STUDY ON EX-VIVO EVALUATION OF RECIRCULATION TOTAL LIQUID VENTILATION SYSTEM

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It is desirable for partial pressure of carbon dioxide (PCO_2) in Perfluorocarbon (PFC) to inject to lungs in a Total Liquid Ventilation (TLV) system to be almost 0 mmHg. In the previous study, the recirculation TLV system was able to reduce below 5 mmHg of PCO_2 in the system on in-vitro experiment. The gas exchange is carried out only by the concentration gradient due to the difference in partial pressure of the gas. Therefore, TLV system is required to maintain arterial oxygen pressure (PaO_2 (more than 200 mmHg)) and arterial carbon dioxide pressure ($PaCO_2$ (35–45 mmHg)) in the arterial. The objective of this study is to evaluate the safety of the TLV system on ex-vivo experiment. The TLV system consists of a reservoir, a piston pump, a bubble trap and the oxygenator for TLV (TLV-OX). The recirculation circuit consists of a peristaltic pump and the prototype oxygenator. Anesthetized Japan rabbits (n=3) were cut the airway to inject PFC in lungs and cannulated carotid artery for blood samplings. Firstly, Rabbit's lungs were ventilated by the oxygen for one hour by the artificial respirator, secondly injected oxygenated PFC. Blood sample from artery was measured PaO_2 and $PaCO_2$ by gas analyzer. As a result, TLV system succeeded in the enforcement of three hours for rabbits. PaO_2 and $PaCO_2$ were not able to maintain constant value. However, PaO_2 and $PaCO_2$ were possible to maintain safety value. In conclusion, these results indicate effectiveness of TLV system.

BIOCOMPATIBILITY EVALUATION OF A NEW RESILIENT HARD CARBON THIN FILM COATING FOR VENTRICULAR ASSIST DEVICES

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Purpose: The purpose was to evaluate the biocompatibility of BioMedFlex™ (BMF), a new resilient hard carbon thin film coating, as a blood journal bearing material in continuous flow right and left ventricular assist devices (RVAD and LVAD). BMF's combined properties of very high hardness with high flexural strength set it apart from commercial diamond like carbon coatings. **Methods:** BMF coating was applied to the rotating assembly in the DexAide RVAD implanted in Calves #1 and #2. In Calf #3, both DexAide RVAD and SmartHeart™ LVAD were implanted with BMF coating on the stators of both pumps and on the rotating assembly of the DexAide pump. **Results:** Calves #1 (18 days) and #3 (29 days) were electively terminated with average measured pump flows of 4.9 L/min (RVAD, Calf #1), 6.2 L/min (RVAD, Calf #3), and 5.2 L/min (LVAD, Calf #3). Calf #2 was terminated on POD 9 due to sepsis. Post-explant evaluation of the blood contacting journal bearing surfaces showed no biologic deposition in any of the 4 pumps. Thrombus inside the inlet cannula of the RVAD in Calf #3 is believed to be the origin of a nonadherent deposition wrapped around one of the RVAD primary impellers. **Conclusions:** BMF coatings can provide good biocompatibility in blood bearing applications. We will continue to use BMF coated pumps in a series of biventricular calf studies.

OPTIMIZATION OF A CHRONIC CYANOSIS MODEL IN PIGLETS

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Purpose: To optimize a chronic cyanosis model for myocardial protection studies. **Methods:** A pulmonary (PA) - left atrial shunt was constructed with an 8 mm PTFE tube graft, via left thoracotomy in 25 anesthetized piglets (10–15 Kg). Shunt flow was adjusted to an oxygen (O_2) saturation (So_2) of 80–85% on 50% Fio_2 by banding the distal PA and graft. At time of chest closure, target So_2 was 75–80% on Fio_2 21% and ≥90% on Fio_2 100%. So_2 was monitored for 3–6 weeks. **Results:** Data are tabulated (mean±standard deviation) (Table 1).

Table 1.

	Non-optimized (10)	Optimized (15)
So_2 (%)*		
Preoperative	99.2 ± 0.6	99.3 ± 0.6
Pre-graft adjustment	79 ± 6.3	85.5 ± 8.8
Post-graft adjustment	84.5 ± 6.4	81.5 ± 8.3
Late postoperative	84 ± 10.9	78.1 ± 13.2
Po_2 (mmHg)		
Preoperative	297.5 ± 109	292.8 ± 116
Pre-graft adjustment	60.3 ± 11.1	67 ± 12.7
Post-graft adjustment	67.4 ± 9.5	69.2 ± 16.1
Survival (%) 50 87	50	87

*$p \leq 0.01$ between preoperative and post-adjustment/ postoperative.

Late survival approached 90%. Risk factor control included meticulous surgical hemostasis, Amiodarone arrhythmia suppression, Aspirin platelet suppression, balanced shunting. Early postoperative support included 100% O_2 by nasal cannulae and Midazolam sedation. **Conclusions:** High survival with clinically relevant So_2 is achievable in piglets with risk factor control.

OBESITY AND LEFT VENTRICULAR ASSIST DEVICE DRIVELINE EXIT SITE INFECTION

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Introduction: Driveline Exit Site (DLES) infection is a persistent problem among LVAD pts. This study investigated the relationship between obesity and DLES infection. **Methods:** Records of LVAD pts implanted at 2 institutions from 1999 to 2008 were queried and analyzed using t-tests. Those with LVAD support <90 days were included. Pts were placed into an infection or a non-infection (control) group. The BMI of each pt was measured at the time of implant and at the conclusion of LVAD support or currently. Other data included pre-implant age, EF, BUN, Cr., diabetes, NYHA class, PCWP, $V0_2$ Max, and inotrope therapy. **Results:** Both groups had similar pre-implant characteristics. BTT and DT differences were not statistically significant. Results are shown below (Table 1).

Table 1.

	Infection Group	Control Group
Number	33	76
Mean Implant BMI (p=0.005)	29.8	26
Mean BMI HeartMate XVE (p=0.01)	30.6	26.5
Mean BMI HeartMate II (p=0.06)	26.7	24.6
Mean BMI Novacor (p=0.05)	29.2	22.7
Change in BMI (p=0.06)	1.02	−1.08
Support Duration (days)	422	690

Conclusions: Pts who developed DLES infections had a significantly higher BMI and tended to continue weight gain over the course of LVAD therapy compared to the control group. Subgroup analysis by device would yield additional clarification. While this association requires further study, implications for clinical practice may include the provision of appropriate nutrition and exercise counseling for pts undergoing LVAD therapy, especially if overweight.

LEVITRONIX CENTRIMAG TEMPORARY MECHANICAL SUPPORT AS BRIDGE TO SOLUTION

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Objectives: Levitronix CentriMag is a magnetically levitated bearingless rotary pump designed for short-term mechanical support.We report our experience with the device. **Methods:** Between 02/2004 and 01/2009,32 consecutive pts were supported with Levitronix at our institution (22men; age: 61.4±12.5, range: 31–76years). Indications for support were: post-cardiotomy cardiogenic shock (CS) in 27 cases (Group A) and post-acute myocardial infarction CS in 5 cases (Group B). **Results**: Overall mean support time was 9.7±6.9 days (range: 3–19 days).A biventricular configuration (BVAD) was established in 10 cases,right ventricle support (RVAD)in 13 and left (LVAD) in 9. Thirty-days mortality was 50% (n=13 pts, Group A; n=3, Group B). Thirteen pts (Group A) were weaned from support. Two pts were transplanted (n=1 pt,Group A; n=1 pt, Group B). In pts (Group A) undergone RVAD support due to right ventricular failure after long-term LVAD placement, CentriMag removal was performed through a right mini-thoracotomy. In 1 pt (Group B)the ungoing CentriMag LVAD support was combined with long-term Thoratec VAD cannulae to avoid re-sternotomy in case of eventual exchange for long-term or permanent Thoratec paracorporeal device support. Bleeding requiring re-operation occurred in 12(37.5%) cases and cerebral haemorrhage in 2(6.2%). There were no device failures. **Conclusions:** The Levitronix proved to be useful in pts with poor prognosis. The device was easy to manage. Survival to explant or a definitive procedure (transplantation or VAD) was encouraging.

EFFECT OF RETROGRADE FLOW IN STOPPED AXIAL AND CENTRIFUGAL LVADs ON SYSTEMIC PERFUSION

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Purpose: Stopped rotary LVADs become aorto-ventricular shunts, with potential clinical manifestation. Aware that shunt resistance is greater in Thoratec's axial-flow HeartMate® II LVAD than in the centrifugal-flow HeartMate III, we sought to quantify differences in pump retrograde flow and aortic flow with an acute in vivo bovine model. **Methods:** An LV to aortic bypass was accomplished in a 128 kg calf with 16 mm polyester graft, bifurcated to produce parallel HM II and HM III branches, rejoining distally. A clamp was used on one branch or the other to alternately isolate one pump. Data acquisition included aortic pressure (AoP), LVP, and RVP by Millar transducer and pump (Qp) and aortic root (QAo) flow by Transonic flowmeter. Subsequently, cardiogenic shock was induced by esmolol and the experiment repeated. **Results:** Upon pump stoppage, Qp changed from antegrade to retrograde, but QAo increased to sustain mean systemic flow (Qs, Table 1); in shock Qs decreased (Table 2).

Table 1.

	pump on	HM III off	HM II off
Qp (L/min)	3.6 ± 0.2	−3.0 ± 0.9	−2.0 ± 0.7
Qao	5.9 ± 0.3	13.5 ± 1.3	11.8 ± 0.8
Qs	9.5	10.5	9.8
AoP (mmHg)	87.1 ± 1.1	78.4 ± 0.8	77.6 ± 1.0

Table 2.

	pump on	HM III off	HM II off
Qp	3.6 ± 0.4	−1.5 ± 0.2	−0.9 ± 0.1
QAo	−0.7 ± 0.1	3.5 ± 0.6	2.6 ± 0.5
Qs	2.9	2.0	1.7
AoP	36.3 ± 1.2	31.9 ± 2.4	27.8 ± 1.5

Conclusions: Retrograde flow depends on AoP, LVP, and VAD flow resistance. Immediately following LVAD stoppage, systemic flow was sustained by compensatory mechanisms at nearly pre-event level despite profound retrograde pump flow. Predictably, compensatory mechanisms were less effective in profound failure.

HI FLOW IN PARALLEL ARTIFICIAL LUNG ATTACHMENT IN A PULMONARY HYPERTENSION MODEL

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Purpose: Most patients requiring a thoracic artificial lung (TAL) will have pulmonary hypertension and right heart strain. A majority of the cardiac output (CO) will flow through the TAL, and ideally, CO will be elevated during rehabilitation. This study evaluates hemodynamics with high TAL blood flows in rest and exercise conditions in a large animal model of pulmonary hypertension. **Methods:** The TAL, the MC3 Biolung®, was attached between the pulmonary artery (PA) and left atrium in eight (60–70 kg) sheep with chronic pulmonary hypertension. An adjustable band was placed around the distal PA and a clamp was placed on the TAL inlet graft to control the percentage of CO diverted to the TAL. PA pressure and flow and TAL flow was obtained at baseline (no flow to the TAL) and with 50–60%, 65–75%, and 80–90% flow diverted to the TAL. These conditions were repeated with 0, 2, and 5 mcg/kg/min of intravenous dobutamine to simulate rest and exercise conditions. **Summary of Results:** Without dobutamine, CO was 7.9±0.6 L/min at baseline and was maintained above 7.2±0.5 L/min under all TAL flows. At 2 mcg/kg/min, CO was 8.8±0.5 L/min at baseline and stayed above 8.2±0.7 L/min for all TAL flows. At 5 mcg/kg/min, CO was 11.7±0.7 L/min at baseline and decreased linearly with increasing TAL flow to a decrease of 25% with 80–90% of cardiac output to the TAL. This suggests that TAL use will not decrease CO with patients during rest or mild exercise but may not allow more vigorous exercise.

A PHYSIOLOGICAL MOCK CIRCULATION SYSTEM FOR OBTAINING PUMP PERFORMANCE OF ROTARY BLOOD PUMPS

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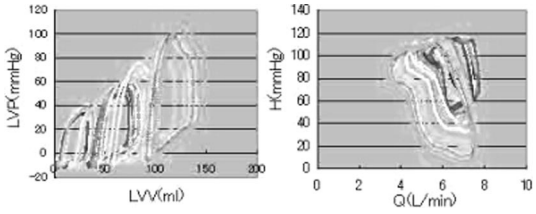
For assessing performances of rotary blood pumps (RBP), we have designed mock loop that can mimic cardiac functions as well as vascular characteristics. The ventricle model simulates passive filling characteristics and contractile strength of the heart can be adjusted to yield Physiological E_{max}. This study dynamically estimated H-Q curves. The ventricle model is placed in compression chamber sealed water and air. The sack is compressed using linear cylinder during systole, while during diastole it is de-coupled to attain passive filling. The air-to-water volume ratio (AWR) is varied to simulate varying cardiac compliance. The dynamic H-Q curve of RBP was obtained from the physiological mock loop E_{max}=0.7. In the P-V diagrams of the ventricle, the end-systolic points were connected to obtain E_{max}. By changing AWR, the physiological values of E_{max} (0.44–1.75) were confirmed. Adjustment of the cardiac compliance resulted in the physiological level of E_{max}. The dynamic H-Q curve was distinguished between systolic and diastolic phase.



And differences as each area inside of dynamic H-Q curve were increased while cardiac external work (EW) elevated. By changing AWR, physiologic cardiac compliance was obtained. The dynamic performances of RBP reflected changing in EW.

