.
Results: There was significant variation in the location of the points selected by the users for the ten cine loops, with a maximum spread of up to 120 pixels (7.8mm) for the top and up to 140 pixels (9.1mm) for the bottom of the vessel wall. This variation in users' point selection contributed to the variation in inter-cardiac measurements (6.41 to 17.68%) as well as distensibility measurements (5.79 - 47.29%). In order to increase the reproducibility and reliability of our open source software to measure vascular distensibility, it is important to minimize user induced variation. Consistency in measurement will help to better understand the physiologic variation in vascular wall compliance and its role in predicting the maturation of AVFs.

REN 4

Identification of Early Biomarkers of Arteriovenous Fistula (AVF) Stenosis: The Role of Circulating Plasma Microvesicles (MV)

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Study: A functional arteriovenous fistula (AVF) is the mainstay to perform adequate hemodialysis (HD). The primary complication that causes AVF failure is stenosis. Surveying for stenosis can be performed by different ways: we evaluated correlations between some clinical parameters and novel biomarkers of microvascular injury such as circulating plasma MV and endothelial-derived von Willebrand factor (vWF) levels in patients with significant (>50% of the access diameter) AVF stenosis.
Methods: 73 HD patients (pts) were enrolled: significant stenoses were identified by Doppler ultrasound (DUS) and then correlated with socio-demographic parameters and data from dialysis, AVF and laboratory (including MV phenotypic characterization and concentration of vWF).
Results: DUS analysis of 73 pts showed 22 AVF with significant stenosis and 51 AVF with non-significant or absent stenosis. We found a good correlation between significant stenoses and low achievement of prescribed blood flow ($p<0.001$), low Kt/V, bicarbonate HD (p 0.014) and previous angioplasty ($p<0.001$). Concentration of plasma MV was significantly higher in pts with significant stenosis and MV derived from stenotic AVF showed an increased expression of markers typical of endothelium (CD31, CD105, CD146) and platelets (CD41, CD42b, P-selectin). We also observed a significant increase in the concentration of vWF in AVF stenosis group (p 0.001). In conclusion, the association between DUS and new biomarkers of microvascular injury, such as vWF and endothelial-/platelet-derived MV, represents a new non-invasive diagnostic tool for monitoring AVF stenosis.

REN 5

Comparative Study Between Ultrasound-guided Arteriovenous Fistula Cannulation Versus Conventional Method in Adult Hemodialysis Patients.

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Study: Although arteriovenous fistula is the preferred mode of vascular access for hemodialysis patients, there are a number for barriers for initiation of hemodialysis using it. The most important among them is timely successful cannulation of arteriovenous fistulae by dialysis staff. Unsuccessful cannulation can lead to several complications as well as discomfort for the patients in the form of pain, fear and anxiety. This study in a randomized controlled trial design will compare ultrasound-guided cannulation and standard practice of blind cannulation.
Methods: Twenty hemodialysis from two outpatient dialysis units in Tucson will be enrolled in the study. Patients will be randomized in to two groups, a group where cannulation will be attempted using ultrasound machine and the other group where cannulation will be attempted using standard cannulation technique. Primary outcome will be patient reported outcomes measured using the Dialysis Patient Satisfaction Survey and Patient-Reported Outcome Measurement Information System. All patients will be followed for a total of twelve weeks from the date of enrollment into the study.
Results: There is limited data on patient reported outcomes in patients undergoing cannulation of AV fistula and this study has the potential to prove that ultrasound guided cannulation of AV fistula might be the most preferred method of cannulation by patients. The novel method of training of nurses and technicians prior to cannulation will allow better competency and improve confidence among the nurses and technicians performing the procedure. In addition to above two, this study has the potential to prove the superiority of ultrasound guided cannulations in reducing time to first cannulation and reducing complications related to cannulation of AV fistula and CVC.

REN 7

Paradoxical Increase of Dialyzer Clearance in Viscous Solutions

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Study: The effect of bulk viscosity on diffusion of solutes is well known in theory, but its effect on hollow fiber dialyzer clearance has been overlooked and poorly studied. Therefore, clearance was measured for small solutes in aqueous solution where viscosity was modified by addition of a natural colloid.

Methods: Clearance was predicted (K_{pred}) from tabulated dialyzer membrane transport coefficients (K_0A) determined in crystalloid solution and corrected for relative viscosity $\eta_{rel}=\eta_{test}/\eta$, where η is the viscosity of the crystalloid solution (0.72 mPa.s at 37°C), and where η_{test} is the viscosity of the test solution. Clearance was also measured (K_{meas}) from dialyzer in- and outflow concentrations under different blood flow (Q_b) and operating conditions. The deviation in experimental clearance was quantified as: $\Delta K\%=(K_{meas}-K_{pred})/Q_b$. Viscous solutions were prepared from dialysate and up to 0.4% sodium alginate (Algizoon, biozoon GmbH, Bremerhaven, Germany). Experiments were done with standard equipment and Ca^{2+} free dialysate to avoid coagulation of alginate. High-flux (HF) and low-flux (LF) dialyzers were studied.

Results: Clearance of low molecular mass solutes (urea, lactate, glucose) was measured in n=57 studies with viscosities η_{test} reaching up to 4.7 mPa.s. For all solutes $\Delta K\%$ significantly increased above baseline (One-Sample Analysis, Null-Hypothesis H_0=0 at η_{rel}=1; ***p<0.001, **p<0.01) with increasing η_{rel} (Tab. 1).

Table 1. Relative increase in measured clearance

η_{rel}	1	1.5-2.49	2.5-3.49	4.5-5.49	5.5-6.49	6.5-7.49
$\Delta K\%$	-0.7±9.2	30.9±4.7***	28.1±6.0***	34.8±5.5***	54.0±4.9**	46.8±7.2***
n	27	6	9	6	3	6

K_{meas} was significantly larger than K_{pred} accounting for the viscosity effect on solute diffusivity. This is unexpected when assuming purely diffusive transmembrane solute transport and points to a convective component such as internal filtration which becomes more important as η_{rel} increases and which is more important in HF compared to LF dialyzers.

REN 8

Tablo Hemodialysis System: A Step Towards Personalized Care

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Study: ESKD patients require dialysis devices to adjust to their complex needs. Despite UF rate recommendations of <10 ml/kg/hr, intradialytic hypotensive events where systolic blood pressure (SBP) drops >40 mmHg continues to occur and remain associated with negative outcomes. A hemodialysis device that incorporates and trends BP, UF rate, and patient reported symptoms during and across treatments can personalize a patient's experience. This data in real time could allow meaningful adjustments and prescription changes that could limit future events.
Tablo is an easy to use, fully integrated (water filtration, BP cuff, saline delivery, disposable cartridge) hemodialysis system with over 70 sensors that allow for robust data collection and reporting capabilities utilizing HIPAA compliant 2-way wi-fi communication.
Methods: We looked at treatment data reported from Tablo in an in-center self-care facility. Treatments were assessed for SBP drops of >40 mmHg. Associated UF rate, clinical events (dizziness, headache, high/low BP, low pulse) and patient or nursing intervention were noted.
Results: Eleven patients had a total of 460 treatments. We observed 16% had a SBP drop of >40 mmHg. Of those, 3% reported symptoms and 43% had nurse intervention (adding a note, administering a saline bolus, or changing UF goal/rate).
Individual patient data did not appear to associate UF rate with a higher risk in BP decrease across the population. Evaluation based on UF rate and a change in HR of >5bpm was not predictive across the cohort but did appear to carry a 2-fold higher risk of BP drop in one patient.
Tablo's data capabilities provide a foundation for more personalized prescriptions that could potentially predict and prevent intradialytic events.

REN 9

High Flux Mixed Matrix Membrane with Low Albumin Leakage for Blood Plasma Detoxification

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Study: Current hemodialysis (HD) therapy removes well small sized toxins but removes less effectively middle molecules and protein-bound uremic toxins (PBUTs). This limited removal has been associated to high mortality of patients due to increased cardiovascular events. Earlier we showed that combination of filtration and adsorption on one hollow fiber membrane, the so called mixed matrix membrane (MMM) can achieve removal of range of toxins, including PBUTs, however, these MMMs either had low flux and therefore were not suitable for convective therapies or had high flux but also albumin leakage which is undesired for the HD therapies. In this work, we present for the first time a new generation of MMM which combines high flux with very low albumin leakage.
Methods: Here, we focus on developing a new high flux MMM with no / or very low albumin leakage. We optimise the fiber fabrication protocols to decrease the fiber dimensions, to improve sorbent accessibility and therefore improve the removal of PBUTs. The morphology of new MMMs is systematically investigated using scanning electron microscopy whereas their transport properties are investigated using pure water, model solutions of PBUTs and human plasma spiked with PBUTs. Our results are compared to several commercial membranes currently used in the clinic.
Results: We successfully developed the dual layered MMMs with small diameter and selective inner layer similar to commercial membranes as well as a sorbent-based layer with optimal particle accessibility leading to superior removal of PBUTs. Importantly, the new MMM has high KUF and much lower low albumin leakage in comparison to membranes used currently in the clinic. In the future, we plan to systematically investigate the membranes in vivo with small animals.

REN 10

Use of a Temporary Left Ventricular Support Device as a Bridge to Combined Heart-Liver Or Heart-Kidney Transplant: Pushing the Boundaries of Temporary Support

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Study: In patients with severe cardiogenic shock, temporary mechanical circulatory support has become a viable strategy to bridge patients to heart transplantation. However, end stage heart failure is often also associated with progressive organ dysfunction of the liver or kidney. In the extreme, this dysfunction can require dual organ transplant for definitive management (combined heart-liver (HL) or heart-kidney (HK) transplantation). Here we describe the use of temporary mechanical support to bridge patients to HL or HK transplant at a single, high-volume center.
Methods: All patients who underwent Impella 5.0 placement from 1/2014-10/2018 were identified. From this dataset, patients who underwent placement as a bridge to dual organ transplant were selected, as were those who underwent Impella as a bridge to isolated heart transplant. Demographics and outcomes, including one-year survival, were then evaluated.
Results: Over the five years evaluated, 105 patients underwent Impella 5.0 placement. Of these, 14.3% (n=15) were identified as potential dual organ recipients (11 HK, 4 HL). In total, 80% (12/15) successfully underwent dual organ transplant (8 HK, 4 HL), with one year survival being 100% in both transplanted groups. Among patients undergoing Impella 5.0 placement as bridge to isolated heart transplant (n=33), 78.8% (26) were successfully bridged, and these patients had a one-year survival of 96.2% post-transplant. Demographics and outcomes compared between groups are shown below (see table).

Demographics and End Points

	Dual organ (n=15)	Non-Dual Organ (n=33)	p
Age	55 (SD14)	55 (SD13)	0.94
Male	93% (14)	78.8% (26)	0.21
Intermacs	1 (SD 0.52)	2 (SD 0.61)	0.57
Successful BTT	80.0% (12)	78.8% (26)	1.0
Listed prior to Impella	73.3% (11)	81.8% (27)	0.70
Duration of Impella	24.7 (SD 18.1)	18.2 (SD 16.5)	0.22
Stroke	0% (0)	6.1% (2)	1.0
Acute renal failure	13.3% (2)	15.2% (5)	1.0
Hemolysis	33.3% (5)	15.2% (5)	0.25

REN 11

TGFβ and AMPK Modulate Renal Tubule Epithelial Transporter Transcription and Activity

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Study: Mechanical and metabolic cues independently contribute to renal tubule epithelial development, homeostasis and disease progression. Understanding the mechanisms underlying these processes is critical to the development of a functional bioartificial kidney. Here we observe that activation of metabolic sensor AMP-activated kinase (AMPK) and inhibition of mechanosensitive Transforming Growth Factor β (TGFβ) pathway synergistically attenuate tubule transporter expression and apicobasal fluid transport.
Methods: Primary human renal tubule epithelial cells were obtained from Innovative BioTherapies (Ann Arbor, MI). Cells were maintained in a 1:1 ratio of glucose-free DMEM/F12 media supplemented with 5.5mM glucose. Cells were plated on 12-mm Transwell inserts at 1 x 10^5 cells/cm^2 under static conditions overnight to facilitate cell attachment, then moved to an orbital shaker to achieve a physiological shear stress of 2 dyne/cm^2. After two weeks in culture, cells were supplemented apically with 200mM Metformin, 10μM SB431542, or both for three weeks prior to transport measurements and RNA collection. RNA collection and quantitative polymerase chain reaction was performed using standard methods. Statistical analysis was performed using Matlab.
Results: Metformin and SB431542 synergistically increase cell barrier function as indicated by transepithelial electrical resistance and apicobasal fluid transport. Transcription of Na-H exchanger 3 (NHE3), Na-K-Cl cotransporter 2 (NKCC2), and Renal outward medullary potassium channel (ROMK) increase synergistically with treatments, implying an increase in luminary proton extrusion, ammonium reabsorption and potassium recycling, respectively. Carbonic anhydrase IV (CA-IV) transcription increases suggesting increased CO_2 hydration and HCO_3 transport. Na-H exchanger 4 (NHE4) and Cyclooxygenase 2 (COX2) transcription decrease, suggesting decreased basolateral ammonium extrusion and prostaglandin synthesis.

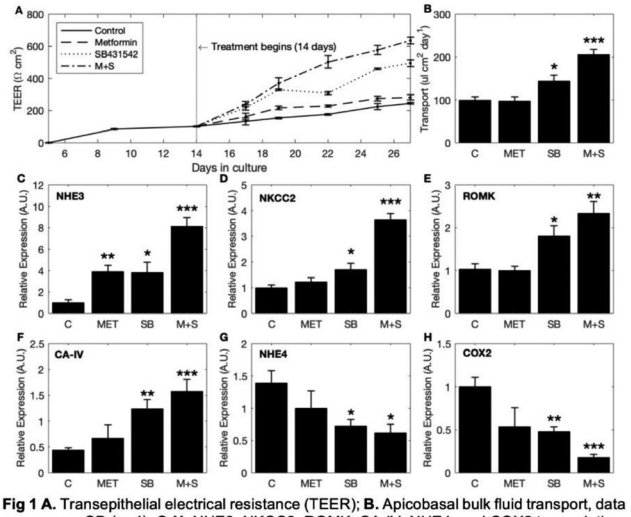

Fig 1 A. Transepithelial electrical resistance (TEER); **B.** Apicobasal bulk fluid transport, data are mean ± SD (n=4); **C-H.** NHE3, NKCC2, ROMK, CA-IV, NHE4, and COX2 transcription, respectively; all data are mean ± SEM (n=4); *p<0.05; **p<0.01;***p<0.001.

REN 12

The Incidence of Hemolysis and Effect on Renal Function After Impella CP Placement

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Study: Hemolysis is a major complication of percutaneous left ventricular assist device (LVAD) Impella (Abiomed, Danvers, MA) placement. The Impella CP is an often-utilized model associated with higher incidences of hemolysis, and hemolysis is a major reason CP is prematurely removed or replaced during a patient's hospital course. However, the effects of intra-CP hemolysis on the renal system have yet to be fully understood. The aim of this study is to analyze the CP's incidence of hemolysis, and its effects on the renal system and overall outcomes.

Methods: This was a single center retrospective analysis. All patients with Impella CP LVAD support between April 2014 and August 2019 were divided into a non-hemolysis group (N=75) and a hemolysis group (N=23). Treatment outcomes, complications, and renal function were analyzed. Hemolysis was diagnosed using Interagency Registry for Mechanically Assisted Circulatory Support criteria. Renal function was measured using serum creatinine (Cr) levels immediately before implantation and at hospital discharge.

Results: 98 Impella CP devices were placed for an average of 2.7±5.6 days. 23 patients (23.5%) were diagnosed with CP-related hemolysis. These devices were placed for an average of 2.82 ±3.27 days. The outcomes of hemolysis over hospital course are shown in Figure 1. The difference in Cr before implant and after explant are shown in figure 2. When comparing hemolysis and non-hemolysis cases, there was no significant difference in Cr change (p=0.50). Though hemolysis is a common complication of Impella CP, most cases are resolved during hospitalization, and may not predict worse renal outcomes.

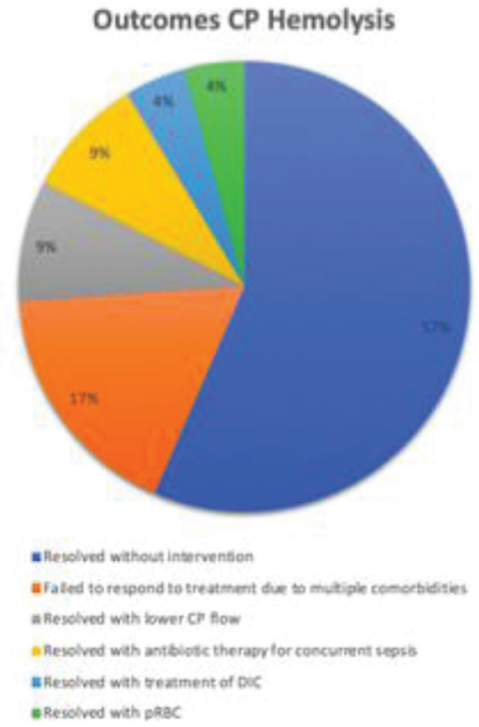

Figure 1: Outcomes of CP hemolysis shows most cases were resolved during hospitalization.

	N	Mean	Median	SD	SE	
ΔCr CP without hemolysis	19	-0.731	-0.500	0.853	0.196	
ΔCr CP with hemolysis	19	-0.975	-1.300	1.425	0.327	P=0.50

Figure 2: There were no significant difference in Cr change between hemolysis and non-hemolysis cases over hospital course (p=0.50).

REN 13

A Novel Automatic Ascites Filtration and Concentration Equipment can Significantly Reduce the Actual Working Time for Ascites Processing During Cell-free and Concentrated Ascites Reinfusion Therapy

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Study: Cell-free and Concentrated Ascites Reinfusion Therapy(CART) is an effective and safe therapy for refractory ascites. However, CART is difficult to perform as ascites processing is a complicated procedure and requires the constant assistance of an operator. Therefore, we developed an automatic CART specialized equipment (mobility CART [M-CART]) that could be used safely with an automatic function to wash a clogged filtration filter and a self-regulation function that allows the autoregulation of concentration ratio. In this study, we performed CART using M-CART and examined the effect of M-CART on shortening the actual working time of an operator.

Methods: We developed and released a novel CART specialized equipment in December 2018. This equipment can wash a clogged filtration filter automatically when the TMP exceeds a set point.

Results: In performing 41 sessions of CART (malignant ascites, 22 sessions; hepatic ascites, 19 sessions) using this equipment in 17 patients, no serious adverse event occurred. An average of 4,494 g of ascites was collected. In this clinical evaluation, the ascites processing flow rate was set at 50 ml/min, and the mean processing time was 111 min. The operator responded on average 3.2 times (3 min 8 s, 2.2% of ascites processing time) to alarm. The mean number and time of automatic washing per session were 0.5 times and 2.0 min, respectively. These results indicate that M-CART can safely and easily process a large quantity of ascites without the constant assistance of an operator.

P1

Design And Fluid-dynamic Analysis Of A Transventricular Axial Blood Pump

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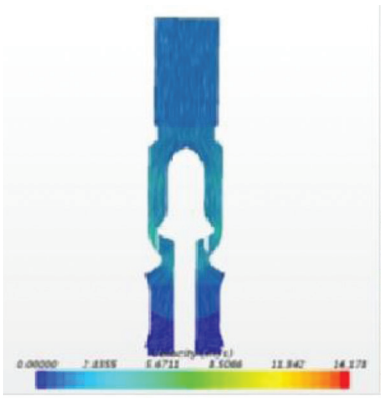
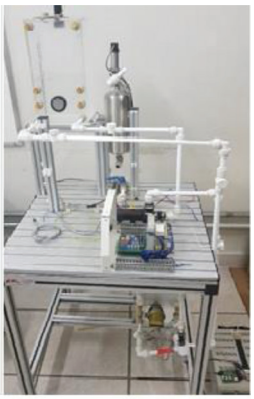
Study: Recent research indicates that the number of patients with heart disease is increasing. Some of these diseases may originate from the heart blood pumping. Some cases a resource like a VAD can be used to assist the heart blood pumping, saving the patient and providing improvement in the clinical condition. In this sense, the objective is to study the geometry of a novel and compact axial pump to be implanted in the left ventricle. This kind of device can be used to assist patients who are awaiting heart transplantation or can also be used as alternative therapy for patients have risks in heart transplantation.
Methods: The model was submitted to computational fluid dynamics (CFD) simulation to evaluate hydrodynamic performance and was printed on a resin 3D printer to perform in Vitro tests comparing the bench model and a computational model obtained. Thus, hydrodynamic performance tests were made using a closed circuit and the pressure, flow, rotation and performance data were recorded.
Results: Graphs were generated showing the pressure and flow data obtained for different rotations of this pump. The designed pump showed satisfactory results and a good performance. However, hemolysis and durability tests need to be carried out to validate the prototype.



CFD Simulation



Cardiovascular Simulator

Fluidodynamic Results	
Pump RPM	Flow [l/min]
4500	3.87
5000	4.37
5500	4.80

P2

Ultrasound Measurement Of Vascular Distensibility Index Based On Edge Detection And Speckle Tracking Using DICOM Data

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Study: This study presents an edge detection and speckle tracking based algorithm to measure vascular distensibility index as the highest percentage of change in vessel diameter during cardiac cycles. Conventionally, due to low resolution of Digital Imaging and Communications in Medicine (DICOM) data, defining the vessel lumen diameter and the distensibility is challenging.
Methods: The Canny edge detector, Vandermonde matrix representation and penalized least squares technique are used to identify vessel lumen edge, track diameter in diastole and systole phases, and calculate the distensibility index. Ten different arteries (one artery per patient) underwent arterial ultrasound examination as part of the pre-operative evaluation before arteriovenous fistula surgery. Three case studies were performed testing the cardiac cycle variability based on DICOM data.
Results: The results demonstrate the effectiveness of the proposed algorithm in automatic edge detection and distensibility analysis on low resolution ultrasound DICOM data. The coefficient of variation (CV) manually conducted from users was 6.14% ±0.03 for peaks and 6.45% ±0.03 for valleys, while the new implementation obtained a CV of 0.4% ±0.001 for peaks and valleys, reducing considerably the variability associated with excessive motion, fluctuations in stroke volume, beat to beat blood pressure changes, breathing cycles, and arm pose.

P3

Mathematical And Experimental Studies On Effect Of Number Of Blades On Centrifugal Pump Used In Left Ventricular Assisted Device (LVAD)

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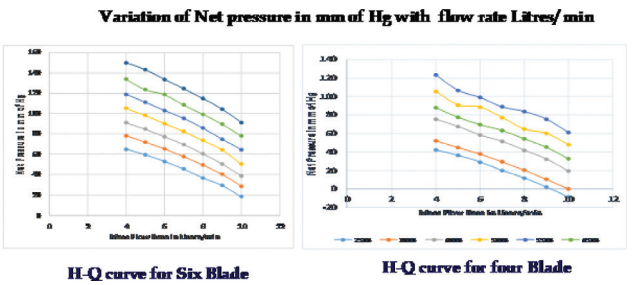
Study: Objective: Effect of number of blades on centrifugal pump used in Left Ventricular Assisted Devices (LVAD) was discussed in this paper. The objective is to obtain optimum number of blades suitable for a pump. Here, a detailed study was made on different parameters that effects the efficiency of a pump.

Methods: Solution Methodology Devices such as an axial flow pump, centrifugal pump, Rota-flow pump, pulsating devices, etc. are used in LVAD. Here, simulation study was performed on centrifugal pump to obtain effect of parameters that influence the efficiency of an artificial heart pump. ANSYS fluent software was used to make the Computational Fluid dynamics (CFD) analysis of the pump. The parameters on pump such as Wrap angle, volume flow rate of blood, outlet pressure and Inlet Pressure head, shear stress, speed, shear rate, velocity of fluid, etc. are considered for the study. A centrifugal pump with casing and an impeller was designed for the purpose. The design includes blood as a working media. The density of the blood is taken as 1060kg/m3 while k-ε turbulence model was used for the study.Detailed simulation and modeling analysis was performed that shows effect of different parameters on the pump. The H-Q curves are generated for various speeds in the range from 2000-8000 rpm for impellers with different number of blades ranging from 2-10 by selecting the appropriate wrap angle.

Results: Experimentation To validate the simulation results, an experimental model was prepared on Mark-forged Mark Two 3D printer. Experiments were performed to generate the H-Q curves by changing the flow rates from 4-6 L/min, Speed 2000-5000 rpm.An In-Vitro set up was installed for testing using water. A LAB-VIEW software was written to capture the data of head and pressure. Pressure sensors and flow sensors are calibrated and used to measure the parameters. As an illustration H-Q curve obtained from the CFD analysis for four and six bladed impeller is shown below.



P4

Effects Of Temperature On *In Vitro* Flow Loop Thrombogenicity Testing Of Biomaterials

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Study: We studied the impact of temperature on in vitro blood flow loop thrombogenicity evaluations. Using room temperature (RT) simplifies the test setup and protocol, whereas testing at body temperature (37ºC) better represents the clinical scenario.

Methods: Donor bovine blood anticoagulated with ACDA was shipped overnight and tested within 24-36 hours of the blood draw. Immediately before starting each flow loop test, the blood was recalcified and heparinized to a donor-specific concentration (0.4 - 1.6 U/mL). The target heparin level was selected based on a static pre-test and verified by a flow loop test with acceptance criteria for thrombus surface coverages of ≤ 10% on the negative control and ≥ 50% on the positive control. For flow loop testing, 26 mL of blood was recirculated through a PVC tubing loop containing a test article for 1 or 2 hours at 200 mL/min using a roller pump at RT and 37°C. Four materials, inserted through the sidewall of the PVC tubing, were investigated in separate loops: negative control (polytetrafluoroethylene, PTFE), positive control (latex), silicone, and high-density polyethylene (HDPE). The metrics for assessing thrombus were percent surface area coverage, thrombus weight, and platelet reduction.

Results: The in vitro flow loop test system was able to effectively differentiate the relative thrombogenicity of the test materials (latex>silicone>HDPE≥PTFE) at both temperatures (**Fig 1**) using bovine blood. However, at 37°C the circulation time had to be increased from 1 to 2 hours and the heparin concentration decreased by approximately 0.2 U/ml to produce acceptable amounts of thrombus deposition on the positive and negative controls when compared to the RT testing. These initial data suggest that performing the test at RT may accelerate in vitro thrombus formation and allow for the comparison of different biomaterials in shorter durations compared to 37°C testing. Additional testing will be performed to verify these results.

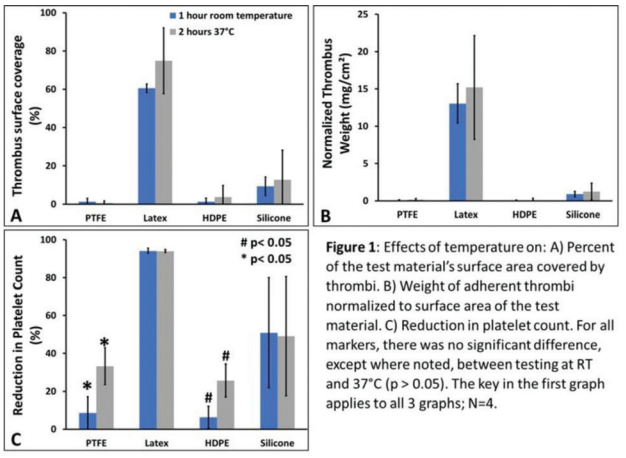

Figure 1: Effects of temperature on: A) Percent of the test material's surface area covered by thrombi. B) Weight of adherent thrombi normalized to surface area of the test material. C) Reduction in platelet count. For all markers, there was no significant difference, except where noted, between testing at RT and 37°C ($p > 0.05$). The key in the first graph applies to all 3 graphs; N=4.

P7

Modeling Of Biventricular Assist Device Support Using Virtual Circulatory Mock Loop

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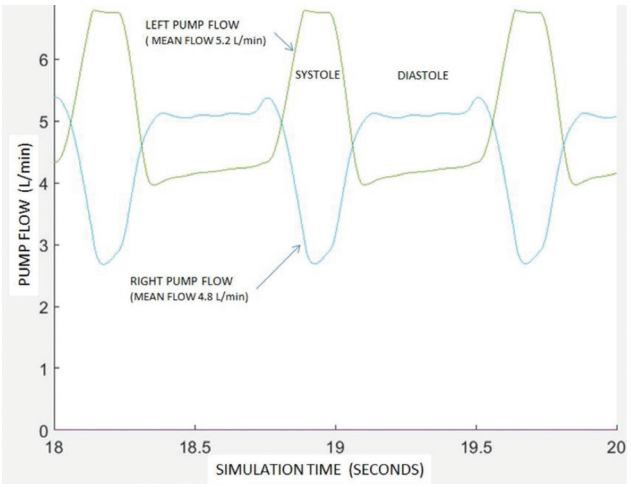
Study: In this early study, we analyzed the hemodynamic environment during simulated biventricular assist device (BVAD) support with various inflow using dual-centrifugal total artificial heart device. The simulation was performed on dynamic system platform, the Virtual Mock Loop (VML), created to model the interactions of a mechanical circulatory support (MCS) pump and patient-specific heart failure conditions.
Methods: The VML was used to input blood flows, pressures, and volumes as they surge through the MCS-supported biventricular heart failure cardiovascular system. The software (MATLAB; MathWorks®, Natick, MA) simulated the hemodynamics using lumped-parameter model, with systemic/pulmonary circulation (values for impedance, systolic and diastolic ventricular compliance, beat rate, and blood volume), and characteristics of the cardiac chambers and valves. BVAD support (run at 5.0 KRPM) was simulated by the VML by inputting BVAD parameters using bench mock-loop values from the Cleveland Clinic pediatric continuous-flow total artificial heart (P-CFTAH). In BVAD configuration, the left/right balancing function of the device based on pressures and flows at the four pump ports, was included. In simulated case scenarios the combinations of left and right systolic heart failure severity were evaluated (Fig. 1).
Results: The BVAD system performed to maintain a systemic flow of 5 LPM (at 5.0 KRPM). The system demonstrated adequate self-regulation and control during BVAD support. The undersized adult BVAD provided support for testing condition as intended. Larger device should be required to cover larger target flows. The simulation-based approach enabled reproducible explorations of the interactions between a variety of heart failure conditions and hemodynamic environments during BVAD support. Fig. 1. BVAD Simulation using P-CFTAH with selected biventricular heart failure case scenarios [severe left and severe right systolic heart failure]. Left and right pump flows are shown.



P8

Meshing Strategies For An FDA Benchmark Blood Pump And The Potential Impact On Solution Accuracy

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Study: In order to assess the state-of-the-art of CFD and its predictive capability for medical devices, the U.S. Food and Drug Administration (FDA) developed two benchmark models for validation. The focus of our novel work is to explore hybrid and multi-block structured meshing strategies and their impact on solution accuracy for one of the benchmark cases, a centrifugal blood pump.
The meshing strategies considered include hybrid viscous unstructured and multi-block structured meshes.
Methods: For the hybrid viscous unstructured mesh, an advancing normal technique starting from a quad-dominant surface mesh generates the required near-wall resolution. During the viscous extrusion process, elements are subject to quality checks allowing the front to stop locally if necessary to improve overall cell quality. The final front of the viscous extrusion transitions to an isotropic tetrahedral off-body mesh that comprises the computational domain surrounding the rotor.
To create the multi-block structured mesh, spatial dimensioning criteria used in the unstructured process served as guidelines for the surface and volumetric blocking topology. Each block of the point-matched structured grid used transfinite interpolation for initialization and elliptic smoothing. The resulting hybrid viscous unstructured mesh contained 7.9M cells and took 3 hours to construct, whereas the multi-block structured mesh contained 8.9M cells and took approximately 50 hours to construct. Caelus v8.04, a derivative of OpenFOAM, was used to perform the simulations.
Results: Results show a minimal impact on overall solution accuracy for this application when comparing the results for each mesh.