VENTRICULAR ASSIST DEVICE SUPPORT FOLLOWING CARDIAC TRANSPLANTATION FOR PRIMARY GRAFT FAILURE LEADS TO VENTRICULAR RECOVERY

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Purpose: Mechanical ventricular assist device(VAD) support after cardiac transplantation has been explored in patients with primary graft failure. Our aim was to examine the efficacy in supporting patients with VAD following cardiac transplant. **Methods:** Study population consisted of 7 pts (M:F 4:3, mean age 60.9, range 46.9 69.2) that underwent orthotopic cardiac transplantation which required immediate post-transplant support with VAD between 5/2002 and 10/2007. Indications for VAD placement were primary graft failure with ventricular dysfunction after ionotropic maximization. Four patients had right ventricular failure: 3 implanted with Abiomed-RVAD and 1 with C-Mag-RVAD. Three patients had biventricular failure: 2 implanted with Abiomed-BiVAD and 1 with C-Mag-Bi. The patients were retrospectively reviewed to assess ventricular recovery and outcomes. **Results:** Six of 7 (86%) pts were weaned from their VAD (median 6.5 days, range 5 13). Two patients with BiVAD required pump exchange to RVAD prior to explant. Survival to discharge occurred in 5 of 7(71%) pts. Complications were sepsis (2 pts), renal failure (2 pts), pneumonia (2 pts), GI bleed (1 pt), and mediastinal bleed (1 pt). Hospital mortality in 2 pts was to sepsis. With median follow-up of 22.2 months, median survival was 36.2 months. **Conclusion:** Given a high percentage of patients achieving ventricular recovery with favorable outcomes, VAD following cardiac transplantation is a viable option and should be considered in patients with primary graft failure.

DRIVING STABILITY OF THE AXIAL FLOW BLOOD PUMP USING GROOVE BEARING

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Introduction: We have been developing the axial flow blood pump using conical spiral groove bearing (CSGB) for left ventricular assist device(LVAD). Spindle Rotor which is composed of CSGB and enclosed-impeller is rotated by external motor. The pump's properties are contactless drive and simple structure. In this study, basic characteristics of pumps and driving stability were investigated. **Methods:** In in-vitro experiment, P-Q curve, a gap between CSGB and pump housing, and internal temperature of motor were measured. In addition, temporal alterations were observed under LVAD conditions. The gap and internal temperature were measured using the eddy current sensor and wire type thermo couple. **Results:** As a result of the in-vitro experiment, this pump was obtained enough P-Q curve and achieved the LVAD condition at a rotational speed of about 10,000rpm. In each rotational speed, a change in the gap by thrust power was about ± 5 μm. Moreover, a change in the gap was little for a few hours, and internal temperature reached a thermal equilibrium at a temperature of 41 °C. **Conclusion:** These results indicated that this pump was obtained sufficient P-Q curve and stability. In addition, this driving stability had been also confirmed for a few hours. In summary, this study suggested that this pump could obtain high durability and reliability by the simple control.

AREA AND DURATION OF AORTIC VALVE OPENING IS REDUCED DURING LVAD USE

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Previous observations show that the aortic valve opens less frequently in LVAD patients, and in some cases remains closed continuously (series flow). These altered biomechanics may underlie valve problems that develop in LVAD patients. The aim of this study was to measure area and timing of valve opening with and without an LVAD under the same flow conditions. A mock loop created a pulsatile cardiac output alone or combined with a Micromed continuous flow LVAD operating at a low speed (7.5 krpm). A digital camera recorded the motion of a bioprosthetic valve mounted in the aortic position during three flow conditions: Norm, Series and Parallel as defined in the table below. The results from three valves show that the valve opened to a maximum area (Max A) and longer opening time (O Time) during the Norm condition. During Series flow conditions, the valve did not open but was subjected to the highest transvalvular pressure (AoP-LVP). Parallel flow conditions produced higher aortic pressure (AoP) and cardiac output (CO), and demonstrated reduced valve opening. The area under the Max A-O Time relation (Integ A*t) showed a 70% decrease with the addition of the LVAD, providing a quantitative measure of the reduction of valve opening during LVAD use under controlled hemodynamic conditions (Figure 1).

Condition	CS	LVAD	AoP	LVP	CO	Max A	O Time	Integ A't
Norm	On	Off	61±15	34±2	1.8±.7	77±16	.42±.04	20.3±7.2
Series	Off	On	61±2	17±3	1.7±.5	0	0	0
Parallel	On	On	77±11	34±2	2.2±.5	37±6	.33±.01	6.4±0.3

ARTERIAL BAROREFLEX SENSITIVITY IN ARTIFICIAL HEART CIRCULATION

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In artificial heart circulation, we cannot check the baroreflex sensitivity, because there is no heart. There is no simple diagnostic method to measure the arterial behavior in Baroreflex system, especially in artificial circulation. Presently, we report the development of a method and associated hardware that enables the diagnosis of baroreflex sensitivity by measuring the responses of the artery. In this system, the measurements are obtained by monitoring an ECG or drive pulse and a pulse wave recorded from the radial artery. The arterial responses were measured in terms of the pulse wave velocity (PWV) calculated from the pulse wave transmission time from the heart to the artery. In this system, we could measure the sensitivity of the baroreflex system of an artery. Changes in the PWV in response to the blood pressure changes were observed. Significant correlation was observed in the time sequence between blood pressure change and PWV change after calculating the delay time by cross-correlation. The slope of parameter changes can also obtained from TAH pulse and PWV. When tested clinically, decreased sensitivity of the baroreflex system in hypertensive patients was observed. This system may be useful when we consider the ideal treatment and follow up of the patients with total artificial heart.

EVALUATION OF THE CONTRACTILITY OF ASSISTED VENTRICLES BASED ON SINGLE BEAT METHODS

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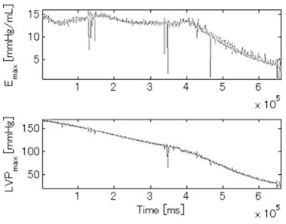
During the assistance with a rotary blood pump as bridge-to-recovery, the accurate detection of the recovery is essential. In order to aid in such detection, conventional cardiac function indices must be re-validated and adapted to the hemodynamics of assisted hearts. Recent studies have shown that, also during the assistance, the maximum ventricular elastance (E_{max}) estimated with the bilinear approximation of the elastance curve was sensitive to the contractility in a steady-state condition. However, the sensibility of this index to gradual changes in the contractility was still uncertain. In this study, we evaluated the estimation of the E_{max} in one adult goat with the left ventricle assisted by the EvaHeart (Sun Medical Tec. Res. Corp., Japan) while the cardiac output was decreasing after the injection of Inderal. The volume-axis intercept (V_0) and the E_{max} were estimated at each cardiac cycle. As shown in the Fig. 1, after the injection of Inderal, there was a fall in the blood pressure and a late depression of the myocardial contractility, which was detected by the estimated E_{max}. In future works, data from other experiments must be evaluated, including also a comparison of E_{max} with other indices of contractility.



CLOSE RELATION BETWEEN FREQUENCY OF NATIVE AORTIC VALVE OPENING AND AORTIC REGURGITATION IN PATIENTS WITH LEFT VENTRICULAR ASSIST DEVICE (LVAD)

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Background: Once aortic regurgitation (AR) develops after implantation of left ventricular assist device (LVAD), it becomes very difficult to control circulatory dynamics. However, predictive factors for the development of AR have not been established. **Methods:** Twenty-six patients receiving long-term (duration 5 to 37 months) LVAD support were enrolled. Their clinical background, duration of mechanical support, device type, echocardiographic data were analyzed. Grade of AR were classified into six groups, i.e. none, trace, grade 1, grade 2, grade 3, and grade 4 and 0, 0.5, 1, 2, 3, 4 point was given to each grade. **Results:** None of the patients had AR≥grade2 preoperatively. Grade of AR was positively correlated with plasma BNP levels ($r=0.371$, $p=0.03$) and negatively correlated with frequency of native aortic valve opening ($r=-0.655$, $p<0.01$). There was no correlation between grade of AR and duration of mechanical support or ejection fraction. AR≥grade2 tended to develop in patients with nonpulsatile flow pump (2 of 4) than in patients with pulsatile flow one (1 of 22, $p=0.05$). **Conclusions:** Less frequent opening of native aortic valve is a predictive factor for the development of AR, which can be a disadvantage for bridge to recovery. Further investigation is required to evaluate whether nonpulsatile flow really induces AR.

INDICATOR ABOUT INVASIVENESS OF CARDIOPULMONARY BYPASS IN LUNG TRANSPLANTATION

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Background: In cardiac operation, pulmonary circulation after cardiopulmonary bypass (CPB) possibly restores prostaglandin E_2 level (PGE_2), systemic tissue perfusion and body oxygen metabolism. However, in lung transplantation (Lx), pulmonary circulation on graft might induce other CPB reactions. We tried to clarify and decrease the adverse effects of CPB in Lx. **Materials & Methods:** Left Lx was performed on dogs (Group-A: during CPB, Group-B: during CPB with hemofiltration at the end of CPB, Group-C: without CPB; n=5, 5, 5). At 30 minutes after CPB (graft perfusion), the right pulmonary artery and bronchus were clamped. Clinical parameters were comparably controlled among three groups except hematocrit level during CPB. **Results:** In spite that the molecular weight of PGs is too big for PGs to be filtrated, PGE_2 was higher in Group-A (A> B> C: $P=0.03$) at 90 minutes after CPB whereas that was comparably changed among three groups before the end of CPB. PGE_2 was correlated with mixed venous oxygen saturation ($R=-0.65$, $P=0.01$) and oxygen extraction rate ($R=0.68$, $P<0.01$), neither with PaO_2/ FiO_2 nor A-aDO_2. **Conclusions:** The combination of Lx with CPB may induce the new inflammatory reaction, which might be prevented by hemofiltration. PGE_2 might be an indicator about the invasiveness of CPB in Lx.

A LOW MORTALITY MODEL OF CHRONIC PULMONARY HYPERTENSION IN SHEEP

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Purpose: To create a low-mortality model of pulmonary hypertension (PH). Previous work by our group demonstrated PH in sheep by injecting sephadex beads (0.75 g) into the pulmonary circulation every other day for 2 months with an associated 30% mortality. We hypothesized that injecting half the dose twice as often would yield comparable results with lower mortality. **Methods:** Ten sheep weighing 62±2 (SEM) kg were injected with 0.375 g of sephadex beads every day for 60 days. Pulmonary hemodynamics were assessed via pulmonary artery catheterization prior to the first injection (BL), and after 14, 28, 35, 42, 49, and 56 days of injections. If mean pulmonary artery pressure exceeded 40 mmHg, bead injections were stopped until the next catheterization date. At the end of the experiment, the heart and lungs were harvested for histological analysis. **Results:** All sheep survived to 60 days. The average pulmonary artery (PA) pressure rose from 17±1 (SEM) mmHg at BL to 35±3 mmHg on day 56 with no significant change in cardiac output (8.7±0.6 to 9.8±0.7). Average PA pressure rose 6–17 mmHg transiently upon injection with no adverse reactions. The right ventricular to left ventricular plus septal weight ratio was significantly higher (0.42±0.01) than a historical group of untreated control animals (0.35±0.01, n=13). **Conclusion:** A model of moderate chronic pulmonary hypertension with significant right ventricular hypertrophy is feasible with low-mortality.

CARDIAC ASSIST WITH A TWIST: APICAL TORSION AS A MEANS TO IMPROVE HEART FUNCTION

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Introduction: During systole, variations in muscle fiber angle across the wall of the LV cause the apex of the heart to turn about 15° in opposition to its base. This twisting action is believed to increase stroke volume (SV) and lower wall stress. Studies show that cardiac torsion is sensitive to various disease states and suggest the LV torsion is an important aspect of cardiac function. Modern imaging techniques have sparked renewed interest in cardiac twist dynamics but no work has been done to determine whether mechanical apical torsion can be used to restore function to failing hearts. Here we test the hypothesis that turning the cardiac apex by mechanical means can displace a clinically significant volume of blood from dilated hearts. **Methods:** An anatomically accurate silicone heart with real-life tissue properties was modified to expel fluid upon apical torsion. AV valves were sealed and the Ao and PA connected to graduated cylinders to measure SV vs. twist angle. A rotary platform was secured to the apex via a suction cup attached to a vacuum line and turned manually with the cardiac base held stationary. **Results:** Volume displacement was proportional to twist angle with LV/RV SVs reaching 22.0±1.3 and 21.0±1.8 mL respectively at 45° rotation. The torque required to rotate the apex was low (52.7±5.3 N-cm, peak) and varied linearly with torsion angle. **Conclusion:** These data suggest that supraphysiologic apical torsion may be a viable means to boost cardiac output without blood contact. Flow increases may be even greater in live hearts due to a concomitant reduction of wall stress.

EXTRACORPOREAL LIFE SUPPORT FOR PANCREATITIS-INDUCED ADULT RESPIRATORY DISTRESS SYNDROME

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Purpose: The adult respiratory distress syndrome (ARDS) secondary to acute pancreatitis is associated with a poor prognosis. We present the largest case series yet of ECLS treatment for pancreatitis-induced ARDS. **Methods:** We reviewed all cases of pancreatitis-induced ARDS that required ECLS at our institution from 1990 through 2007, $n=8$. We summarized their clinical courses and calculated summary statistics. **Results:** Results for the eight patients treated with ECLS are summarized below.

Table 1. Eight Cases of Acute Pancreatitis Requiring ECMO

Case	Age	Etiology	Run Length (days)	Operation on ECMO	Survival
1	29	Alcohol	3	Ex. Lap.	Yes
2	34	Billiary	29	Debrid.	No
3	28	Alcohol	7	Ex. Lap.	Yes
4	36	Alcohol	3		Yes
5	43	Unknown	25	Debrid.	No
6	27	Unknown	5	Debrid.	Yes
7	30	Alcohol	3		Yes
8	47	Alcohol	2		No

Seven of eight had VV-ECMO; one had VA-ECMO. Average time from presentation to ECMO was 6.3±6.1 days. Of the eight patients, five (63%) survived. Two of those who died had run lengths that were substantially longer than the rest of the patients'. Five patients (63%) underwent operations while on ECMO, and three of those five (60%) survived. Bleeding complications occurred in 5/8 (63%) patients, including all three who died. We conclude that ECLS may be useful in treating severe pancreatitis-induced ARDS.