P9

Intracranial Aneurysm CFD Study Using Automatically Generated Cartesian Cell And Adaptive Mesh Refinement

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Study: Accurate and cost-effective prediction of hemodynamics and wall shear stress (WSS) of intracranial aneurysm (IA) is essential to evaluate the growth and rupture of IA with least invasiveness, and could provide useful guidance for treatment such as embolization. Computational Fluid Dynamics (CFD) has often been used to model the IA flow. Time cost is usually high to generate good quality IA CFD mesh due to irregular geometry and the flow unsteadiness, and it is even more time-consuming to study the mesh sensitivity or to consider IA deformation. A CFD approach with automatically generated Cartesian cell is adopted to study a patient-specific aneurysm model and corresponding recreated normal model (Fig. 1), with minimum user meshing time. Important flow quantities and WSS are predicted and compared against previous study with other code. And model uncertainties are quantified.

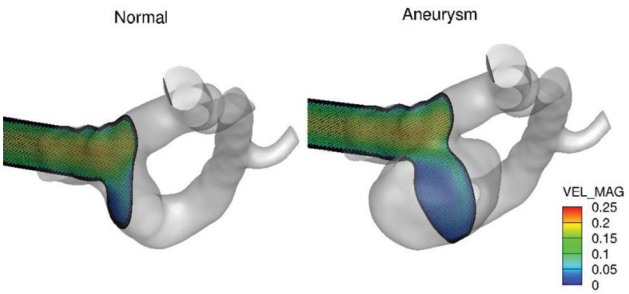

Fig. 1. Model Geometry

Methods: The mesh is generated on-the-fly and the domain volume is strictly conserved. Adaptive mesh refinement is used to refine the mesh autonomously based on local flow gradients. Carreau-Yasuda model is used to account for the non-Newtonian effect of the blood flow. Variable flow rate for multiple cardiac cycles are used and pressure oscillation at outflow is considered. To enhance the WSS prediction, boundary layer mesh around the aneurysm is incorporated. And a membrane model based on pressure difference is used to study the effect of IA deformation on the flow.

Results: Mesh sensitivity study is performed, which suggests 3E6 cells with 30 micron finest cell has enough resolution. 3D transient flow field and WSS for both models are presented. The flow/WSS profile shows correct peak location as well as flow recirculation within the IA. The magnitude of velocity are within 5% error and 10% for WSS compared with previous result. The uncertainty study suggests the credibility of the adopted numerical approach is high compared with other factors such as boundary condition.

P10

Modulation Of Membrane Cholesterol Content Decreases Shear-Mediated Platelet Activation And Aggregation

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Study: Cholesterol is known to modulate cell membrane fluidity and is non-atherogenic at low doses in the non-oxidized form. We hypothesized that platelet uptake of exogenous cholesterol may hold promise as a means of modulating SMPA.

Methods: To modulate platelet membrane cholesterol content, human gel filtered platelets were incubated with a cocktail of 1 mM cholesterol + 10 mM methyl-β-cyclodextrin (MBCD) (enrichment), 10 mM MBCD (depletion), or 3) untreated control for 30 min at 37°C. Platelets were then exposed to shear stress in a hemodynamic shearing device (70 dyn/cm^2, 10 min). Platelet activation was assessed via chromogenic thrombin generation assay. Light transmission aggregometry was used to measure platelet aggregation induced with thrombin.

Results: Modulation of platelet membrane cholesterol resulted in a modest increase of platelet activation. Thus, platelet thrombin generation rate reached 63 and 14 following enrichment and depletion, respectively (Fig. 1A). Conversely, both enrichment and depletion of membrane cholesterol led to a notable decrease of platelet aggregation by 63% and 14% of control level (Fig. 1B). After shear exposure, platelet activation was drastically elevated in control but not in cholesterol-modulated platelets (Fig. 1A). Platelet exposure to shear stress slightly decreased thrombin-induced platelet aggregation in control and cholesterol enriched platelets. While cholesterol-depleted platelets showed minimal aggregability after shear (Fig. 1B).Modulation of membrane cholesterol content resulted in the decreased platelet sensitivity to SMPA. Cholesterol-enriched (but not depleted) platelets maintained their ability to aggregate in response to thrombin. Since membrane cholesterol modulation itself was found to cause modulation of platelet function, further investigation is required to define an optimal dose for cholesterol to be used as a “mechanoceutical” agent limiting SMPA.

P11

Effect Of Viscosity On Mechanical Hemolysis Of Heartware HVAD *In Vitro*

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Study: The HeartWare HVAD (HVAD) is a centrifugal left ventricular assist device (LVAD) used clinically in patients with end-stage heart failure, however, this LVAD still presents adverse complications such as mechanical blood cell damage, leading to hemolysis and thrombosis. Previous experimental and numerical studies reported that the clearance gap between HVAD rotor and housing is altered by speed and blood viscosity. Consequently, both viscous and Reynolds shear damage environment within the pump is affected. The goal of this study is to experimentally isolate the influence of viscosity on the mechanical blood damage caused by the HVAD, independent of the hematocrit.

Methods: A vertical reduced volume *in vitro* flow loop incorporating the HVAD operating was constructed to circulate bovine red blood cells (RBCs) resuspended in a fluid of varying viscosities for a total of 3 hours. Donor bovine blood was washed and resuspended in phosphate buffered saline (PBS) at hematocrit of 30 ± 1%. To increase the viscosity, PBS solution was mixed with dextran-40 to achieve a range of viscosities up to 10 cP, keeping the hematocrit consistent. This enabled experiments to be conducted with altered gap height and shear stress in HVAD while maintaining similar speed and hemodynamic conditions. Hemolysis (plasma free hemoglobin) measurements were recorded and calculated at 1-hour intervals as Normalized Index of Hemolysis (NIH).

Results: Early findings have revealed a positive correlation between hemolysis and blood viscosity at similar hematocrit and flow conditions. This confirms the complexity of mitigating hemolysis and subsequent thrombosis, in HVAD patients who present a wide range of blood viscosities. These results will be used to improve CFD models analyzing the hemolysis in LVADs.

P12

MCS Shear Stress Exposure Induces Platelet Mitochondrial Membrane Depolarization And Scrambling Without Inducing Apoptosis

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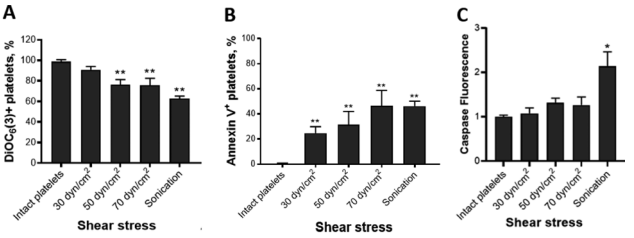

Figure 1. Platelet exposure to low and intermediate shear stress induces dissipation of mitochondrial membrane potential (ΔΨm) and augmentation of phosphatidylserine externalization (PSE), while no caspase 3 activation occurred. In contrast, sonication induced typical proapoptotic phenotype with decrease of ΔΨm, notable PSE and caspase 3 activation: A – the number of platelets accumulating mitochondrial probe $DiOC_6(3)$ indicating intact ΔΨm, B – the number of platelets binding annexin V detecting PSE, C – fluorescence intensity of FITC-DEVD-FMK positive platelets indicating caspase 3 activation. Mean ± SD, n = 6-8, ANOVA: * - $p < 0.05$, ** - $p < 0.01$.

P13

Fast And Effective Method To Conduct Flow Visualization On Blood Pump

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Study: Flow visualization of a left ventricular assist device or any blood pump is essential for the research and development of the device. However, the cost of fabricating a transparent prototype can be prohibitive, especially for research groups in low-resource settings. 3D printed parts offer a cost-effective method for rapid prototyping, however the optical properties of most resins do not provide sufficient visualization of the flow field. Therefore the goal of this research was to develop a methodology to create translucent parts from standard 3D printed parts that are suitable for flow visualization.

Methods: The prototype parts were printed using SLA 3D printing technique with a clear resin, and the supports were removed and sanded with successively finer grit sandpaper. The parts were then rinsed in acetone for 5 seconds then allowed to dry. After assembly, the transparent prototype was inserted into a simple mock circulatory loop, with a small concentration of NaCl to increase the refractive index of the circulating fluid.

Figure 1.1. The translucent 3D printed part (left), transparent part prior to solvent polishing and final transparent part (right.)

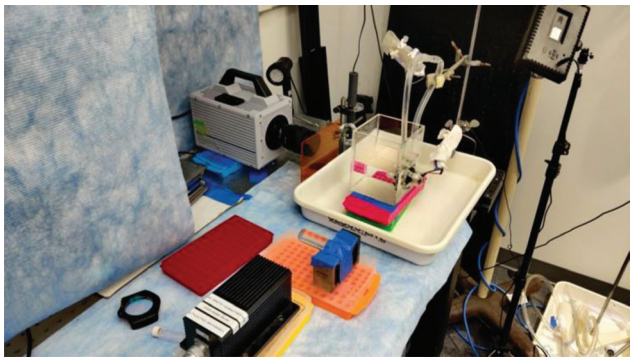


Figure 1.2. Flow visualization setup including laser and a high-speed camera.)

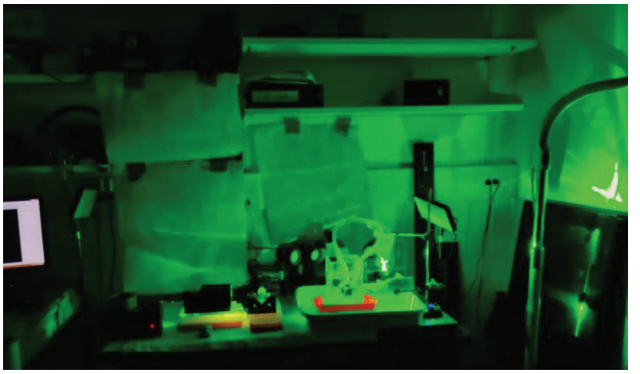
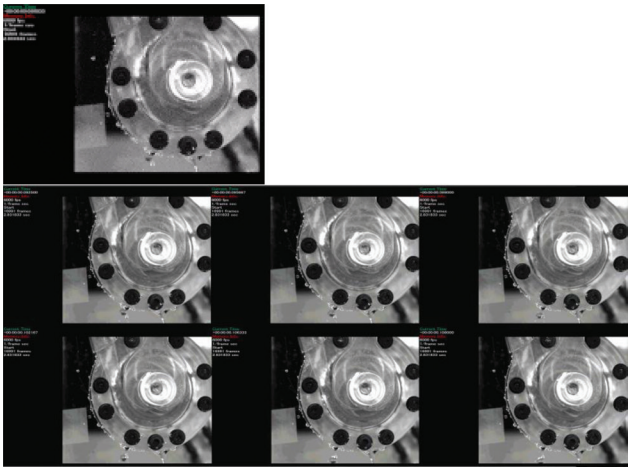


Figure 1.3. Flow viz setup with laser-illuminated.).

Results: A video was recorded at 6000 FPS with the impeller rotating at 4000 RPM with 5 lpm flow rate and 100 mm Hg pressure.



P14

Quality Improvement Project: A Single Center Evaluation Of Patient Survival By LVAD Type

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Study: Although the HeartMate 3 has been shown to have superior outcomes relative to the HeartMate II, studies evaluating left ventricular assist device (LVAD) patient survival by device type have found differing results when comparing the HeartMate II, HeartMate 3, and HeartWare HVAD. The aim of this study was to analyze patient survival by device type at our center for quality improvement.

Methods: We retrospectively reviewed 220 LVAD patients who were implanted from 2006 to 2019. Survival by device type was then compared using Kaplan-Meier analysis, and the Log-rank test was used to obtain the associated p-values. Statistical analysis was performed using IBM SPSS Statistics 26.

Results: Of the 220 patients, 107 (48.64%) received a HeartMate II, 47 (21.36%) received a HeartMate 3, and 66 (30%) received a HeartWare HVAD. The median age at implant for all patients was 57 years. The overall rate of survival at 4.5 years post-implantation was 70.9%. Patients with a HeartMate 3 had the highest survival (85.1%), followed by the HeartWare HVAD (74.2%). HeartMate II patients had the lowest survival (62.6%). The HeartMate 3 had significantly better survival (p = 0.012) compared to the HeartMate II. However, the differences in survival between the HeartWare HVAD and the HeartMate II and HeartMate 3 were not significant (p = 0.171 and p = 0.191, respectively). At our center, the use of the HeartMate 3 has significantly improved survival. We sought to elucidate the differences in survival within our own program patient demographics to offer a quality improvement strategy, if necessary. Although our results mirror previous studies in certain findings, they differ in others due our unique demographic population. Thus, we continue to offer each device on an individual basis.

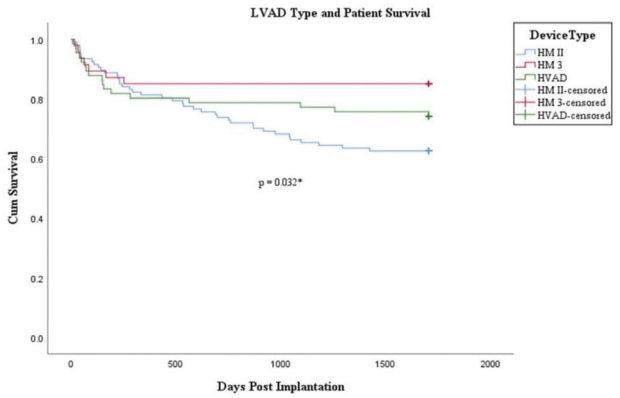

Figure 1: Survival by Device Type

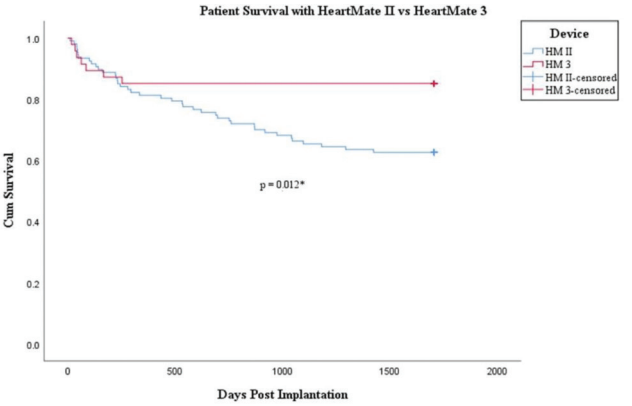

Figure 2: HeartMate II vs HeartMate 3

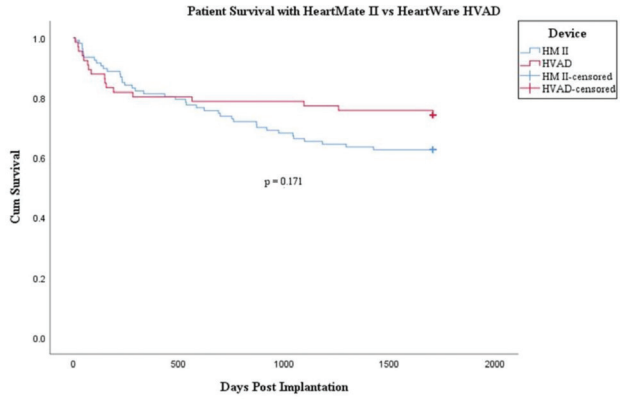

Figure 3: HeartMate II vs HVAD

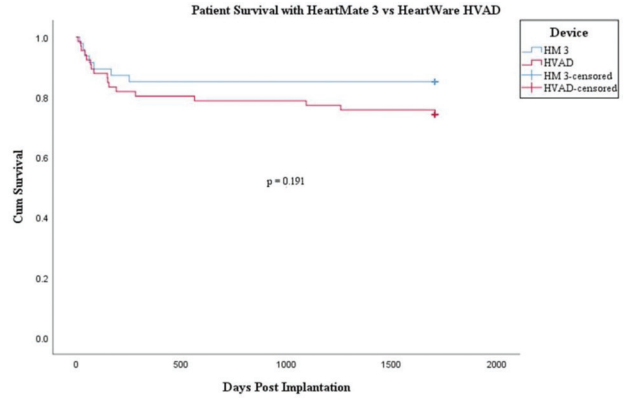

Figure 4: HeartMate 3 vs HVAD

P15

Control Optimization For A Ventricular Assist Device For Pediatric And Adult LVAD, RVAD And BVAD Patients

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Study: A control software as part of the new EXCOR® Active driving unit for the Berlin Heart EXCOR® System was developed. The goal was to realize a small and light mobile driving unit which is able to support all pumps and cannulas for LVAD, RVAD and BVAD even for newborns and children. The challenge was to achieve equivalence to the established stationary Ikus driving unit in terms of pump wash out and blood stress. Further, a good usability, a long lifetime and an acceptable disturbance rejection were major development goals.
Methods: The characteristics of the driving unit, blood pumps and the cardiovascular system where determined experimentally and from literature. A detailed Simulink model and a mock loop for control development were built. The resulting controller moves the piston of a pneumatic cylinder on an optimized trajectory to operate the pump's diaphragm reproducibly and fast while keeping wear and current consumption low. Friction estimation and a nonlinear current control model are part of this loop. Different pressure targets for the opening of an air mass regulating valve ensure easy adjustability by the user and a good rejection of disturbances. Changes in atmospheric pressure and the pump pressure amplitude are captured with multiple sensors and compensated directly. An adapting valve model keeps power consumption low and prevents slow control behavior. Verification was done using state of the art tests: Mock loop in vitro tests, endurance tests and flow visualization (PIV).
Results: In vitro tests show: a) The control software meets its functional requirements. b) All Berlin Heart EXCOR® pumps together with the wide range of cannulas can be operated (0.6 to 5.7 lpm). c) The battery runtime is up to 7 hours. Endurance tests prove: A maintenance interval of 34 million pump cycles can be supported. PIV measurements confirm that fluid dynamics with EXCOR® Active are equivalent to those with the stationary Ikus driving unit.

P16

CFD Simulation To Evaluate Shear Stress Affected By BLDC Motor-gap Geometry For A Blood Shear Stress Device

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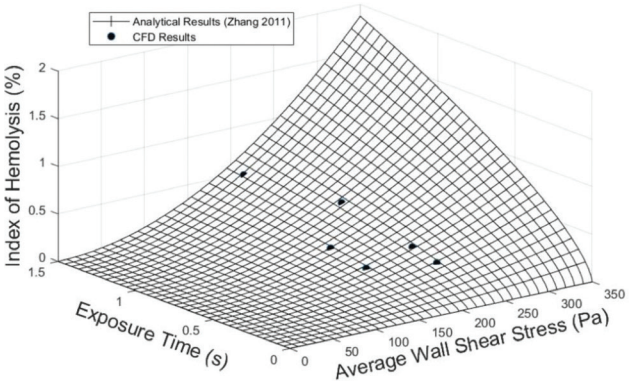
Study: Good hemocompatibility is essential for left ventricular assist device (LVAD) implant; therefore, we proposed a blood shear stress device (BSSD) that features an exchangeable rotor to evaluate the hemocompatibility of each individual LVAD component. An enlarged air-gap BLDC motor coupled with magnetically levitated bearing was proposed as an alternative to a contact bearing, improving BSSD blood compatibility. To facilitate design of the BSSD, a computational fluid dynamics (CFD) model was established to simulate the effect of annular channel geometry on blood shear stress inside the motor gap, ensuring acceptable range for blood exposure time and shear stress.
Methods: A numerical model was established in Fluent R19.0 to simulate the blood flow driven through different air-gap size for the BLDC motor. Two different radial air-gap models (1.35mm vs. 2.35 mm) were evaluated at three different flow rates (100, 200 and 300 mL/min) to simulate the flow patterns through the BLDC motor. Blood flow was defined as Newtonian and incompressible with density of 1050 kg/m^3 and dynamic viscosity of 0.0036 kg/m-s under transient conditions. The inlet was assigned a velocity boundary condition, and the outlet pressure was assigned as zero. The rotational speed was set to 20,000 rpm. A k-omega SST model and SIMPLE solution method were selected with second order upwind transient formulation for accuracy.
Results: As the radial gap in the annulus decreases from 2.35 mm to 1.35 mm, the average wall shear stress increased by 12% at 100 mL/min and 30% at both 200 mL/min and 300 mL/min flow rate. Varying the flow rate from 100 mL/min to 300 mL/min, a decrease was observed in the average wall shear stress for a radial gap of 2.35 mm (from 197.4 Pa to 172.0 Pa). In contrast, there was a negligible increase in the average wall shear for a radial gap of 1.35 mm. This numerical model enables us to rapidly iterate and refine motor geometry in our future work.



P17

Cannula flow physics

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Study: In extracorporeal membrane oxygenation (ECMO), the blood is drained and returned to the patient's circulatory system through cannulae of different sizes and designs. The flow conditions to which the blood is exposed to is non-physiological and may consequently be associated with complications such as thromboembolic and hemorrhagic events. It is important to understand the stresses acting on the blood components, but also the mixing properties of the returned oxygenated blood. These factors vary with cannula design and position in vessel and the concomitant flow conditions. This study focuses on mixing properties in the co-flow of return cannulae of different cannula tip design and position in the vessel.
Methods: Cannula flow was experimentally assessed using Particle Image Velocimetry (PIV) and Planar Laser Induced Fluorescence (LIF). Different co-flow to cannula flow rates and cannula positions were investigated for different cannula tip designs. The fluid was water and the vessel and cannula diameters were relevant for venovenous ECMO.
Results: Due to the relatively high volume flow to ECMO cannula diameter, the resulting cannula jet has a Reynolds number of approximately 7.000, i.e. in the transitional flow range. Homogenous mixing was obtained after 10 - 15 cannula diameters as compared to 25 - 30 cannula diameters needed to fully develop a jet. Increased shear stresses and prolonged residence times were observed close to cannula tip and in recirculation zones, respectively. Moreover, back-flow structures were formed due to the confinement of the geometry (vessel). The results highlight the differences due to cannula design and flow conditions and the potential effect on platelet activation and hemolysis

P18

Outcomes Of Patients Who Had CPR And A Temporary Ventricular Assist Device Before Implantation Of Left Ventricular Assist Device Support

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Study: Patients with severe refractory cardiogenic shock undergoing cardiopulmonary resuscitation (CPR) may require temporary ventricular assist devices (tVAD) as a bridge to durable long-term cardiac support with a left ventricular assist device (LVAD). We sought to analyze our experiences of these patients.
Methods: Between May 2012 and June 2018, in our prospectively collected database, we identified 19 consecutive patients with severe refractory cardiogenic shock undergoing CPR who received tVAD support from 6 hours up to 13 days before LVAD implantation.
Results: Nineteen men, aged 54±10 years, developed cardiogenic shock in the hospital, required CPR, and underwent tVAD support before LVAD implantation. The duration of CPR before tVAD was >10 minutes in all except in one patient (<5 min). Fifteen patients received only one form of tVAD support: 6 patients received extracorporeal membrane oxygenation (ECMO), 6 intra-aortic balloon pump (IABP), 2 Impella, and 1 TandemHeart before LVAD. The other four patients had multiple tVAD: 1 had an IABP followed by ECMO; 2 had an Impella followed by ECMO; and 1 had an Impella (ABIOMED) followed by TandemHeart (Livenova). The HeartMate II (Abbott Laboratories) was implanted in 11 patients, and 8 received the Heartware device (Medtronic). Four patients (21%) died within 30 days after LVAD implantation. 13/19 (68%) survived over 1 year. Three died on LVAD support after 535, 692 and 1072 days, respectively; 4 underwent heart transplant after 554±211 days on LVAD; and 6 were still on LVAD support from 1071 to 2395 days (Figure 1).
Conclusions: In patients with severe refractory cardiogenic shock undergoing CPR, the tVAD implant seems to allow these critically ill patients to stabilize prior to undergoing LVAD implantation and achieve long-term survival.

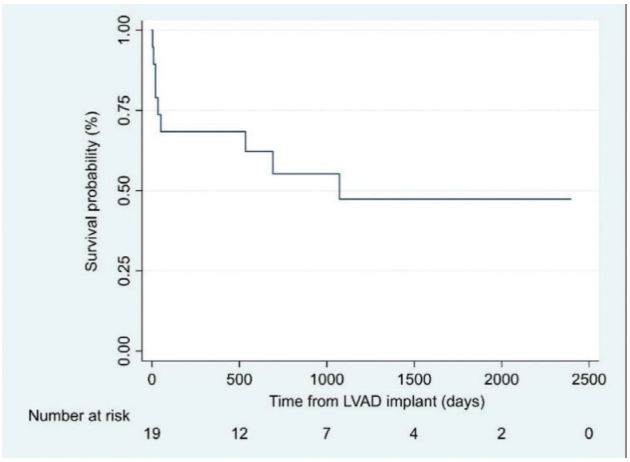

Figure 1. Kaplan-Meier survival curve for patients undergoing CPR and tVAD before LVAD implantation

P19

Cytal Wound Matrix Device May Reduce Driveline Infection Rates In Left Ventricular Assist Device Patients

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Study: Driveline infection is still one of the most common complications in patients on left ventricular assist devices (LVAD) support. Cytal wound matrix device (ACell Inc.) is comprised of a naturally-occurring urinary bladder matrix (UBM), which plays a role as a non-crosslinked wound management scaffold that enables cellular infiltration and neovascularization. We hypothesized that improving the cellular healing process around the driveline using Cytal might help to reduce the driveline infection rate.
Methods: From April 2018 to July 2019, 56 patients underwent LVAD implantation, and the Cytal wound matrix device was implanted in 8 patients around the Dacron velour portion at the driveline exit site. The driveline infection data were collected for all patients who survived >3 months.
Results: Six men and 2 women, aged 41±17 years, had the Cytal implanted during LVAD implantation (5 Heartware, 2 Heartmate 2 and 1 Heartmate 3). Average follow-up time was 15±5 months with a median of 18 months (range 7 -22), and a total follow-up of 10 patient-years. None of the patients in the Cytal wound matrix device group had driveline infection in comparison to 6 driveline infections among the other 48 patients (39 men, 9 women; age 52±13 years) from the same period with a follow up 13±6 months. **Conclusion:** This report on a small number of patients using a scaffold stimulated cellular wound healing response and neovascularization that might improve driveline infection rates. Further prospective randomized studies are warranted.

P21

A Novel 4-Step Assessment Of Myocardial Recovery Prior To LVAD Explant

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Study: Myocardial recovery (MR) occurs in 21% of the patients with nonischemic cardiomyopathy (NICM) who require LVAD, with ~1% leading to explant (per INTERMACS). Freedom from recurrent heart failure(HF) requiring reimplantation/transplantation is 74% at 3.5 years. We present a novel assessment strategy for sustainability of MR in addition to echocardiography(Echo), cardiopulmonary exercise test(CPET)and right heart catheterization(RHC).

Methods: A case series of 2 patients who were assessed by 4-step approach for proposed LVAD explant. 1st 3 steps include Echo(target EF>45%,LVEDd<6cm and LVEDs<5cm), CPET(VO2max>16ml/kg/min) and RHC (PCWP<15 mmHg and CI >2.2 L/min/m2). 4th step requires ICU admission and reduction in LVAD speed (HM2 6000rpm, HM3 4000rpm) to achieve zero net forward flow for >96 hrs, while patient remains on IV heparin. Continuous hemodynamic monitoring is performed at rest and post ambulation targeting mean PCWP<15mmHg and CI>2.2L/min/m2, as required criteria to explant.

Results: Case 1 and 2 were 45 and 70 years old male who had LVAD for cardiogenic shock with underlying NICM and INTERMACS profile 2 and 1, respectively. Pre & Post-Implant characteristics are shown in Table 1. MR was assessed by 4-Step approach(Table 2). After successful explant a structured approach (Echo,RHC, CPET,NTproBNP) was used to asses post-explant sustainability of MR. In Case 1, EF remained >50% with NTproBNP range 119-252pg/ml at 18 months. RHC & CPET at 1 year showed PCWP 15mmHg & Peak VO2 23ml/kg/min. Case 2 maintained EF >55% and NTproBNP range 170-274pg/ml at 1 & 3 months. There were no reported HF hospitalization and both patients continue to have NYHA class I HF symptoms. **Conclusion:** Novel 4 step assessment of MR prior to LVAD explant is an easy tool, providing additional data while patient is on minimal support for a prolonged period. We also demonstrate that it is also safe to perform prolonged(>96hours) LVAD low-speed operation with zero net flow to comprehensively assess for myocardial recovery.

	Case1 (HM3)		Case 2 (HM2)	
Parameters	**Preimplant**	**6-month Post Implant**	**Preimplant**	**6-month Post Implant**
LVEF %	20	55	10	55
LVEDd (cm)	6.4	5.2	6.0	3.9
LVEDs (cm)	5.7	3.8	4.9	2.9
PCWP (mmHg)	23	10	33	5
NTproBNP (pg/mL)	4576	78	-	253
BNP (pg/mL)	-	-	809	-

Table 1. Preimplant and 6-Month post implant parameters (LVEDd LVEDs, Left ventricular end diastolic dimension in (d) diastole or (s) systole; PCWP, pulmonary capillary wedge pressure; LVEF, left ventricular ejection fraction)

	Case 1	Case 2
1.Echocardiography		
LVEF %	60%	55%
LVEDd (cm)	5.26	4.49
LVEDs (cm)	4.07	3.15
2.RHC		
PCWP (mmHg)	8	6
CI (L/min/m2)	2.2	2.2
3.CPET		
Peak VO2 (ml/kg/min)	20.4	17.3
4.Net Zero LVAD flow for >96 hours		
PCWP (mmHg)	14	10
CI (L/min/m2)	2.8	2.6

Table 2. 4-Step Assessment of Myocardial Recovery (CI, cardiac index; peak VO2, peak oxygen uptake)

P22

Mechanical Circulatory Support In Takotsubo Cardiomyopathy

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Study: Mechanical circulatory support (MCS) has been proposed to carry shorter recovery time and improved survival in cardiogenic shock (CS). We present a case of Takotsubo cardiomyopathy (TTCM) where percutaneous MCS served as a bridge to recovery.
Methods: A 73 year old female with recent diagnosis of Non-Hodgkin's lymphoma and planned chemotherapy 1 week after her presentation of chest pain that lasted for 30 minutes. Electrocardiogram showed anterior STEMI. She reported tremendous psychosocial stress due to the lymphoma diagnosis. Coronary angiogram showed normal coronary arteries. Echocardiogram revealed apical akinesis with spared left ventricular base and an ejection fraction of 15%. Findings suggestive of apical ballooning syndrome or TTCM. Her hemodynamic state deteriorated in the next 24 hours due to deteriorating clinical status that needed immediate MCS.
Results: An Impella CP™ device was inserted to provide hemodynamic support at a flow rate of 3.3 L/min. Within 5 days, the patient showed signs of improvement and MCS was weaned off. The patient fully recovered and was able to undergo successful chemotherapy induction leading to successful remission of her. Of note, ProBNP at time of admission was 59,081 pg/ml, which decreased to 613 pg/ml at the time of discharge from the hospital. **Discussion and Conclusion:** The use of percutaneous MCS in the setting of deteriorating CS due to TTCM has been shown to be an effective support modality in select patients. Eight cases have been reported in the literature where MCS with Impella™ was used. Six of which were case reports, and a case series that included two patients with TTCM. The main selection criteria to place patients on MCS in the setting of TTCM include early identification of CS, absent primary valvular disease and LVOT obstruction, and relatively preserved kidney function. The presentation of TTCM often don't present in CS, and can be supported often times with conservative measure. CS can result from TTCM, and further study on optimal support measures should be done.