DEVELOPMENT OF A WEARABLE PUMP-LUNG

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A wearable pump-lung has been developed to provide ambulatory respiratory support for adult patients with acute and chronic lung failure. In this study, both computational simulations and in-vitro experiments were conducted to investigate the functional and biocompatible performance of the device. The wearable pump-lung integrates an oxygenation component and a magnetically levitated pumping component into one ultra-compact device, which can be driven by a reusable pump motor. The pump-lung is comparable in size to a 12 oz soda can. Using computational aided design (CAD) and computational fluid dynamics (CFD), the device's impeller/diffuser assembly was carefully designed to optimize the flow field. Fully functional prototypes were built and in-vitro hydrodynamic, oxygen transfer and hemolysis experiments were carried out in mock flow loops using ovine blood. The in-vitro results showed that the device with an Oxyplus membrane surface area of 0.7 m^2 was capable of pumping blood from 1 to 4 L/min against a wide range of pressures and transferring oxygen at a rate of up to 180 ml/min at a blood flow of 3.5 L/min. Standard hemolysis testing demonstrated low hemolysis (NIH<0.05) at a flow rate of 3.5 L/min against 100 mmHg afterload. Both in-vitro studies and CFD simulations confirm that the device can provide sufficient oxygen transfer with good biocompatibility. In-vivo experiments are now being conducted to evaluate the long-term functional performance and biocompatibility.

EXTRACORPOREAL LIFE SUPPORT FOR SEVERE *LEGIONELLA* PNEUMONIA IN ADULTS

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Purpose: We describe our experience with patients who developed ARDS from *Legionella* pneumonia and required extracorporeal life support (ECLS). **Methods:** We reviewed the medical records of all patients who developed ARDS associated with *Legionella* pneumonia and required ECLS at our institution from 1994 to 2006. Data collected included demographics, clinical course, details of ECLS treatment, complications and survival. **Results:** Twelve patients underwent ECLS for *Legionella*-induced ARDS between 1994 and 2006; all received VV-ECMO. The average ECLS run length was 11.3±6.8 days. Nine of the twelve (75%) were successfully treated and weaned off ECLS. Two of the twelve (13%) died of multisystem organ failure, one patient (8%) died from global hypoxic encephalopathy, and one patient (8%) was weaned from ECLS but ultimately died of liver failure. Eight patients (67%) had comorbid illnesses; most frequently diabetes (4/12, 33%). Eleven of the 12 (92%) required tracheostomy; 8 of 12 (67%), including all those who eventually died, required some form of dialysis. The overall rate of survival to hospital discharge was 67%. ECLS should be considered for adult patients who fail ventilatory management with severe *Legionella* pneumonia.

DURABILITY OF GYRO CENTRIFUGAL PUMP AS PERCUTANEOUS CARDIOPULMONARY SUPPORT

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Pre-connected percutaneous cardiopulmonary support (PCPS) circuit is well-established system, but not designed for long term use. We report our experience of Gyro centrifugal pump (Medtronic) and silicone-coated heparin-coated hollow-fiber membrane oxygenator (Mera) as long-term use of PCPS. The Gyro pump is a centrifugal blood pump that has an impeller suspended by double pivot bearings inside the housing. Silicone-coated heparin-coated hollow-fiber was developed to prevent plasma leakage during long-term use. To combine Gyro pump and silicone-coated membrane oxygenator, we could support patient in status of LOS for 13–14days without remarkable hemolysis.

TREATMENT OF RIGHT VENTRICULAR FAILURE WITH RIGHT TO LEFT ATRIAL SHUNTING AND VENO-VENOUS EXTRACORPOREAL LIFE SUPPORT

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Objective: Right ventricular (RV) failure is a severe complication in lung transplant candidates. An atrial septostomy with tricuspid insufficiency (TI) and veno-venous extracorporeal life support (VV ECLS) could be a treatment option. **Methods:** Adult male sheep (54±2 kg, n = 4) underwent a clamshell thoracotomy and instrumentation to measure right and left atrial (RA, LA), pulmonary artery (PA) and RV pressures. Cardiac output (CO) was evaluated with a flow probe on the ascending aorta. Under ECLS, pulmonary hypertension and RV failure was established by banding the PA until CO decreased 40%. The atrial septostomy was simulated by connecting both atria with a 31 French cannula. A 13 French catheter was passed through the tricuspid valve to create TI. Hemodynamic data was collected at baseline, during RV failure, and for one hour at 100 (fully open), 70, 50 and 30% of shunt flow. **Results:** From baseline to RV failure CO decreased from 5.2±0.2 L/min to 2.2±1.1 L/min, mean RV pressure increased from 12.7±1.2 to 24±2 mmHg. With the shunt fully open shunt flow was 1.4±0.8 L/min, CO returned to 4.8±1.0 L/min, and thus RV failure was eliminated. CO decreased as shunt flow decreased to 3.9±0.6 L/min at a 30% shunt flow of 0.4±0.2 L/min. ECLS maintained mean O_2 tensions of 289±76 mmHg and mean CO_2 tensions of 37±6 mmHg during the entire experiment. **Conclusion:** Right to left atrial shunting of oxygenated blood with VV ECLS is capable of eliminating RV failure while maintaining normal arterial blood gases.

SUCCESSFUL MANAGEMENT OF PATIENTS WITH HEPARIN INDUCED THROMBOCYTOPENIA REQUIRING MECHANICAL ASSISTANCE

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Heparin induced thrombocytopenia (HIT) is a complex problem. To overcome the complications of cardiopulmonary bypass using anticoagulation with direct thrombin inhibitors, our approach has been to use off pump and/or left heart bypass techniques for VAD implantation in HIT patients. Patients are listed for transplant when heparin antibodies resolve. Heart transplant is accomplished using heparin. **Methods:** 4 patients with HIT underwent VAD placement. Inotropes and/or an intra-aortic balloon pump (IABP) were used to maintain hemodynamics. Bivalirudin was used at the time of operation to achieve an ACT of 250–300 s. The outflow graft was anastomosed to the aorta using a partial occlusion clamp. An apical suction device was used to expose the left ventricular apex. Hemodynamics during placement of the apical sewing ring and subsequent LV coring were supported with an IABP (N=2) or a Tandem Heart (Cardiac Assist, Inc,) (N=2). Rapid ventricular pacing was used to prevent ejection during coring and pump connection. **Results:** 2 patients were transplanted once their HIT antibodies resolved. 1 patient remains listed. 1 patient is recovering in the perioperative period. **Conclusion:** In this small series, excellent outcomes have been achieved by avoiding cardiopulmonary bypass in HIT patients requiring mechanical assistance.

INITIAL PERFORMANCE AND STABILITY TESTING OF THE PENN STATE/ABI TESLA PUMP

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Penn State University and Advanced Bionics Incorporated have developed a unique Tesla type blood pump. The pump has been designed and developed using computational fluid dynamics and experimental testing. The pump consists of a passively suspended rotor that employs multiple disks to form a Tesla pump. The Tesla impeller is a form of centrifugal impeller that uses fluid viscous shear to effect energy transfer between the fluid and parallel rotor disks instead of impulse and reaction transfer between the fluid and blades, as in the typical centrifugal impeller. The rotor is passively suspended and stabilized in the axial direction by the motor stator axial magnetic force. The passive radial stabilization is unique in that it is not a conventional hydrodynamic bearing or magnetic support. Instead, the rotor is centered by a body force that is created by the centrifugal forces on the rotating blood that in turn imparts a body force on the rotor. Initial performance testing of the pump has demonstrated flows in excess of 8 liters per minute with a pressure rise of 70 mmHg. High speed video analysis has been performed to assess radial stabilization, and the rotor offset position was verified to be less than 0.015 in. for operating speeds between 7000 and 10000 rpm. A sinusoidal commutation algorithm was implemented to reduce torque ripple. The motor operates at 90% of maximum power at 10000 rpm. System efficiency and control continue to be improved.

CHRONIC IN VIVO PERFORMANCE OF THE CLEVELAND CLINIC PEDIPUMP LEFT VENTRICULAR ASSIST DEVICE

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We evaluated pump performance of the PediPump as a left ventricular assist for 30 days. Since June 2008, the PediPump was implanted in six healthy lambs (25.6±1.4 kg) between the left ventricular apex and the descending aorta. Pump speed was adjusted to 2 L/min with heparin administration. Three lambs were sacrificed prematurely due to respiratory dysfunction (0 day and 8 days) and deteriorating pump performance due to depositions inside the pump (17 days). Three lambs were electively sacrificed 30 days after implantation with stable hemodynamics and pump flows ranged between 1.23 and 3.61 L/min with pump speeds of 10.9–13.7 krpm and motor currents of 0.69–0.96 A. There was no sign of hemolysis. There were inconsistent results from anticoagulation assays under heparin administration. During autopsy, depositions were observed at the front (n=1) and rear touch points (n=5); Improved polishing techniques on the stationary touch point and the addition of a hard carbon, thin film coating on the rotating touch point reduced deposition in the last two experiments. In conclusion, the PediPump system showed reliable mechanical and electronic console operation and expected hydraulic performance for 30 days. Focus will continue on effective anticoagulation management in lamb model as well as further refinements of the pump surfaces and local flow patterns.

MINIATURE CARDIOPULMONARY BYPASS SYSTEM FOR MICE

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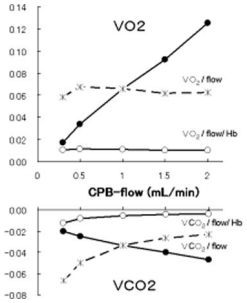
Purpose: A miniature cardiopulmonary bypass (CPB) system is developed using silicone membrane oxygenator and tubing to make CPB possible in mice. **Methods:** A membrane oxygenator consisting of 192 silicone hollow fibers with an internal diameter 0.2 mm were packed in a housing allowing for gas exchange surface of 60 cm^2 and priming volume less than 1.0 cm^3. The oxyganator, pump head and a miniature online reservoir were connected with a 1 mm silicone tube to complete a CPB system, which has approximately 1.2 mL as the priming volume. A roller pump (Regro, Ismatec) generates a smooth, exact, and pulseless flow, ranging from 0.001 mL/min to 24 mL/min. **Results:** The CPB system is assembled and filled with rodent venous blood to test its function as an oxygenator with the flow rates changing from 0.3 to 2.0 mL/min, the average cardiac output of mice. The oxygenation (upper panel) was more efficient than CO_2 removal (lower panel), which still appeared to be sufficient under the tested flow ranges. **Conclusion:** We developed a whole silicone miniature CPB system, which is capable of providing sufficient oxygenation and CO_2 removal to be used in mice (Figure 1).



HEARTMATE II: SUSPECTED FLOW OBSTRUCTION AND RESULTS POST-TRANSPLANT

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A HeartMate II(HMII)(Thoratec, Pleasanton, Calif) has been implanted in a 38 year old male with Dilated Cardiomyopathy (DCM). Target INR of 2.5–3.5 was chosen because of an existing mitral prosthetic valve. Four months post-implant, echocardiogram showed an Left Ventricle End Diastolic diameter (LVEDd) of 83 mm with 9400 Rotations Per Minute (RPM) by the device. Fourteenth months post-implant, LVEDd had been increased to 100 mm. An attempt to improve unloading of the left ventricle by increasing the RPM to 9800 did not result in a decrease of LVEDd. Apart from this, computer tomographic scanning revealed an ingrowth of the rim of the inflow cannula in the myocardium of the left ventricle over an angle of approximately 140°. Suspicion of flow limitation did raise. Nevertheless, patient was in extremely good clinical condition without signs of heart failure. Furthermore, no significant changes in HMII data were observed during the period of support. Nineteen months post-implant, patient was transplanted and the ingrowth of the rim was found. It was not considered to be a serious inflow obstruction. Inspection of the HMII revealed a clean housing and impeller. However, thrombus formation was observed in the inflow cannula at the level of the flexible section and was exposed. The diameter of the graft in the flexible section is 15 mm and was reduced to approx. 7 mm. The thrombus formation represents a reduction of the flow area of approx. 78%. Future investigations will be performed to clarify influence of flow obstructions with regard to HMII parameters.

VALIDATION OF AUTOMATED MONITORING OF BIVENTRICULAR PACING OPTIMIZATION

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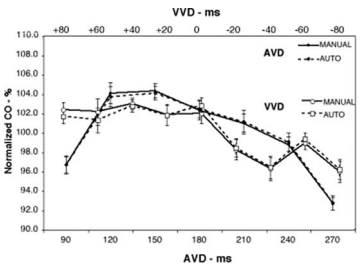
Purpose of Study: Biventricular pacing (BiVP) ameliorates acute heart failure after cardiac surgery. Optimization of atrioventricular (AVD) and interventricular (VVD) pacing delay increases cardiac output (CO). We compared real-time automated analysis (AA) of optimization with manual analysis (MA) in a right ventricle (RV) pressure overload model. Methods Used: In 6 pigs, pacing leads were placed on the right atrial appendage, RV, and LV. Complete heart block was induced. RV systolic pressure was doubled with a pulmonary artery snare. AVD was varied randomly between 90 and 270 ms and VVD between +80 (RV first) and −80 ms at optimal AVD. Data were collected for two LV pacing sites. CO was measured by aortic flow probe. Interexaminer Reliability Coefficient (IRC) was determined with ANOVA for two 10 second runs in each animal. Summary of Results: CO-AVD and CO-VVD relations were similar for AA and MA.



IRCs were 0.997 and 0.994 for MA vs. AA. AA was available in real-time. MA was delayed 2–3 hr. AA is accurate and immediately available. AA merits development for optimization of temporary BiVP.

STUDY ON OPTIMIZATION OF IMPELLER GEOMETRY IN ALL-IN-ONE IMPLANTABLE OXYGENATOR WITH CROSS FLOW BLOOD PUMP

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Introduction: We are developing all-in-one implantable oxygenator with Cross Flow Blood Pump (CFBP) for right ventricle assist. In a previous research, it have been reported that hydrodynamic performance was improved by optimizing of the impeller in CFBP. However, the strength of the impeller is not investigated. In this study, we designed and evaluated newly impeller for optimizing in strength and flow efficiency. **Method:** CFBP consisted of an impeller, a pump housings, bearing and a blush-less DC motor. Specification for Model A as a prototype were the impeller length is 72 mm, outer diameter is 30 mm and inner diameter is 21 mm, the impeller is composed of 26 blades, and blades angle is 36 degrees. Model A as a prototype, and B model as newly impeller was added 4 blades in center of Model A. The strength of impellers was calculated by computational structural analysis. In addition, the hydrodynamic performances of the impeller were evaluated mock circulatory loop. A glycerol solution of 33% was used for the working fluid. **Results:** Model B was improved 130% compared with Model A by strength analysis. In addition, the flow rate of the CFBP was 3.0 L/min at 2600 rpm when the pressure heads were 140 mmHg of Model A and 107 mmHg of Model B. The performances of Model A and Model B were sufficient for right ventricle assist. From what has been discussed above, we can conclude that newly impeller equipped the strength and sufficient for the hydrodynamic performance.

STUDY ON OPTIMIZATION OF HEAT EXCHANGER FOR AN EXTRACORPOREAL CIRCULATION

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Miniaturization of the artificial heart lungs is required performance improvement of heat exchanger (HE) for an extracorporeal circulation. However, development of HE is important not only heat transfer efficiency (HTE) and pressure drop (PD), but thrombus formation due to stagnation of blood flow. In previous study, we constructed an automatic optimization system of the HE using MOGA (Multi Objective Genetic Algorithm). This system was able to develop the housing design of anti-thrombogenicity and uniform blood flow. In this study, we investigated optimum pipe array and pipe interval of internal HE using CFD (Computational Fluid Dynamics). The analysis conditions were blood properties at 37°C and water properties at 8°C. Blood flow rate was 3 L/min and water flow rate was 12 L/min. First, pipe array was investigated relation between mixing ratio of zigzag / square array and HTE. HTE was most improved mixing ratio at 75%. Second, we investigated relation between pipe interval and HTE, PD. Pipe interval was set at 0.2, 0.6, 1.0, 1.2, 1.8 mm. The 0.6 mm of pipe interval was highest HTE and low PD. Finally, optimum model (mixing ratio of array at 75%, 0.6 mm of pipe interval) was designed by CFD and MOGA. As a result of CFD and MOGA, this model was improved by 18.5% in HTE compared with the BIOCUBE 6000 (NIPRO Co., Tokyo Japan). In conclusion, these results indicated that performance of HE was depend on pipe array and pipe interval. Therefore, it was possible to achieve miniaturization of HE.

DEVELOPMENT OF COMPUTER SIMULATION TECHNIQUES TO IMPLANT ARTIFICIAL HEARTS: STRESS SIMULATION OF INTERNAL ORGANS USING THE FINITE ELEMENT METHOD

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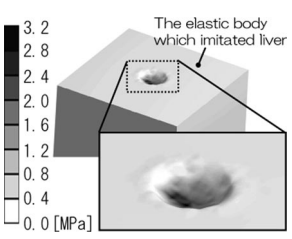
We have been developing an implantable Total Artificial Heart (TAH) in collaboration with National Cardiovascular Center. Preoperative evaluation of anatomical compatibility is necessary because the TAH is implanted in limited space in a patient. In this study, stress simulation of organs using ANSYS Workbench software of finite element structural analysis was examined to evaluate contact and stress between the TAH and peripheral internal organs quantitatively. In particular, the liver under the TAH was investigated. The TAH and the liver were expressed as a hard-sphere (radius r=25 mm) and a hyper-elastic rectangular parallelepiped (200 × 200 × 150 mm), respectively. Stress values by deformation of the liver were calculated using the ANSYS Workbench. As a result, when the hard-sphere was pressed 10 mm deep in the hyper-elastic rectangular parallelepiped, the maximum stress value was 3.06 MPa. In conclusion, the possibility of quantitative evaluation for anatomical compatibility was suggested using our simulation techniques (Figure 1).



HEART RATE VARIABILITY ASSESSED WITH CONVENTIONAL FFT AND WAVELET TRANSFORM IN LVAS PATIENTS AIMING FOR BRIDGE TO RECOVERY

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Background: We examined the feasibility of HRV as a diagnostic tool for the patients with LVAS aiming recovery (BTR). **Methods:** ECG recordings obtained from healthy volunteer (group H, n=13), patients with medical heart failure (group F, n=3) and the patients with LVAS (group L, n=7). Time domain indices included mean NN (R-R interval), SDNN (standard deviation of NN interval), TI (triangular index of NN). Frequency domain indices (LF, HF and LF/HF ratio) were obtained using the fast Fourier transform (FFT) for 24 hours and using wavelet transform (WT) for 10 minutes. Clinical data including brain natriuretic peptide (BNP), ejection fraction by UCG were also analyzed with HRV data. **Result:** In group F, the value of VLF, LF, SDNN, TI and LF/HF was significantly lower than in group H (SDNN 74.7±24.7 vs. 124.7±28.7 msec, TI 18.9±6.1 vs. 25.2±7.7, VLF 710.8±56.0 vs. 943.0±228.8 msec2, LF/HF 0.68±0.15 vs. 0.64±0.14 in F and H, respectively). In group L, each indices were significantly lower than other groups (SDNN 63.7±24.5 msec, TI 14.9±2.5, VLF 215.0±183.8 msec2, LF/HF 0.34±0.07. These indices improved with the decrease in BNP after LVAS. The results using FFT and WT had same tendency. Conclusion: HRV can be used to estimate the cardiac status of the heart even with LVAS. WT with only 10 minutes of data acquisition can be an alternative to the FFT with data from at least several hours.

PEDIBOOSTER EXTRACARDIAC VAD: *IN VIVO* RESULTS WITH NEONATAL HEART FAILURE MODEL

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Purpose: The PediBooster is a minimally invasive, non-blood contacting BiVAD for pediatric use. It is intended as a palliative therapy for acute heart failure (HF) following surgery to correct congenital heart defects. **Methods:** The PediBooster extracardiac wrap is pneumatically actuated to circumferentially compress the heart, providing copulsation support. Attachment is via a novel hydrogel coating. Four acute studies of the final wrap design were done in piglets (5.1±0.3 kg). The combination of ASD and PA banding induced HF that would cause cardiac arrest within 10–20 min *if support were not initiated*. Data included routine hemodynamic values, TEE, video of the exposed heart, and cardiac histology. **Results:** The model was stable during support ranging from 30 min to 16 hr. The wrap restricted the heart in 3 of the 4 animals, as evidenced by increased diastolic LVP, decreased AoF, and decreased PAF during support compared to the failure condition. TEE and video data showed good attachment and function of the wrap during the final 16 hr study (Table 1).

Table 1. PediBooster Hemodynamic Data (n=4, mean±SD)

Measurement	Healthy	Failure	Support
LVP (mmHg)	105/8 ± 15/3	68/7 ± 34/2	109/15 ± 48/8
AoF (lpm)	0.54 ± 0.21	0.35 ± 0.18	0.25 ± 0.18
PAF (lpm)	0.69 ± 0.18	0.42 ± 0.32	0.37 ± 0.30
O2 Sat (%)	98 ± 2	79 ± 6	74 ± 22
CVP (mmHg)	5 ± 2	9 ± 5	16 ± 4

Conclusions: The novel pediatric HF model shows promise for 2472 hr studies. Ventricular filling may be improved by adjusting wrap dimensions to eliminate end diastolic restriction.

CONVERSION OF THE AVALON ELITE™ Bi-CAVAL DOUBLE LUMEN CANNULA FROM VV ECMO TO VA ECMO

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The highly efficient Avalon Elite™ Bi-Caval Double Lumen Cannula (DLC), formerly referred to as the Wang-Zwisch cannula, is designed for VV ECMO, with minimal (<2%) recirculation and less blood trauma. The purpose of this study was to show that the DLC could be converted to VA ECMO to provide cardiopulmonary support. Methods and materials: The initial circuit bench testing was performed with 38% glycerin at room temperature. Both the DLC (27 Fr) drainage lumen and infusion lumen were connected to achieve effective venous drainage to a CentriMag pump-Affinity Oxgenator-15 Fr Jostra cannula. The ratio of drainage lumen to infusion lumen cross- sectional area is 1.6:1. At 27 mmHg drainage pressure, total drainage flow through the DLC was 3.16 l/min (2.0 l/min from drainage lumen, 1.16 l/min from infusion lumen). This circuit was also tested in two adult sheep (50–55 kg) with the DLC inserted into the jugular vein and a 14 Fr infusion cannula inserted into the carotid artery. At 2.47 L/min, VA ECMO achieved a drainage flow rate of 1.6 l/min through drainage lumen and 0.86 l/min through infusion lumen. Conclusion: The DLC for VV ECMO can be converted to VA ECMO for patients needing cardiopulmonary support. Both lumens of the DLC drain blood at a 1.6:1 ratio (drainage to infusion lumen) to allow adequate VA support without necessitating additional venous cannulation.

RISK FACTORS FOR LEFT VENTRICULAR ASSIST DEVICE RELATED INFECTION

Sunil Pauwaa, Mary Gregory, Michael A Sobieski, Joseph Sleep, Colleen Gallagher, Laura Coyle, Antone J Tatooles, Geetha Bhat. *Center for Heart Transplant and Assist Devices, Advocate Christ Medical Center, Oak Lawn, IL.*

Purpose of Study: The goal was to evaluate preoperative risk factors for Left Ventricular Assist Device (LVAD) related infection in patients receiving Heartmate II LVAD as destination therapy. **Methods:** Nutritional parameters and other data were collected on thirty-four patients approximately one week prior to LVAD implantation. Patients were divided into those that developed LVAD related infections and those that did not (Figure 1).

	Non-Infected (n=17)	Infected (n=17)	p-value
Male	82%	76%	.56
Ischemic/Non-ischemic	7:10	13:4	p≤.05
Previous Sternotomy	41%	53%	.58
Body Mass Index (kg/m^2) mean +/- SD	24.8 (+/-5.1)	26.2 (+/-5.6)	.92
Age (years) mean +/- SD	65.6 (+/-10.3)	61.5 (+/-14.5)	.32
Diabetes	29%	59%	.14
Laboratory Data mean +/- SD			
Hemoglobin A1C (%)	5.96 (+/- 0.7)	6.04 (+/- 0.6)	.8
Creatinine (mg/dL)	1.6 (+/- 0.7)	1.4 (+/- 0.4)	.41
Albumin (gm/dL)	3.1 (+/- 0.5)	3.2 (+/- 0.4)	.70
Pre-Albumin (mg/dL)	16.6 (+/- 7.2)	17.7 (+/- 5.7)	.63
Cholesterol (mg/dL)	111.4 (+/- 28.2)	115.9 (+/- 33.5)	.77
Total Protein (gm/dL)	6.7 (+/- 0.7)	6.6 (+/- 0.6)	.75
WBC count (thousand/mcL)	6.7 (+/- 2.0)	7.9 (+/- 2.2)	.10
Lymphocytes (%)	7.9 (+/- 11.3)	2 (+/- 3.0)	p≤.05
Erythrocyte Sedimentation Rate (mm/hr)	24.8 (+/- 17.1)	38.6 (+/-18.2)	.43
B-type Natriuretic Peptide (pg/mL)	1180.4 (+/- 913.7)	1266.3 (+/- 917.6)	.77
Total Bilirubin (mg/dL)	1.4 (+/- 0.9)	1.6 (+/- 0.9)	.71

Results: 17 patients receiving Heartmate II LVAD developed a total of 18 LVAD related infections (1 sternal infection, 7 pocket infections, and 10 percutaneous lead infections) at a mean of 236±219 days. Ischemic etiology and low lymphocyte percentage were found to be significantly associated with LVAD related infection (p≤0.05). **Conclusion:** Ischemic etiology appears to be associated with LVAD related infection although there was no difference in the number of previous sternotomies. Lymphocyte percentage is a nutritional marker and appears to be associated with LVAD related infection. Our study suggests that serial monitoring and nutritional management of low lymphocyte percentage may be beneficial in decreasing LVAD related infections.

STATUS OF THE MAGNETICALLY LEVITATED MiTi*HEART*® LVAD

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The MiTi*Heart*® LVAD is a rotary centrifugal blood pump with a low power magnetic bearing system. Features include a simple and direct flow path for both main and washing blood flows, non-contact pump rotor and relatively large clearances between the pump rotor and housing. *In vitro* testing has confirmed stable, reliable operation under a wide variety of test conditions, producing 5 L/min of flow against 100 mmHg at approximately 4000 rpm. Constructed from titanium alloy, all blood-contacting surfaces have been treated with a unique biocompatible coating. Test results have confirmed significant decrease in platelet adhesion as a result of the coating. Hemolysis tests were performed in pulsatile and non-pulsatile conditions. Results demonstrated low levels of hemolysis under all conditions with an average NIH of 0.005 mg/dl. A total of 600 hours of animal testing has been performed at the Hershey Medical Center. A wearable control system has been designed and tested. The new control system is compact and efficient, allowing 4 hours of operation before battery recharge is needed. The performance of the control system has been validated during a series of in vitro and animal implant studies. The results demonstrate the efficacy of the MiTi*Heart*® LVAD system.

DEVELOPMENT OF ASSAYS TO DETECT LYMPHOCYTE ACTIVATION IN OVINES

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Infection is a major complication observed following clinical VAD implantation and may be associated with activated circulating lymphocytes. Reducing infection risk is an important design goal for pediatric ventricular assist devices, commonly evaluated in ovines. Therefore we sought to develop assays that could quantify ovine lymphocyte activation. Blood was collected via jugular venipuncture into citrate and added to tissue culture wells containing heparinized cell culture medium (control), or medium with 5 μg/mL concanavalin A, or 0.2 μM phorbol myristate acetate for 96 h. Following incubation blood/media aliquots were incubated with monoclonal antibodies (MAbs) to ovine CD4 for T-cells and either ovine CD25 (IL-2 receptor alpha chain), major histocompatibility complex (MHC) subunit DQ or subunit DR. MAb binding to activated CD4 T-cells was quantified by flow cytometry. The anti-ovine CD25, MHC DQ and MHC DR MAbs all preferentially bound to the activated CD4 T-cells. These assays were then used to assess lymphocyte activation during 3 current year implants of the PediaFlow™ VAD. Lymphocyte activation did not increase above baseline in the first two studies (16=30 d implants) but did show a gradual rise in a 70 d implant. The rise in lymphocyte activation might be expected in the longer study given the prolonged open driveline wound. Assays that can detect circulating activated ovine lymphocytes, when coupled with previously developed assays for ovine platelet activation, may allow broader assessment of cardiovascular device blood biocompatibility during preclinical testing.