P23

Outcomes Of Left Ventricular Assist Device Support In Patients With Peripartum Cardiomyopathy

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Study: Peripartum cardiomyopathy (PPCM) is a significant cause of pregnancy-related morbidity and mortality. Guideline directed medical therapy remains the mainstay of management. In refractory cases, left ventricular assist devices (LVADs) have shown to be effective treatment as a bridge to recovery, destination therapy, or transplant. We aim to describe patient complications and outcomes in a series of patients with refractory PPCM managed with LVADs.
Methods: A single center retrospective review of patients with LVADs from 2010 through 2019. Only the first LVAD supporting native heart in PPCM patients were included.
Results: Of the 1036 patients screened, we identified 13 patients with age of 33±6 years and BMI of 34±11.3 Kg/m^2. 11 patients were African American and 2 were Caucasian. The LVADs implanted were HeartMate II (6 patients), HeartMate III (1 patient) and HeartWare HVAD (6 patients). The LVADs were implanted as bridge-to-transplant in 6 patients and destination therapy in 7 patients. Complications and outcomes are summarized in Tables 1 and 2 respectively. Mean time on the device was 20±12 months.

Table 1. Complications in PPCM patients with LVAD support

Complications, N (events/100 patient-months)	
Major bleeding requiring transfusion	5 (2.68)
Stroke	1 (0.43)
LVAD driveline infection	9 (6.06)
Bacteremia/possible device infection	4 (1.44)
LVAD thrombosis/hemolysis	5 (1.61)
Driveline malfunction	1 (0.42)

Table 2. Outcomes in PPCM patients with LVAD support

Outcomes, N	
Alive on device	2
Orthotopic heart transplant	2
LVAD explant	4
LVAD exchange	2
Death	1
Lost to follow up	2

Conclusion: Peripartum cardiomyopathy patients on LVADs represent a very small population (~1% of LVAD patients in our center), limiting knowledge of complications and outcomes. In our series, outcomes are comparable to the general LVAD population. More research is needed to describe risk factors and guide therapy in this subgroup.

P24

Composite Pulmonary Vascular Impedance Measured Pre- Or Perioperatively Indicates No Difference In RV Afterload For Patients With RV Failure Post LVAD Implant

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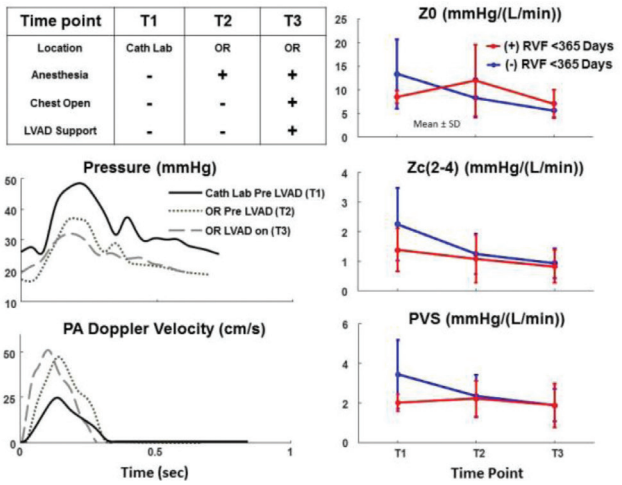
Study: Approximately 20% of LVAD recipients have RV Failure (RVF) post-implant. Pulmonary vascular impedance (PVZ) describes RV afterload in the frequency domain, and has not been studied in these subjects. Using standard of care (SoC), asynchronous, pulmonary artery pressure (PAP) and flow (PAQ) waveforms, we calculated a composite (c)PVZ. We sought to determine if there are differences in cPVZ when grouped by RVF outcome in the 1st year post implant.

Methods: Re-digitized waveforms of PAP acquired via Swann-Ganz catheter, and PAQ obtained via pulsed wave Doppler velocity and PA diameter were captured at 3 timepoints: T(1), Retrospective, pre-operative with patient conscious; and T(2) and T(3), both prospective with patient anesthetized, and either pre-sternotomy or chest open with LVAD, respectively (Fig.). Harmonics (z) of waves were calculated by Fast Fourier Transform (FFT). cPVZ(z) was calculated as FFT(PAP)/FFT(PAQ). Total pulmonary resistance Z(0); characteristic impedance Zc, mean of cPVZ(2-4); and vascular stiffness PVS, sum of cPVZ(1,2), were compared at T(1,2,3) between +/-RVF groups. Mann-Whitney U test with significance defined as $p < 0.05$ was performed.

Results: Data were obtained for 51 recipients (8 female; 27 ischemic) age 57±12 yrs. Within 365 post-op days (POD), 9 subjects had +RVF determined by ICD10 code or expert adjudication; 6 others died and 5 received transplant before POD 365, both -RVF. Standard hemodynamics were not significant. Median time between PAQ and PAP at T1 was 2.7 days (range .02-60) and time to implant from last procedure was 3 days (range 1-37); median time between captures was .034 minutes (range .05-65) for T2 and T3. Z0, Zc, and PVS between groups were not significant at any T. (Fig.)

In conclusion, a cPVZ calculated from SoC measures indicates no difference in RV afterload for +RVF patients post-implant. Focus should be placed on cardiac function in these subjects moving forward.



P25

The Case For Bridge Strategies With Ambulatory Temporary MCS In Patients With Advanced Heart Failure And Resectable Tumors

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Study: Acute on chronic systolic heart failure with cardiogenic shock often have comorbidities that might preclude patients from transitioning to remission or replacement therapies. We present a case of a patient with intra-abdominal neuroendocrine tumor and cardiogenic shock bridged to abdominal tumor resection with the use of a high profile ambulatory temporary microaxial flow pump.

Methods: 65 year old male with ischemic cardiomyopathy with ejection fraction of 15%, ventricular tachycardia and advanced systolic inotrope dependent heart failure was referred for evaluation of advanced therapies in heart failure. He was found to have an adrenal mass presumably pheochromocytoma based on imaging and biochemical data, halting transitions towards left ventricular (LV) assist device/cardiac transplant. Patient received catecholamine blocking agents (doxazosin/beta blockers) and experienced progressive deterioration leading to hospitalization for LV predominant hemometabolic cardiogenic shock refractory to escalating inotropes and counterpulsation. He was transitioned to Impella 5.0 as a bridge to decision.

After hemodynamic and end-organ stabilization, a multidisciplinary team decided to proceed with abdominal tumor resection via laparotomy on Impella 5.0. He underwent complex surgery with resection of 4 cm adrenal mass and right nephrectomy as the mass was adherent to renal vessels. The mass was histologically interpreted as a paraganglioma without vascular invasion and with free margins suggesting low likelihood of metastatic disease. The patient was then deemed eligible for replacement therapies and continued care as per standard protocol. HeartMate 3 left ventricular assist device was then later implanted.

Results: We report, to our knowledge, the first case of a patient bridged from abdominal tumor resection to replacement therapies in advanced heart failure with the use of high profile ambulatory temporary microaxial flow pump.

P26

Occlusion Of Left Ventricular Inflow Cannula By Distorted Inter-Ventricular Septum Causing Reduction In LVAD Flow And Ventricular Tachycardia

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Study: There is no consensus on coronary revascularization prior to implantation of durable left ventricular assist device (LVAD). We describe a patient with ischemic cardiomyopathy treated with a Heartmate 3 LVAD who developed ischemic right ventricular (RV) dysfunction leading to pump failure and recurrent arrhythmia. We consider whether revascularization could have improved outcome.

Methods: A 64-year old woman was admitted with an acute coronary syndrome. Coronary angiography demonstrated chronic occlusion of the right coronary artery, 90% stenosis of both left anterior descending (LAD) and dominant circumflex (Cx) arteries. Echocardiography confirmed severely impaired left ventricular (LV) function and a mildly impaired RV. MRI showed minimal LAD viability. The prohibitive risk of acute revascularization led to LVAD implantation. Following surgery, the patient improved with good LVAD flows and no alarms. However, she developed low-flow alarms with mobilization on post-operative day (POD) 7. Echocardiography demonstrated a decompressed LV and a dilated RV, causing bowing of the interventricular septum and occlusion of the inflow cannula of the LVAD (see image 1). Each episode of obstruction caused ventricular tachycardia and hemodynamic compromise. Despite reduction in the LVAD speed, fluid resuscitation and escalating doses of milrinone, the patient did not recover and died on POD 8.

Results: We speculate that the deterioration in RV function resulted from acute occlusion of the Cx which provided collaterals to the RV. Additional procedures at the time of LVAD implantation are associated with poorer outcomes; however, there may be benefit in revascularization of the RV, in an attempt to preserve function.

Awareness of acute ischemic RV dysfunction should prompt consideration of revascularization at the time of LVAD surgery. Recognition of this complication may have prevented pump failure in our patient.

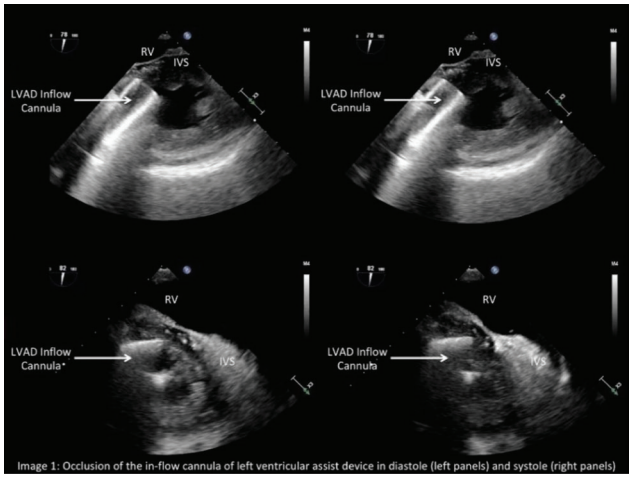

Image 1: Occlusion of the in-flow cannula of left ventricular assist device in diastole (left panels) and systole (right panels)

P27

Risk Factors For Success - Technology Versus Medical Management

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Study: We present a case of a 74-year-old man with a history of dilated cardiomyopathy, CKD, ICD implant, ventricular tachycardia, mechanical AVR and MVR.

The patient was evaluated in 2015 for worsening fatigue, dyspnea on exertion and lower extremity edema. Assessment at that time found NYHA Class IV symptoms, labile renal function, hypotension, low cardiac output, elevated BNP, resistance to diuresis, and LVEF of 24% with moderate MR and severe TR. His LHC was unremarkable. Due to poor renal function, the patient was not a candidate for transplant but was deemed appropriate for LVAD as DT. He was admitted and started on inotropes after a diagnosis of cardiogenic shock. He underwent implantation of a HM3 LVAD, biologic AVR and MVR, TV repair, and ASD repair in 10/2015.

Methods: Hospital discharge instructions included the directive to call the VAD team at a direct line with any issues. Early in the first year, the patient had 3 driveline communication failure alarms resolved by the VAD coordinator who was able to promptly direct modular driveline and controller exchanges. He has since had no interventions to the device and has never missed an appointment. At each clinic visit, controller care and infection control precautions are reinforced and the device is interrogated to adjust settings, if needed. Frequent remote checks to the patient are conducted by the VAD team.

Results: This case is unique in that the patient has had no unplanned readmissions in the 4 years post-implant. To our knowledge, this is the longest readmission-free case after HM3 implantation. Excellent social support, adherence to medical therapy, early intervention to device alarms, remote care, and the modular nature of the HM3 device are factors that contribute to this patient's success.

P28

In Vitro **Hemocompatibility Evaluation Of The Heartware Ventricular Assist Device Under Systemic, Pediatric And Pulmonary Support Conditions**

C. Chan[1], *K. Ki*[2], *I. Chu*[2], *J. Rolls*[2], *S. Morris*[1], *T. Lee*[2], *S. Bindorfer*[1], *J. Pauls*[1], *I. Idachi*[3], *J. Fraser*[4]; [1]*School of Engineering and Built Environment, Griffith University, Brisbane, AUSTRALIA,* [2]*Faculty of Medicine,, The University of Queensland, Brisbane, AUSTRALIA,* [3]*Division of Congenital Heart Surgery,, Texas Children's Hospital, Houston, TX,* [4]*Faculty of Medicine, The University of Queensland, Brisbane, AUSTRALIA.*

Study: The development of right ventricular assist devices (RVADs) and pediatric ventricular assist devices (pediatric VADs) have significantly lagged behind compare to adult use left ventricular assist devices (LVADs). Currently there are no FDA-approved implantable devices specifically designed for RVAD and pediatric VAD. As an alternative, the HeartWare Ventricular Assist Device (HVAD) intended to be used for adult's systemic support, is increasingly used off-label for pulmonary and pediatric support. Due to different hemodynamics and physiology, however, the HVAD's hemocompatibility profiles can be drastically different when used in the pulmonary circulation or in children, compared to its intended usage state, which could have a direct clinical and developmental relevance. Taking these considerations in mind, we sought to conduct *in vitro* hemocompatibility testing of HVAD in systemic, pediatric and pulmonary support conditions.

Methods: Two HVADs coupled to custom-built blood circulation loops were tested for 6 hours using bovine blood at 37°C under systemic, pediatric, and pulmonary flow conditions (flow rate = 5.0, 2.5 and 4.5 L/min; differential pressure = 100, 69, and 20 mmHg, respectively).

Results: Normalized index of hemolysis for systemic, pediatric and pulmonary conditions were 0.0083, 0.0039 and 0.0017 g/100L, respectively. No significant difference was seen in platelet activation for these given conditions. High molecular weight von Willebrand factor multimer degradation was evident in all conditions ($p<0.05$).

In conclusion, alterations in the usage mode produce substantial differences in hemocompatibility of the HVAD. These findings would not only have clinical relevance but also provide an insight into future RVAD and pediatric VAD development.

P29

Outcomes Of Extracorporeal Membrane Oxygenation In Multi-Organ Transplantation

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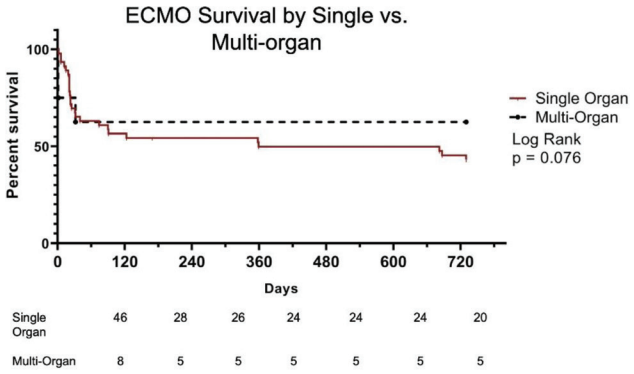
Study: In the United States the number of patients undergoing multi-organ transplantation has doubled in the past 6 years. These transplants involve critically ill patients who may require extracorporeal membrane oxygenation (ECMO) support. While extensive research been conducted on ECMO use in single-organ transplantation, no research to date has examined the efficacy of ECMO in patients undergoing multi-organ transplantation. There is a need to better understand the value of ECMO therapy in the growing multi-organ transplant patient population.

Methods: We retrospectively reviewed 342 patients requiring ECMO support at our institution from 2007-2019 and identified 54 patients who underwent organ transplantation. A total of 46 patients were single-organ transplants and 8 patients underwent multi-organ transplantation. The multi-organ transplant cohort comprised 7 patients who received heart-lung and 1 patient who received heart-liver transplantation (5 venoarterial (VA), 1 venovenous (VV), 1 VV-VA, 1 VV-VAV). The single-organ transplant cohort was comprised of 24 lung (17 VV, 4 VA, 3 VV-VA) and 22 heart transplants (22 VA).

Results: Mortality on ECMO for multi-organ versus single-organ was 38% versus 37% respectively ($p = 0.98$). The mortality at 1 year was 63% in multi-organ and 50% in single-organ ($p = 0.79$). The 2-year survival was 63% in multi-organ and 43% in single-organ ($p= 0.47$). Multi-organ patients were in the ICU for an average of 41 days (16-66) versus 39 days (19-59) for single-organ transplant ($p = 0.93$).

Among patients that require ECMO support, there are no significant differences in outcomes between patients with multi-organ compared to single-organ transplantation. The use of ECMO support for multi-organ transplantation is a safe and effective means to ensure long-term survival.



P30

Driveline Damage And Repair In Continuous Flow-left Ventricular Assist Devices: A Systematic Review

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Study: With mounting time on continuous-flow left ventricular assist device (CF-LVAD) support, patients may sustain damage to the device driveline. Outcomes associated with external and internal driveline damage remain poorly documented. We sought to combine the existing evidence in a systematic review.

Methods: Electronic search was performed to identify all relevant studies published. 15 studies were selected for analysis comprising 55 patients who suffered CF-LVAD dysfunction due to driveline damage. Patient-level data were extracted and pooled for systematic review.

Results: Median patient age was 51 years [IQR 42, 60] and 85.5% (47/55) were male. One patient was supported on HeartWare HVAD, while the remaining patients (54/55) were supported on HeartMate II LVAD. Driveline damage was more commonly reported at an internal location as opposed to an external location [69.1% (38/55) versus 30.9% (17/55), $P < .01$]. Median time to driveline damage was 1.9 years [IQR 1.0, 2.5]. The majority of patients presented with some form of CF-LVAD alarm [94.5% (52/55)]. Initially, 14.5% of patients (8/55) underwent an external repair of the driveline and 5.5% (3/55) were treated with rescue tape. 5.5% of patients (3/55) were placed on an ungrounded cable, indicating a short-to-shield event occurred. Furthermore, 49.1% of patients (27/55) underwent CF-LVAD exchange, 5.5% (3/55) were weaned off the CF-LVAD to explantation, and 5.5% (3/55) underwent heart transplantation. The median length of hospital stay was 12 days [IQR 7, 12]. The 30-day mortality rate was 14.5% (8/55). There was no significant difference in the 30-day mortality rate between patients who experienced external versus internal damage [11.8% (2/17) versus 15.8% (6/38), $P > .99$]. Driveline damage was more commonly reported at an internal location as opposed to an external location. Despite being a well-recognized complication, mortality still appears high.

P32

Towards Standardizing Flow Performance Tests For Ventricular Assist Devices

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Study: Ventricular assist devices (VADs) are a growing treatment option for those with advanced heart failure (HF). Complex HF etiology coupled with the dynamic nature of the cardiovascular system warrants the need for additional pre-clinical assessments of VAD-patient interactions. The current VAD standard (ISO 14708-5) provides general testing guidelines but would benefit from quantifiable metrics to characterize recent technological advancements that affect pump performance. Thus, we aim to establish consensus test conditions for evaluating the flow performance of VADs by initiating an interlaboratory study. The objective of this research is to identify and simulate different target HF hemodynamic conditions requiring VAD therapy, in vitro.
Methods: Based on observations from past clinical studies and with input from cardiologists and cardiac surgeons, critical HF profiles requiring different levels of VAD support were identified as target test conditions. The hemodynamics for the test conditions were characterized using a mock circulatory loop (MCL) comprised of the left heart chambers and valves coupled with pressure and flow sensors.
Results: As shown in the figure, three pathophysiologic conditions tested using the MCL were cardiogenic shock with and (a) without VAD support, (b) left ventricular hypertrophy with hypertension, and (c) coronary artery disease. The diagnostic indices and pressure waveforms were distinct for each pathophysiologic condition and different than those of a healthy adult [HR: 72 BPM, CO: 5 L/min, systolic/diastolic pressures: 120/80 mmHg, LA pressure: 9 mmHg]. Testing the full range of VAD support modes in conjunction with target HF conditions provides valuable information for assessing the device flow performance prior to clinical use. The test plan presented here is the basis for an upcoming interlaboratory study involving experts from around the world to develop a consensus protocol for evaluating VADs using representative NYHA Class IV HF profiles.

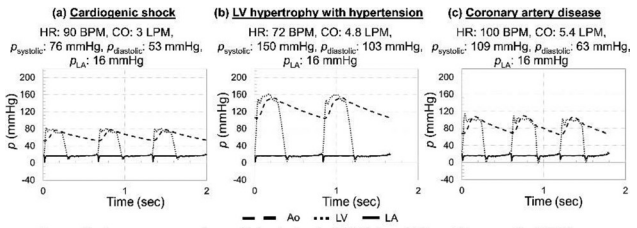

Figure. Cardiac pressure waveforms obtained using the MCL for target HF conditions requiring VAD therapy. (HR – heart rate, CO – cardiac output, *p* – pressure, Ao – aorta, LV – left ventricle, LA – left atrium)

P33

Normalization Of Coagulation With Four-factor Prothrombin Complex Concentrate And Repeat Dosing Of Alteplase For HVAD Pump Thrombosis

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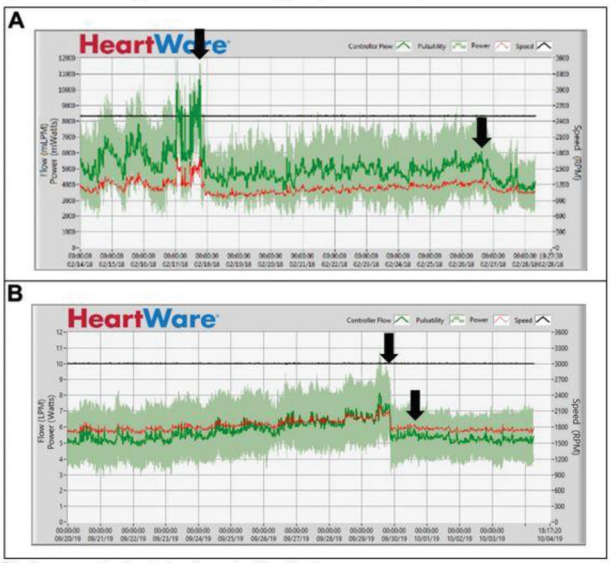
Study: Despite advances in design and hemocompatibility, pump thrombosis remains a significant cause of morbidity for patients implanted with durable left ventricular assist devices (LVAD). Pharmacologic fibrinolysis may be preferred as initial therapy because it obviates a surgical procedure. Yet, it historically has been associated with a significant risk of secondary intracerebral hemorrhage (ICH).
Methods: We implemented a novel protocol to treat HVAD pump thrombosis and minimize risk of ICH that consisted of the following: initiation of a non-titrating heparin infusion at 500 units/hr; normalization of international normalized ratio (INR) by giving a flat dose of 1,000 units of four-factor prothrombin complex concentration (4F-PCC); and administration of alteplase as a 10 mg bolus followed by 40 mg given over 3 hours.
Results: Two patients underwent treatment with the above protocol for presumed HVAD pump thrombosis based on clinical signs of hemolysis and elevations of power on log-file analysis. One patient was 2 months from HVAD implant and the other 13 months. Both patients had subtherapeutic INR in the preceding weeks. Following administration of alteplase, log-file analysis demonstrated immediate resolution of power elevations (Fig. 1). Both patients had a subsequent rise in power requiring repeat alteplase dosing. No bleeding or thrombotic events occurred with treatment. One patient underwent heart transplant a month after treatment and is doing well; the second patient is stable on HVAD support 4 months following alteplase. Combining 4F-PCC to temporarily normalize the INR with repeat dosing of alteplase was effective at resolving HVAD pump thrombosis without bleeding complications and should be investigated further.

Figure 1. HVAD log-files demonstrating response to alteplase



**Black arrows indicate treatment with alteplase*

P34

Optimized Cannula Design Preserves Physiological Cerebral Perfusion During CBP

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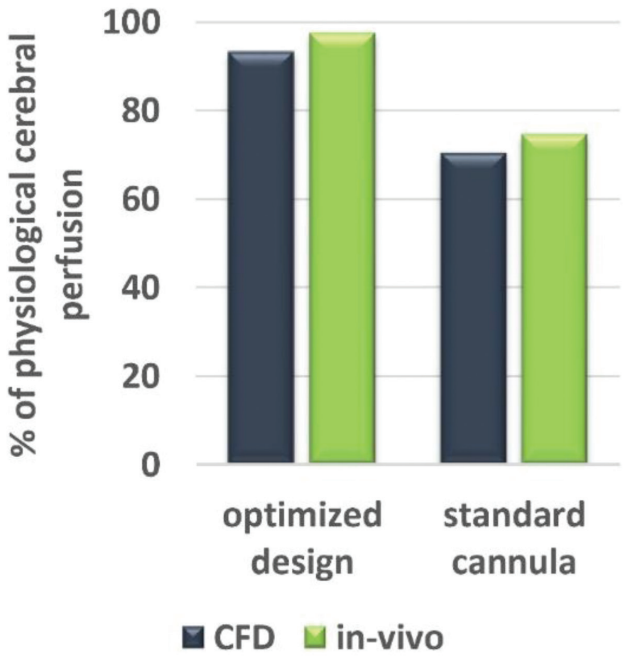
Study: Cardiopulmonary bypass (CPB) is a standard procedure in cardiac surgery, with a 2-3% stroke prevalence, increasing towards 13% in high risk patients. Among the main reasons for stroke are diminished brain perfusion and release of atherosclerotic plaques, which are both related to altered flow conditions in the aortic arch caused by the outflow cannula. Here, we present an optimized cannula design (optiCAN), which increases brain perfusion during CPB while decreasing stress on potentially calcified aortic walls. This could reduce the prevalence of stroke in high risk patients, while maintaining a small incision site and minimal blood trauma.
Methods: Computational fluid dynamic (CFD-)simulations were conducted to predict an optimal cannula design. Final design featured an inner surface inducing helical flow, which is preserved and transported to the aortic arch via an innovative tip. Prototypes were manufactured using injection molding. Qualitative cannula outflow was tested in-vitro using dye staining in water baths. Hemolysis was tested in-vitro according to ASTM standard. In-vivo cannula perfusion was evaluated in open thorax surgery on two pigs under extracorporeal life support. Carotid artery flow was measured with flow sensors during surgery.
Results: CFD-simulation predicted a decelerated and widened cannula outflow, which was confirmed qualitatively in-vitro. Normalized index of hemolysis ranged between 0.015 and 0.025 mg/dl for both standard and optiCAN design. As confirmed by CFD-simulation and in-vivo experiments, optiCAN restores the physiological level of cerebral perfusion (see Figure below): an overall increase of >20% compared to standard cannulas emphasizes the great potential of our novel design.



P35

Preliminary Evaluation Of Compliance When Testing Pulsatile Loops For Hemolysis Evaluation

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Study: Pulsatile blood flow is defined by a surge in flow and pressure. The stretch or compliance of the components in a mock loop system will manage the surge differently which can impact the circulating blood components. The compliance of loop components was changed to simulate more clinically representative situations, and its impact on hemolysis comparing the VentriFlo® True Pulse Pump (VentriFlo, Inc., Pelham, NH, USA) to the Medtronic Bio-Medicus BP-80 (Medtronic plc, Dublin, Ireland). VentriFlo is a new pulsatile blood pump intended for use during short-term circulatory support including cardiopulmonary bypass (CBP).
Methods: Pulsatile tests (n=9) were compared to the non-pulsatile BP80X pump (n=2) in a temperature-controlled loop with whole bovine blood. A typical set up used one bag as reservoir and compliance chamber. To achieve desired afterload conditions, extreme clamping of the tubing occurs. To adjust compliance and afterload without extreme clamping, a 3-bag set up with an additional reservoir in contact with an air bladder packed between two metal plates was used (Test 5-9). An elevated outlet pressure and beat rate were run in each set-up. Pump flow and pressures were monitored and free hemoglobin measurements at timed intervals were collected to determine the normalized index of hemolysis (NIH).
Results: The difference in the average NIH between the 70 beats per minute (BPM), 1-bag test (Test 1-3) and the 70 BPM, 3-bag (Test 5-8) was 17% with the 3-bag test having a higher average NIH of 0.041 g/100L. The elevated beat rate against a higher afterload presented the highest NIH of 0.092 g/100L in the 1-bag set up (Test 4) which was 20% higher than the 3-bag, elevated beat rate and afterload condition (Test 9). The BP80X performed with an average NIH of 0.04 mg/100L.*Design Mentor, Inc reincorporated as VentriFlo, Inc (a Delaware Corporation) in August 2019VentriFlo® True Pulse Pump is registered trademark of VentriFlo, Pelham, NH, USA and is protected by US and International Patents.

Description		Beat Rate (BPM)	Day tested after blood draw	Flow Mean L/min	Flow Avg Max L/min	Flow Avg Min L/min	Outlet P Mean mmHg	Outlet P Avg Max mmHg	Outlet P Avg Min mmHg	dP Mean mmHg	Inlet P Mean mmHg	Inlet P Avg Max mmHg	Inlet P Avg Min mmHg	NIH g/100L
1 bag (Driver 1)	Test 1	70	Day 1	2.5	6.6	-0.8	123	217	46	104	18	27	3	0.028
1 bag (Driver 1)	Test 2	70	Day 2	2.5	7.4	-0.7	107	217	30	105	3	12	-14	0.025
1 bag (Driver 1)	Test 3	70	Day 2	2.5	7.4	-0.6	106	211	30	104	1	10	-15	0.052
1 bag (Driver 1)	Test 4	90	Day 2	2.5	6.6	-0.5	199	552	9	182	18	273	-179	0.092
3 bag (Driver 1)	Test 5	70	Day 2	1.8	6.8	-0.9	105	217	29	93	12	19	-3	0.049
3 bag (Driver 1)	Test 6	70	Day 2	2.5	8.0	-0.2	110	155	78	108	2	16	-18	0.031
3 bag (Driver 2)	Test 7	70	Day 2	2.5	8.4	-0.4	105	154	72	96	9	23	-3	0.033
3 bag (Driver 2)	Test 8	70	Day 3	2.5	9.1	-0.4	103	150	71	103	1	16	-15	0.051
3 bag (Driver 2)	Test 9	85	Day 3	2.5	8.8	-0.7	149	193	120	144	4	17	-14	0.074
3 bag (BP80X, 1600 RPM)	BP80X		Day 2	2.3			114			106	8			0.06
3 bag (BP80X, 1510 RPM)	BP80X		Day 3	2.5			105			108	-3			0.02

P36

Outcomes Of Percutaneous Right Ventricular Device Support: Dual Lumen Protek Duo Cannula Vs. Alternative Percutaneous Right Ventricular Support Cannulation Strategies

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Study: The Protek Duo (PtD) dual lumen cannula was developed as a percutaneous system for temporary mechanical support, inserted through the internal jugular vein (IJ) for both right atrium and ventricle inflow and pulmonary artery outflow. Prospective advantages include avoiding full sternotomy and permitting early mobility. Prior studies evaluated PtD safety and feasibility. However, outcomes of PtD compared to alternative Percutaneous Right Ventricular Assist Device (pRVAD) methods have not been reported.