SERIAL ASSESSMENT OF COAGULANT ACTIVITY DURING ONE YEAR AFTER AORTIC VALVE REPLACEMENT USING ON-X VALVE

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The ON-X valve has reported to require less anticoagulation and to show lower thrombo-embolic incidence compared with previous mechanical prostheses. We evaluated postoperative coagulant activity data including prothrombin time-international normalized ratio (PT-INR) and thrombin-antithrombin III complex (TAT), measured every month in 14 ON-X AVR patients during the postoperative 1 year. The results were divided into 4 time intervals after the operation: 1 to 3 months (P-1), 4 to 6 (P-2), 7 to 9 (P-3), and 10 to 12 (P-4). Warfarin in combination with aspirin 100 mg was started targeting PT-INR of 2.00 to 2.25. The values of TAT in P-1, P-2, P-3 and P-4 were 1.25±0.58 (ng/ml), 0.62±0.45, 0.79±0.51, and 0.68±0.52, respectively, showing significantly high values in P-1. Furthermore the TAT values of P-1 and P-2 within the range of PT-INR less than 2.00 were 2.75±1.91 (ng/ml) and 1.29±0.72; demonstrating statistical difference between them. The coagulant activity assessments suggest that warfarin therapy with PT-INR over 2.00 during the first three months is necessary for ON-X AVR patients to keep the TAT within the normal range.

AORTIC VALVE PERFORMANCE DURING SYSTOLE WITH TRANSAORTIC VENTRICULAR CANNULA

James D Cezo, Steven W Day. *Mechanical Engineering Department, Rochester Institute of Technology, Rochester, NY.*

A novel transaortic ventricular cannula, known as the Double Barrel Cannula (DBC), is designed to minimize the invasiveness of VAD implantation by combining the inlet and outlet cannulae into a single dual lumen cannula. Both cannulae will pass through the left ventricular apex with the outflow then continuing through the aortic valve. This design offers several advantages over current state-of-the-art cannulation. By routing the outflow through the aortic valve, the need to access the external structure of the ascending aorta is eliminated, potentially eliminating the need of open heart surgery (Figure 1).

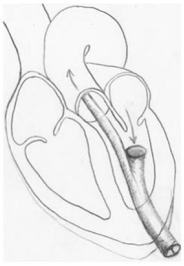

Figure 1 – Double Barrel Cannula in left ventricle

In an effort to determine the DBC's physiological combatibility, several designs are being analyzed and compared via in vitro experimentation. The purpose of this study is to determine the effect of the DBC's presence on the natural systolic flow through the aortic valve and select a design that minimizes this effect. For each, PIV was used to characterize flow through the aortic valve at peak systolic flow of 5 liters/min. Attention was paid to the fluid shear stress as a way to estimate hemolysis. The shear stress and time exposure data was compared to existing models correlating shear stress to hemolysis. Results from the 4 geometries are compared and the design exhibiting the least amount of induced shear stress was considered for further testing.

LIFEBRIDGE B_2T—A NEW PORTABLE CARDIOPULMONARY BYPASS SYSTEM

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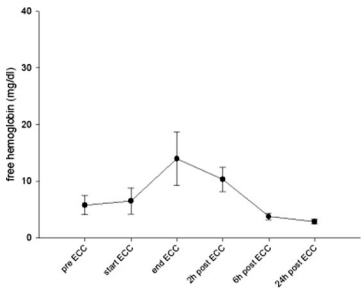
The LIFEBRIDGE B_2T is a new portable cardiopulmonary bypass system designed for temporary circulatory support. The LIFEBRIDGE B_2T consists of a disposable patient unit with a cardiopulmonary bypass circuit, a control and a base unit. The system weighs 20 kg. We used the LIFEBRIDGE B_2T in 4 patients for circulatory support in beating heart CABG for complete revascularisation. The LIFEBRIDGE B_2T was connected via percutaneous femoral cannulation. Concentrations of free haemoglobin (fHb), IL-6 and IL-8 were measured. For venous blood drainage 22–24 Fr and for arterial cannulation 16–20 Fr cannulas were used. Average ECC time was 61±18.6min. During circulatory support fHb concentration increased from 5.8±1.7 mg/dl to his maximum of 14±4.7 mg/dl. Also IL-6 and IL-8 increased from 2.1±0.06 U/L to 503.3±200.4 U/L and 5.9±0.9 U/L to 66.5±23.4 U/L, respectively (Figure 1).



The LIFEBRIDGE B_2T is a new portable and safe circulatory support system. Connected via percutaneous femoral cannulation, the system provides adequate arterial blood flow and an acceptable negative pressure at the venous cannula. Concentrations of fHb, IL-6 and IL-8 showed only a moderate increase.

A NOVEL IMPLANTABLE MECHANICAL CIRCULATORY SUPPORT SYSTEM: THE ARTIFICIAL VENTRICLE

Hisham MF Sherif. *Cardiac Surgery.*

Purpose: We introduce a novel design for a new totally internal mechanical circulatory support pump for replacement of one or both ventricles. The device has a long projected service life, a totally implantable, readily available and off-the-shelf energy source. **Materials and Methods:** The proposed device is a pulsatile, positive-displacement blood pump composed of a compliance chamber, constructed of a biocompatible, non-thrombogenic material. At its base, this chamber incorporates two bioprosthetic valves in opposite orientation- an inlet valve and an outlet valve. The two valves are each connected to a vascular graft. The chamber is surrounded by radially-arranged contractile elements, made of an electro-active polymer and connected to a common stimulating electrode. The entire assembly is housed in a hermetically sealed biologically inert shell. The electrode is connected to the output of a conventional implantable permanent pacemaker. The energy output from the pacemaker will cause the deformation of the contractile elements and thus compression of the compliance chamber, effecting ejection of the blood through the outlet valve. **Results and Conclusions:** Based on a design emulating the natural anatomic configuration and utilizing a new class of materials, the device shall provide mechanical assistance or replacement of the native heart function for an extended period of time. The proposed design is completely implantable; composed of readily available materials; has minimal energy requirements and an extended service life on internal power supply.

DYNAMIC IN VITRO CALCIFICATION OF POLYURETHANE TRILEAFLET HEART VALVES

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Purpose of Study: The overall goal of this project is to address the issue of calcification of polyurethane valve prostheses which require lower anticoagulation levels than mechanical valves, yet offer the potential for reduced calcification and increased durability when compared to tissue valves. The valve leaflets are fabricated from Angioflex®, a proprietary polyetherurethane material that has been successfully and clinically evaluated by ABIOMED, Inc. **Methods:** 3 Angioflex® valves were cyclically loaded on a Vivitro Hi-Cycle accelerated valve tester within a calcification solution containing 3.87 mM CaCl2, 2.32 mM K2HPO4, and 0.05 M Tris Buffer. The test was running at 1000 cycles/min for 52.7 M-cycles with weekly solution changes. Leaflets of each valve underwent SEM (Scanning Electron Microscopy), EDX (Energy Dispersive X-ray) spectroscopy and ICP (Inductively Coupled Plasma) spectrometry techniques. **Summary of Results:** SEM/EDX analysis demonstrated that all valves were calcified on the leaflet surface. The amount of calcium deposits measured by ICP was quantified as a mean value of 87±10 mg/g dry weight. Compared to M.Deiwick et al.'s in vitro calcium results for tissue valves (205±64.87 mg/g dry weight), the Angioflex® polyurethane heart valves contain less calcium (p-value=0.036). The lower amounts appear to be the result of decreased subsurface calcification. These results suggest that polyurethane valves have the potential to offer increased durability compared to tissue valves. **Reference:** Deiwick M, et al.Thorac. Surg 2001 Apr; 49(2):78–83.

NON-INVASIVE BLOOD PRESSURE ASSESSMENT BY THE NEXFIN MONITOR DURING REDUCED ARTERIAL PULSATILITY

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Non-invasive blood pressure assessment is difficult when arterial pulsations are reduced, as during continuous-flow circulatory support. Therefore, we evaluated the performance of the Nexfin monitor to assess non-invasive blood pressure during conditions of reduced arterial pulsatility in fifteen patients. The Nexfin Monitor provides non-invasive continuous arterial blood pressure based on the measurement of finger arterial pressure with a finger cuff. During cardiac surgery, non-invasive reconstructed brachial artery pressure (NAP) measured by the Nexfin Monitor were recorded additional to invasively measured radial artery pressure (IAP). A roller-pump-based heart-lung machine created small periodic oscillations in arterial blood pressure during the cardiopulmonary Bypass (CPB) phase. Thirty minutes data in the CPB phase were selected. NAP-IAP absolute pressure differences were analyzed to compare invasive and non-invasive measurements. Mean (SD) for IAP were 57.2 (5.47) mmHg while the mean (SD) amplitude of pressure oscillations induced by the roller-pump were 6.7 (3.5) mmHg. NAP-IAP differences were -1.31 (6.4). A student-T test showed no statistical difference between NAP and IAP ($P<0.05$). The Nexfin HD monitor was able to measure arterial blood pressure similar to invasive radial pressure under conditions of reduced arterial pulsatility. This monitor can be applied as a non-invasive alternative for the assessment of arterial blood pressure of patients on continuous-flow circulatory support.

COMPARATIVE ANALYSIS OF VON WILLEBRAND FACTOR PROFILES IN PULSATILE AND NONPULSATILE LVAD RECIPIENTS

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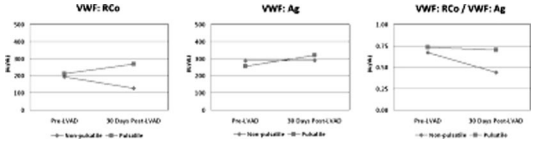
The study compares von Willebrand factor (VWF) profiles in nonpulsatile and pulsatile LVAD recipients to explore mechanisms for the development of post-implant non-surgical bleeding. A higher rate of non-surgical bleeding has been observed in nonpulsatile LVAD recipients (1). The axial flow non-pulsatile LVAD mechanism may induce VWF deformation and cleavage creating a deficiency of high molecular weight (HMW) VWF multimers. These multimers are essential for maintaining hemostasis in high shear stress areas. HMW deficiency should result in low RCo: VWF Ag ratios reflecting abnormal platelet binding activity. VWF profiles were measured pre and post LVAD placement from 11 non-pulsatile (HeartMate II) and 3 pulsatile (HeartMate XVE) LVAD recipients (Figure 1) (Figure 2).

Laboratory parameters	Normal Values	Non-pulsatile (n=11)				Pulsatile (n=3)			
		Pre-LVAD		30 Days Post-LVAD		Pre-LVAD		30 Days Post-LVAD	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD
Factor VIII (%)		179.59	42.32	161.56	46.37	156.40	40.09	139.87	4.14
VWF:Ag (IU/dL)		286.56	171.60	267.60	158.71	255.90	167.96	318.37	154.01
VWF:RCo (IU/dL)		193.95	136.48	127.02	84.55	212.43	215.78	268.81	286.45
VWF:RCo/VWF:Ag	>0.65	0.67	0.28	0.44	0.09	0.73	0.35	0.70	0.44



All nonpulsatile LVAD recipients demonstrated low RCo/VWF:Ag by 30 days after device implantation. These data suggest nonpulsatile recipients develop imparied VWF platelet binding abiliy that may contribute to their observed increase in non-surgical bleeding. Further investigation is ongoing to identify specific causes of VWF impairment in this population such as HMW VWF multimer deficiency. 1. Crow S et al. JTCVS 2009.

VALIDATION OF DESTINATION THERAPY RISK SCORE IN RECIPIENTS OF LEFT-VENTRICULAR ASSIST DEVICES (LVAD)

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Purpose: Destination Therapy Risk Score (DTRS) allows to prospectively estimate the operative risk of LVAD implantation in pts referred for destination therapy (DT). We sought to investigate whether the DTRS correlates with outcomes of LVAD recipients at our center, including bridge to transplantation (BTT). **Methods and Materials:** Between 1/2003 and 9/2008, 183 pts underwent primary LVAD implantation. The DTRS correlated with 90-days in-hospital mortality. Results were compared with the DTRS derivation cohort of 280 pts who underwent HeartMate I implantation as DT between 11/2003 and 6/2005 in the U.S. **Results:** Of the 183 LVAD recipients, 44 died. DTRS correlated significantly with 90-days in-hospital mortality ($p<.001$) and 6-months survival ($p<.001$) (Table 1).

Table 1.

Operative Risk	DTRS	N	% Probability 90-Days In-Hospital Death	% Probability 6-Months Survival
Low	≤8	59	3.1	94
Medium	9–16	84	24.9	71.9
High	>16	40	47.6	51.3

DTRS was an independent predictor of 90-days in-hospital mortality ($p<.001$), whereas the type of device and indication showed no significant correlation. **Conclusions:** DTRS is a helpful tool in candidate selection for LVAD. The DTRS appeared to correlate with the operative risk, irrespective of the indication or type of implanted LVAD.

A NOVEL PERCUTANEOUS POLYMERIC TRILEAFLET HEART VALVE PROSTHESIS

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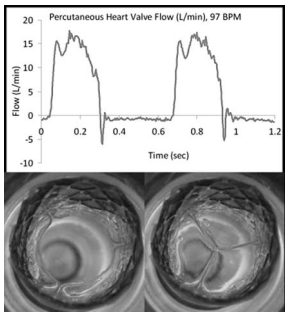
Purpose: The requirements for a percutaneous valve include adequate hemodynamic performance, ease of delivery and fixation, as well as avoidance of migration, obstruction of coronary ostia, and paravalvular leakage. A novel method for attaching flexible polymeric leaflets to a collapsible stent was developed. The purpose of this study is to characterize the performance of the polymeric valve. **Methods:** A prototype valve was developed using flexible Angioflex® (proprietary polyetherurethane) leaflets, a collapsible 23 mm nitinol stent and ABIOMED's solvent-casting process. The prototype valve was crimped to fit in a 24-French delivery device. Valves were evaluated *in vitro* for hydrodynamic performance. **Results:** A pressure drop of 11 mmHg at 10 L/min steady flow was measured. Backflow leakage was acceptable (5.4 mL/sec with 85 mmHg backpressure). Pulsatile flow testing showed complete leaflet opening and closure, with closing volume losses of only 1.2 mL. **Conclusions:** The polymeric valve meets the hemoodynamic requirements for a replacement valve. Feasibility of mounting polyurethane leaflets to a collapsible metal stent is shown. Further development is required to address the remaining requirements common to other percutaneous valves (Figure 1).