Methods: Retrospective analysis of prospectively collected data was performed. Patients who received pRVAD from 2016-2019 were classified into PtD (n=17, Figure 1A) and Non-Protek (N-PtD, n=12) groups. N-PtD group included 4 patients cannulated via bilateral IJs, with RIJ as drainage and LIJ as infusion cannula (Figure 1B), and 8 patients cannulated by fluoroscopic guided access of the femoral vein for drainage and IJ for infusion (Figure 1C). All patients had oxygenator in circuit. Survival curves were generated by Kaplan-Meier method. Outcomes were assessed with Student's t-test or Mann-Whitney U-test for continuous and Pearson's X^2 or Fisher's exact test for categorical variables.

Results: No survival differences were detected at 1week (p=0.89) or 30days (p = 0.32) post-RVAD. There were no differences in hospital LOS (p=0.22), in-hospital mortality (p=0.15), duration of support (p=0.72), prolonged mechanical ventilation (p=0.50), tracheostomy (p=0.77), or days on dialysis (p=0.37). Only 2 patients ambulated prior to RVAD liberation, both with PtD. However, no statistically significant difference was noted in time to out-of-bed (p=0.12) or time to ambulation (p=0.10) between groups. Thus, outcomes associated with PtD were comparable to those with N-PtD peripheral cannulation strategies for providing right ventricular support and no significant difference in patient mobility was noted.

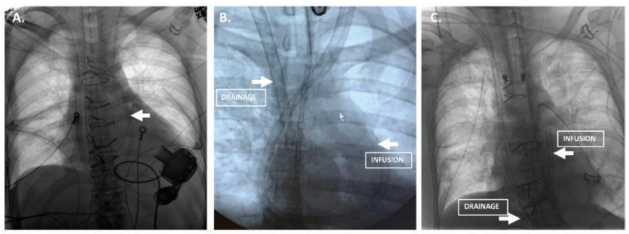

Figure 1. Chest radiographs demonstrate placement of A) PtD with right IJ cannulation, B) Bilateral RIJ+LIJ cannulation and C) Fluoroscopic-guided RIJ+FV cannulation for right ventricular support.

P37

Hemodynamical Study of the Flow over a Ventricle Assist Device Impeller

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Study: Mechanical circulatory support devices have improved the management, survival and prognosis of many patients with Acute or Chronic Heart Failure. However, there is still a high mortality and a wide burden of disease, mostly due to related thrombosis and embolization, thus requiring anticoagulation. Most of the current approved ventricle assist devices (VADs) operate far beyond the critical threshold for biological damage which increases those disease. The need for VADs that minimized blood damage is critical. In this study we examined the effect of impeller design on functional and hemodynamic VAD efficacy using numerical models.

Methods: A new VAD with a range of VAD impeller geometries was studied. Steady and transient numerical simulations of rotating frame using ANSYS CFX were developed. The simulations were utilized to estimate the shear stress, regions of stasis and global pump performance such as flow rate, pressure head and power. Level of platelet activation was estimated along trajectories pathlines. An experimental system was used to validate the performance results, and PIV visualization techniques were used to validate flow patterns downstream the impeller.

Results: Good agreement was found between the numerical model and wet experiments conducted. This implies that the numerical models have potential in predicting both hemodynamic and thromboembolism characteristics. All results indicated that larger hub diameter showed better pump and better hemodynamical performance, with both regions of high shear stress and regions of stagnations being smaller. Understanding the impact of the geometry on pump performance and blood damage may provide the ability to optimize new VAD design.

P38

Veno-Arterial Extracorporeal Membrane Oxygenation In Cardiogenic Shock And Rate Of Vascular Events: Single Center Report After Augmented Multidisciplinary Approach

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Study: Veno-arterial extracorporeal membrane oxygenation (VA ECMO) is a modality of mechanical circulatory support that brings both advantages and complications, including adverse vascular outcomes. After implementing several changes, we performed a single center retrospective review of those on VA ECMO and report of vascular complications.
Methods: Single center, retrospective review was performed between 2016-2018. All patients were on VA ECMO for cardiogenic shock, with or without other indications. 105 patients fit criteria. Vascular complication rates were measured.
Results: Average age was 57 years with 67.6% of the 105 patients being male. Indications of VA ECMO included cardiogenic shock alone (80%), cardiogenic shock with respiratory failure (18.1%), and cardiogenic shock with hemorrhagic shock (1.9 %). 46.7% of those on ECMO were post cardiotomy. Peripheral access was most utilized (83.8%). Placement of VA ECMO occurred at the bedside (15.2%), in the cath lab (7.6%) or in the operating room (77.1%). Of the ECMO patients, 53.3% also had Impella, and 21% with an intra-aortic balloon pump. 71% of impellas were the CP type. Thrombectomy rate was 1.9%. No amputations or fasciotomies occurred while on ECMO. Average time on ECMO and in ICU were 5.94 and 16.44 days. Mortality rate was 65.7% (survival rate 34.3%). Average Survival After VA ECMO score was -8.6 with an estimated probability of in hospital survival of 30%.
Discussion: Our results reflect much lower rates of vascular adverse outcomes with ECMO when compared to similarly sized cohort (Bonicolini 2019). Our efforts towards improvement included early recognition through tailored exams and set triggers, strict adherence to optimal anticoagulation therapy, early intervention and early decannulation. Other unmeasured factors may also play a role but multidisciplinary efforts indeed minimize risk of adverse vascular events in those on ECMO.

Patient Characteristics and Measures

	Mean	Standard Deviation	Median	Percentile 25	Percentile 95
Age	57.11	13.80	59.00	50.00	76.00
SBP	73.41	14.35	73.00	66.00	94.00
CVP	16.90	7.25	17.00	12.00	29.00
PAs	46.46	16.90	44.00	38.00	78.00
PAd	26.81	10.75	25.00	20.00	42.00
PAm	34.03	11.68	32.50	28.00	50.00
PCWP	24.63	8.01	25.00	19.00	40.00
CO	4.31	1.71	3.89	3.10	7.80
CI	2.08	0.78	1.90	1.56	3.87
SVR	1282.19	705.61	1087.50	828.00	3208.00
CPO	0.71	0.32	0.64	0.49	1.48
BNP	3445.38	7508.77	849.00	404.00	20008.50
Troponin	65.38	135.60	2.33	0.19	399.56
eGFR	53.79	13.52	61.00	50.50	61.00
Creatinine	2.07	1.80	1.50	1.06	4.12
Sodium	138.90	6.05	139.00	135.00	148.00
Bicarbonate	21.48	5.94	22.00	18.00	30.00
Lactate (mg/dL)	9.13	5.57	7.60	4.20	19.10
Lactate (mmol/L)	7.01	5.17	5.70	2.80	18.00
pH	7.25	0.16	7.29	7.16	7.46
ALT	775.35	3098.71	87.00	38.00	5001.00
AST	1397.32	5106.28	168.00	44.00	8539.00
Total bilirubin	1.92	2.21	1.30	0.65	5.00
LDH (post ECMO)	2265.93	3300.28	928.00	524.00	12001.00
INR	1.82	1.28	1.40	1.20	3.20
RDW	15.39	3.03	14.80	13.45	20.80
CRP	5.36	6.25	2.22	0.56	18.74
Units of RBC transfused	7.54	2.44	6.00	6.00	12.00
Units of Platelets Transfused	4.72	1.90	6.00	3.00	6.00
Units of FFP transfused	2.30	1.22	3.00	2.00	3.00
SAVE score	-8.60	6.48	-9.00	-14.00	2.00
Days on ECMO	5.94	6.08	4.73	1.77	12.10
Days in ICU	16.44	21.29	10.00	4.00	51.00
Total Cost Observed (2017 Risk Model)	179604.44	130737.14	137384.50	96133.50	447191.00
Charges Observed	794898.65	570907.79	610324.50	452158.50	2099941.00

Table 1: All measures above were taken prior to ECMO (except LDH levels).

ECMO with or without Impella

	Frequency	Percent
With	56	53.3
Without	49	46.7
Total	105	100.0

ECMO with or without IABP

	Frequency	Percent
With	22	21.0
Without	83	79.0
Total	105	100.0

Legend (in order of appearance):
SBP – systolic blood pressure. CVP – central venous pressure. PAs – systolic pulmonary artery pressure. PAd – diastolic pulmonary artery pressure. PAm – mean pulmonary artery pressure. PCWP – pulmonary capillary wedge pressure. CO – cardiac output. CI – cardiac index. SVR – systemic vascular resistance. CPO – cardiac power output. BNP – b-type natriuretic peptide. eGFR – estimated glomerular filtration rate. ALT – alanine transaminase. AST – aspartate transaminase. LDH – lactate dehydrogenase. INR – international normalized ratio. RDW – red cell distribution width. CRP – c-reactive protein. RBC – red blood cells. FFP – fresh frozen plasma. SAVE – survival after VA ECMO. ICU – intensive care unit.

P39

Managing Acute Pump Thrombosis With Tpa: How Much Is Really Enough? A Case Series

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Study: Hemocompatibility in LVAD pts remains a challenge to pt survival. Overall, the rates of Pump thrombosis have decreased with the introduction of centrifugal flow pumps, but the literature still shows a 6-10% occurrence. There is paucity in the current literature on the use and dosing of tPA as a treatment for acute pump thrombosis as an alternative to pump exchange.
Methods: This is a case series of 5 pts treated with tPA when they presented with pump thrombosis. The pt age ranged from 26-71 years of age. The LVAD type also varied, including 1 Heartmate 2 and 4 Heartware. Thrombosis was determined by CTA, Echocardiogram, hemolysis labs, waveform analysis & clinical presentation. All but 1 of these pts were deemed Destination Therapy and therefore treatment options like higher priority listing for OHT were not a treatment option. The dosing of tPA and route of administration varied by each pt. Total administered tPA dose ranged from 41-208mg. The intraventricular dosing was administered in the Cath Lab under fluoroscopy by an Interventional Cardiologist.
Results: Three of the 5 pts had complete resolution of pump thrombosis with the use of tPA. This was demonstrated by resolution of hemolyis labs, waveform analysis and clinical presentation. The 2 pts that did not have successful treatment had other factors that likely contributed to the ineffectiveness of the tPA treatment. Intraventricular administration of tPA in combination with systemic tPA infusion has demonstrated successful treatment of acute pump thrombosis in our small case series. There were no major AE associated with the use of tPA at high doses. This is especially important to note as the current literature shows a max infusion of 100mg and associated bleeding complications such as hemorrhagic CVA or massive hemothorax and epitaxis. In our case series, pts were treated with multiple rounds of tPA ranging from 41-208mg & none of them suffered a bleeding complication. All of the pts included in this case series had an INR of 2 or greater during tPA treatment.

Patient	Intraventricular Alteplase Cumulative Dosing	Peripheral Alteplase Cumulative Dosing	Other Treatment	Device Type
A*	0	29mg	Eptifibatide (0.5mcg/kg/min x 55 hours)	Heartware
B	25mg	183mg	N/A	Heartware
C	0	53mg	N/A	Heartware
D*	5mg	100mg	N/A	Heartmate 2
E	5mg	143mg	N/A	Heartware

**Unsuccessful treatment with tPA*

P40

Targeting von Willebrand Factor Degradation via ADAMTS13: A Potential Treatment Strategy for Ventricular Assist Device (VAD)-Associated Bleeding

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Study: While the use of VADs in heart failure patients is widespread, bleeding remains a major obstacle to wider use. One possible cause of bleeding is an increase in the breakdown of high molecular weight (HMW) von Willebrand factor (vWF) multimers by VAD-induced (VAD-like) shear. Each vWF multimer is a large blood circulating glycoprotein that is cleaved by the metalloprotease ADAMTS13. HMW vWF multimers assist in platelet aggregation to form a clot. However, the extent of the influence of shear stress on the interaction between ADAMTS13 and vWF remains unclear. Therefore, we hypothesised that the loss of HMW vWF multimers under VAD-like shear is due to proteolysis by ADAMTS13 in a shear-dependent manner.

Methods: Human blood components were subjected to VAD-like shear stress to investigate HMW vWF degradation by ADAMTS13. Immunoblotting and FRET-vWF73 substrate were used to analyse the inhibitory effect of doxycycline, a clinically used antibiotic, EDTA and an anti-ADAMTS13 antibody. Moreover, we examined the functional aspect of platelet activation and aggregation, by flow cytometry and aggregometry, following *in vitro* VAD testing.

Results: Our data suggest that while the activity of ADAMTS13 is shear-independent, the cleavage of HMW vWF by ADAMTS13 is governed by shear stress. Anti-ADAMTS13 antibody inhibits HMW vWF degradation significantly when compared to doxycycline. Conversely, shear stress increased platelet activation and impaired thrombin platelet aggregation, highlighting the distinct roles of platelet receptors. Thus, this study clarifies the central role of ADAMTS13 in bleeding complications and proposes the potential use of ADAMTS13-specific inhibitors for the treatment or prevention of gastrointestinal bleeding in VAD patients. While ADAMTS13 is indirectly linked to pro-thrombotic events, we are yet to pinpoint the contribution of its interaction with vWF on platelet function in VAD patients.

P42

Robo MI - Fabrication Of A Medical Implant To Generate Myocardial Infarctions In Mice

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Study: Myocardial infarction is one of the leading causes of death worldwide. As a result, research interest in novel treatments and drugs is rising. In order to characterize these therapeutics and obtain regulatory approval, there is a need for representative animal models. Currently, the most commonly used models are mice, rats and pigs, with mice being preferred due to their low cost, well-known anatomy, and the existence of genetically modified strains. The main disadvantage is that due to their size, myocardial infarction is achieved surgically by ligating the desired artery with a suture. The invasiveness of this procedure can have undesirable influences, which can confound results.To deal with this problem, we propose a novel implant which can subsequently induce a myocardial infarction by remote user control, and also simulate a reperfusion by reopening the artery. This enables the study of myocardial infarction, reperfusion and preconditioning, even in an awake mouse.
Methods: The working principle of the implant is to replace the suture that is usually passed around the artery for coronary ligation with an inflatable tube. By pressurizing the tube, the increase in diameter closes the artery. Using a syringe-pump style actuator and a simple Bluetooth-enabled microcontroller powered by an implantable battery, remote actuation is possible. This enables the researcher to control the duration and frequency of vessel closure over time, with just one initial surgery.
Results: First, the inflatable tube was tested *in vitro* using silicone to simulate the tissue. Using a differential pressure measurement over the closed part of the silicone artery while applying a constant flow, we assessed different implantation techniques for the end effector. A higher pressure gradient across the vessel for a given actuator pressure is desired as this decreases both the energy needed to close it and the risk of tube rupture. We demonstrated that placing the tube around the entire artery is the most promising.

P43

Complex LVAD Implantation In A Patient With LV Free Wall Rupture

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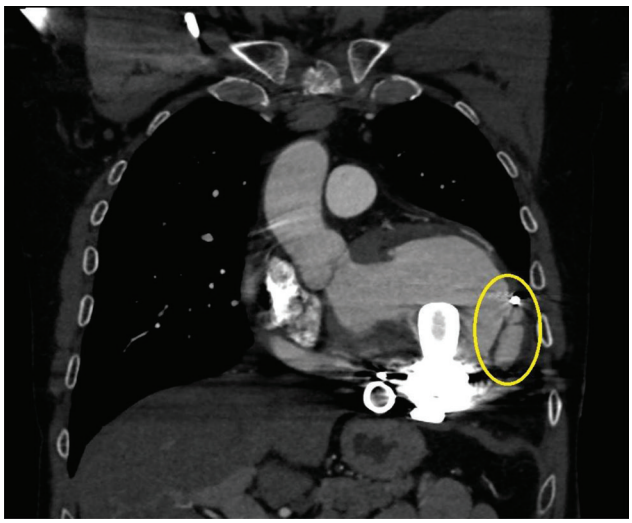
Study: A 62 year old male with late-presentation anterior STEMI and tamponade underwent emergent PCI of the LAD and evacuation of a hemopericardium in the setting of contained LV free wall rupture. He was initially discharged on guideline-directed medical therapy for heart failure but continued to functionally decline. He ultimately became neurohormonal therapy-intolerant and was approved for durable LVAD placement. He was not a cardiac transplant candidate at the time due to tobacco use.
Methods: Echo was notable for a borderline dilated basal LVIDd of 5.6 cm and a severely aneurysmal LV apex. The patient underwent LVAD implantation with a Medtronic HVAD, which required resection of the LV aneurysm, bovine patch reconstruction of the apex and incorporation of the LVAD inflow cannula into the repair.
Results: The patient eventually returned to work post-LVAD implant. His course was complicated by a driveline infection and he was placed on chronic suppressive antibiotics. Ten months after the initiation of suppressive antibiotics, the patient presented to the hospital with acute onset of bloody discharge from the driveline exit site. CT angiography was consistent with an LV pseudoaneurysm near the LV inflow cannula site concerning for LV patch dehiscence.
The patient had abstained from all tobacco products following his initial MI and so was emergently listed for cardiac transplantation, which occurred 13 days after listing at UNOS status 3. Pathology of the patient's explanted heart showed bacteria with abscess and inflammation. His post-transplant course has been devoid of rejection or other significant complications including graft infection. Durable VAD support is a feasible salvage strategy with acceptable results in select, high-risk patients with LV aneurysm.



P44

Contemporary Outcomes Of Temporary Percutaneous Right Ventricular Support In A Heterogeneous Right Ventricular Failure Cohort

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Study: Right ventricular failure occurs in a variety of clinical settings, and is associated with reduced survival. We sought to describe our recent clinical experience with two temporary percutaneous right ventricular assist devices (RVAD): TandemLife Protek Duo (TPD; TandemLife, Pittsburgh, PA), and Impella RP (Abiomed, Danvers, MA).
Methods: A prospectively collected institutional heart failure device registry was mined for clinical data related to TPD and Impella RP devices. Baseline demographic characteristics, etiology of heart failure, indication for RVAD support, and timing of implantation in relation to the onset of right ventricular (RV) failure were characterized for both temporary percutaneous RVADs. Specific clinical outcomes, including overall survival, time on temporary percutaneous RV support, device explant, and device exchanges were analyzed. Outcomes were further analyzed among the cohort of explanted patients.
Results: Between 2015-2018 19 TPD devices and 10 Impella RP devices were implanted. Indication for RV support included post-left ventricular assist device (LVAD) implantation RV failure, post-cardiotomy cardiogenic shock, and post-transplant (TPx) RV failure. Mean (median) device support duration for TPD was 16(12) days, and 5(4) days for Impella RP. Among TPD patients, 11(57.9%) were explanted, 4 (21.0%) died, and there were no device exchanges. Among Impella RP patients, 5 (50.0%) were explanted, 3 (30.0%) died, and 1 (10.0%) required device exchange. Among TPD patients explanted, 7(63.6%) recovered and were weaned, 3(27.2%) died, and 1(9.1%) required a durable RVAD. Among Impella RP patients explanted, 4(80.0%) recovered and were weaned, and 1(20.0%) required a durable RVAD.

P45

Transcatheter Balloon Dilatation Of Twisted Outflow Graft Of HeartMate 3 Left Ventricular Assist Device

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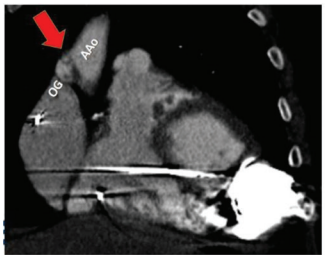
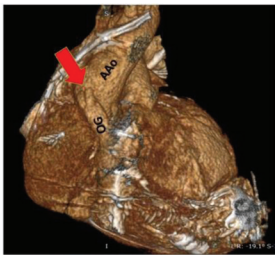
Study: Left ventricular assist device (LVAD) is a common option for patients with terminal heart failure (HF). Outflow graft (OG) twisting is a rare complication after LVAD placement and treated surgically - graft replacement. Transcatheter balloon dilatation as an alternative option appears to be relatively safe procedure.
Methods: A 58-year-old man with ischemic cardiomyopathy had undergone an implantation of LVAD HeartMate 3 (Abbott, Chicago, IL, USA) in 2015. After 4 years on support, the patient presented to our hospital with signs of HF and low flow alarms.
Results: Laboratory studies revealed no signs of hemolysis. He underwent transthoracic echocardiography-monitored speed ramp test: pump speed increasing from 5200 revolutions per minute (RPM) to 6000 RPM presented no changes of the left ventricular end-diastolic internal diameter (LVIDd) of 97 mm. Cardiac CT revealed OG twisting at the site of anastomosis with ascending aorta (AAo). Given the high risk for redo surgery, it was decided to attempt percutaneous intervention. Standard regulations were followed for informing patient about potential risks and benefits. The procedure was performed under a local anesthesia in catheterization laboratory. During the selective angiography the narrowing at the OG insertion site was confirmed. Maximal pressure in the OG was 213/141-165 mmHg and AAo pressure was 101/78-86 mm HG. The pressure gradient (PG) at the narrowing part was 112 mm Hg. A stiff guidewire was placed in the OG proximal part and MaxiLD 14/40 dilatation balloon (Cordis, The Netherlands) was inflated thrice at the anastomosis to a maximal pressure of 4 atm. On the control angiography, there was an expansion of the narrowed area without signs of extravasation. After dilatation, a decrease in pressure was observed in OG to 136 / 94-108 mm Hg, PG - 35 mm Hg. This allowed to reduce the pump speed to 5100 RPM, with an optimal flow. LVIDd decreased from 97 mm to 87 mm. The patient was discharged 5 day later and remain stable to current date.





P46

Novel Surgical Intervention For Intrapericardial Left Ventricular Assist Device Malposition

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Study: Left ventricular assist device (LVAD) inflow cannula (IFC) malposition results in suboptimal left ventricular unloading and increased risk of ectopy and thromboembolic complication. No technique has been described to alter IFC position of an intrapericardial LVAD once the ventricular apex has been cored.
Methods: We retrospectively reviewed four patients implanted with a HeartWare HVAD who underwent IFC repositioning within 24hrs postop for refractory low flow (n=2) or at pump exchange (n = 2) (Fig. 1). All patients were implanted via hemi-sternotomy and anterior-lateral thoracotomy. A suture was placed around the proximal region of the HVAD driveline and then tacked to an adjacent rib, where tension was adjusted to alter the inflow cannula position. Color Doppler TEE and the HVAD waveform (Fig. 2) were used to confirm optimal angling towards the mitral valve. The angle axis was defined as the line between the apex and mitral valve; the change in angle was quantified in reference to the axis through pre and post-operative CTA imaging.
Results: The average change in angle of the lateral and anterior plane after IFC repositioning were 14.5° and 21.5° respectably, and all patients had an acutely uncomplicated hospital course without recurrence of IFC-related morbidity. This demonstrates that substantial changes can be made to intrapericardial LVAD inflow cannula position even after placement of the sewing ring and apex coring.

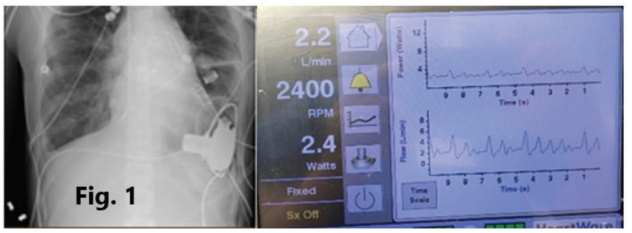

Fig. 1

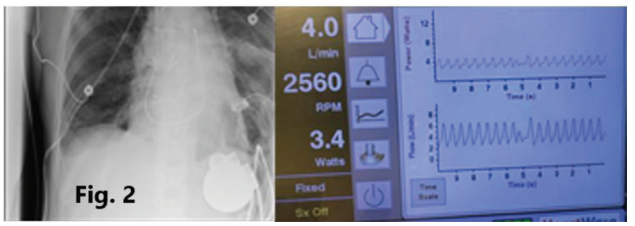

Fig. 2

P47

Treatment For Device Thrombosis In The Heartware HVAD

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Study: Device thrombosis (DT) is a life-threatening event in patients with a left ventricular assist device (LVAD). Optimal treatment strategy for device thrombosis in HeartWare HVAD is still controversial. The purpose of this study is to summerize our clinical experience of DT in HVAD patients.
Methods: Consecutive patients undergoing a HVAD implantation between 2010-2019 were included. DT was diagnosed with comprehensive assessments including a ramp test, laboratory data (lactate dehydrogenase, plasma hemoglobin, haptoglobin), device parameters (e.g. power spike), and clinical presentations (e.g. hematuria). Surgical device exchange was considered if DT was refractory to medical therapy, and/or if it caused end-organ impairment and/or hemodynamic instability.
Results: A total of 122 patients underwent a HVAD insertion during the period. Thirteen patients (10.7%) were diagnosed with DT. Heparin was initiated in all patients. Among them, antithrombotic therapy with tissue plasminogen activator (tPA) was used in 5 patients, while the other 8 patients continued heparin only. Two patients with tPA and 3 patients with heparin alone eventually required a device exchange (N=5). All device exchange was performed through a median resternotomy and there was no surgical mortality. Overall, there were 3 mortality in the cohort. The cause of death included sepsis (n=1) and cerebral hemorrhage (n=2), all from heparin alone group. DT was successfully treated in 5 patients in device exchange group (5/5, 100%), 2 patients in tPA group (2/5, 40%), and 1 patient in Heparin alone group (1/5, 20%). Two patients (1 patient with tPA, 1 patinet with heparin alone) were decided to decommission the LVAD with the catheter-based occlusion technique due to non-medical reasons. In conclusion, for the treatment for DT in the HVAD, antithrombotic therapy with tPA was effective in certain patients. Device exchange provided the highest success rate to resolve DT in selected patients and should be considered as the first line of the treatment if indicated.

P48

A Porcine Model Of Inflammation And Air Exposure During Cardiopulmonary Bypass

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Study: Cardiopulmonary bypass (CPB) during cardiac surgery is associated with an inflammatory response due to air exposure to blood and platelet and leukocyte function alteration. We aimed to develop a porcine model to mimic this air exposure and characterize the associated organ injury and inflammatory response.
Methods: Swine (n=6) were cannulated via the right atrium and aorta through a right mini-thoracotomy for 2h of full CPB and then recovered from anesthesia. Air exposed animals (n=4) had a 20-25% blood shunt in which air was mixed via a negative pressure valve at an approximate 4:1 ratio to mimic cardiotomy suction and venting. Control animals (n=2) were placed on CPB in which no air was administered. Blood was sampled at baseline (prior to CPB), end of CPB, 6h post CPB; and then daily. At termination, tissue samples were sent for histopathological analysis.
Results: Animals exposed to air had higher morbidity and mortality than the control group. No animals in the control group survived more than 24h, while control animals all survived 4d. Serum lactate was higher at 6h post CPB in air animals compared to controls (4.2 ± 1.8 mmol/L, 0.9 ± 0.3 mmol/L, p = 0.07). Platelet counts showed more consumption in the air group after 2h of CPB compared to controls (29.0% ± 6.4% from baseline, 59.0% ± 6.7% from baseline, p = 0.007). Granulocyte CD11b activation was higher in the air group compared to controls at 6h post-CPB (351 ± 100.1 MFI, 179 ± 28 MFI, p = 0.09). Histopathology showed greater evidence of inflammatory injury to the lungs, liver, and kidneys of the air group. This model demonstrates that higher air exposure during CPB is associated with greater platelet consumption, leukocyte activation, and organ injury.

P49

Continuous-flow LVADs Are Distinctly Free Of Mechanical Failure & Markedly More Durable Than Pulsatile-Flow LVADs

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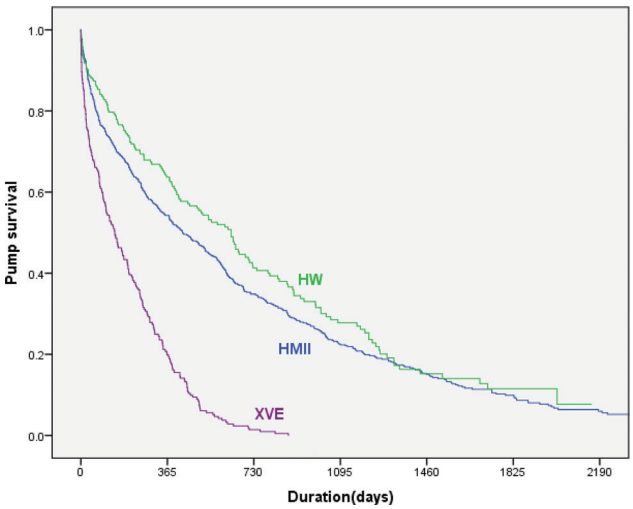
Study: Continuous-flow (CF) left ventricular assist devices (LVADs) have replaced pulsatile-flow (PF)-LVADs for mechanical cardiac assistance. We compared pump durability and incidence of mechanical complications between PF-LVADs, axial-flow CF-LVADs and centrifugal-flow CF-LVADs
Methods: We retrospectively reviewed all LVAD implantations at our institution from 1991 to 2018. Reasons for and time to LVAD removal were recorded.
Results: 1059 pumps were implanted: 212 PF-LVADs (1991-2010) and 847 CF-LVADs (591 axial-flow [2003-2018] and 256 centrifugal-flow [2009-2018]). Pump survival was significantly longer for the centrifugal-flow (median 634, mean 758 days) and axial-flow (median 429, mean 705 days) CF-LVADs than for the PF-LVAD (median 143, mean 197 days; p < 0.001) (Figure). Reasons for LVAD removal were cardiac transplant, death, and LVAD exchange or explant. Thrombosis or hemolysis was the most common reason for CF-LVAD exchange or explant. Other reasons for exchange included infection, inflow or outflow graft problems, driveline malfunction, biventricular failure, heat generation, and low-flow alarms. CF-LVAD explants were performed for patients with cardiac recovery (23 cases), thrombosis or hemolysis, and infection (Table). Mechanical failure occurred in only one CF-LVAD patient. **Conclusions:** CF-LVADs are more durable than PF-LVADs and enhance survival. Although thrombosis, hemolysis, infections, and driveline problems do contribute to CF-LVAD failure, CF-LVADs are remarkably free from mechanical failure directly attributable to the pump mechanism. Primary mechanical failure occurred in only one CF-LVAD patient.



P50

Medtronic TAVR Heart Valve In Animals With Biventricular Dysfunction

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Study: Transcatheter aortic valve replacement (TAVR) is a type of minimally invasive aortic valve replacement that has a non surgical approach. The Medtronic TAVR heart valve is designed to work like your own heart valve. Our clinical observations suggested the hypothesis that the Medtronic TAVR is a viable option for patients with heart disease due to severe aortic stenosis of the native valve and patients with a failing surgical aortic valve who are at high risk or extreme risk for complications during surgery, and has short and long term prognostic significance.
Methods: Retrospective chart review of five cases of aortic valve replacement treated primarily with transcatheter aortic valve replacement and left ventricular assist device. A median sternotomy access was performed; due to hemodynamic instability, procedure proceeded with cannulation and ECC using both femoral vessels following full heparinization. The 29mm Medtronic Core valve was deployed from the thoracic cavity through the SVC using the fluoroscopy and stent valve device was advanced to the atriocaval junction and deployed. No leak could be shown with contrast injection. Further the heart was lifted up and using several interrupted U stiches the inflow ring was sutured onto LV apex.
Results: The procedure aided in experimenting how to safely deploy the valve. We understand the valve must be deployed at 13mm by having the distance between atriocaval junction and tip of skirt being 15mm or less. There was deployment of 29mm medtronic core valves in subjects who presented with heart failure. In acute experiments, the valve was successfully place distal to the cavoatrial junction with adequate flow, no paravalvular leaks; resulting in a clearly sealed atrio-caval junction without rupture with no protrusion into the the tricuspid valve.There was a pressure difference recorded of 5mm hg. The Medtronic Valve has clearly shown, in subjects with bi-ventricular dysfunction, the subject is able to maintain MAPs of over 60 on moderate doses of inotropic support.