IMPROVED QUALITY OF LIFE WITH CONTINUOUS FLOW LEFT VENTRICULAR ASSIST DEVICES IN A DESTINATION THERAPY POPULATION

Laura A Coyle,[1] Colleen T Gallagher,[1] Mark S Slaughter,[2] Micheal Sobieski,[1] Geetha Bhat,[1] Antone Tatooles.[1] *[1]Center for Heart Transplant and Assist Devices, Advocate Christ Medical Center, Oaklawn, IL; [2]Cardiovascular Surgery, University of Louisville, KY.*

Purpose: Improved survival and quality of life (QOL) remain imperative to the overall success of destination therapy (DT). Our goal was to evaluate the impact of left ventricular assist devices (LVADs) on QOL. **Methods:** Data was collected prospectively on patients (n=23) supported >365 days with a Heartmate II LVAD for DT since 03/2005. Pre-implant NYHA classification, 6 minute walk and Minnesota Heart Failure questionnaires (MLHF) including physical and emotional dimension scores were compared at 90,180 and 365 days post-implant. **Results:** Average age of patients was 60 yrs (28–78) with 804 days (367–1318) on device support. Patients were discharged postoperatively after an average of 18 days (10–38). One patient was explanted after 702 days, 3 died after average of 768 days and 19 remain on device support. There was a statistically significant improvement ($p<0.05$) in NYHA classification, 6 minute walk test, and MLHF survey scores including the physical and emotional domains at 90, 180 and 365 days (Table 1).

Table 1. QOL Data

n = 23	Baseline	90 Day	180 Day	365 Day
NYHA	3.7	1.4*	1.2*	1.2*
6 min Walk	122.7	414.3*	487.4*	478.4*
MLHF Total	76.5	32*	26.4*	28.2*
MLHF Physical	34.7	13.4*	11.3*	10.6*
MLHF Emotional	15.0	5.9*	5.2*	6.1*

* $p < 0.0001$.

Conclusions: Patients with a HM II LVAD have significant improvement in quality of life after implantation which is sustained out to one year. Our analysis supports DT as a viable treatment option and urges additional studies to evaluate QOL in this population.

IN ANIMAL TEST OF AN ADULT AXIAL BLOOD PUMP AT FU WAI HOSPITAL

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Different ventricular assist devices (VADs) had been developed for clinic use in recent years. A multidisciplinary research team in FuWai hospiatal of Peking Union Medical College has designed and developed a novel axial flow left VAD which called FW axial blood pump for adults. This VAD, which was developed after numerous times of CFD analysis for the flow characteristics of the pump, is 58.5-mm long, 30-mm wide (including DC motor), and weighs 240 g. The pump can deliver 5 L/min for pressures of 100 mm Hg over 8000 rpm. The hemolysis, which was evaluated in vivo test, was a bit higher than normal value (free hemoglobin value was around 30mg/dL). Evaluation of serum biochemical data showed that implantation of the FW blood pump in sheep with normal hearts did not impair end organ function. Performance of the pump in vitro and in vivo was considered sufficient for a left ventricular assist device, although further design improvement is necessary in terms of hemolysis and antithrombosis to improve biocompatibility of the pump.

PULSATILITY INDEX AS A MEASURE FOR VENTRICULAR CONTRACTILITY IN LEFT VENTRICULAR ASSIST DEVICE PATIENTS

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Purpose: To non-invasively assess the contractile function of the native heart using the pulsatility index (PI), which, as defined by Thoratec, is the ratio between peak to peak values of left ventricular assist device (LVAD) flow and mean LVAD flow. **Hypothesis:** PI is directly proportional to contractility and less dependent on other heart features. **Methods:** The HeartMate II LVAD was mounted in a heart model controlled mock circulation. The heart model features the contractile behavior of the muscle fibers as a function of time, length, contraction velocity and contractility, i.e. the maximum stress the fiber can generate. Other model parameters are ventricular wall- and cavity volume. In the mock loop, LVAD and aortic valve flow rate, together with left-ventricular and aortic pressures, were measured. Contractility, left ventricular cavity- and wall volume were varied and PI determined. The latter was based on mock loop flow measurements. The results were compared with PI as measured during speed-change echo procedures on 6 patients. **Results:** PI decreases with a decrease in contractility in the heart model. With increasing LVAD speed PI also drops. These results concur with patient data obtained during speed change echo procedures. LV volume changes have less influence. **Discussion and Conclusion:** PI and contractility in the heart model are closely correlated, which is also reflected in the patient data. PI can be a parameter for contractility assessment in patients with axial flow mechanical circulatory support.

INTRA-OPERATIVE EXTRACORPOREAL CIRCULATORY SUPPORT TECHNIQUES IN LUNG TRANSPLANTATION SURGERY: COMPARISON OF STANDARD CARDIOPULMONARY BYPASS WITH ECMO

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Objective: Extracorporeal circulatory support such as cardiopulmonary bypass (CPB) is required in some lung transplantation (LTX) operations requiring full heparinization increasing the risks of bleeding/complications. We report of replacing CPB with heparin-bound low dose heparin ECMO. **Methods:** 44 patients (53±10.3 years of age underwent LTX (65% single) for IPF (42.5 %), COPD (45%), CF (5%) and PPH (7.5 %). 60 % of all patients: mean PAP > 45 mm Hg (systolic PAP 83±24.5 mm Hg). In 45% of the LTX operations ECS was required for intolerance of single lung ventilation and instability (9 CPB, 9 ECMO). CPB and ECMO connections through femoral venoarterial canulation and all patients had limited access muscle-sparing thoracotomies without sternum-transection (limited thoracotomy). **Results:** Units (U) of blood transfusion during the operation/72 hours were 14.2±5.1 (ECMO) vs. 3.3±2.2 U on CBP (p=0.001) vs. 1.3±1.4 U without ECS. The increased 90-day mortality rate of the ECMO patients (p=0.056) was related to infectious complications (3 vs. 1). One-year survival was reduced in ECMO (p=0.004, log-rank test). **Conclusions:** The advantages of femoral canulation rather than conventional central connections in LTX led to an undisturbed operative field. Significantly more blood transfusions were required in ECMO patients, which could contribute to increased infection/mortality rates. CPB remains the standard of support technique if extracorporeal circulation is required for LTX surgery.

LONG-TERM EFFECT OF CONTINUOUS FLOW LEFT VENTRICULAR ASSIST DEVICES ON RENAL FUNCTION

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Purpose: Evaluate the effect of continuous flow (CF) left ventricular assist devices (LVADs) on renal function in a destination therapy (DT) population. **Methods:** All patients (n=23) supported <65 days with a CF LVAD for DT were retrospectively analyzed. Renal function was assessed by calculated glomerular filtration rates (GFR) using the Modification of Diet in Renal Disease (MDRD) and the Cockcroft-Gault (C-G) derived creatinine clearance at baseline, 30, 90, 180, 365 and 730 days for those eligible. Blood pressure (MAP), LVAD settings, and medical therapy were also evaluated. **Results:** Average age of patients 60 yrs (28–78), EF% 17 (5–25), and peak VO^2 of 8.8 (6.4–11.6). Pump flow and medical regimen did not differ among patients. There was a statistically significant improvement (p<0.05) in mean MDRD derived GFR (p=0.008) and the C-G calculated CrCl (p=0.046) 30 days post implant. Patients maintained improved renal function with an increased mean MDRD GFR and C-G calculated CrCl at 90, 180 and 365 days (p=NS). Patients supported >730 days demonstrated a trend toward maintenance of improved renal function (Table 1).

Table 1. Renal Function with CF LVAD

n = 23	Baseline	30 Day	90 Day	180 Day	365 Day
Creatinine (mg/dl)	1.6	1.3*	1.3*	1.4	1.4
MDRD (ml/min/1.73^2)	56.3	66.9*	62.3	59.4	58
C-G (ml/min)	60.5	69.9*	65.6	65.2	65
MAP (mmHg)	74.9	93.1*	91.1*	91.7*	91.1*
LVAD flow		5.2	5.3	5.4	5.3

*p ≤ 0.05.

Conclusion: Patients with CF LVADs for DT achieve significant improvement in renal function and MAP 30 days post implant and maintain improvement out past one year.

CONTROL OF A MAGNETICALLY LEVITATED BLOOD PUMP

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A magnetically levitated axial-flow blood pump is a promising option as an implantable ventricular assist device. Magnetic suspension has several advantages over traditional bearings including eliminating the need for lubrication, reduction of cell damage, and increase of the device's durability. This research deals with the development, simulation and testing of the control system of one such device, which actively centers the rotor within the pump housing. In this application, the gap between magnetic components in the rotor and housing is large enough to allow blood flow, thus reducing actuator effectiveness. In addition, Hall Effect sensors are used to measure shaft position because they offer a non-invasive measurement through the blood and the different housing components. These sensors are susceptible to electromagnetic interference as well as variations in magnetic field (magnetic runout). These system characteristics make magnetic suspension a difficult control problem especially at high rotational speeds. A Proportional Integral Derivative, PID, control scheme was shown to be sufficient to achieve levitation while stationary and rotating at low speeds. However, additional filtering methods, including a Kalman estimator and notch filtering, were added to make the system robust at higher rotational speeds. In addition to simulations, a prototype of the device was able to pump water at 6 L/min and 80 mmHg (6000 RPM). The investigation includes the application of performance optimization methods, such as the Linear Quadratic Regulator, to lower power consumption and increase robustness to disturbances.

"END-USER" INFLUENCE ON DEVELOPMENT OF A LVAD SYSTEM

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The HeartWare® Ventricular Assist System was developed using "end-user" research with clinicians, and hazard and risk analyses. The development process led to the final design of system components. These include the pump driveline, redundant pump motor design and motor commutation software, water-resistant patient peripherals, 2 line LCD display for the controller, alarm prioritization handling, and power source switching. The features and test analyses of the pump driveline, dual motor construction and water resistant components are highlighted. HeartWare designed its driveline with conductors used in pacemakers. Flex testing was performed to the implantable medical device standard of 47,000 cycles. Dual motor construction was designed to mitigate pump stoppage due to motor, pump connector or motor drive circuitry failure. Pump operation on a single motor was subjected to in-vitro testing. Finally, the controller and battery were designed for water resistance. The level of water resistance was determined during UL safety testing. Driveline flex testing achieved a 4x multiple of the target. Pump performance testing showed the pump could run on either motor. The controller and battery casings achieved IPX7 rating defined as protection against water immersion for 30 mins. at a depth of 1 meter. HeartWare's integration of "end user" research and hazard and risk analyses into its product development process has led to the development of the system features presented. Caution: Investigational device. Limited by United States law to investigational use.

HEMODYNAMIC COMPARATIVE STUDY OF CONTINUOUS AND PULSATILE LEFT VENTRICULAR ASSIST DEVICES AT A PEDIATRIC END-TO-SIDE ANASTOMOSIS

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Over 35,000 babies are born with heart defects annually in the US. Transplantation has been an option but limited donor organs are available. Pediatric ventricular assist devices (PVADs) are in development to bridge the gap. The motivation here is to compare hemodynamic parameters during pulsatile and continuous PVAD support. A physiologically relevant graft anastomotic model is used with a graft attached on the ascending aorta. The flow is simulated using a previously validated time-accurate Navier-Stokes flow solver. Transitional turbulence is modeled using an implicit large eddy simulation approach. These data are crucial to analyze the potential short-term and long-term risk of graft failure for patients with pulsatile and continuous PVADs. Continuous PVAD support largely reduces the pulsatility in the great vessels and the descending aorta. Pulsatile PVAD support increases the flow in the great vessels, with a maximum total increase of 12.77% from the healthy aorta to total support. In comparison, continuous support decreases the flow in the great vessels by 11.11% and 9.8% for partial and total support, respectively. Pulsatile mode provides higher time-averaged wall shear stress and oscillatory shear index distribution when compared to continuous mode during both intermediate and complete support. This study is the first complete comparison of important hemodynamic parameters between pulsatile and continuous PVAD support.

CONE BEARINGS ENABLE SUB-MINIATURE PERMANENT BLOOD PUMPS

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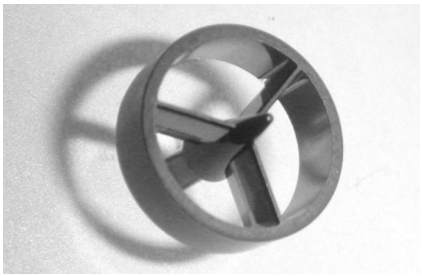
Tiny permanent blood pumps must operate entirely free of thrombus with low level anticoagulation. Every bearing supporting a pump rotor on a stationary hub has a circumferential crevice between the rotating and stationary parts. A ring of thrombus forms in this crevice and is anchored around the bearing. High flow washing can minimize thrombus, but the risk of occlusion or thrombo-embolism remains in the Jarvik 2000, HeartMate II, MicroMed, Circulite, and others. The cone bearing structure eliminates any circumferential crevice and has remained free of thrombus for months in animals. The smallest pump tested to date is 9.5 mm diameter, 4.2 cm long, 3cc, and weighs only 10 grams. Yet it can pump 3–4 L/min and produce 300 mmHg (Figure 1).



Cone bearings use a rotor shaft tapered at each end. The tapered shaft tips use hard ceramic and mate perfectly with the tips of three streamlined ceramic support posts. Thus the rotor can rotate freely but all other degrees of motion are prohibited. The fit between the posts and conical shaft is controlled to 10 millionths of an inch, far smaller than a red cell. The posts act as wipers to prevent thrombus from adhering to the shaft. These bearings are successfully used in the Jarvik 2000 pediatric pumps and are under development as an improvement in the adult Jarvik 2000.

A NEW METHOD FOR FIXATION AND STABILIZATION OF A CLINICAL VENTRICULAR ASSIST DEVICE PERCUTANEOUS LEAD

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The stabilization of a ventricular assist device (VAD) percutaneous lead is key to maintaining the tissue integrity of the skin exit site and minimizing the possibility of exit site infection. Abdominal binders have been used as a fixation technique to provide percutaneous lead stabilization. Although successful in their application, abdominal binders can be very uncomfortable for patients, particularly in warmer, humid climates. We present an effective alternative fixation technique for VAD percutaneous leads designed for ease of application and patient comfort. The percutaneous lead mount is made from a piece of sticky-back Velcro® pile 2″×4″ with off-set pairs of slits at each end to pass a piece of ½″ wide, two-sided Velcro® strap material 2″ long. The Velcro® is stuck to a piece of 2″×4″ DuoDERM Signal (Convatec, Princeton, NJ) wound dressing material and the corners rounded for patient comfort. The adhesive side of the DuoDERM is stuck to the patient's side (or dressing adjacent to the exit site) a few inches above and lateral to the percutaneous lead exit site. The percutaneous lead is then fastened down by the two Velcro® straps. Eight patients supported for 1 to 8 months report reduced skin rash and greater comfort and quality of life with this new percutaneous lead mounting device than with the abdominal binder and that it may last up to four weeks before needing to be replaced. Long-term follow-up will confirm efficacy of stabilization and reduction of exit site infection.

IN VIVO EVALUATION OF A DISPOSABLE Mag-Lev CENTRIFUGAL BLOOD PUMP: MedTech DISPO

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Background: MedTech Dispo (23ml priming volume) is a newly developed disposable mag-lev centrifugal blood pump intended for one month extracorporeal circulatory support. Non-contact suspension and rotation of the impeller is realized by a two-degree-of-freedom active and passive magnetic bearing in combination with an inner radial magnetic coupling. The purpose of this study is to evaluate electro-mechanical and physiological reliability of the MedTech Dispo through the initial two-week in vivo experiments. **Materials and Methods:** The MedTech Dispo was implanted in seven calves (mean BW 73 kg) in a left atrium-descending aorta bypass configuration. Hemodynamics and pump performance were continuously monitored and blood samples were obtained daily to assess in vivo system performance, major organ function and plasma free hemoglobin levels (pfHb). Autopsy was performed electively to inspect for thrombus formation with gross examination of major organs. **Results:** During two-week operation, pump performance was stable with a mean flow of 4.81 ± 0.25 L/min at mean speed of 2105.6 ± 50.9 rpm and the mag-lev system revealed stable rotor position control under normal activity of calves. The pfHb remained below 4mg/dL and no thrombus was found in any of the pumps explanted. **Conclusion:** The MedTech Dispo demonstrated reliable electro-mechanical and physiological performances through two-week in vivo study.

INITIAL CLINICAL EXPERIENCE WITH THE LEVITRONIX PediVAS SYSTEM

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Purpose: Over 3,500 cardiopulmonary support patients have been treated with CentriMag devices, including 150 pediatric patients. A new pediatric version of this device, designed for 30 days VAD or ECMO use, has been developed. Described is this unique technology, preclinical validation, and the worldwide clinical pediatric experience with the CentriMag and PediVAS systems. **Methods:** PediVAS is a polycarbonate centrifugal pump without bearings or seals, one moving part, a magnetically levitated impeller, 14 ml priming volume, flows from 0.5 2.4 lpm, and compatible with CentriMag hardware. PediVAS was studied in 20 juvenile ovine animals with flow from 0.5 to 2.4 lpm. Upon successful completion of validation studies and CE Mark approval the device was commercially released. **Results:** Successful studies were completed demonstrating safe operation, reliable hemodynamic performance, and excellent biocompatibility of the PediVAS for 30 days of animal support. The combined worldwide pediatric experience with the CentriMag and PediVAS pumps includes over 150 patients. The majority of patients were treated with ECMO support for cardiac and pulmonary indications. **Conclusions:** With safety, performance and reliability features similar to the CentriMag, the PediVAS is optimized for pediatric support. Preclinical validation testing and initial clinical use of the PediVAS has been successful. A clinical trial is being initiated to evaluate 30 day use of the PediVAS as a VAD. **Supported in part by NIH Grants R44 HL071376 & R44 HL074628**

A COMPUTATIONAL ANALYSIS OF O_2 AND CO_2 TRANSFER IN A SEGMENT OF A HOLLOW FIBER BUNDLE IN AN OXYGENATOR

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We tried to estimate the gas transfer behaviors in a hollow fiber bundle of an oxygenator by means of a developed computational analysis method and compared its results with actually measured gas transfer performance. The rectangular bundle consists of parallel and staggered arranged hollow fibers. Blood flows perpendicular to the hollow fibers. Lengths of a segment model are 30 mm in the blood flow direction (full length of the bundle: 138 fibers) and 4 mm in the gas flow direction (sufficient length for comparing with actual data). The computational analysis method deals mass transfer and fluid dynamics including blood-gas reaction. Conditions of inflow blood were set at the AAMI values in both computational analysis and in-vitro experiment (PO_2: 37 mmHg, PCO_2: 45 mmHg and Hb: 12 g/dL). PO_2 and PCO_2 of ventilated gas were set at 713 mmHg and 0 mmHg. The computational analysis demonstrated 71.4, 163.6, and 221.9 mL/min O_2 transfer rates and 101.4, 247.9, and 342.9 mL/min CO_2 transfer rates at 1, 3, 5 L/min blood and gas flows, respectively. In the in-vitro experiment, O_2 transfer rates were 55.4, 153.1, and 229.4 mL/min and CO_2 transfer rates were 99.5, 117.5, and 151.9 mL/min at 1, 3 L/min blood and gas flows, respectively. We conclude that our computational analysis method is basically available for estimating gas transfer performance in an oxygenator.

ULTIMATE TEST BENCH FOR PEDIATRIC BIVENTRICULAR ASSIST DEVICE BASED ON ARTIFICIAL MUSCLES

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Introduction: We developed a Test Bench to assess the performances of biventricular assist device made of smart materials (smart biVAD). Reproducing the physiological heart work, the smart biVAD exert a stronger pressure on the wall of the left ventricle than on the wall of the right ventricle. Up to now, there is no evaluating system enabling us to measure its performances without animal experimentation. **Method:** A heart model may be constructed by 3D scanning (NextEngine) and 3D printing (Fab@Home) of a child's heart to reproduce an identical 3D model in silicone. This model may be fitted with the smart biVAD. Two pipettes filled with water and attached to the silicone ventricles reproduced the preload and the after load of each ventricle. An ultrasonic sensor (Baumer) was placed on the top of each pipette allowing for the real time measuring of the fluid height variation, that varies according to the difference of exerted pressure by the smart biVAD. Then LabView software extrapolated the precise volume displaced and the pressure generated by each side of smart biVAD. **Results:** A developed standardized protocol permitted the validation of the Test Bench for in vitro evaluation of a smart biVAD using a modifiable physical variables such as power intensity and for reproducibility of data. **Conclusion:** A Test Bench was validated by a standardized protocol to certify a platform for measuring the performance of an artificial muscle biVAD based on shape memory alloys.

WAVE INTENSITY ANALYSIS OF INTRA- AND PARA-AORTIC COUNTER-PULSATILE CIRCULATION SUPPORT

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Counter-pulsatile circulation support has been clinically proven to be viable, however, why counter-pulsation, i.e. systolic unloading and diastolic coronary perfusion augmentation, can help the diseased myocardium recover has not been completely understood. The present research hypothesizes that it is the energy wave propagation which enables a long-range energy transport that improves the perfusion in the microvessels of the myocardium. Clinically counter-pulsation perfusion has been implemented using either intra-aortic balloon pump (IABP) or para-aortic blood pump (PABP). These counter-pulsatile devices differ in pumping and wave characteristics owing to whether or not the aortic lumen is occluded. A hybrid circulation model combining together a one-dimensional flow and a lumped-parameter model was developed. The one-dimensional flow is incorporated to simulate the nonlinear flow and wave propagation phenomenon occurring in the aorta. It was found that different wavelet energy budgets were contained in the augmented aortic flows associated respectively with IABP and PABP assistance. Wave intensity analysis shows that PABP provides more effective systolic unloading and diastolic augmentation than does IABP. Moreover, the non-occlusive characteristics of PABP support generate much intensified downstream traveling wavelets, implying a better remedial effect provided for end organ recovery. Porcine experiments were also performed and the in-vivo results agree in principle with the analytic findings.

EXTRACORPOREAL MEMBRANE OXYGENATION (ECMO) FOR RESPIRATORY FAILURE: COMPARISON OF VENOVENOUS VERSUS VENOARTERIAL BYPASS

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Purpose: We compared respiratory status before and during ECMO in patients receiving venovenous (VV) and (venoarterial) VA ECMO to evaluate the choice of ECMO in patients with respiratory failure. **Method:** Between January 2003 and December 2007, 16 patients with respiratory failure required ECMO in our ICU. VV bypass and VA bypass were used in 9 cases (VV group) and 7 cases (VA group), respectively. Respiratory status before and during ECMO was compared between the two groups. **Results:** The percentage of patients requiring renal replacement therapy prior to ECMO use was significantly higher in the VA group than in the VV group. There were no significant differences between the two groups in PaO_2/FIO_2, $AaDO_2$, pulmonary compliance, and lung injury score prior to ECMO use. Those parameters were gradually improved in both groups, however, no significant inter-group differences were seen for up to 96hrs after ECMO introduction. There was also no significant difference between the two groups in ECMO removal rate (VV group: 56%, VA group: 43%). **Conclusion:** Our results suggest that VV ECMO is relatively comparable to VA ECMO and has the possibility to maintain sufficient respiratory support when VV ECMO is introduced to respiratory failure patients lacking evidence of renal and/or heart failure.

CONTINUOUS FLOW TOTAL ARTIFICIAL HEART PHYSIOLOGIC RESPONSE TO EXERCISE IN CALVES

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A continuous flow total artificial heart (CF-TAH) is under development that is smaller and simpler than previous TAHs. Hemodynamic and metabolic response to exercise in 3 calves implanted with the CFTAH were characterized. Aortic, pulmonary artery, left and right atrial pressures were measured via indwelling catheters; pulmonary and systemic CFTAH output were measured by transit time Doppler. Arterial and mixed venous blood gasses were obtained at rest and during exercise. Calves, 2 to 4 weeks after CFTAH implantation, were made to ambulate on a motorized treadmill at speeds varying from 0.8 to 1.6 mph for up to 40 minutes without undo fatigue or evidence of hemodynamic or respiratory compromise. The balance between systemic and pulmonary flow was maintained at peak exercise and increased autonomously from 12 L/min at rest to 13.7 L/min with exertion. Oxygen consumption (VO_2), oxygen delivery (DO_2), and oxygen extraction (EO_2) were calculated at rest and with exercise and demonstrated a physiologic increase proportional to the level of exertion. Blood lactate levels remained normal. These findings suggest that lack of pulsatile perfusion does not adversely affect the calf's ability to exercise and supports the further development of a CFTAH. The finding that systemic and pulmonary flow remained balanced and increased autonomously with exercise in response to increased venous return and filling pressures suggests that a device of this sort may be more responsive to changing physiologic demands than prior TAH designs.

CARDIAC CONTRACTILITY OF THE ASSISTED HEART CAN BE DETERMINED FROM PUMP SIGNALS ONLY

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Purpose: In rotary blood pump patients, the knowledge of cardiac contractility is important for recovery and cardiac protection. Determination of real contractility independent of preload and afterload is difficult. A method for determination of contractility from pump parameters without additional diagnostic requirements was developed. **Methods:** The developed new index (I_Q) is defined as the slope of a linear regression between the maximum derivative of the pump flow and its peak-to-peak value, at small changes of pump speed. I_Q was compared with two classic contractility indices (based on ventricular pressure and volume). All indices were investigated first in-silico with variations of contractility, preload, afterload and pump speed. Second they were evaluated in 7 acute sheep experiments using a MicroMed-DeBakey® VAD, with pharmacological variation of contractility. **Results:** The regression of I_Q was confirmed to be linear in both computer model and animal experiment. All indices were sensitive to contractility changes, with I_Q being even more robust against changes in preload and afterload than the classic indices. **Conclusion:** The new index allows sensitive and robust determination of cardiac contractility from pump parameters only, allowing a simple and continuously applicable estimation of cardiac performance.

PERIOPERATIVE RISK FACTORS PREDICTIVE OF RIGHT VENTRICULAR FAILURE — POST-LEFT VENTRICULAR ASSIST DEVICE IMPLANTATION

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Purpose: To determine perioperative risk factors for development of right ventricular failure (RVF) in pts undergoing LVAD implant in order to improve survival via objective pt selection. **Methods:** Data was obtained for 175 pts who received an LVAD from 1993–2008 (BTT 58%, DT 42%). RVF was defined by the need for nitric oxide ≥48 hrs, inotropic agents >14 days, and/or RVAD implant. Clinical, hemodynamic, and echocardiographic variables (n=76) were evaluated for association with RVF. Survival was analyzed at 30, 180, and 365 days post-implant by Kaplan-Meier analysis. **Results:** RVF post LVAD occurred in 44% of pts (n=77). Survival rates for pts with RVF were 80%, 67%, and 55%, respectively. In comparison, survival rates for pts without RVF were 96%, 88%, and 77%. By multivariate logistic regression, 3 pre-operative factors were significantly associated with RVF (see Table 1). **Conclusion:** DT, elevated PVR (>6 WU), and the need for preoperative IABP counterpulsation were the most significant predictors of RVF. More advanced heart failure patients portend a worse outcome. These findings may lead to improved patient selection for LVADs (Table 1).

Table 1. Multivariate Predictors of RV Failure

Variable	Odds Ratio	P Value
Destination therapy (DT)*	3.18	0.004
Inotrope	2.05	0.131
Obesity	1.71	0.151
IABP*	3.41	0.002
PVR*	1.31	0.01
ACE/ARB	0.49	0.054
β-Blocker	1.60	0.258

$P<0.05$ is considered statistically significant.