P51

Accounting For Von Willebrand Factor In A Multi-Scale Thrombosis Model Under High Shear Rate Conditions: Simulation Of Platelet Function Assay PFA-100.

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Study: The PFA-100 is a commonly-used coagulation assay that is sensitive to platelet function and von Willebrand Factor (vWF) level. However, current chemo-fluidic models of thrombosis are unable to replicate this test due to the omission of the effect of vWF. This study was performed using a recently introduced model of vWF-mediated high-shear platelet deposition to simulate the thrombus formation dynamics within the PFA-100.
Methods: Chemo-fluidic numerical simulations of the platelet function assay PFA-100 were performed. Specifically, pressure-driven aspiration of blood was simulated within the central orifice of the cylindrical cartridge. The time to occlusion of the central orifice was computed which is indicative of platelet function/dysfunction. The thrombosis model considers mechanical and chemical activation of platelets, platelet deposition, and cleaning as a function of wall shear stress. To account for the effect of vWF in platelet deposition, vWF unfolding was computed as a function of elevated shear rate and extensional strain. Then, in regions were unfolded vWF was present, the platelet bond strength was locally amplified.
Results: Shear rates of about 5000 to 6000 s-1 were obtained at the central orifice of the PFA-100 promoting vWF unfolding. Interestingly, our simulations show that when vWF is not considered, occlusion did not take place. (See Fig. 1.) Conversely, the revised vWF-enhanced thrombosis model was able to replicate platelet deposition within the time scale observed in actual PFA-100 whole blood tests. These results provide the opportunity to perform patient-specific simulations of thrombosis that are calibrated to a patient-specific coagulation assay.

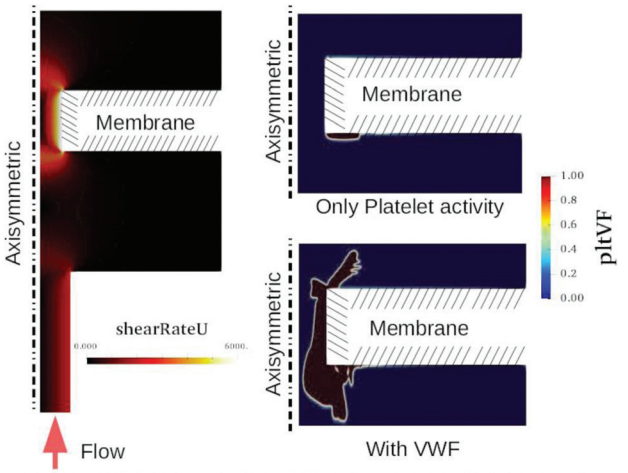

Figure 1. Shear rate scalar field inside PFA-100 (left). Platelet volume fraction (pltVF) deposition at 150s with and without VWF (right).

P52

Salvage Transcatheter Mitral Repair For Refractory Hemometabolic Shock

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Study: We present a case of salvage transcatheter mitral repair for refractory hemometabolic shock supported with a transvalvular micro-axial flow pump.

Methods: A 60-yr-old man with dyslipidemia was referred, in cardiogenic shock due to NSTE ACS. He underwent LHC revealing total occlusion in OM2 and RCA territory. Echocardiography reported EF 20%, akinesis of postero-inferior, and lateral wall, elevated RVSP, moderate MR and Moderate TR. His deterioration required emergent intubation, vasopressor and mechanical cardiac support (MCS) via transvalvular microaxial flow pump (Impella CP).

Due to persistent inadequate hemodynamic support MCS was upgraded to Impella 5.0 via subclavian approach. Echocardiography was repeated to evaluate for possible MCS malpositioning. There was severe (4+) MR due to posteromedial papillary muscle tear leading to prolapse of anterior mitral leaflet. Multiorgan failure led to minimal options. Heart team approach deemed surgical options had a high risk of mortality. He underwent percutaneous Mitral valve repair with Mitral clip placement as a salvage procedure. A total of 3 Mitral Clip XRT were successfully implanted resulting in significant reduction in MR from 4+ to 1+ with corresponding decrease in LA mean pressure from 50mmHg to 18mmHg. A dramatic clinical and hemodynamic improvement ensued and he was discharged to subacute rehab.

Results: Ischemic Mitral Regurgitation associated with mechanical complications after AMI requires an integrative diagnostic approach with imaging and invasive hemodynamics that often leads to surgical intervention at a high mortality based on the degree of additional multi-organ injury. Our case demonstrates the value of a multidisciplinary heart team approach in which hemodynamically driven mechanistic transitions can help achieve a successful clinical outcome. We report the combination of high profile minimally invasive transvalvular micro-axial flow pumps as a bridge to corrective percutaneous mitral valve interventions.

P53

Effectiveness And Reliability Of Virtual Ramp Test In Patients Implanted With HeartMate 3

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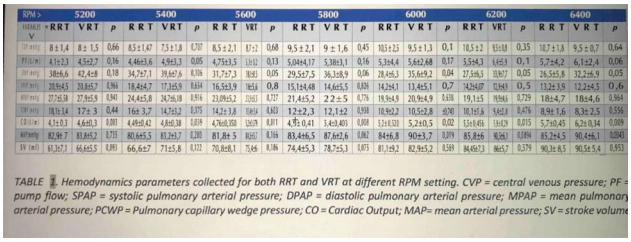
Study: In patients implanted with left ventricle assist device (LVAD) a simulation-based approach may be an additional tool to obtain accurate predictions of devices performance in a clinical setting. The aim of our study was to compare the data of the simulations(using the HARVI simulator), with the data obtained during the real ramp test.

Methods: Real Ramp Test(RRT): 15 patients implanted with HM 3underwent the real ramp test (RRT) during right heart catheterization. All the patients included in the study had stable clinical conditions and were adequately supported by mechanical assistance. The study was conducted after 8,3 ± 2,4 months from implantation. **Virtual Ramp Test(VRT):** The preimplantation hemodynamic parameters were entered into the ***patient simulator*** function of the Harvi simulator. Using the devices function, a ***mag lev*** device was selected and the revolutions per minute(RPM) set at5200. Both systemic and pulmonary preload and afterload were modified to reproduce a hemodynamic profile as close as possible to the real basal catheterization. Both for the RRT and for the VRT the rpm were increased from 5200 to 6400. For each setting hemodynamic parameters were collected and compared as shown in table 1. Differences between groups were assessed using unpaired t-tests

Results: For or all the different setting of RPM, there was no significant difference between the data obtained with the RRT and those obtained during the VRT

According to our results, the Harvi simulator could be used to predict the optimization of patients' hemodynamic profile, which is dependent on the complex interaction between the individual patient's pathophysiology and pump characteristics.



RPM >	5200			5400			5600			5800			6000			6200			6400		
VARIABLES	RRT	VRT	p	RRT	VRT	p	RRT	VRT	p	RRT	VRT	p	RRT	VRT	p	RRT	VRT	p	RRT	VRT	p
CVP (mmHg)	8 ± 1,4	8 ± 1,5	0,66	8,5 ± 1,47	7,5 ± 1,8	0,707	8,5 ± 2,1	8,7 ± 2	0,68	9,5 ± 2,1	9 ± 1,6	0,45	10,5 ± 2,5	9,5 ± 1,3	0,1	10,5 ± 2	9,5 ± 1,8	0,35	10,7 ± 1,8	9,5 ± 0,7	0,64
PF (L/m)	4,1 ± 2,3	4,5 ± 2,7	0,36	4,46 ± 3,6	4,9 ± 3,3	0,05	4,75 ± 3,5	5,9 ± 3,2	0,13	5,04 ± 4,17	5,38 ± 3,1	0,16	5,3 ± 4,4	5,6 ± 2,68	0,17	5,5 ± 4,3	6 ± 3	0,1	5,7 ± 4,2	6,1 ± 2,4	0,06
SPAP (mmHg)	38 ± 6,6	42,4 ± 8	0,18	34,7 ± 7,1	39,6 ± 7,6	0,106	31,7 ± 7,3	38 ± 3	0,05	29,5 ± 7,5	36,3 ± 8,9	0,06	28,4 ± 6,3	35,6 ± 9,2	0,04	27,5 ± 6,3	33 ± 7	0,05	26,5 ± 5,8	32,2 ± 6,9	0,05
DPAP (mmHg)	20,9 ± 4,5	20,8 ± 5,7	0,96	18,4 ± 4,7	17,3 ± 5,9	0,634	16,5 ± 3,9	14 ± 5,6	0,8	15,1 ± 4,48	14,6 ± 5,5	0,826	14,2 ± 4,1	13,4 ± 5,1	0,7	14,2 ± 4,07	12 ± 4,5	0,5	13,2 ± 3,9	12,2 ± 4,5	0,6
MPAP (mmHg)	27,7 ± 5,38	27,9 ± 5,9	0,94	24,4 ± 5,8	24,7 ± 6,18	0,914	21,09 ± 5,2	23 ± 6,1	0,727	21,4 ± 5,2	2,2 ± 5	0,776	19,9 ± 4,9	20,9 ± 4,9	0,638	19,1 ± 5	19 ± 6	0,729	18 ± 4,7	18 ± 4,6	0,964
PCWP (mmHg)	18,1 ± 3,4	17 ± 3	0,44	16 ± 3,7	14,7 ± 3,2	0,375	14,2 ± 3,8	13 ± 3,4	0,453	12 ± 2,3	12,1 ± 2	0,938	10,9 ± 2,2	10,5 ± 2,8	≤0,70	10,1 ± 1,6	9,4 ± 2	0,476	8,9 ± 1,6	8,3 ± 2,5	0,336
CO (L/m)	4,1 ± 0,3	4,6 ± 0,3	0,001	4,49 ± 0,42	4,8 ± 0,38	0,019	4,76 ± 0,350	5 ± 0,29	0,011	4,9 ± 0,41	5,4 ± 0,403	0,008	5,1 ± 0,320	5,2 ± 0,5	0,02	5,1 ± 0,416	5,4 ± 0,3	0,015	5,7 ± 0,45	6,2 ± 0,34	0,009
MAP (mmHg)	82,36 ± 7	83,8 ± 5,2	0,733	80,6 ± 5,5	83,2 ± 6,2	0,201	81,8 ± 5	80 ± 5,1	0,186	83,4 ± 6,5	87,6 ± 2,6	0,062	84 ± 6,8	90 ± 3,7	0,019	85,8 ± 6	92 ± 6,1	0,004	85,2 ± 4,5	90,4 ± 6,1	0,043
SV (ml)	61,2 ± 7,1	66,6 ± 5,5	0,093	66,6 ± 7	71 ± 5,8	0,122	70,8 ± 6,1	75 ± 6	0,186	74,4 ± 5,3	78,7 ± 5,3	0,073	81,1 ± 9,2	82,9 ± 5,2	0,589	84,6 ± 7,3	86 ± 5,7	0,579	90,3 ± 8,3	90,5 ± 5,4	0,953

TABLE 1. Hemodynamics parameters collected for both RRT and VRT at different RPM setting. CVP = central venous pressure; PF = pump flow; SPAP = systolic pulmonary arterial pressure; DPAP = diastolic pulmonary arterial pressure; MPAP = mean pulmonary arterial pressure; PCWP = Pulmonary capillary wedge pressure; CO = Cardiac Output; MAP= mean arterial pressure; SV = stroke volume

P54

Effect Of BMI On Survival To Discharge Following VA-ECMO

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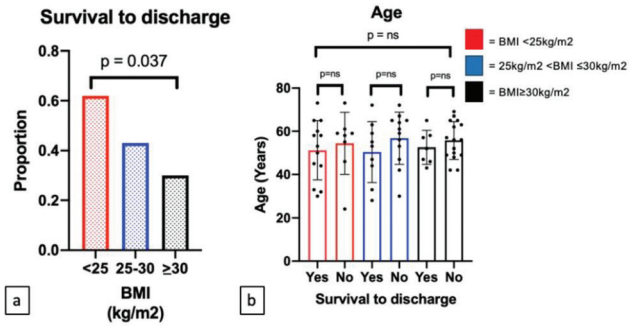
Study: The Survival after VA-ECMO (SAVE) calculator predicts survival to discharge following VA-ECMO using bodyweight. However, categorization based on bodyweight may not accurately assess body habitus. We sought to analyze the association between BMI and survival to hospital discharge following VA-ECMO.

Methods: Data was retrospectively collected from medical records of patients ≥18 years old who underwent first run VA-ECMO at our institution from July 2013-December 2017. Patients who required VA-ECMO for cardiogenic shock (CS) or respiratory dysfunction were included. Patients cannulated at an outside hospital were excluded. Patients were trichotomized into: BMI<25, 25≤BMI<30, and BMI≥30 with survival to discharge as the primary outcome. Age and complications were also analyzed.

Results: Sixty-five patients were included in this study. Average BMI was 28.9 ± 7.9kg/m^2 and average age was 53.4 ± 11.7 years. Indication for VA-ECMO was CS in 92.3% (60/65). Overall rate of survival to discharge was 44.6% (29/65). As BMI increased, rates of survival to discharge significantly decreased (61.9% (13/21); 42.9% (9/21); 30.4% (7/23); p for trend=0.037) (Figure a). Age did not significantly differ between those who did and did not survive to discharge within each stratum or between strata, although those who did survive to discharge tended to be younger (Figure b). Of 54 patients who were peripherally cannulated, 34 experienced limb ischemia. Incidence of limb ischemia did not differ significantly between strata (61.1% (11/18); 50.0% (8/16); 75.0% (15/20); p=0.298). In patients who did not survive to discharge, incidence of infection was similar between strata (37.5% (3/8); 25.0% (3/12); 37.5% (6/16); p=0.755).

Conclusion: Survival to discharge following VA-ECMO significantly decreased as BMI increased. Larger studies are required to determine the effect of interaction between BMI, age, and other comorbidities on survival to discharge following VA-ECMO.



P55

Single Center Series Of VA-ECMO To Durable LVAD

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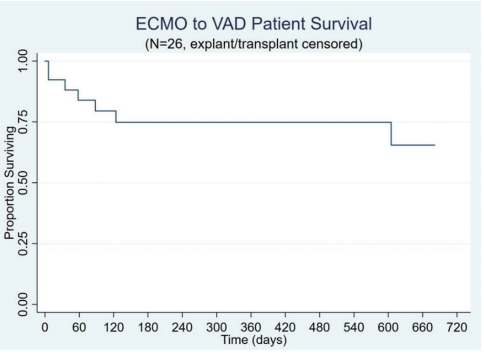
Study: Veno-arterial extracorporeal membrane oxygenation (VA ECMO) is an accepted modality in the treatment of refractory cardiogenic shock (RCS), but may be reluctantly used as a bridge to durable mechanical support due to concerns about long term outcomes.

Methods: We performed a retrospective review of patients at our institution from January 2012 to April 2017, who were implanted with a durable left ventricular assist device (LVAD) following VA ECMO for RCS. We assessed baseline demographics, ECMO support characteristics, short- and long-term survival, as well as and NYHA Functional Class up to two years after discharge from index hospitalization.

Results: A total of 26 patients (21 males) with a mean age of 52.1±16.4 years were analyzed. All patients were INTERMACS profile 1. Twenty-two (87%) patients were implanted with a HeartMate II, 3 (12%) with an HVAD, and 1 (4%) with HeartMate 3. Median time on ECMO support was 137 hours [89 - 202], and median length of stay was 40 days [31 - 52]. Median peak creatinine was 2.1 mg/dL [1.7, 2.9]. Median peak troponin was 20 ng/mL [0.6, 142.3]. Median peak lactate was 3.7 mmol/L [2.4, 5.4]. Median peak CK was 762 U/L [199, 3106]. Mean minimum hemoglobin was 7.5 g/dL (.08). Fourteen patients (54%) underwent CRRT. In regards to discharge disposition, 35% went home, 39% went to rehabilitation, 19% expired, and the remaining 7% were went to long term care or transitional care. Thirty day, six month, one year and two year survival was 79% (n=19), 68% (n=13), 65% (n=11), and 60% (n=9) respectively (Figure 1). Eighty three percent of patients were NYHA functional class I/II at 6 months and remained stable over the 2 year follow up period. Outcomes are presented in Table 1. In conclusion, patients who received a continuous flow LVAD from VA ECMO at our institution have favorable long term outcomes that are superior to previously reported.[1] VA ECMO support should not be an absolute contraindication to durable LVAD implant.



	Outcomes	
Follow Up Phase	NYHA Functional Class	Outcome
1 month	I: 1 (5.3%) II: 7 (36.8%) III: 10 (56.2%) IV: 1 (5.3%)	LVAD: 22 (84.6%) Transplant: 0 (0.0%) Explant: 0 (0.0%) Expired: 5 (19.2%)
6 month	I: 7 (58.3%) II: 3 (25.0%) III: 2 (16.7%) IV: 0 (0.0%)	LVAD: 17 (65.3%) Transplant: 2 (7.7%) Explant: 1 (3.8%) Expired: 6 (23.1 %)
1 year	I: 6 (60.0%) II: 3 (30.0%) III: 1 (10.0%) IV: 0 (0.0%)	LVAD: 14 (53.0%) Transplant: 4 (15.4%) Explant: 1 (3.8%) Expired: 7 (26.9%)
2 year	I: 4 (66.7%) II: 2 (33.3%) III: 0 (0.0%) IV: 0 (0.0)	LVAD: 8 (30.8%) Transplant: 7 (26.9%) Explant: 2 (7.7%) Expired: 9 (34.6)

P56

A Standardized Approach To Extracorporeal Membrane Oxygenation For Postcardiotomy Shock

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Study: Postcardiotomy shock is historically associated with substantial morbidity and mortality. We investigated the outcomes of our standardized team-based approach to veno-arterial extracorporeal membrane oxygenation (ECMO) therapy for postcardiotomy shock.
Methods: We retrospectively reviewed 60 postcardiotomy shock patients who required ECMO following major cardiac surgery from January 2017 to September 2019. A dedicated multidisciplinary ECMO team was involved in the care of all patients. Our standardized approach includes early institution of ECMO, preferential peripheral ECMO cannulation, partial flow, pulmonary artery catheter guided post-op management, and conservative use of heparin. Data collected included lactate level, hemodynamics variables, and vasopressor/inotropes dosing prior to ECMO insertion. Vasoactive-Inotropic Score (VIS) was calculated.
Results: Median age of the cohort is 65 (IQR 55-75), and 63% were male. Major cardiac surgery included CABG (n=10), valve (n=23), valve and CABG (n=12), root surgery (n=10), and others (n=5). Seven patients (12%) had preoperative cardiogenic shock. Median cross clamp time was 121 minutes (IQR 77-198). Thirty-eight patients (63%) had ECMO placed at the index OR. Median lactate level, systolic blood pressure, central venous pressure, and mean pulmonary artery pressure before ECMO were 3.2 mmol/L, 80mmHg, 15mmHg, and 29mmHg, respectively. Fifty-nine patients (98%) were on 2 pressors and 54 (90%) were on 2 or 3 inotropes. VIS was 30 (IQR 25-49). 80% of patients received peripheral ECMO and 20% were centrally cannulated. Median ECMO flow index was 1.61 (IQR 1.4-2.0) L/min/m^2. Anticoagulation was not given in 12 (20%) patients during ECMO support. Major adverse events included chest re-exploration (15%), stroke (6.7%), renal replacement therapy (22%), and limb ischemia (5%). The 30-day mortality was 22% and 40 patients (67%) survived to discharge.

P57

Veno Arterial Extra Corporeal Membrane Oxygenation With Axillary Artery Cannulation Reduces Cannulation Related Adverse Events

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Study: The aim of this study is to review outcomes of axillary artery cannulation for venoarterial extra corporeal membrane oxygenation (VA ECMO).
Methods: A total of 426 adult patients were supported with VA ECMO for cardiogenic shock at our institute from Nov 2009 to Oct 2019. Patients with axillary artery cannulation (group Ax, N=220), and femoral artery cannulation (group FA, N=156) were compared. Other cannulation sites were excluded (N=50). .
Results: Pre-ECMO backgrounds were comparable between 2 groups regarding indication, male sex (group Ax: 64.1 vs. group FA: 69.9%), body surface area (1.99 vs. 2.02 m^2), lactate level (6.2 vs. 6.8 mmol/L), transaminase (569 vs. 668 IU/L), prevalence of co-morbidities except for peripheral artery disease (13.6 vs. 6.4%, p=.024). The rate of intra-aortic balloon pump (47.3 vs 53%), and Impella (11.8 vs 11.5%) were similar. Mean age was higher in group Ax (59.9 vs. 56.3, p=.009). Hospital mortality (40 vs. 43.3%), the incidence of cerebrovascular accident (12.3 vs. 10.2%), temporary dialysis (29.1 vs. 36.9%), prolonged ventilation (62.3 vs. 65%), cannulation related bleeding (15 vs. 16.7%), and length of ECMO support (7.8 vs. 7.5 days) were comparable. The incidences of cannulation related limb ischemia (0 vs. 8.9%, p<.001), and wound complication (WC) (2.7 vs. 15.3%, p<.001) which needs surgical intervention were significantly higher in group FA. Of the patients in group FA who had WC, 47.8% required sartorius muscle flap. In multiple logistic regression analysis, FA cannulation and primary graft failure (PGF) after transplant were independent risk factors for cannulation related WC. In PGF patients, the incidence of cannulation related WC was significantly higher in group FA (3.6 vs. 39.1%, p=.001). Although most major adverse outcomes are not influenced by arterial cannulation site choice, Ax cannulation reduces incidence of WC, and may be benefit for patients requiring VA ECMO due to PGF after heart transplant.

P58

Investigation Of Pulsatility With Trans-Valve Axial Flow Blood Pump Implanted At Aortic Valve Position

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Study: We have developing a trans-valve left ventricular assist device(LVAD). The purpose of this study is to demonstrate the hydrodynamic performance of the trans-valve LVAD in an *in vitro* experiment.
Methods: The trans-valve LVAD mainly consists of a rear impeller axial flow blood pump(AFBP) and a polymer membrane valve. The rear impeller AFBP belongs to second generation pumps that the rotation of the impeller is sustained by a ceramics pivot bearing and a fin bearing. The diameter and length of the rear impeller AFBP was 12 mm and 63 mm, respectively. The figure of the polymer membrane valve is similar to the jelly-fish valve, and it consists of a valve leaflet made of silicone rubber, valve ring and valve spokes. The polymer membrane valve had a diameter of 25mm and a thickness is 5mm. The trans-valve LVAD was examined in a mock circulation using 33% glycerin solution to study its performance. An implantable pulsatile flow ventricular assist device(PFVAD) was used to simulate the left ventricle, and the trans-valve LVAD was placed at the output port of the PFVAD like as an outflow valve.
Results: According to increase of the motor rotational speed until 26400 rpm, a mean aortic flow increases from 4.2 L/min to 5.3 L/min and mean aortic pressure increases from 83.4 mmHg to 100 mmHg, and the mean motor current of the PFVAD decreases from 1.18 A to 0.94 A (unloading effect -21 %). EEP increases from 85.2 mmHg to 102 mmHg, and SHE slightly decreases from 2364 erg/cm^3 (baseline) to 1999 erg/cm^3 (-15.4 %).
Conclusion: The trans-valve LVAD has an advantage that it can preserve pulsatility without any complicated mechanism and it is one of a new promising LV support device.

P59

Distal Perfusion Monitoring: Comparing Flow And Skeletal Muscle Oxygen Saturation

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Study: Monitoring flow in distal perfusion catheters (DPCs) in patients with femoral artery extracorporeal membrane oxygenation (ECMO) reduces the risk of limb ischemia requiring intervention. Another form of limb perfusion monitoring, near-infrared reflectance spectroscopy (NIRS), is used to monitor skeletal muscle oxygen saturation (StO2) but there is little information comparing flow rates and StO2. This study aims to compare NIRS with DPC flow to determine advantages in either form of monitoring.
Methods: A retrospective chart review was performed on patients who underwent Veno-arterial (VA) ECMO via the femoral artery with DPC in place from 2018 through 2019. DPC flows were monitored with flow probe and StO2 via NIRS. All parameters were documented in the medical record while patients remained on support.
Results: We reviewed 53 patients on VA ECMO via the femoral artery with DPC placement and concurrent StO2 monitoring via NIRS. Average DPC flow in all patients was 0.23lpm (SD=0.056). Average StO2 was 75.09% (SD=11.25). Correlation between perfusor line flow & StO2 was significant ($r = .362$, $p = 0.008$). There was one limb complication requiring intervention (hematoma evacuation) which did not result in loss of limb or digits. Discussion: Higher flows correlate with improved StO2, and use of either DPC flow probe or NIRS will effectively prevent limb complications, thereby resulting in low ischemic risk. Additionally, DPC flow probes are ideal at monitoring second to second perfusion wherein acute clotting can be rapidly identified and treated to restore limb perfusion. NIRS may have an advantage over greater periods of time, as downward trends in StO2 may indicate a change in the patient's overall status that may affect limb perfusion.

P60

Mechano-Acoustic Mediated Platelet Activation in Ventricular Assist Devices

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Study: Ventricular assist devices (VADs) remain plagued with thrombo-embolic events leading to stroke. Shear-mediated platelet activation due to supra-physiological flows has been identified as a major factor in these events. Beyond flow abnormalities, vibration and acoustic abnormalities may also drive SMPA. In prior work we have demonstrated that thrombus-prone and thrombus-laden VADs did indeed make detectable noise. To explore this further, here we captured acoustic/vibrational frequencies of obstructed VADS and explored the effect of these frequencies on platelet activation *in vitro*. We hypothesized that frequency specific mechano-acoustic vibration will lead to mechanically-mediated platelet activation.

Methods: A MEMS-based vibration sensor (300 mV/g, 0.5 - 550 Hz) was placed on VAD housings of both HeartMate II (HMII) and HeartWare (HW), with VADs incorporated into a flow loop with water and glycerol. Different occlusion levels were introduced (0%, 50%, 70%, and 90%), VADS were operated and vibrational data was collected and analyzed using acoustic spectral analysis. A mechano-acoustic emulator was then used to expose platelets to an identified high energy frequency peak (200Hz x 40min.) found within the range of the acoustic spectral analysis. A frequency outside this range (900 Hz) served as a control. Platelets response was examined using a chromogenic platelet activity state assay, n=6.

Results: For both partially occluded VADs the highest energy was found between 100 and 300Hz throughout the differing occlusion levels, for both the HMII and HW. Employing 200 Hz *in vitro* a 40% increase in platelet activation was observed vs control ($p < 0.05$). In contrast exposure to 900 Hz had no significant effect.

Conclusion: Mechano-acoustical characteristics of VADs can lead to platelet activation. With further investigation, the acoustic spectrum of VADs may provide diagnostic information vital to in the prevention and treatment of thrombo-embolic events.

P61

AI (Artificial Intelligence) For Predicting Cardiac Surgical Outcomes

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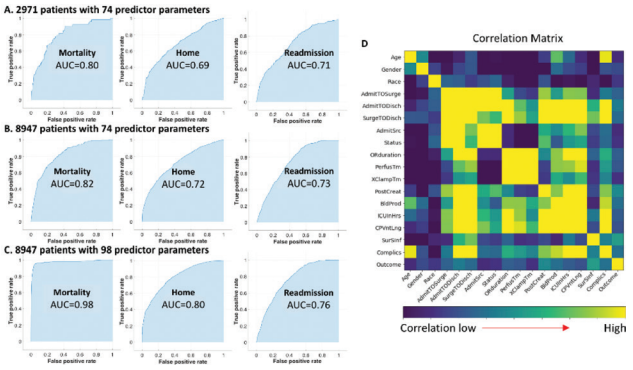
Study: Predicting outcomes in open-heart surgery can be challenging. Unexpected readmissions, long hospital stays, and mortality has economic implications. Artificial intelligence (AI) shows promise in accurately predicting outcomes.

Methods: We evaluated patients undergoing cardiac surgery from April 2006 to January 2018. Preop parameters were used to predict readmission and mortality. For each event, the classical logistic regression model and five different random forest models were used for prediction. Five-fold cross-validation was used to estimate model performance. Each AI model was evaluated by generating predictive discriminating variables such as the receiver-operating characteristic (ROC) curve and the area under the ROC curve (AUC), which implies predictive power. The AI performance was systematically evaluated by increasing testing populations from 2,971 patients who underwent isolated coronary artery bypass graft (CABG) surgery to 8,947 patients in total and by sequentially including additional predictor parameters.

Results: AI performance improved by training on further test populations and parameters (Fig 1A, B, and C). The predictive power AUC improved with an increased test population for all outcomes. The addition of perioperative parameters increases predictive AUC for mortality close to 1 (near perfect prediction). The correlation matrix shows parameters highly correlated with the outcome (Fig 1D). AI performance decreases when only 17 features are included to predict the outcome whereas logistic regression performance significantly improves. Four different metrics were analyzed based on the confusion matrix: accuracy, precision, recall (sensitivity), and F score. Boosted trees algorithm turned out to be the most effective AI model in terms of sensitivity improving the performance of predicting mortality and readmissions from the true classes by 40% and 245% respectively compared to the logistic regression model.



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Predicting Post-LVAD Outcome - Is There A Role For Cognition?

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Study: Cognition has been found to influence risk of stroke and death for a variety of patient samples but this association has not been examined in heart failure (HF) patients who receive left ventricular assist devices (LVAD). This study explored the relationship between cognition and stroke and death in patients who underwent LVAD surgery. It was hypothesized that cognitive test results obtained prior to LVAD placement would predict these outcomes after surgery.
Methods: In a retrospective review of a HF database, 59 patients had cognitive assessment prior to LVAD placement. Cognitive assessment included measures of attention, memory, language, and visualmotor speed. Survival analyses, censored for transplant, evaluated predictors for stroke and death within a follow-up period of 900 days.
Results: The mean patient age was 53.54 ± 12.95 years, 17 (29%) had strokes, and 7 died (12%). For patients with stroke during the follow up period, the average cognitive z-score predicted post-LVAD stroke (HR=0.513, 95% CI=0.31 - 0.86, p=0.012) and death (HR=0.166, 95% CI=0.06 - 0.47, p=0.001). Cognitive performances were lower in the patients who suffered stroke or died. No other variable predicted stroke and death within the follow up period when the cognitive variable was in the model.
Summary and Conclusions: Cognitive performance was independently associated with post-LVAD risk of stroke and death. Cognitive scores were lower for patients who suffered stroke or died. Results are consistent with findings from other studies in non-LVAD samples and may reflect early signs of neurologic vulnerability. Further studies are needed to clarify how cognition influences LVAD outcomes and, thereby, to optimize LVAD management and advanced care planning.

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Successful Electroconvulsive Therapy For Management Of Depression In Left Ventricular Assist Device Patient At A Non-Implant Center

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Study: For patients with end stage heart failure, left ventricular assist devices (LVADs) provide lifesaving and life prolonging therapy. Many patients experience an improved quality of life after LVAD implantation, however some experience worsening anxiety and depression requiring intervention. Some patients do not tolerate pharmacologic intervention and continue to experience refractory function limiting depression. Traditionally, electroconvulsive therapy (ECT) is considered when pharmacologic intervention fails. The effects of ECT on the cardiovascular system is well understood, however it has not been studied in LVAD patients. Our patient suffered from disabling depression which severely impacted his quality of life. He did not tolerate pharmacologic therapy and ECT was offered, after multidisciplinary discussion. There are few case reports of the safety and efficacy of ECT in LVAD patients and prior reports were only documented at LVAD implant centers.
Methods: ECT was performed on our patient at a non-implant center with direct supervision from cardiac anesthesia and heart failure clinicians trained in LVAD management. Patient hemodynamics and LVAD parameters were closely monitored during ECT sessions.
Results: There was no observed hemodynamic compromise or LVAD complication. Our findings suggest that ECT is safe and efficacious in LVAD and is reasonable to consider in patients at both implant and non-implant centers with close hemodynamic monitoring and heart failure clinician expertise.

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Using A Mock Flow Loop To Characterize The Effects Of Artificial Pulse Waveforms Generated With A Centrifugal VAD Model

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Study: One significant technological advancement in newer generation continuous flow ventricular assist devices (VADs) is the addition of pulsatility control algorithms to minimize stasis and potentially decrease device-related adverse events. The purpose of this study was to configure a centrifugal pump to simulate different types of pulsatile flows using a benchtop test system to better understand the dynamic behavior of VADs in clinically relevant scenarios.
Methods: A variable-speed centrifugal pump was modified to produce time-dependent flow algorithms representative of emerging VADs. The pump control algorithm was modulated for a range of pump speeds, cardiac outputs, interval durations, and artificial pulse waveforms. For each simulated pump waveform, pressure and flow measurements were collected in a glycerin/water solution proximal and distal to the VAD model, as well as at various anatomical positions within the mock flow loop for representative heart failure profiles.
Results: We have demonstrated that different types of pulsatile flow waveforms (e.g. sine wave, step functions) can be reproducibly generated using a research-grade variable-speed centrifugal pump. It was observed that the cardiac output (3 - 8 L/min), the flow through the VAD model (0 - 8 L/min), pulsatility index (0 - 10), aortic pressure (up to 180 mmHg), and left ventricular pressure (up to 180 mmHg) were all impacted by the artificial pulse algorithm inputted into the VAD model (n=5). The test protocol and results established during this study will help support the development of standard pre-clinical test methods to effectively evaluate the impact of artificial pulses on the flow performance of VADs earlier in the total product life cycle. Synchronization of the pump speed modulation with the native heart function will be examined in upcoming mock flow loop studies.

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Reduced Risk Of Spinal Cord Ischemia With Multilayer Flow Modulators In Type-B Aortic Dissection Patients

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Study: Spinal cord ischemia (SCI) is one of the most devastating complication post thoracic heart interventions following both post-surgery and following endovascular repairs posing the risk of paraparesis and paraplegia. We sought to quantitatively analyze the spinal cord perfusion using patient-specific computational models following different repair strategies using a fenestrated Transcatheter Endovascular Aortic Repair (TEVAR) device and Multilayer flow modulator (MFM).
Methods: We reconstructed subject-specific geometries of aorta in Type-B AD patients pre- and post-intervention applying in-house semi-automatic segmentation routines to computed-tomography images. Time-dependent flow patterns, shear stress metrics, and perfusion to vital organs and spinal cord were computationally studied in pre-intervention (PI), and post-intervention cases with a fenestrated TEVAR (PT) and MFM (PM). A lumped-parameter module was coupled to the finite volume solver to dynamically assign appropriate outlet boundary conditions.
Results: Both endovascular treatments were effective in increasing blood flow in true lumen and regulating wall shear stress. However, MFM achieved significant reduction in false lumen flow on top of eliminating local flow disturbances, maintaining physiologic perfusion of peripheral vital organs and, more importantly herein, restoring spinal cord blood supply; thus promisingly reducing the paraplegia risk. This promising performance of MFM is attributed to laminarizing the former turbulent blood flow in dissected lumen, yet allowing the blood flow to permeate through its mesh to perfuse vital organs and major outlets.

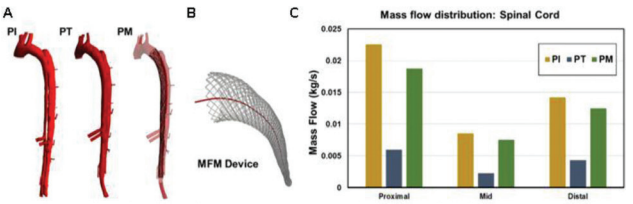

Fig. 1: *(A) Reconstructed patient-specific geometries of pre-intervention (PI) as well as post-TEVAR (PT), and post-MFM (PM) implantation cases. (B) Computationally-adapted MFM device. (C) Accumulated spinal blood supply over a cardiac cycle in proximal, mid, and distal aorta. MFM device restores physiological flow patterns while minimally compensating the spinal perfusion.*

P66

Ratio Of Mean Arterial Pressure To Right Atrial Pressure At The Time Of Right Heart Catheterization Is Associated With Increased Risk Of Incident End-Stage Renal Disease After Left Ventricular Assist Device Implantation

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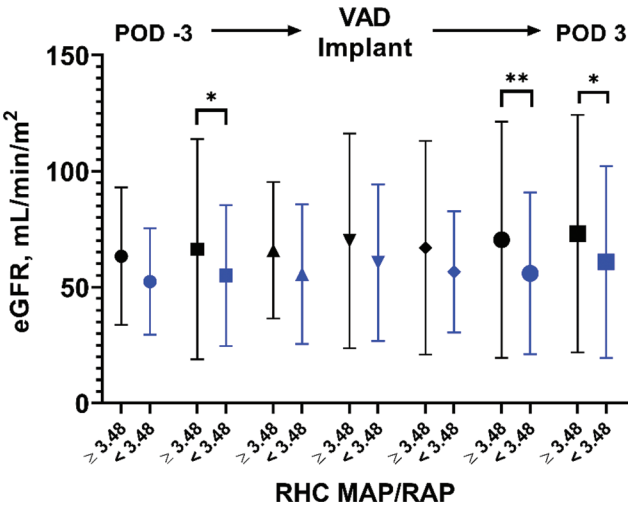
Study: Several hemodynamic markers are associated with elevated risk of acute kidney injury after implantation of a left ventricular assist device (LVAD), but markers associated with the development of incident end-stage renal disease (ESRD) are sparse.

Methods: A retrospective review of patients undergoing LVAD implant between 2007 and 2017 was undertaken. A bootstrap forest portioning method was utilized to screen candidate hemodynamic variables at the time of right heart catheterization (RHC), 6-hours post-RHC, and at the time of LVAD implant with respect to the risk of initial AKIN stage 3 (sample rate 17%) and incident ESRD post-LVAD (rate 7%) We examined the prognostic utility with logistic regression analysis and multiple-comparison ANOVA with adjustment for false discovery rate.

Results: We included 365 patients (79% male, mean age 59 ± 13, 46% ischemic, and 63% destination therapy). Mean arterial pressure / right atrial pressure (MAP/RAP) at the time of RHC outperformed all other candidate pre-operative variables and was significantly associated with incident ESRD development post-LVAD (AUC 0.77, *P*<0.001). A MAP/RAP ratio below the optimal cut-point of 3.48 (sample rate of 21%) was associated not only with an elevated risk for AKIN stage 3 (OR 4.8, 95% CI 2.6-8.9, *P*<.0001) and early eGFR (see figure) but also with a markedly elevated risk of ESRD (OR 12.1, 95% CI 4.4-33.6, *P*<.001). A lower MAP/RAP ratio at the time of RHC pre-LVAD was associated with a markedly increased risk of incident ESRD post-LVAD. Optimizing patient selection and instituting aggressive medical and device therapy to augment MAP and lower RAP may improve the risk of long-term dialysis though this hypothesis remains untested.



P67

***In Vitro* Characterization Of Ingested And Ejected Thrombus From The HeartMate 3 And HVAD Ventricular Assist Devices Using High-Speed Videography**

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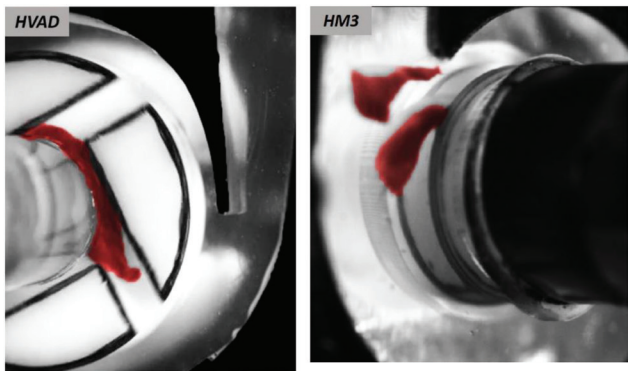
Study: The introduction of contemporary centrifugal ventricular assist devices (VADs) has significantly reduced the frequency of pump thrombosis (PT); however, the incidence of stroke remains a major adverse event in patients implanted with the HVAD and HeartMate 3 (HM3). Recent evidence suggests thrombi originating upstream of the pump—from stagnant regions such as the left atrial appendage or within the ventricle itself—are either ingested and ejected by the VAD or become deposited within the blood flow path, increasing the risk of ischemic stroke. This study was conducted to visualize in real-time the ejection of emboli from both the HVAD and HM3 and quantify the prevalence of deposition within these pumps due to thrombus ingestion.

Methods: Clinical explant images were assessed to determine the approximate size and microstructure of thrombi observed in VADs. Corresponding clot analogs of varying compositions (40% Hct, 20% Hct, fibrin) and sizes (0.5cc, 1cc, 2cc) were synthesized and individually introduced into an *in vitro* flow loop with a transparent replica of either the HM3 or HVAD operating under physiological conditions. High-speed video was employed to observe the ingestion of thrombi resulting in deposition within the pump or the subsequent disruption and ejection from the VAD.

Results: Thrombi of varying compositions and sizes were observed mechanically attaching to the impeller of both the HM3 and HVAD. Emboli discharged from both VADs, regardless of microstructure and original volume, ranged from 0.01-0.20cc -- appropriate size to occlude an intracranial vessel. In some instances, ingested thrombi physically obstructed portions of the blood flow path. 100% (n=5) of 1cc fibrin clots became lodged within the HM3 while, in contrast, all 40% Hct clots of the same volume were ejected from the pump. Therefore, ingested thrombus may explain, in part, elevated stroke rates in centrifugal blood pumps in the absence of adherent PT.



P68

Diaphragm and Cannula Tears with the Total Artificial Heart

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Study: We sought to assess the incidence and severity of cannula and diaphragm tears experienced by patients implanted with the SynCardia TAH-t to determine the durability of the cannulae and diaphragms.
Methods: We performed retrospective review of all customer experiences reported to the manufacturer between 1982 and April 2019
Results: There were 1892 TAH-t implants with over 701 patient years of support. Reported events and failure investigations for twelve (12) diaphragm tears and 74 cannula tears were analyzed. **Diaphragm tears:** A diaphragm failure rate of 0.63% (12/1892) was calculated based on the 1892 implants during the review period. There were ten blood diaphragm (BD) tears which resulted in 8 deaths, 1 transplant and 1 TAH replacement. One air diaphragm (AD) tear resulted in death and the device was not returned for analysis in one remaining case (patient was transplanted). Root causes - BD: 7 contact abrasion, 1 thinning, 1 bubble in BD leading to focused wear, 1 no root cause identified; Root causes - AD: Hole developed through 4-layered AD; BD remained intact. The average time to event was 660 days (range 124 - 1680 days). **Cannula tears:** An overall failure rate of 1.96% was calculated based on 3784 cannulae (1892 implants) in which 74 tears were reported. The first events occurred in patients supported by the Excor Driver in Europe; rate of occurrence was 0.07/patient year (5 events in 5 of 79 patients). The rate of occurrence in patients supported by the Freedom Driver System was 0.24/patient year (69 events in 49 of 403 patients). Temporary repairs with rescue tape or replacement of damaged sections of the cannulae resulted in no permanent harm or deaths. **Conclusions:** Examination of the worldwide experience with the SynCardia TAH-t reveals that the device is durable and diaphragm and cannula tears are rare. Diaphragm tears are often fatal and early recognition is imperative.

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Venoarterial Extracorporeal Membrane Oxygenation (VA-ECMO) For Cardiogenic Shock: Partial Or Full Flow?

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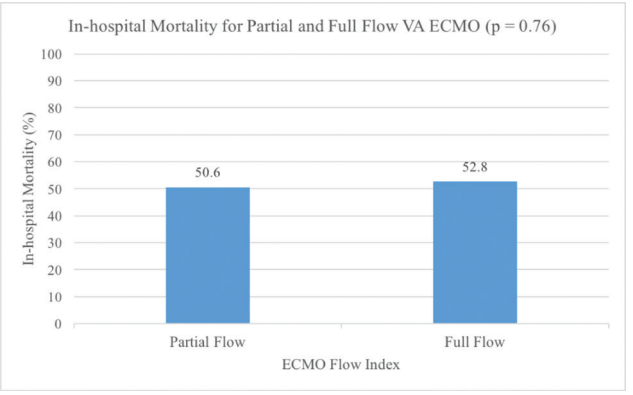
Study: ECMO is increasingly used to provide cardiopulmonary support in refractory cardiogenic shock. There is controversy regarding the optimal blood flow strategy (partial vs. full) in VA ECMO use. Our institution has implemented the use of partial flow VA ECMO to avoid left ventricular (LV) distention and intracardiac stasis. Herein we compare outcomes in patients placed on full flow (F) versus partial flow (P) VA ECMO.
Methods: Retrospective review of all patients placed on VA ECMO from 2007 to 2018 was done. Based on initial blood flow index (Flow/BSA), patients were divided into full flow (flow index > 2.2 L/min/m^2) and partial flow (flow index < 2.2 L/min/m^2) groups. In-hospital mortality and markers of end-organ perfusion -- lactate, creatinine, and liver function tests -- were compared between groups balanced for risk factors using propensity score based inverse probability of treatment weighting (IPTW).
Results: A total of 488 patients were placed on VA ECMO, with 373 patients (76%) in the partial flow group, and 115 (24%) in the full flow group. Mean flow index in the partial group was 1.63 ± 0.29 L/min/m^2 versus 2.43 ± 0.19 L/min/m^2 in the full flow group. After IPTW no major differences in age, gender, comorbidities, or etiology of shock were found. There were no differences in in-hospital mortality between F and P groups (50.6% vs 52.8% p = 0.76). At 72 hours post-ECMO initiation there was no difference in the change in renal function, hepatic function, or lactate from baseline nor in the rates of continuous venovenous hemofiltration initiation between groups (p = 0.12). There was, however, a trend towards decreased incidence of LV distention requiring IABP, Impella, or LV vent placement between F and P groups (12.5% vs 4.9%, p = 0.08). In conclusion, compared to full flow VA ECMO, partial flow VA ECMO provides similar in-hospital mortality and end-organ perfusion for the treatment of refractory cardiogenic shock while potentially reducing the incidence of LV distention.



P70

Impact Of Minimally Invasive LVAD Implant Techniques On Outflow Graft Position For Future Sternotomy

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Study: One potential challenge during heart transplantation for the LVAD patient is the position of the outflow graft. An outflow graft located below the sternum is more likely to be cut during sternotomy, possibly requiring emergent bypass, a more complicated hemodynamic course, more blood product, and a longer bypass run. Minimally invasive implant techniques (e.g. thoracotomy) may present a solution to this problem.
Methods: CT imaging of the chest was obtained on 21 patients implanted with HeartMate 3 and HeartWare LVADs. 13 were implanted via sternotomy, 5 via thoracotomy with hemisternotomy for graft anastomosis, and 3 via thoracotomy with robotic-assisted outflow graft placement.
Results: Evaluation revealed grafts positioned mostly along the anterior to lateral aspect of the right ventricle for LVADs implanted via sternotomy. Grafts anastomosed with robotic assistance were positioned along the lateral aspect of the right ventricle while grafts anastomosed via hemisternotomy were located along the anterior aspect of the heart. Of 5 grafts anastomosed through hemisternotomy, 2 were positioned to the left of the sternum, 2 to the right of the sternum, and one partially directly below the sternum (Figure 1). Of the 21 sets of patient imaging reviewed, 3 outflow grafts were determined to follow the sternum below a potential future sternal incision, 2 grafts anastomosed via sternotomy and one via hemisternotomy. These 5 graft anastomoses via hemisternotomy were the first performed at our center; graft position may improve with adjustments to surgical technique during future minimally invasive implants. However, this data suggests robotic anastomosis results in more reliably lateral outflow conduit position which should lead to safer reentry.

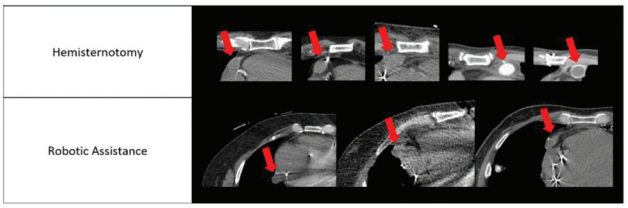

Figure 1. LVAD outflow graft position comparison between hemisternotomy vs. robotic assistance for anastomosis.

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Left Ventricular Assist Device Support In Patients With Restrictive Physiology: Review Of Outcomes And Word Of Caution

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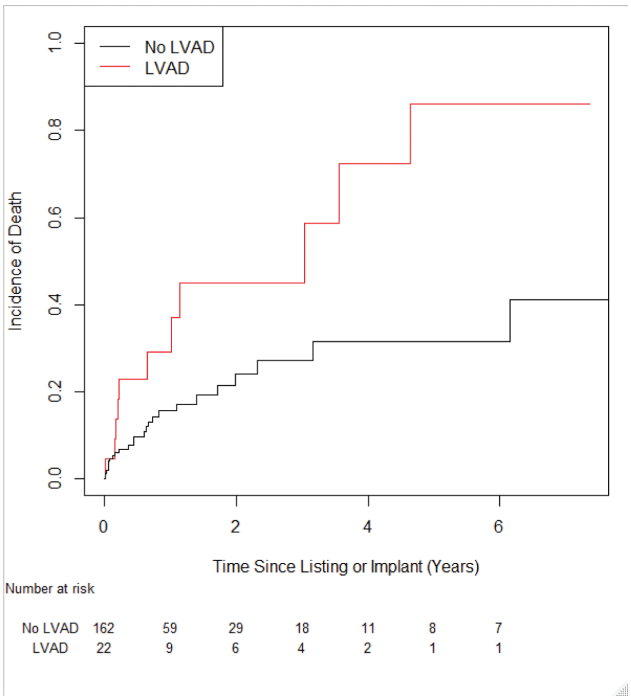
Study: Cardiomyopathies with primary restrictive physiology (RCM) are traditionally considered unconventional candidates for LVAD therapy. We aimed to investigate LVAD utilization, incidence of heart transplant waitlist death, and overall mortality in RCM patients comparing them to those with dilated (DCM) and ischemic (ICM) cardiomyopathies and to RCM patients bridged to transplant with medical therapy alone.
Methods: This was a retrospective study of 397 patients who underwent primary implant of a durable continuous LVAD between February 2007 and October 2018, and 162 RCM patients bridged to transplant on medical therapy alone. Outcomes were assessed by survival with LVAD support until heart transplantation or all-cause mortality.
Results: Indications for LVAD were DCM (45.8%, n=182), ICM (41.0%, n=163), RCM (8.3%, n=33), and other (4.8%, n=19). The mean age at implant was 60 years ± 12.4 and 317 (79.9%) were male. LVAD patients with RCM and ICM had a significantly lower overall survival rates than DCM patients (HR 2.12, 95% CI 1.35-3.64, p=0.002, and HR 1.45, 95% CI 1.05-1.98, p=0.02, respectively). There was no significant difference in overall survival post-LVAD between RCM and ICM patients (HR 1.53, 95% CI 0.96-2.45, p=0.076). Overall mortality for RCM patients treated with LVAD as BTT compared to destination therapy was similar (HR 1.23, 95% CI 0.51-2.96, p = 0.64). LVAD pump type did not significantly impact on overall survival (HR 1.30; 95% CI = 0.43, 3.87; p = 0.642). RCM patients with LVAD as BTT had poor waitlist survival compared to those bridged with medical therapy alone (figure 1).



RCM patients treated with LVAD as BTT had poorer outcomes on the waitlist compared with their medically-treated counterparts. Overall survival post-LVAD implantation was comparable between RCM and ICM patients irrespective of indication. LVAD for DT as primary utility in RCM patients may be reasonable in absence of better advanced heart failure therapies.

P72

Percutaneous Temporary Right Ventricular Mechanical Support With Double Lumen Cannula During Left Ventricular Assist Device Implantation - A Word Of Caution

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Study: The aim of our study was to analyze hemocompatibility and end-organ perfusion in patients with percutaneous in comparison to surgical temporary RV mechanical support after LVAD implantation.
Methods: We retrospectively reviewed data collected during 5 days after implantations of percutaneous and surgical temporary RVAD within 24 hours of LVAD between 2017 and 2019.
Results: We used 29 Fr double lumen cannula inserted through RIJ vein for percutaneous support in 5 patients. Surgical approach involved implantation of the return cannula into main PA and drainage cannula into RA via graft (7 patients). There were no differences in basic demographic and clinical variables between the groups at the time of RVAD insertion (Tab 1). Median duration of RVAD support in 7 hospital survivors (60%) was 16 days (min 7, max 31) with no difference between the groups (P =.62). The median RVAD and LVAD flow, RVAD to LVAD flow ratio and RVAD speed are depicted in Fig 1. Although there were no differences in patients' end-organ perfusion (lactate P=.98), patients with percutaneous support had significantly lower platelet count (Fig 2). Main findings of our study are: 1) higher speed of RVAD required to generate desired flow and 2) lower platelet count during the first 5 days in patients with percutaneous support. Limitations are small sample size and short study period. The directions for future research are: a) investigate other markers of hemolysis (LDH, haptoglobin), b) further elucidate clinical implications of thrombocytopenia, and c) identify patients' characteristics associated with favorable outcome with percutaneous and surgical approach. In conclusion, we advocate caution when using percutaneous RVAD in patients requiring > 4L of flow and low baseline platelet count.

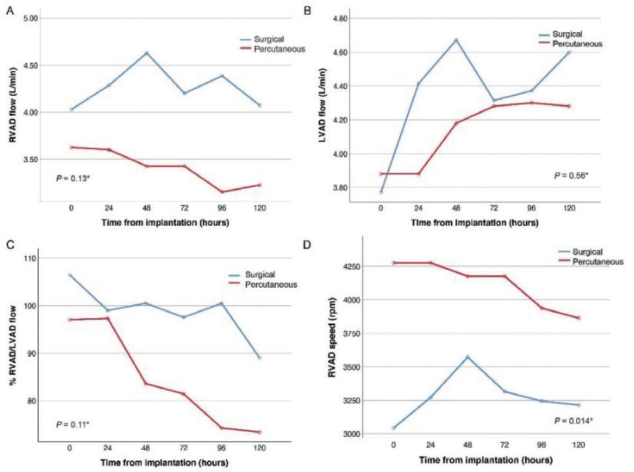

Figure 1. Time course of A) RVAD flow, B) LVAD flow, C) RVAD/LVAD ratio and D) RVAD speed over the first 5 days after implantation
*Repeated measures ANOVA with between - subjects analysis

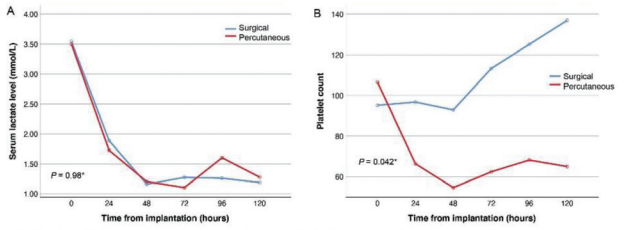

Figure 2. Time course of A) serum lactate level and B) platelet count up to 5 days after RVAD implantation
*Repeated measures ANOVA with between - subjects analysis

P73

Ambulatory, Chronic Veno-arterial Pumping For Treatment Of Congestive Heart Failure

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Study: Hypothesis Veno-arterial pumping (V-A) was explored in the fifties and later in the seventies for the treatment of cardiogenic shock following open heart surgery. The technique employed an external pump, without an oxygenator, to removed partially desaturated venous blood and return it to the femoral artery. V-A pumping had two beneficial hemodynamic effects; first, it significantly reduced venous congestion and, secondly, it increased the arterial perfusion pressure to critical organs. Animal studies and limited clinical trials demonstrated improvement in survival. Since the return of blood to the systemic circulation was via the femoral artery, the theoretical risk of stroke would be expected to be much lower than present day LVADS. The technique was abandoned with the advent of more powerful left ventricular assist devices.
Methods: Proposal It is proposed that an existing miniature LVAD could be adapted to chronic ambulatory V-A pumping and used to treat less severe cases of CHF. An LVAD with a passing profile compatible with placement via the femoral or iliac vein could be advanced into the inferior vena cava. An outlet cannula or graft would then exit the vein and be connected to the femoral or iliac artery. The power line would exit the vein and tunneled to exit the abdominal wall.
Results: Discussion Although the magnitude of assistance would be about 2 lpm, it would be sufficient to significantly benefit class III and II patients. This patient population is much larger than is currently addressed by present LVADs and could be implemented with a minimally invasive technique. It is probable that strokes would be significantly reduced and GI bleeding may be reduced since physiologic pulsatility would be largely preserved.
Conclusion Based on the prior demonstration of efficacy of V-A pumping in assisting the failing circulation and the advent of durable LVADs with small passing profiles, a new form of mechanical circulatory assistance should be explored.

P74

Ventricular Septal Movement During LVAD Assistance - An *In Vivo* Observation

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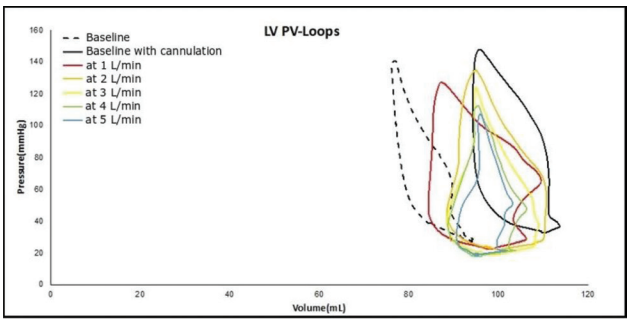
Study: Right ventricular failure (RVF) occurs in more than 40% of left ventricular assist device (LVAD) patients and is associated with a mortality greater than 70%. The decrease in RV function was mainly due to the shortening of the RV free wall resulting from impeded functioning of the left ventricle (LV). In order to investigate the pathophysiology of post-LVAD RVF and to develop mitigation strategies, an in vivo study was proposed to evaluate the LVAD effect on animal ventricular septum movement.

Methods: An extracorporeal LVAD was tested in the porcine models. The inflow cannula was inserted into LV while the outflow cannula was anastomosed to the aorta. PV loop catheter was placed in the LV and RV to record the ventricular pressure and volume changes. The baseline Echo was performance before and during the pump started to monitor septal wall movement. LVAD speed was adjusted to reach the target graft flow ranging from 1 L/min to 6 L/min at 1 L/min step until noticeable ventricular septal wall movement occurred. A series of pressure and flow rate at different locations were recorded.

Results: As the pump flow increased from 1 L/min to its maximal flow 5.4 L/min, the average pulmonary artery flow (PAQ) gradually increased by 22.5%, while the aortic flow (AoQ) decreased rapidly from 5.2 L/min to zero. The average pulmonary artery and central venous pressure maintained the same (14.6 ± 0.1 mmHg, and 22.0 ± 0.6 mmHg), while the average aortic pressure increased by 20.3% (from 61 to 73 mmHg). PV-loop shows that the difference between end systolic (ESV) and diastolic volume (EDV) of LV decreased as the pump flow increased, indicating restrained movement of LV chamber. Although PAQ was less affected than AoQ, both ESV and EDV of RV increased by 25% as flow changed from 1 to 2L/min and maintained the same for the rest of study, indicating ventricular wall was moving towards the LV side. This study provided extensive septum and heart physiological data for the studies on LVAD-heart interaction for the post-LVAD RVF pathophysiology.



P75

Simulated Thrombosis Patterns In HVAD Depend On Axial Clearance Gap And vWF Activity

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Study: We recently reported a numerical study of thrombus deposition patterns within the Medtronic HVAD, assuming a nominal gap and rotor speed (RPM). A recent experimental study by Thamsen et al. (2018) revealed the axial clearance gap of the blood lubricated bearing of the HVAD is dependent on RPM and fluid viscosity. Therefore, the current study investigates the influence of gap and von Willebrand Factor (vWF) activity on the thrombus deposition patterns.

Methods: We employed our recently developed numerical model of vWF-mediated thrombosis to simulate adult (5 L/min, 2800 RPM) and pediatric (2.5 L/min, 2200 RPM) operating conditions in HVAD. At both conditions, we performed thrombosis simulations with the axial clearance gap set at 25 and 50 microns. The effect of vWF was modeled through its increased bond strength with platelets, hence increased resistance of deposited platelets to shear cleaning.

Results: Thrombosis patterns predicted by our computational model corresponded to those found in explanted blood pumps. (See Figure 1.) Thrombosis patterns were affected by both axial clearance gap and vWF function. Results for the 25-um gap distance in the absence of vWF are shown in Figure 1A. Under these conditions, flow reversal takes place within the wedge region of the blood-lubricated bearing and drives platelet deposition in the resulting stagnation zone -- but not the high-shear zone. When vWF *is present* in physiological concentration, platelets accumulate in the high-shear zones (Figure 1B), and the onset of thrombosis takes place earlier in the simulation. These results suggest that both the axial gap and vWF function could drive the variability in thrombosis patterns observed in explanted HVAD pumps.

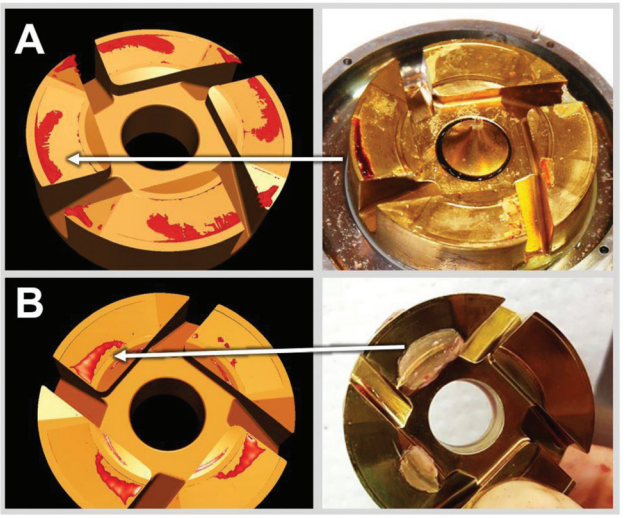

Figure 1. Simulated thrombosis results at 25 um axial gap without vWF (A) and with vWF activated (B).

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Left Ventricular Decompression On VA-ECMO Support: Single Center Experience

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Study: LV distension is a recognized complication of VA ECMO that can lead to pulmonary edema,increased wall stress and myocardial oxygen consumption.Thus,LV decompression is critical for accelerating recovery of the left ventricle and improving outcomes.LV decompression can be successfully provided via various percutaneous methods, such as IABP, PBAS, and percutaneous Ventricular Assist Devices like TandemHeart™ and Impella.Apical or left atrial venting through left anterior mini-thoracotomy or sternotomy are the main surgical interventions preferred for LV decompression.These methods may have lifethreatening complications including bleeding, hemolysis and increased risk for infection.The TandemHeart™ and Impella are effective options for decompression of left chambers, but both of the pVADs are not available in our country.In this single center study, we aimed to review LV decompression techniques performed in our hospital when severe LV loading is diagnosed after VA ECMO.

Methods: Among 448 adult patients who underwent VA ECMO from March 2015 to October 2019,53 patients who performed left ventricle decompression were analyzed.Demographic data, cardiac data (CVP,LAP,PAP and LAd),morbidity and mortality were recorded in these patients.

Results: Decraese of CVP,LAP,PAP and LAd after decompression,which can describe the signs of left heart decompression,were significantly higher in left ventricle apical venting group. Besides this effectiveness complications of surgical left ventricle apical venting wasn't rare.Some of these complications were bleeding,thrombosis of the venting canulla,ventricular arrhytimas,and canulla malpositions causing impaired decompression of the LV.Criteria for the recognition of this entity and timing and type of LV unloading method is not clearly defined in the guidelines. In this study,we aimed to review outcomes of percutaneous and surgical interventions that have successfully been used in clinical practice to unload the LV.

P77- WITHDRAWN

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Chronic Right Heart Support In Isolated Terminal Right Ventricular Failure

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Study: Isolated terminal right heart failure of either origin unresponsive to escalated medical therapy is a deadly disease with few therapeutic options. While chronic left ventricular mechanical circulatory support (MCS) is well established, isolated chronic mechanical right heart support is still in its infancy. So far, right heart assist devices (RVAD) are not available so that left ventricular assist devices (LVAD) have to be implanted right sided while standardized surgical approaches are lacking. We firstly report on 2 patients with refractory isolated right heart failure supported by chronic right heart support by Abbott HeartMate 3™ LVAD and present a new diaphragmatic implantation technique.

Methods: Both patients, 67,3 and 52,4 years, were in refractory cardiogenic shock due to isolated fulminant right ventricular failure of unknown etiology post multiple trauma or post failed RCA-PCI. Temporary MCS was initiated immediately to achieve RV recovery for 16 or 22 days prior to chronic right heart support. RVAD inflow was placed into the diaphragmatic surface of the right atrium. RVAD outflow was attached to the main pulmonary trunk bypassing the right ventricle. Anticoagulation was secured by Apixaban 5 mg bid and Clopidogrel 75 mg.

Results: Both patients were successfully discharged home and are currently supported for 874 and 154 days, respectively without any clinical or mechanical compromise. Neither suction nor pump displacement was detected. Chronic MCS by commercially available contemporary LVADs supporting the failing right ventricle could be a new therapeutic option to patients in refractory right ventricular. Diaphragmatic pump placement and RA access could be another option for chronic RVAD therapy

P79

Rebuilding With ECMO: A Case Of ECMO Supporting Airway Reconstruction

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Study: Traditionally, patients suffering from respiratory failure can be supported on veno-venous (VV) extracorporeal membrane oxygenation (ECMO) to facilitate lung recovery. However, recent cases have demonstrated the utility of ECMO in a variety of clinical scenarios. In this case study, we demonstrate how a patient who underwent neck and pharyngeal reconstruction following cancer can be supported with VV ECMO when standard ventilatory techniques are not possible anatomically.
Methods: A 71-year-old female presented with a history of T3N2 squamous cell carcinoma (SCC) of the right tongue. The patient underwent a hemiglossectomy, resulting in a multi-year remission. Seven years after initial diagnosis, the patient developed recurrent hypopharyngeal SCC requiring a laryngopharyngectomy with reconstruction. Recovery was complicated by wound breakdown, a persistent pharyngocutaneous fistula, and stomal dehiscence which required tracheal reconstruction, transhiatal esophagectomy, and gastric pullup. Shortly after surgery, bilateral chest opacities developed and the patient required increasing FiO2. Due to a tenuous airway and surgical wounds, tracheal intubation was not possible.
Results: The patient received mechanical ventilation via right and left mainstem intubation through the tracheal stoma, but gas exchange was inadequate. Therefore, the patient was cannulated through the right and left femoral veins to initiate VV ECMO, 10 days after surgery. This also allowed for a decrease in positive pressure ventilation to facilitate healing of the respiratory tract. In this patient, jugular cannulation was not possible due to surgical wounds in the neck. ECMO was continued for 74 days, supporting the patient through treatment for acute interstitial pneumonia and wound healing. Before decannulation, the patient received a conventional tracheostomy tube. She was subsequently stabilized and discharged to a long-term care facility eight days later.

P80

Anticoagulation Management Following LVAD Implantation In Bovine Model

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Study: Left ventricular assist devices (LVADs) are used to treat patients with severe heart failure. Advanced LVAD bearing technology and manufacturing methods have improved hemocompatibility. However, thrombosis and bleeding are still significant LVAD-related complications; thus, an effective anticoagulation regimen is important for successful postoperative management. In this study, the long-term effective anticoagulation regimen was investigated in a bovine model after the LVAD implant for up to 60 days.
Methods: The same LVAD were implanted in ten calves with inflow cannula inserted into the left ventricle and outlet cannula anastomosed to the descending aorta. The animals were heparinized up to 300 units/kg IV throughout the procedure to maintain the activated clotting time (ACT) above 250 seconds prior to and throughout cardiopulmonary bypass. Heparin infusion (25,000 units/250ml NaCl) started from postoperative day 1; when no bleeding observed, warfarin started orally to maintain an international normalized ratio (INR) between 2.0 and 3.0. The heparin infusion was then gradually discontinued. Pump performance, animal condition, and hematology results were recorded throughout the study. After termination, complete necropsy and histologic examination were performed to check for thrombosis in the LVAD, graft, anastomosis site and/or infarction in major organs.
Results: The results show that the LVAD was well tolerated in the bovine model with no significant thrombus, necrosis, or hemorrhagic lesion in distal end organs. Average plasma free hemoglobin is 4.00± 1.73 mg/dL within the reference range. The average ACT value was 168.30 ± 11.18 s, and the average INR value was maintained 2.15± 0.14 postoperatively. Under the established anticoagulation regimens, the coagulation system can be well controlled to avoid thrombosis and bleeding complications in our bovine model.

P81

Lemierre's Syndrome: A Sore Throat Even ECMO Struggles To Cure

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Study: Lemierre's syndrome (LS) is characterized by a primary oropharyngeal infection followed by thrombophlebitis of the internal jugular vein (IJV) and severe sepsis with septic emboli. This syndrome can deteriorate rapidly with progression to acute respiratory distress syndrome (ARDS) and shock. Here we demonstrate extracorporeal membrane oxygenation (ECMO) for the management of two young patients with LS.
Methods: Our first case was a 19-year-old female who presented with a flu-like illness which progressed to ARDS, requiring veno-venous (VV) ECMO support. She was diagnosed with LS after *F. necrophorum* growth on her blood cultures and neck/chest computer tomography (CT) demonstrated left IJV thrombophlebitis and septic emboli to the lungs. Following 9 days of ECMO support, she was decannulated, extubated, and discharged home in stable condition. Our second patient was a 17-year-old male who presented with headache, lethargy, nausea, vomiting, and diarrhea in addition to thrombocytopenia and hyperbilirubinemia. Blood cultures and CT showed similar findings and LS was diagnosed. Despite intubation and aggressive therapy, the patient deteriorated and required veno-arterial (VA) ECMO. Head CT following cannulation showed cerebellar hemorrhage, basal ganglia infarcts, midline shift, and uncal herniation. Following discussion with the family, care was withdrawn.
Results: Both of our patients suffered from LS with subsequent ARDS requiring ECMO support. Although the first patient had an excellent outcome, our second patient had worsening septic and cardiogenic shock despite ECMO and did not survive. Our cases, along with the limited reports of ECMO use in LS in the literature, demonstrate the potential for ECMO as a possible early treatment option in these patients.

P82

Development Of Prolonged Normothermic Isolated *Ex Vivo* Heart Perfusion

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Study: We have shown that cross-circulation of plasma from a paracorporeal animal allows successful ex-vivo heart perfusion (EVHP) for 3 days. Still, little is known about the feasibility of prolonged heart perfusion without a paracorporeal animal. These experiments were designed to evaluate fresh plasma exchange compared to paracorporeal cross-circulation.
Methods: Ten hearts were procured from 7-10 kg piglets using standard technique and underwent EVHP. Plasma was infused and removed by filtration at the rate of 1mL/hr/g heart (n=5). Controls used the same EVHP without plasma exchange (n=5). Plasma was obtained from porcine stored blood (4°C for ≤ 7 days) the day of the experiment. The EVHP circuit was primed with blood-derived perfusate and consisted of antegrade aortic perfusion. Perfusion protocol included aortic root pressure set at 60-100 mmHg, normothermia (37°C), and hemoglobin ≥ 7 g/dL.
Results: All experimental hearts were successfully perfused for 24 hours compared to the controls. Hearts in the control group failed with decreased left ventricular (LV) contractility and rising lactate starting at hour 12. The plasma exchange hearts had a higher LV systolic pressure and oxygen consumption (0.30 dL/min/100g versus 0.19 dL/min/100g, $p < 0.05$) compared to controls. Weight gain between control and plasma-infused hearts was (M = 23%±4.4 versus 14%±13.4, $p > 0.05$). These results highlight that EVHP can be successfully maintained for at least 24 h using continuous plasma exchange, eliminating the need for a paracorporeal animal, a step towards clinical application.

P83

ERAS Your VAD To A Shorter Length Of Stay

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Study: It is well established in the literature the morbidity, mortality and the societal cost of heart failure. Reduction in length of stay (LOS) in the adult population has been reported as a way to reduce morbidity and cost associated with heart failure. Left ventricular assist device (LVAD) implants have been shown to improve heart failure survival, however are beset with long hospitalizations. We report the case of a 22 year old male admitted with heart failure, underwent LVAD implant and discharge home 4 days later.
Methods: On admission LVEF 18%, left ventricle was dilated with a thin septum concerning for significant chronicity. Further testing notable for prolonged QTC, elevated filling pressures and critically reduced cardiac index. Given history, echocardiogram and MRI findings, it was felt coronary angiography or biopsy was not indicated. Inotropes, LVAD workup and enhanced recovery after surgery (ERAS) protocol was initiated and team ultimately recommended LVAD as bridge to recovery. Patient underwent HeartMate 3 LVAD implant and was discharged home post op day 4.
Results: Review of factors possibly contributing to this shortened LOS include proficiency in the evaluation process, patient age, lack of comorbidities, incorporation of an ERAS protocol, sternal sparing surgical approach and use of a customized LVAD patient engagement application. Further studies are needed to understand factors contributing to shortened post op LOS.

Patient Characteristics	Admission	Implant	Discharge
Wgt	92.3 kg	84.6 kg	85.3
BMI	28.3	25.64	25.86
Creatinine	1.21	0.96	0.86
Tbili	1.7	1.0	1.5
Albumin	4.1	4.5	4.0
INR	1.6	1.5	1.8
Hct	40	39	34

P84

What Do You Think? A National Survey Regarding The Role Of VAD Social Workers

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Study: This national survey ascertains the VAD Social Worker's (SW) role in the psychosocial aspect of care, as well as the opinions of team members regarding the VAD SW's value for patient selection and care.
Methods: A 23 question survey was distributed using Survey Monkey© to 30 centers. Centers with multiple respondents were consolidated to one response. The majority response for a single center was chosen for factual questions. The average of yes(1), sometimes (.5), and no(0) was determined for opinion questions. Values >0.5 were considered yes and <0.5 were considered no for questions without a "sometimes" option.
Results: A total of 29 responses were received from 22 centers. Of the 22 centers, 19 (86%) have dedicated VAD SWs. Nine (41%) centers use SIPAT for assessments, however 6 (27%) centers were unsure whether SIPAT was used. VAD SWs at all 22 (100%) centers present their assessment during VAD patient selection meetings. While 18 (82%) centers had a majority of respondents indicate that SW assessments are a deciding factor in patient selection, 10 (45%) of these centers indicated that the team "realistically" makes an informal decision before the SW's assessment. The most important functions of VAD SWs were indicated to be related to caregiver and living arrangements (Figure 1). Only 5 (23%) centers thought their VAD SW was underutilized. All (100%) centers felt that the VAD SW added value to the team. When asked whether the respondent trusts their VAD SW(s), the average score was 0.912 (n=22, SD=.174). Some doubt was indicated due to variability of individual SWs. Further studies should investigate the exact methods that VAD SWs utilize in their role.

Ranking of Social Worker Roles

Role	1	2	3	4	5	6	Total
Caregiver Presence and Involvement	11	5	3	2	0	0	21
Living Situations	4	9	4	3	1	0	21
Long-term Success with the Device	2	4	0	3	3	8	20
Compliance/Adherence	3	2	10	4	2	0	21
Financial Status	0	1	3	6	8	2	20
Education Status	1	0	1	2	6	10	20

P85

Standardizing And Streamlining VAD Education

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Study: As a large VAD program supporting 230 patients, we recognized a need to ensure all staff members caring for VAD patients had consistent education and hands on skills opportunities, and that education needed to be standardized to ensure all members were receiving the same information. The previous model of renewal education consisted of only psychomotor skills. There was no opportunity for cognitive education in conjunction with psychomotor skills. Additionally, departments caring for VAD patients at the "user" level exist across our organization and include inpatient nursing units, an acute rehabilitation floor, Clinical Resource Nurse (CRN) staff, ambulatory departments, as well as several others.
Methods: The VAD leadership partnered with the service level educators to develop online learning modules that focused on the necessary cognitive pieces for annual training as well as initial training. This provided an opportunity to standardize content covered and decreased the amount of in-class time necessary since prelearning could be completed during standard work hours. Classes were offered in frequent intervals where psychomotor skills were addressed after the cognitive prelearning was completed by the individual. The classes were taught by the VAD Educator ensuring consistency with content.
Results: The streamlining of VAD education ensures that departments who may not see VAD patients with the same frequency as inpatient units could complete cognitive education as frequently as desired and attend psychomotor skill sessions at their desired intervals. This helped for units where VAD patients are seen as low frequency/high risk populations. Additionally, nursing leadership could easily pull a report from the learning management system on trained staff making it easier to meet regulatory requirements and track compliance. This educational approach has decreased the physical number of hours needed for class offerings and has increased staff satisfaction with the process and consistency of information.

P86

A Single Center Examination Of Driveline Infection Occurrences And Contributing Factors

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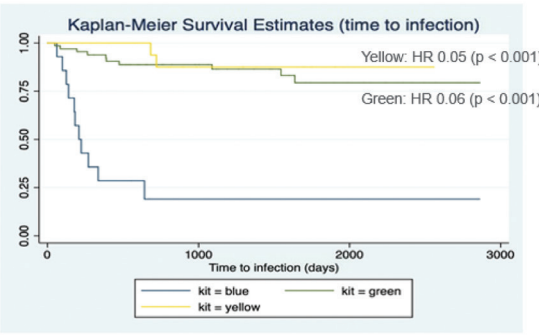
Study: Infections of the percutaneous lead site remain a frequent and costly complication for patients supported with durable left ventricular assist devices (LVADs). This retrospective analysis compares the use of three different driveline management kits and the occurrence of infection experienced at a single center. The kits used differ based on cleansing solution and adhesive covering. The primary "green" kit utilizes chlorhexidine for cleaning and a tegaderm as the adhesive component. Patients that experienced peripheral irritation remote from the exit site were switched to the "yellow" kit, which includes chlorhexidine and bordered gauze. The last kit, the "blue" kit uses povidone iodine and bordered gauze and is reserved only for those with a chlorhexidine allergy.
Methods: All patients that were implanted with a durable LVAD device at a single center were included in the analysis. Patient data was extracted that included the following information: occurrence of a driveline infection, which management kit was used, which device was implanted, additional diagnosis of diabetes, presence of a caregiver and other demographics. The sample of patients that experienced driveline site infections was further examined to extract clinically significant influences.
Results: Data from 104 patients was included in the analysis. 70 were implanted with the Heartmate II device and 34 with the HVAD. The age range for the population was 23-77. The gender breakdown included 78 males and 26 females. A total of 23 patient infections were appreciated. Statistical analysis of the infected sample showed a higher rate of infections associated with use of the "blue" kit that contains povidone iodine instead of chlorhexidine. It also was noted that incidence of infection was higher in younger patients and decreased with age. Diabetes, the presence of a caregiver, type of LVAD device and gender did not show statistically significant findings.

Type of dressing kit



compared to green kit, patients with blue kit had 14 fold increase in risk for infection (controlling for age, gender, device, diabetes, caregiver presence)

compared to yellow kit, patients with blue kit had 20 fold increase in risk for infection (controlling for age, gender, device, diabetes, caregiver presence)

P87

Collecting Patient Generated VAD Health Data: Increase Patient Engagement, Decrease Clinical Workload Pilot Study

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Study: Can health data patients self-collect into the electronic health record (EMR) decrease workload for VAD Coordinators? Can increased engagement and early detection and intervention of symptoms from patients decrease readmissions? The purpose of increasing the use of our electronic medical record's patient portal is to have patient's take ownership of their health by taking daily weights, blood pressure, and checking VAD parameters on a consistent basis. Prompted by a text from the EMR, patients can report their vitals to their providers. As providers receive consistent health information real time intervention can take place. To prevent alarm fatigue, providers only receive email alerts through the EMR if patient's reported vitals fall out of ideal range (Blood pressure above 90mmHG, weight increase of 3-pounds from last measurement or a 5-pound weight gain in one week). Current status: Michigan Medicine's VAD Program as a standard of care makes on average 70 patient calls per week for routine patient follow up, often not able make contact will all patients for various reasons. The median time spent on each call is 11 minutes equaling about 12.3 hours per week. As of 2/2/20 4 patients have been enrolled in the free program. Since implementing a coding error needed to be corrected, where the patient was not getting the messaging alert. When enrolling one patient it was discovered that they did not have a blood pressure cuff.

Methods: As a pilot study the VAD Coordinators timed each of their calls to gather baseline data and will compare to the time it takes for those in the pilot. Our goal is to have 10 patients enrolled by March 1st and then compare with our current standard. We are enrolling patients if they are interested or if they are being admitted for heart failure.

Results: As a pilot we have not concluded our study.

P88

Impact Of Initial Warfarin Dosing On Time In Therapeutic Range For Post-Operative Left Ventricular Assist Device Patients

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Study: Patients implanted with a left ventricular assist device (LVAD) require lifelong anticoagulation with warfarin. Previous outpatient studies suggest increased time in therapeutic range (TTR) of the international normalized ratio (INR) reduces adverse events. The purpose of this study is to determine what initial warfarin dosing strategy might optimize immediate post-operative TTR in LVAD patients.

Methods: This single-center, retrospective, observational study included adult patients implanted with LVADs from August 2012 to September 2019. Patients had to start warfarin within 5 days of implantation and have at least 1 INR per day for 5 days after achieving a therapeutic INR. Patients treated with a direct thrombin inhibitor after implantation, were hospitalized for pump re-implantation, or were implanted with a total artificial heart were excluded. The primary endpoint was post-operative TTR measured during the 5 days following first INR ≥ 2. Comparative groups were defined as either high (≥3mg) or low (<3mg) initial dosing based on average daily dose over 3 days prior to first therapeutic INR. Hospital and ICU length of stay were compared between groups and bleeding/clotting events, re-initiation of parenteral anticoagulation, and anticoagulation reversal were assessed.

Results: A total of 236 patients were available for analysis after applying exclusion criteria. Baseline characteristics for total population included a mean age of 58 (±13) years and mean BMI of 31 (±7) kg/m^2. The most prevalent device implanted was HeartMate II (64%), then HeartMate 3 (28.8%), and HeartWare (7.2%). Destination therapy was the most common implant strategy (69.5%). The mean ICU length of stay was 8 (±7.4) days and hospital length of stay was 30.4 (±14) days. Final data analysis will compare the TTR between high and low dose warfarin dosing. Multivariable regression analysis will be used to explore the effect of dose group on TTR adjusting for potential confounders.

P89

Preoperative Prealbumin As A Survival Predictor In Ventricular Assist Devices

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Study: Ventricular assist devices (VAD) are a widely adopted therapy for advanced heart failure. Poor nutrition and increased inflammatory states are thought to be poor prognostic signs in the VAD patient selection process. Prealbumin level is a simple laboratory value that is impacted during both of these clinical states. The present study tested the hypothesis that preoperative prealbumin levels are predictive of VAD implant outcomes including survival, length of stay (LOS) and discharge location.
Methods: A retrospective, observational chart review was performed on n = 82 adult patients with VADs implanted at a single center from 2012-2019. Logistic regression analyses were conducted to determine whether prealbumin levels were predictive of the outcomes of interest including survival to discharge, survival to 1 year, and discharge to home. A linear regression model tested whether LOS following implant was predicted by prealbumin levels.
Results: Of the patients screened, 95% of patients had preoperative prealbumin levels measured. Overall patient outcomes in this population included 90% survival to discharge, 74% survival at 1 year (with 10% of patients lost to follow up), 45% discharge to home, and LOS averaging 25.9 ±16.8 ($\bar{x} \pm s$). Preoperative prealbumin levels significantly predicted survival to discharge and at one year, such that for each one unit of prealbumin levels, the odds of surviving to discharge increased by 18.1% ($p < 0.04$) and the odds of surviving to one year increased by 16.6% ($p < 0.03$), respectively. Prealbumin levels were not significantly predictive of LOS or discharge to home following implant. In this small, retrospective study VAD patients' preoperative level was significantly predictive of survival to discharge at 1 year. Further research is needed to validate these findings in a larger patient cohort, and perhaps evaluate if correcting prealbumin prior to implant can impact survival, as well as how inflammation versus malnutrition impacts prealbumin levels.

P90

Development Of Ventricular Assist Device Remote Monitoring Best Practices

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Study: Ventricular assist devices (VAD) are a widely adopted therapy for advanced heart failure. Remote patient monitoring (RPM) has emerged as a tool to potentially improve VAD patient aftercare by decreasing adverse events (AE) with earlier identification. An increasing volume of VAD centers are implementing RPM, yet there are no VAD specific RPM best practices (BP) to date. We aimed to develop the first set of BP guidelines for VAD RPM.
Methods: A literature review regarding RPM in VAD and general heart failure populations was performed. Results from a 2019 survey distributed to VAD coordinators regarding RPM was integrated in with the literature review to develop BP guidelines.
Results: Nine VAD RM BPs guidelines were developed: 1) Patients remain responsible for directly contacting their VAD team with abnormal values. 2) Patients are provided the RPM equipment needed to collect and transmit data (e.g., scale, blood pressure cuff or doppler.) 3) Multiple biometric parameters are collected to provide a robust clinical picture (e.g. weight, mean arterial pressure, VAD parameters.) 4) Patients transmit data daily. 5) VAD Coordinators review data daily. 6) Significantly abnormal values are promptly addressed by discussing with provider and communicating back to patient. 7) Driveline exit site photos are transmitted via RPM. 8) A data summary is reviewed by the VAD clinical team at regular intervals. 9) Centers develop RPM quality measures to measure cost effectiveness and impact on AEs. Consensus statements were written regarding RPMs impact on patient adherence, VAD team perceptions, billing practices and future technology. These did not fit into guidelines but were felt to be important aspects of RPM. Based on available evidence it is reasonable to use RPM in VAD patients. Nine BP guidelines for VAD RPM were developed as a framework to standardize RPM across centers. Multi-center studies are needed to demonstrate RPM's impact on clinical outcomes and cost effectiveness.

P91

Frequency Of Depression In Female Patients After 2 Or More Years Of LVAD Support

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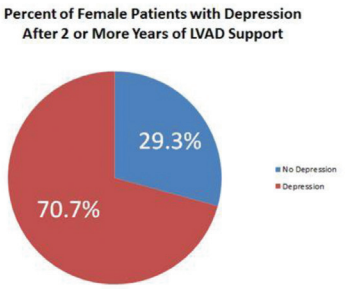
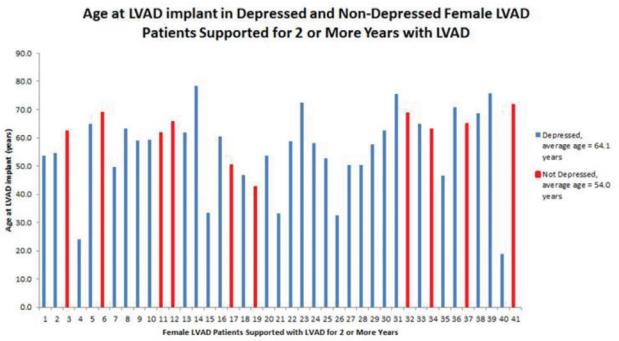
Study: Frequency of depression in women after longer-term left ventricular assist device (LVAD) support is not well described in the literature. We sought to identify frequency of depression in women supported with presently available FDA approved LVADs at a large single implanting center in the United States.

Methods: We retrospectively reviewed all patients who underwent VAD implantation from January 2007 until December 2019 at our institution. Data was abstracted for adult female patients supported for 2 or more years with an FDA approved LVAD. Of 437 patients, 41 patients met criteria for inclusion and were predominately destination therapy (58.5%) patients with HeartMate II (61.0%), HeartWare (36.6%), and HeartMate III (2.4%) devices with an average age of 57 years at time of LVAD implant. Primary outcome was defined as patients diagnosed with depression who received medical treatment for depression post-VAD.

Results: VAD patients experience depression both pre and post VAD, but little is known about depression after longer-term LVAD support. Of 437 patients implanted with durable FDA approved LVADs at our center, 9.4% (n=41)are women supported with an LVAD for 2 or more years. Of these women, 70.7% (n=29) were depressed. Those without depression (n=12) tended to be older with an average age of depressed patients of 54.0 years at implant compared to average age of 64.1 years at implant in non-depressed patients (n=29). There was no observable trend difference with bridge to transplant (BTT) or destination therapy (DT) designation nor device specific trends and the presence or absence of depression. Recognition of the frequency of depression in female patients supported with an LVAD for longer duration is important to ensuring appropriate treatment in this subset of the LVAD population.





P92

Durable Ventricular Assist Device Support In A Case Of D-Transposition Of Great Vessels With Systemic Ventricular Failure

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Study: Failure of the systemic, morphologic right ventricle remains a major long-term complication in patients with D-transposition of great vessels (D-TGA) corrected with Mustard procedure. Ventricular assist devices (VADs) and orthotopic heart transplantation (OHT) are reasonable options in advanced, refractory cases. However, due to the unique physiology of patients with D-TGA after Mustard procedure, outcomes of VADs implantation remain unclear.
Methods: We present a case of 35 years old male with D-TGA who developed heart failure (HF) and received a durable VAD as a bridge to OHT.
Results: Patient is a 35-year-old male with a history of D-TGA and ventricular septal defect (VSD) who underwent Mustard procedure and VSD repair at age 6 months. In his twenties, patient had superior baffle stenting due to superior vena cava stenosis and developed wide complex tachycardia with intermittent episodes of atrial fibrillation for which he received dual-chamber implantable cardioverter-defibrillator. At the age of 34, patient developed systolic and diastolic systemic ventricular failure. He presented to our center with advanced, ACC/AHA Stage D, HF and was found to have pulmonary hypertension (PHTN). He subsequently received HeartWare HVAD implantation to the systemic ventricle as destination therapy given his PHTN. Upon improvement of his PHTN (243 days on LVAD support), he was listed on OHT waitlist. As seen in this case, HF can develop later in life after Mustard procedure as the morphologic right ventricle is unable to support the systemic circulation. Our patient also developed PHTN as a result of systemic ventricular dysfunction. VAD support helped unload the systemic ventricle and was life-saving. It also allowed for improvement in pulmonary pressures and subsequent listing on OHT waitlist.

P93

Conversion To Biventricular Support In A Failing Glenn

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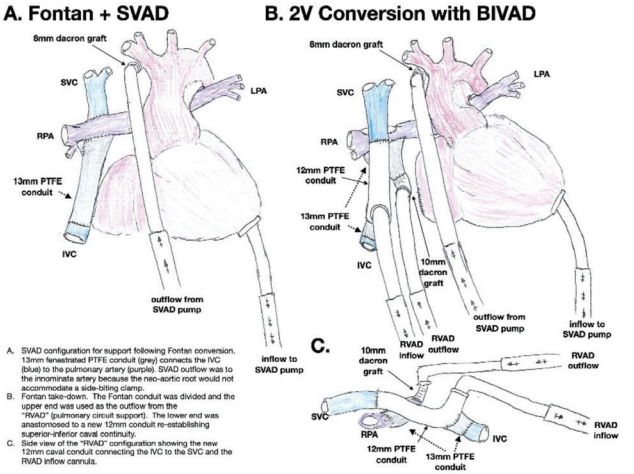
Study: Mechanical support of patients with cavopulmonary connections is fraught. The relative impacts of PVR, collateral flow and ventricular failure are difficult to separate. We report the conversion from a superior cavopulmonary connection to separate pulmonary and systemic circulations to support a patient with failure of a superior cavopulmonary connection.
Methods: A 14 mth old, 10kg child with HLHS palliated through a Glenn shunt presented with viral respiratory symptoms on a background of tricuspid insufficiency and moderately depressed ventricular function. He was cannulated for ECMO following a hypoxic cardiac arrest; converted to central ECMO but could not be weaned due to hypoxia. In order to improve his pulmonary blood flow, we attempted a Fontan (fenestrated, 13mm PTFE extra-cardiac conduit) with placement of a systemic ventricle VAD (apical and innominate artery cannulation with Berlin Heart EXCOR cannulae and a PediMag pump). PVR and Fontan pressures remained high and he required a second inflow cannula in the Fontan conduit with an oxygenator in the VAD outflow circuit. Weaning from the oxygenator was unsuccessful; after 15 days (28 days after ECMO initiation), the Fontan circuit was taken-down, SVC to IVC continuity was reestablished with a 12mm PTFE graft, the pulmonary artery was reconstructed, and pulmonary circuit VAD cannulae were attached to the caval conduit (6mm Berlin Heart atrial cannula) and to the pulmonary artery (6mm aortic cannula) (Figure). At that operation, he was found to have a necrotizing right lower lobe pneumonia, but the oxygenator was removed 6 days later. He remains on biventricular support with normal renal function and improving ventilatory gas exchange awaiting clinical improvement sufficient to achieve transplant candidacy.
Results: Our experience demonstrates that conversion to biventricular mechanical support is a viable option for support of a failing superior cavopulmonary connection in the setting of elevated pulmonary vascular resistance.



A. SVAD configuration for support following Fontan conversion. 13mm fenestrated PTFE conduit (grey) connects the IVC (blue) to the pulmonary artery (purple). SVAD outflow was to the innominate artery because the neo-aortic root would not accommodate a side-biting clamp.
B. Fontan take-down. The Fontan conduit was divided and the upper end was used as the outflow from the "RVAD" (pulmonary circuit support). The lower end was anastomosed to a new 12mm conduit re-establishing superior-inferior caval continuity.
C. Side view of the "RVAD" configuration showing the new 12mm caval conduit connecting the IVC to the SVC and the RVAD inflow cannula.

P94

Effects of Hematocrit on the Fluid Dynamics of the Pulsatile Penn State Pediatric Ventricular Assist Device at Elevated Beat Rate

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Study: The Penn State pediatric ventricular assist device (PVAD) was developed as a bridge to transplantation device for patients on the organ transplant waiting list. Prior studies have evaluated this device at 75 bpm with a blood analog matching 40% hematocrit blood despite average heart rates of 100 - 180 bpm and hematocrit levels of 20 - 60% in pediatric patients. This study aims to quantify the fluid dynamics in the PVAD at elevated beat rates and varying hematocrit using particle image velocimetry (PIV).

Methods: An acrylic model of the Penn State 12cc PVAD was placed in a mock circulatory loop. Three blood analog fluids were used to match the properties of pediatric blood at 20%, 40%, and 60% hematocrit. Data were collected at 75 bpm and 120 bpm. The loop was modified to obtain physiologically relevant pressure and flow conditions. PIV was used to image the flow at three planes within the device.

Results: The higher beat rate flow created a higher velocity inlet jet that led to a recirculation region forming earlier in diastole and lasting longer into systole. This recirculation region lead to a strong outlet jet at the higher beat rate. The increase in hematocrit lead to a more viscous fluid with more inertia. The inertial effects increased the percentage of time the recirculation region was present during the cycle.

P95

Ventricular Assist Device Simulation Training For Pediatric ICU Fellows

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Study: Identification and initial management of urgent ventricular assist device (VAD) conditions requires education of providers who are immediately available but who may not have VAD expertise. We developed multimodality VAD simulations to evaluate impact of training on pediatric ICU fellow knowledge in such events.

Methods: We developed 3 rotations: 1) cognitive case simulations involving pediatric heart failure and simulations with human actors portraying teenagers on VAD therapy experiencing 2) syncope and 3) stroke. A group of 3 fellows was called by a nurse to the VAD patient's room due to syncope and a second time due to altered patient response. Video display of actual corresponding VAD waveforms was utilized. Prior to boot camp, each learner completed a survey to ascertain prior VAD exposure and training and a pre-test to evaluate VAD knowledge. A post-test was completed 2 months later.

Results: Nineteen fellows participated from 10 programs. 53% (10/19) of fellows had prior experience with at least one type of durable VAD. 32% (6/19) of fellows correctly interpreted low flow/pulsatility HeartWare waveform and 63% (12/19) interpreted and initiated management for an underfilled Berlin Heart pump on the pre-test, compared to 100% correct interpretation for both on post-test. None were able to successfully complete all 3 objectives for the human patient simulations. For syncope, only 1 fellow altered patient position to improve preload and while the abnormal waveform was noted by 2 groups, only 1 fellow used this information to assist with management. While all groups stated the patient was having a stroke, none noted VAD waveform suggestive of thrombus. While 2 groups wanted to obtain imaging and one mentioned a stroke protocol, none were aware of how to activate it. Only one fellow in 3/6 groups, interacted with VAD patient to discuss their concerns in either sim. The majority of fellows (90%) had no prior VAD simulation training experience, while 100% of fellows stated they would like additional sessions.

P96

Compassion, Field Trips, And The Long Journey Home: A Case Study In Pediatric Mechanical Circulatory Support

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Study: Case report of a 19-year-old woman with Down Syndrome and heart failure secondary to congenital heart disease requiring biventricular (BiVAD) support including the first use of the Berlin Heart Mobile Driving Unit (BH-MDU) in the United States.
Methods: Long-term BiVAD support was accomplished with a HeartWare LVAD and a Berlin Heart EXCOR RVAD (off-label use). Compassionate use application to the United States FDA for the BH-MDU was approved.
Results: Patient had a prolonged initial hospital stay with eventual multiorgan recovery and resolution of previously demonstrated pulmonary hypertension. The BH-MDU provided excellent mobility which enhanced her rehabilitation. Initial "field trips" provided excursions out of the hospital which were accompanied by hospital personal. These trips allowed her father to gain confidence in caring for his daughter independently with two separate heart assist devices. Hospital discharge was accomplished fourteen months after implant. In the fifteen months since discharge she has 1) attended a year of public school completing her special education program to graduate with her class, 2) traveled via a commercial airline to visit her sister, 3) been an active member of her family and community cared for by her father without home nursing services, 4) turned 21-years-old including a visit to a local establishment with many members of her family and care provider team to celebrate. She has required readmission a total of three times. Once for a syncopal event while attending school, once for routine annual exchange of the EXCOR chamber, and once for a membrane disruption of the EXCOR device requiring exchange. No admission required longer than a 36-hour stay. Rehabilitation and discharge of patients on complex circulatory support is possible and can be successful with a committed care provider and medical team.

P97

Intra-Operative Extracorporeal Membrane Oxygenation In Fontan Requiring Heart And Liver Transplant

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Study: Patients with congenital heart disease often require complex surgical intervention. In the Fontan procedure, systemic venous blood flow is directed to the pulmonary artery. We report a case of a Fontan who suffered from both heart and liver failure. This case was particularly challenging since the patient had six prior sternotomies, essentially no pericardium with little elasticity in the surrounding tissue, and significant underlying pulmonary vascular resistance which was not noted prior to the operation.
Methods: A bicaval technique was used for transplantation. To address the mild donor tricuspid regurgitation, a DeVega tricuspid annuloplasty was performed. The patient underwent a simultaneous heart and liver transplant with the support of veno-arterial extracorporeal membrane oxygenation (VA ECMO) and an intra-aortic balloon pump (IABP) during the procedure. Successful ECMO decannulation was achieved three days later. The patient was successfully discharged several weeks after the procedure.
Results: We present the first recorded case of a heart and liver transplant in a patient with congenital heart disease requiring ECMO support intra-operatively. Our case report articulates the treatment of a high-risk patient with a rare condition and complex physiology with a heart and liver transplant featuring pulmonary artery and hepatic reconstruction. In describing our experiences treating a Fontan patient requiring multiorgan transplantation, we have shown that challenging cases such as this one can have successful outcomes if multidisciplinary collaborations and proper treatment strategies are utilized at the optimal timing, along with family support and patient cooperation.

Figure 1. Complex Fontan Physiology
PA, pulmonary artery

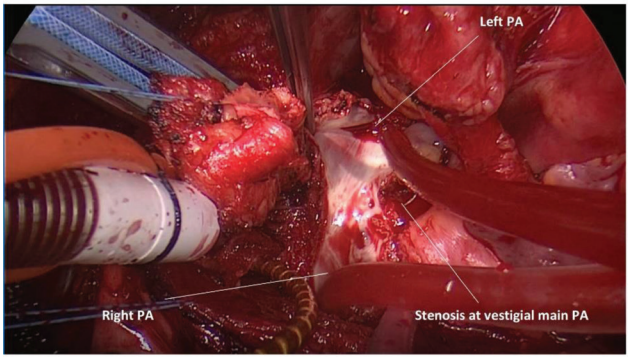
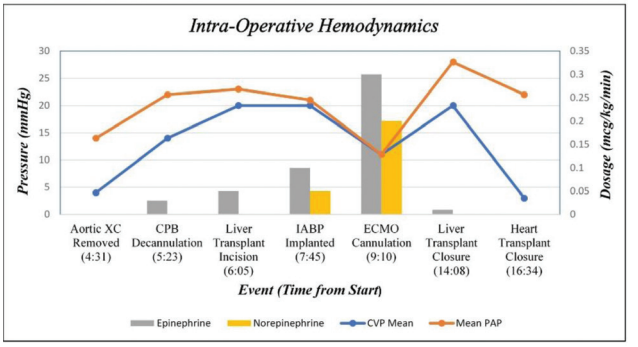


Figure 2. Intra-Operative Hemodynamics
CPB, cardiopulmonary bypass; CVP, central venous pressure; ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; PAP, pulmonary artery pressure; XC, cross clamp



P98

Regional Differences In Pediatric VAD Therapy Strategies And Cost

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Study: With the rise of long-term ventricular assist device (VAD) therapy in pediatric heart failure patients, these patients are now able to extend time to or possibly avoid heart transplantation. The purpose of this study is to investigate the regional differences in pediatric VAD use across the United States.
Methods: The Pediatric Health Information System (PHIS) was used to identify patients (age ≤21 years old) who have undergone VAD implantation (ICD-9 procedure codes 37.60, 37.62, 37.65, 37.66) from 2004 to 2015. The institutions in which these implants occurred were divided by the following geographic regions of the United States: West, Mid-West, South, and Northeast.
Results: 513 cases of VAD implantation were identified. Western hospitals made up 25%, Mid-West 26%, South 31%, and Northeast 18%. Median age and gender did not significantly differ between the regions. 263 patients underwent VAD implantation without heart transplantation during the same admission. Of these cases, both median length of stay and age were similar across all regions. The proportion of VAD patients discharged home (West 61%, Mid-West 44%, South 56%, and Northeast 48% (p=0.217)) and overall in-hospital survival (p= 0.111) was similar across all regions. Mean total charges per admission was significantly different amongst the regions, from lowest to highest: Mid-West $1,885,488, Northeast $1,944,887, South $2,161,473, and West $2,812,692 (p<0.001). In conclusion, patients who received VAD implant had similar rates of discharge home and in-hospital mortality across regions but disparate costs. Multi-institutional efforts such as Advanced Cardiac Therapies Improving Outcomes Network (ACTION) should be encouraged to help standardize discharge protocols in order to improve the efficiency and numbers of children being discharged on VADs, which would hopefully result in lower costs nationwide.

P99

Where Do Broken Hearts Go?

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Study: Some studies have established that congenital heart disease is dependent on geographical and genetic factors. We as biomedical engineers tend to concentrate on devices for treatment, and sometimes we miss the big picture that improving diagnosis and access to care may have a larger impact on people´s health. For example, our institution in Colombia receives each year around 20 pediatric patients with ductal-dependant circulation. However, the estimated incidence for this condition is close to 200, for which we have previously developed a catheter for ductal stenting.
Methods: So we decided to pursue the question what happened to the other 180 sick children and how can we systematically improve their diagnosis and treatment. We devised a comprehensive program to do so.
Results: DELFOS is a multidisciplinary program for improving early diagnosis (fetal and neonatal), traceability, and access to care of children with congenital heart disease. In this program will collaborate physicians including cardiac surgeons, cardiologist, genetists, and gynecologists, and biomedical engineers from several universities and hospitals. The program is composed of 5 projects: The first aims to characterize the situation in Bogotá and Cali (two of the most populated cities in Colombia). The second looks for the actual correlation between fetal ultrasound detection and diagnosis. The third will develop a tool based on artificial intelligence to help the diagnosis, and the fourth will establish if such diagnostic tool is cost-effective. The fifth will determine if the Colombian health system is prepared to offer a proper and timely access to care. Recently we have secured funding for the program for the next three years.

P100

Preliminary Results From A Single Center Assessing The Impact Of *Ex Vivo* Lung Perfusion On Peripheral Blood And Bronchoalveolar Lavage Profile After Lung Transplantation

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Study: Ex-vivo lung perfusion (EVLP) promises to be a comprehensive platform for assessment, reconditioning, and preservation of organs unsuitable for immediate transplant. However, the biological mechanisms of EVLP and its implications on primary graft dysfunction (PGD) are poorly understood. We investigated bronchoalveolar lavage (BAL) and peripheral blood (PB) cell and cytokine profile in lung transplant (LTx) with EVLP vs Non-EVLP.

Methods: Methods: In 25 consented participants (EVLP n=10, Non-EVLP n=15), that received any type of extracorporeal circulatory support (CPB or ECMO) during surgery, PB was collected at baseline (pre-LTx), and 6h, 24h, 48h, 72h post-LTx, and BAL was collected at baseline and 6h post-LTx. PGD was graded using 2016 ISHLT definitions of high-grade "PGD3" at 48-72h post-LTx. Flow cytometry and multiplex were used to evaluate 23 cell populations and 27 circulating cytokines in plasma, respectively. A linear mixed model was used to determine changes over time in each biomarker and a T-test was used to determine differences in BAL samples (p-value <0.05).

Results: We did not observe differences in HG-PGD (40% vs 46.7%; p=1.0) Please see table 1 for BAL results. Moreover, in circulating cell populations we observed a gradual increase in T helper cells starting at 24h in comparison to baseline in the EVLP group, this was not observed in the Non-EVLP cohort. In circulating cytokines in the EVLP group we observed a decrease in MIP1-a at 48h and 72h in comparison to baseline and in the Non-EVLP group an increase in IL-6 starting at 24h and 72h in comparison to baseline.

Conclusions: The use of EVLP led to distinct differences in the immune profile at baseline and throughout reperfusion after lung transplants. The effect of these differences in outcomes such as PGD and chronic lung allograft dysfunction requires further investigation.

Bal	EVLP	Non-EVLP	P value
Pre-Transplant			
Lymphocytes,	8.3 ± 6.52	1.68 ± 1.77	0.03
Classical monocytes	87.81 ± 9.33	64.84 ± 15.09	0.0098
Intermediate monocytes	9.54 ± 9.54	32.8 ± 11.4	0.008
Neutrophils	31.92 ± 15.34	56.08 ± 12.86	0.02
Delta at 6h			
Lymphocytes	-4.157 ± 1.32	13.19 ± 4.21	0.011
Neutrophils	-12.28 ± 18.83	12.22 ± 11.21	0.014

P101

Oxygenated Right Ventricular Assist Device As A Bridge To Lung Transplantation

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Study: Oxygenated right ventricular assist device (RVAD) becomes more easily applicable after the invention of dual lumen pulmonary artery cannula. Oxygenated RVAD could provide the oxygenation support with right heat support as an alternative to Extracorporeal Membrane Oxygenation (ECMO) as a means of bridge to lung transplantation.

Methods: A single-institution, retrospective analysis was performed for 4 patients who were placed on oxygenated RVAD with a dual-lumen pulmonary cannula with the intention of bridge to lung transplantation between June 2019 and October 2019.

Results: All patients had idiopathic pulmonary fibrosis. Mean pulmonary artery pressure at pre-transplant evaluation was 28.8 ± 6.3. All of the patients were in the intensive care unit with 40 - 70 L/mins high flow nasal cannula and dual lumen pulmonary artery cannula cannulation were performed in the operating room after being intubated. Three patients were extubated after being placed on oxygenated RVAD and ambulation was achieved in 2 patients. In 2 cases, the patients became hypoxic with oxygenated RVAD and required conversion to venoarterio-venous ECMO. Waiting time for transplantation was 61 ± 27 hours after being placed on oxygenated RVAD and the Lung allocation score at the time of lung offer was 88.2 ± 1.0. All the patients successfully underwent double lung transplantation. All lung transplantation was performed on cardiopulmonary bypass. Two patients stayed on oxygenated RVAD and one patient placed on venovenous ECMO after transplantation. Primary graft dysfunction score at 72 hours after transplantation was grade 1 for 3 patients and grade 3 for 1 patient.

Oxygenated RVAD with dual-lumen pulmonary cannula can provide oxygenation and right heart support to the patients with end-stage lung disease. Dual lumen pulmonary cannula can be used for the ambulatory bridge to lung transplantation. It is still unknown whether oxygenated RVAD is feasible for long term bridge to lung transplantation.

	Patient #1	Patient #2	Patient #3	Patient #4
Diagnosis	IPF	IPF	IPF	IPF
Pre-transplant PA mean (mmHg)	24	35	35	21
Oxygen requirement (L/min)	40	70	50	70
Wait time after RVAD initiation (hours)	56	107	40	42
Lung Allocation Score	88	86.9	88.3	89.9
Conversion to other mechanical support	No	Yes	No	Yes
Post-transplant mechanical support	RVAD	RVAD	None	VV ECMO
PGD grade at 48 hours	1	3	1	3
PGD grade at 72 hours	1	1	1	3

P102

The Ethical Implications Of Vaping; Its Affect On All

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Study: Smoking e-cigarettes or 'vaping' has become a common practice in the US. There have been several reported instances of patients being hospitalized with significant lung injury requiring support of veno-veno extracorporeal membrane oxygentation (VV ECMO). Indications for VV ECMO are bridge to lung transplant or recovery. Given 'vaping' or smoking is often a contraindication for transplant, a huge ethical issue is presented when patients on support are destination to nowhere.
Methods: We report a case study of a 25-year-old patient with a medical history of anxiety who 'vaped' and presented to the ED with nausea and vomiting. He developed Acute Respiratory Distress Syndrome (ARDS) and bilateral pneumothoraxes and required VV ECMO. Our institution flew out to cannulate onto VV ECMO at the outside hospital and transferred the patient.
Results: This patient was on ECMO support for a total of 62 days. He required transition to ambulatory veno-arterial support on day 14 to improve brain oxygenation and be able to rehab with PT. Patient was not a candidate to transplant due to history of vaping, uncontrolled anxiety, and vocal cord atrophy. He had no signs of lung recovery. The patient had no viable options to come off ECMO, yet he was awake, alert and young. Ultimately, palliative care and ethics became involved and ultimately the patient chose to proceed with withdrawal of care and expired immediately. Cases with acute lung injury due to vaping may cause significant lung injury that will require the support of ECMO. If recovery and transplant are no longer options but the patient is alert and awake; patients, families and providers will face ethical and moral challenges when caring for these patients. Our program held a debriefing meeting for all nursing and staff involved to provide support and discuss areas of improvement. Implications on transplant and ECMO criteria need to be discussed as more patients will be presenting with these symptoms. Guidelines and standards are needed when faced with these situations to minimize the distress.

P103

***Legionella* Pneumonia-induced ARDS Requiring ECMO Support**

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Study: *Legionella* pneumonia (LP) can be severe with mortality rates up to 33% in patients requiring intensive care, some of whom progress to acute respiratory distress syndrome (ARDS). The diffuse, rapidly progressive nature of the infection can be managed with extracorporeal membrane oxygenation (ECMO), however, reports of its use and outcomes in LP-induced ARDS has been limited. Here we present two patients with LP complicated by ARDS requiring ECMO support.
Methods: Our first case was a 66-year-old woman diagnosed with LP after positive urine antigen. Due to worsening hypoxia and hypotension on mechanical ventilation, she was placed on veno-venous (VV) ECMO and transferred to our institution. Upon arrival, she suffered a cardiac arrest and was converted to veno-arterial (VA) ECMO followed by V-AV ECMO. During her hospitalization, she was switched to a temporary biventricular assist device for heart and lung support and left ventricular decompression, and was ultimately decannulated after 18 days on ECMO and discharged on day 28. Our second patient was a 39-year-old male with a history of e-cigarette use. Although his respiratory failure was attributed to E-cigarette, or Vaping, Product Use-Associated Lung Injury at first, LP was diagnosed after positive urine antigen. Further social history indicated fishkeeping as a hobby. He also failed mechanical ventilation and was placed on VV ECMO. He was decannulated after 12 days on ECMO and discharged on day 35.
Results: Both of our patients suffered from LP which progressed to ARDS requiring ECMO support due to failure of mechanical ventilation. Despite requiring tracheostomy for ventilation dependence, both patients were decannulated and discharged to acute rehabilitation in stable condition. Our cases, along with the limited reports of ECMO usage for LP in the literature, suggest this therapy as an effective option when mechanical ventilation fails.

P104

Ambulatory ECMO Utilizing An Extracorporeal VAD As Destination Therapy

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Study: Chronic lung diseases result in over 168,000 deaths and 726,000 hospitalizations each year. Lung transplant remains the only curative option for treatment of chronic lung disease, but as there are only 2600 transplants each year, a means of long-term respiratory support is needed. Currently, extracorporeal membrane oxygenation (ECMO) cannot provide this support, as its oxygenators fail within 1-4 weeks due to clot formation, and systemic anticoagulation causes bleeding complications. Current ECMO systems are over-designed for chronic lung disease patients and too bulky for normal ambulation. The purpose of this study was to test a new, lightweight (2.3kg), low thrombogenicity ECMO system purposefully designed for chronic lung disease patients.
Methods: It utilizes a novel, small (0.9 m^2) gas exchanger, the pulmonary assist device (PAD), with a ventricular assist device (VAD) modified to act as an extracorporeal pump. This ECMO system fits in a small wearable pack to foster patient mobility. The system was attached to two sheep in a veno-venous configuration with a bicaval dual-lumen cannula placed in the jugular vein for 7 and 14 days.
Results: The sheep was able to independently walk briskly around the room on the system, demonstrating the first application of truly ambulatory ECMO in sheep. Unlike its typical application, the VAD must provide sufficient power to pump through the resistance of a cannula, the oxygenator, and tubing when used in an extracorporeal circuit. During this study, the VAD achieved 2.0 L/min of flow at 11.8 kRPM with a 24 Fr cannula and at 9k RPM with a 28 Fr cannula with no significant change over two weeks. This study demonstrates the importance of using large-bore cannula to enable lower pump speeds, despite the smaller flow rate needed to support chronic lung disease patients. Our next step is to perform these experiments utilizing a commercial quality PAD with polycarbonate housing and a polycarboxybetaine antifouling surface coating for up to two months with regular ambulation.

P105

Ultrafiltration Of High Protein Concentration Solutions Through Hollow-Fiber Filters

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Study: The effect of high protein concentration on the critical flux (J_{crit}) during the ultrafiltration (UF) of Bovine Serum Albumin (BSA) solutions was investigated using the constant-flux method.
Methods: Miniature Dialyzers containing polysulfone hollow fiber membranes with a molecular weight cut-off of 65 kDa and a total active surface area of 0.023 m^2 were used. A setup capable of monitoring effective transmembrane pressure (TMP_{eff}) increments as low as 1 mm Hg by controlling the permeate rate at a constant value has been built and is schematically shown in Figure 1.
Results: Figure 2 shows a typical constant-flux mode filtration experiment where the TMP_{eff} is measured at different UF fluxes for solutions containing 5, 10 and 15 wt.% BSA. The experiment started with a specified flux of 1 $Lm^{-2}h^{-1}$ and was increased until TMP_{eff} would not stabilize. J_{crit} is defined in this work as the highest value of the region of the graphs at which the membrane resistance remains constant, represented by a linear relationship between flux and TMP. Results show that values of J_{crit} were all of the "weak form" indicating that the relationship between TMP_{eff} and UF flux is linear, but the slope of the line differs from that of clean pure water. They decreased with the increase in protein solution and were 33.5, 16.8 and 4.9 $Lm^{-2}h^{-1}$ for solutions containing 5 wt.%, 10 wt.% and 15 wt.%, respectively. The fact that controlled permeate rate filtration was achieved for solutions containing high protein concentrations with no fouling is of significance. The J_{crit} values give us insight for efficient and long term UF of solutions with BSA concentrations up to 15 wt.%.

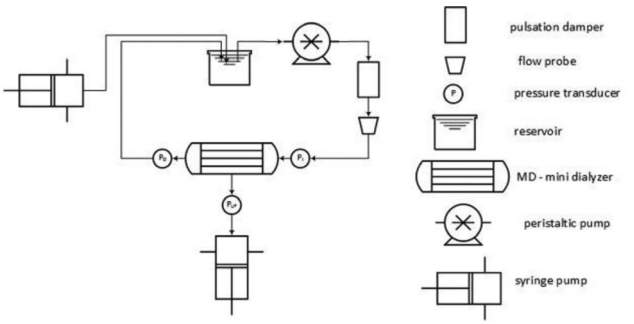

Figure 1. Schematic representation of the experimental setup

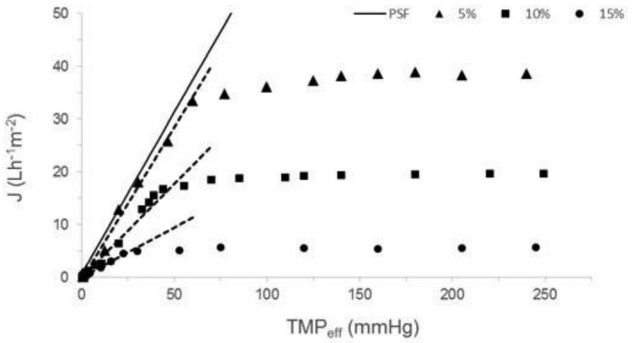

Figure 2. UF flux as a function of TMP_{eff} at bulk concentrations of 5wt.%, 10wt.% and 15wt.%. Solid line is from measurements of flux with pure water. Dashed line corresponds to regions of the graphs where J varies linearly with TMP_{eff}.P106

P107

The Use Of Ultrafiltration After Cardiac Surgery - A Single Center Experience

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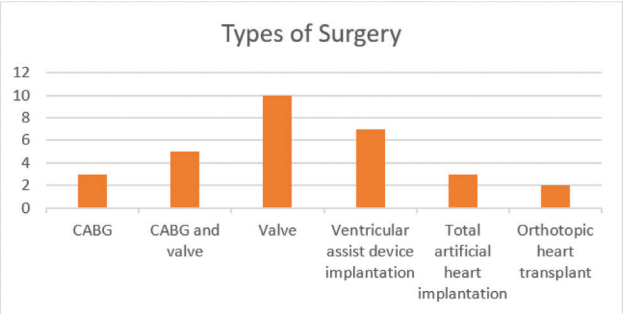
Study: Hypervolemia is common after cardiac surgery. Ultrafiltration (UF) is used frequently to decongest patients in acute heart failure, but its utility post-cardiac surgery has not been studied. We sought to explore the use of UF in this setting at our institution.
Methods: We conducted a retrospective chart review of all cardiac surgery cases registered in the Society of Thoracic Surgeons database and INTERMACS at our center from October 2016 to June 2018. Patients were identified using search terms "ultrafiltration," "aquapheresis," "Aquadex," or "CHF solutions."
Results: A total of 136 charts were identified. Of these, 30 patients underwent UF post-operatively. The remainder were excluded as they had "ultrafiltration" recorded in their charts for continuous veno-venous hemofiltration (CVVH) only. Mean age of the patients was 63±15 years, and 63% were male. Chronic kidney disease stage 3 or higher was present in 14 patients (47%), and 5 (17%) were on chronic dialysis for end-stage renal disease. Most patients had valvular surgery (alone or with CABG), while the rest had advanced heart failure therapies.
Majority underwent UF as an adjunct to CVVH/HD (n = 27). In most of these cases, UF was done to augment fluid removal in the setting of acute kidney injury. Only 3 patients received UF alone for acute kidney injury with fluid overload that was unresponsive to diuretics (without need for renal clearance by CVVH/HD). Overall, 33% (n = 10) of the patients had recovery of renal function, and 12 patients died in-hospital.
Conclusion: UF was used in a sick post-cardiac surgery population mostly as an adjunct to CVVH or HD to augment fluid removal. Among these, one-third experienced renal recovery. Further research is needed to understand the benefits or risks of UF in the post-cardiac surgery population.



	Outcomes		
	Renal recovery	Dialysis	In hospital Death
UF + CVVH or HD (n = 27)	7	8	12
UF alone (n = 3)	3	0	0

P108

Reinforced Corrugated Nanofiber Tissue Engineered Vascular Graft To Prevent Kinking For Arteriovenous Shunts In An Ovine Model

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Study: Tissue engineering vascular graft (TEVG) is a biodegradable scaffold to promote autologous cell proliferation and functional neo-tissue regeneration, accordingly having antithrombogenicity. Therefore, TEVG can be an alternative prosthesis for small diameter graft. However, due to limitation of the graft materials, most of TEVGs are rigid and easily kinked when implanted in limited spaces, which precludes future clinical application. We have developed novel corrugated nanofiber graft to prevent kinking of the graft.
Methods: TEVGs with corrugated walls (5 mm internal diameter by 10 cm length) were created by electrospinning using a blend of poly-ε-caprolactone (PCL) and poly(L-lactide-co-caprolactone) (PLCL). As this graft might not be durable enough to endure blood pressure, we also created the graft wrapped with Polydioxanone (PDO). The biodegradable grafts were then implanted between the carotid artery and the external jugular vein in U- shape using an ovine model. PCL-PLCL graft was implanted on one side of a sheep and PCL-PLCL wrapped with PDO was on another (n=3, grafts=6). The grafts were explanted three months after implantation and subject to mechanical and histological analyses. Graft patency was confirmed by measuring graft diameter and blood flow velocity using ultrasound, which was performed every week after implantation.
Results: All sheep survived postoperatively. The average graft patency rate of both grafts was 66.7% (two grafts out of three) with one grafts in both groups becoming occluded in the early phase after implantation. There was no significant kinking of grafts. Overall, re-endothelialization was observed in the grafts three month after the surgeries without graft rupture, calcification or aneurysmal change.Our novel corrugated nanofiber vascular graft for atriovenous shunt displayed neotissue formation without kinking or rupture in large animal model.

P109

Use Of Telemedicine In The Care Of End-Stage Renal Disease Patients On Hemodialysis In A Remotely Located Satellite Hemodialysis Unit

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Study: Despite the technological advances the disparity in the distribution of hemodialysis care is growing wide. The dearth of dialysis facilities and physicians is most notable in areas close to the US-Mexico border. Under these circumstances, we need to come up with a solution which can give equitable quantity and quality of care and at the same time reduce the burden on healthcare funding institutions like medicare. One such solution is the implementation of telemedicine in the care of hemodialysis patients.

Methods: The objective of the study is also to determine the feasibility of telemedicine as a means to improve the quality of dialysis care and analyze whether telemedicine can act as a substitute for the current face-to-face requirement by Medicare. Primary outcomes measured include rate of hospitalization as well as emergency room visits and rate of access related interventions. This will be a 12-month intervention study using telemedicine. Participants are patients undergoing hemodialysis at DCI Douglas unit a border town in Arizona. The telemedicine system allows the physician at a remote site real-time access to the patient. Data collected will include demographic, laboratory results, vascular site examination, quality of care markers, depression scoring, nutritional assessment scoring and quality of life assessment.

Results: The implementation of telemedicine visits as a substitute for the 3-4 monthly face-to-face visits over a one-year period will improve quality of life as judged by quality of life index, decrease cost expenditures for patients and caregivers, improve patient satisfaction and will provide the same if not improved outcomes when judged by a composite of quality of service markers like reduced hospitalization rates, less number of vascular access procedure, reduced time to transplant listing and increased utilization of service.

P110

Powering Newly Compact, Forearm Wearable, Artificial Kidney (FWAK)

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Study: Nearly full replacement of kidney function, with convenient, newly low profile, efficient, ambulatory dialysis and ultrafiltration device. No donor shortage to contend with. No anti-rejection drugs. No rejection. Continuous therapy overall more effective than intermittent, in compartmentalized physiologic systems. Clean out 5L of blood and 65K of solid tissue remain relatively untouched.

Methods: "InSitu DeBranched Vein Fistula Conduit (VFC) With Compressions" A/V Blood Access. Amply 24/7 powered, Tidal, Sorbent DiaUltrafiltration (TSDU) device. Sorbent dialysis—toxins adsorbed from ultrafiltrate, before large proportions of numerous small quantities are re-ultrafiltered back into the blood. Tidal Ultrafiltration---Filtrate accumulation and membrane fouling discouraged by immediate reversal of flow

Results: POWERING of (2-way) ambulatory ultrafiltration device? Requires much greater pressure, not so much greater flow? Small physiologic VFC A/V powering part avoids air embolism, by first-source assuring greater than ambient pressure throughout the extracorporeal component. Soft, non-negative-pressure, open caged pump ventricles, also guarantee no drawing of air into blood. Powerful pump ventricles, rather than weak centrifugal-impeller pumps. Also, similar increased pressure required through sorbent cartridge. Ganged pneumatic valves and pumps desirable---multiple options: Electric efficient and inexpensive with new rechargeable batteries. Mini-gas cylinder. Manual. Pedal. Sit on or roll over onto WHOOPIE CUSHION. Another major benefit of switching from solenoid pumps-valves to pneumatic, is elimination of several heavy, bulky, magnetic cores and windings, resulting in a much smaller, sleeker profile and a much lighter weight, style-setting forearm enhancement.

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