FLOW DISTRIBUTION DURING CPB IN DEPENDENCY ON THE OUTFLOW CANNULA POSITIONING

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Purpose: Device cannulation to the cardiovascular system is an important consideration for cardiopulmonary bypass (CPB). The position of the outflow cannula influences the blood flow in the outgoing arteries. In particular, cerebral perfusion may be insufficient. Traditionally, the cannula returns blood to the ascending aorta. Some surgeons however prefer cannula positioning in the subclavian artery. To gain insight into the flow within the aorta and greater vessels, a CFD analysis of blood flow was undertaken, dependent on cannula position. **Methods:** Aorta and outgoing vessels were reconstructed from CT/MRI data. A CFD study of 65 different cannula positions inside the aorta and subclavian artery was performed, using a non-Newtonian blood model. A three-dimensional Particle Image Velocimetry validation was undertaken, using a fully transparent silicone model, based on the same CT/MRI records. **Summary:** Cannulation of the aorta is sensitive to cannula location and angle. In some cases, a negative blood flow in the right carotid artery was observed. Cannulation of the subclavian artery however showed good blood flow to all distal vessels, if the cannula tip is sufficiently far away from the vertebral artery. Otherwise, a negative flow in the vertebral artery occurred. The negative blood flow in the carotid or vertebral artery may be responsible for the reduction in cerebral perfusion seen clinically. New applications and novel cannulae can be analyzed with this method.

THE IMPACT OF DIFFERENT INLET CONFIGURATIONS FOR THE BOCAD LVAD SYSTEM

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Purpose: BOCAD is an implantable LVAD that includes a magnetically driven and hydro-dynamically suspended centrifugal impeller, capable of providing full circulatory support. The pump features a double volute to decrease rotor radial force and a dual axial motor to balance magnetic axial force. In this study, a single vs. double inlet configuration was evaluated using CFD to determine the influence on hydraulic axial force. **Methods:** The pump geometry was modelled using a combined structured/unstructured mesh. Identical working points of 100 mmHg and 5 L/min at 2500 rpm were simulated for both inlet configurations. Characteristic performance curves were initially validated using experimental results. Rotor axial and radial hydraulic forces, as well as flow fields near the blades and in the hydrodynamic bearing, were each compared to determine the influence of inlet configuration. **Summary:** Pump characteristic performance and radial hydraulic force were not influenced by the inlet design. However, flow fields and axial hydraulic force were affected, as demonstrated by calculated values of 1N for the single inlet and 0.01N for the double inlet. Inlet configuration had the greatest impact on rotor axial hydraulic force. A double inlet exhibited minimal axial force, while a single inlet created a small axial force imbalance. This may be overcome by balancing hydraulic with motor magnetic forces, thus maintaining a single inlet configuration to improve anatomical compatibility.

CONTEMPORARY EXPERIENCE WITH RVAD BRIDGE TO RECOVERY AFTER ISOLATED RIGHT VENTRICULAR INFARCTION AND SHOCK

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Purpose: To date there are no published clinical series reporting exclusively on patients who have undergone isolated RVAD support for right ventricular myocardial infarction (RVMI). We report here on our series of four patients over a 3-year span (2006–2008) who underwent salvage RVAD placement for RVMI. **Methods:** The records of all patients were retrospectively reviewed. **Results:** Four patients underwent salvage RVAD placement for RV shock. All patients had an occluded RCA as their culprit lesion. The RVAD was ultimately weaned in all four patients, but 1 died shortly after explantation. Follow-up echocardiogram revealed moderate RV dysfunction in all 3 survivors. Further details for each patient are listed in Table 1.

Table 1. RVAD Patient Data

Patient	Age	Type of Surgery	Duration of Support	Outcome	Duration of Follow-Up	NYHA Class
A	62	RVAD/CABG	4 days	Explanted, alive, at home	3 years	2
B	71	RVAD/CABG/PFO closure	10 days	Explanted, hospital mortality	NA	NA
C	78	RVAD/CABG, off-pump	28 days	Explanted, alive, at home	8 months	3
D	62	RVAD/CABG, off-pump	21 days	Explanted, alive, at home	2 months	2

Conclusion: Patients with RVMI complicated by medically refractory cardiogenic shock can be successfully bridged to RV recovery with surgically implanted RVADs. Most patients return to a reasonable functional capacity despite persistent postoperative right ventricular dysfunction.

LONG-TERM (5.5 YEAR) SUPPORT WITH A JARVIK 2000 AXIAL FLOW PUMP

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Second-generation left ventricular assist devices (LVADs) can support patients longer than earlier pumps. We describe a patient supported by a Jarvik 2000 LVAD for more than 5 years. A 64-year-old man had ischemic CMP and NYHA class IV symptoms necessitating maximal inotropic support. He had an EF of <20%, PCWP of 20 mmHg, and CI of 1.9. He could not tolerate IABP because of frequent PAC and PVC. A Jarvik 2000 LVAD was implanted via a subcostal incision, and the outflow graft was anastomosed to the supraceliac aorta without CPB. The patient recovered uneventfully and was discharged home 32 days post-op. At 1 year, his follow-up vs pre implant laboratory values, respectively, were: creatinine, 0.9 vs 1.1 mg/dL; total bilirubin, 0.6 vs 1.7 mgdL; SGOT, 36 vs 32 U/L; and SGPT, 12 vs 42 U/L. He had no thrombotic complications, infection, or arrhythmias. He was rehospitalized for 4 days for a suspected TIA; test results were negative, and his symptoms were not LVAD related. He completed the Minnesota Living with Heart Failure Questionnaire (MLHFQ) every 2 months during the first year, then at every follow-up visit. His mean score was 29 (range, 1181; min. 0; max. 105). His most recent MLHFQ score was 17. He remains a transplant candidate and, for the past 3 years, refused an upgrade of his UNOS category. He made it through a recent hurricane by moving 2 hours north of town. He felt secure in knowing that he would have more than 72 hours of battery power. The Jarvik 2000 LVAD can support patients for more than 5 years while providing a good quality of life.

PROGRESS ON DESIGN AND DEVELOPMENT OF A BI-LEAFLET MITRAL BIOPROSTHETIC VALVE

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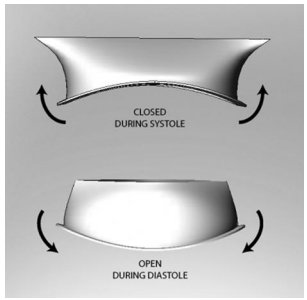
Background: This study aims to develop a bi-leaflet bioprosthetic heart valve (BHV) for mitral position whose annulus' saddle shape curvature changes dynamically according to the shape of the cardiac base, imitating the a natural mitral valve. Unlike the current BHVs, this valve yields to a flow field similar to natural transmitral flow while does not restrict the motion of the base in a cardiac cycle. **Methods:** The annulus is made of super-elastic Nitinol due to its nonlinear recoverable behavior. Accordingly, the chorda tendinae were replaced by Nitinol prongs that hold the leaflets from being prolapsed. The cusps are substituted with pericardial tissue with comparable mechanical properties to natural leaflets. The saddle-shape annulus is shaped by constraining the Nitinol while it was exposed to high temperature during heat-treatment process. A 3D model representing the valve is shown in Figure 1. **Results:** We developed the mitral prosthesis that consisted of a saddle-shape annulus that deflects due to the pressure change facilitating the unidirectional flow. This deflection results in a geometrical transformation allowing the valve to open and close effectively. The curvature of the annulus base and the angle of the supporting prongs are currently being adjusted to attain desired hydrodynamics.



IMPLANTABLE CARDIAC DEVICES AND POTENTIAL COMMUNICATION INTERACTIONS

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Introduction: ICDs and LVADs have become an integral part of the treatment of congestive heart failure as more patients receive both devices. As these implantable devices depend on wireless technology for communication and power distribution, device-device interaction is possible. We encountered two cases of such interactions which prompted a study on ICD and LVAD interaction potential. **Methods:** Bench test data of major devices, literature review and technical information of the commonly used ICDS and LVADs were used for the study. **Results:** We found that device-device communication interference could occur at two levels: 1. "Hand Shake", telemetry link, where ICDs are identified by the programmer and vice versa. 2.Operating frequency at which the data transfer occurs both in wireless and non-wireless devices. When LVADs produce interfering frequencies that are near or equal to those frequencies, interaction sets in. Frequency interference at either level will blind the wand communication with the ICD and is inversely proportional to the inter-device distance (Table 1).

Table 1. Device Frequencies

ICD/LVAD Type/ Specification	Handshake (kHz)	Non-Wireless Device:Operating Frequency (kHz)	Wireless Device: Operating Frequency (mHz)	LBT Protocol	LVAD Frequency
Boston Scientific	50	50	914	No	
St. Jude Medical	8	8 (Old Generation) 64 (New Generation)	402–405	Yes	
Medtronic	175	175	402–405	Yes	
Biotronik	32	32	N/A	N/A	
LVAD/PWM					7.2 kHz
LVAD motor generated frequency					266 Hz@6,000–500 Hz@ 15,000 RPM

LBT = Listen before talk protocol, PWM = Pulse Width Modulation.

Discussion: With the growing number of LVADs implanted for destination therapy in heart failure patients, this knowledge is crucial.

DEVELOPMENT OF A POWER SUPPLY UNIT FOR A COMPACT WEARABLE PNEUMATIC-VAD DRIVE UNIT

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The purpose of this work is to develop a power supply unit for a compact wearable pneumatic drive unit for ventricular assist device. The performance of the newly developed lithium-ion secondary battery was examined in an overflow type circulation mock and an animal test. The weight of the battery is 392g. The output voltage and discharged capacity of the battery are DC14.8V and 4400mAh, respectively. The drive unit with the air hose of 2m using a Toyobo blood pump of 70mL stroke volume was powered. The beating rate was set at 80bpm and the mean bypass flow was maintained at 4.5 L/min in the circulation mock. The battery-1 and battery-2 demonstrated the battery operation time of 171minutes and 168minutes, respectively. The electric discharge for 5hours and 39minutes was possible at continuous use in the circulation mock. The beating rate was set at 80bpm and the mean bypass flows were maintained at 3.3 L/min in the animal test. The battery-1 and battery-2 demonstrated the battery operation time of 165minutes and 163minutes, respectively. The electric discharge for 5hours and 28minutes was possible at continuous use in the animal test. These results indicate that the newly developed battery has a potential to power the wearable drive unit for the Toyobo VAD pump.

A VALIDATED COMPUTATIONAL MODEL OF ENSION'S INTEGRATED pCAS

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Background: Ension, Inc. (Pittsburgh, PA) has developed a pediatric cardiopulmonary assist system (pCAS), which is comprised of a small centrifugal blood pump and integrated oxygenator. The computational fluid dynamics code FLUENT (ANSYS, Inc. Pittsburgh, PA) was previously used to model the flow field in individual components of the pCAS. Results were validated against in vitro measurements. The flow models yielded reliable predictions of pressure drop and flow, and user-defined functions leveraging mass transfer and hemolysis index correlations also yielded accurate predictions of oxygenation and red blood cell damage, respectively. **Objective:** The objective of this work was to extend the validated component-based solutions to a fully integrated computational model of the entire pCAS. Analyzing the combined geometry increases the level of accuracy because the effects of the manifold and oxygentor on the pump flow are no longer estimated. A more accurate inlet profile is also present at the oxygenator inlets. **Methods:** FLUENT v6.3 was used to create a "tip to tip" model of the pump-oxygenator. In vitro validation testing was subsequently performed at Ension, Inc. **Results:** The computational flow models and complimentary mass transfer and blood damage correlations yielded predictive results when compared with experimental data. **Conclusions:** The computational results offer unique insights to the relationships between design features and device performance characteristics. Furthermore, the validated models and functions are relatively flexible and easily adaptable to the design and optimization process of other blood-contacting devices.

PEDIATRIC JARVIK 2000 HEART EXPERIENCE UPDATE

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Previously, we described our initial experience with the child size Jarvik 2000 heart. During our initial trials, we faced some challenges. There was thrombus formation on the pump bearings leading to pump malfunction. Since then we have modified our pump with conical bearings in an attempt to eliminate thrombus formation. Here we describe our current experience with the modified pump. Four juvenile Dorsett hybrid sheep were implanted with the child size Jarvik 2000 for acute fit and chronic performance evaluation. Daily hemodynamic measurements of cardiac output and pump output at varying pump speeds were taken. In addition, plasma free hemoglobin, lactic acid dehydrogenase, and platelet activation from blood samples were determined at baseline, after implantation, and twice a week thereafter. Post mortem necropsies were performed to determine end organ damage. Mean survival was 53.8±8.9 days. There was no device malfunction over the course of the study for each animal. The mean cardiac output of the animals was 3.60 ±0.18 (L/min). The measured flow through the outflow graft at increasing speeds from 10,000 rpm to 14,000 rpm with an increment of 1,000 rpm were 1.31±0.52, 1.61±0.62, 1.93±0.62, 2.16±0.52, 2.32±0.38 (L/min). The baseline plasma free hemoglobin was 6.97±3.37 (mg/dL), with subsequent mean values being <12 mg/dL at post implantation and weekly post implantation measurements. Both lactic acid dehydrogenase and platelet activation showed an acute increase within the first week after implantation with subsequent return to baseline by 2 weeks after surgery.

TEMPORARY VENTRICULAR ASSIST DEVICES AS RESCUE FOR PRIMARY GRAFT FAILURE POST HEART TRANSPLANTATION

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Objective: Heart transplantation (HTx) registries indicate a trend toward improved survival over time, appearing mostly in the early post-Tx course. Primary graft failure (PGF) is the leading cause of death in the first 30 days after Tx. We examined our experience with the use of temporary VADs as rescue for PGF. **Methods:** Included were pts who required VAD support for PGF after HTx from Dec. 2002 to Apr. 2006. PGF was defined as the inability to be weaned from cardiopulmonary bypass despite appropriate high-dose inotropes, use of an IABP, or a non-functioning ventricle. VADs used for left, right, or biventricular support were the Centrimag (Levitronix, LLC) and the Bio-Medicus (Medtronic, Inc.). **Results:** Out of 56 transplanted pts, 6 met inclusion criteria. Average age was 47.5 yrs and 87% were male. Indication, type, duration of support and survival outcomes are detailed below (Figure 1).

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6
Age at Implant	62	33	52	73	13	52
Indication	Cardiac Arrest	Graft Failure	RH Failure	RH Failure	Graft Failure	RH Failure
Device	Centrimag BiVAD	Biomedicus BiVAD	Centrimag RVAD	Biomedicus RVAD	Centrimag BiVAD	Biomedicus BiVAD
Support Duration (days)	3	6	9	6	3	RVAD 10 LVAD 5
Implant to Discharge (days)	98	23	44	50	20	78
Survival to Discharge	yes	yes	yes	yes	yes	yes
Survival to Date (Days)	1325	2163	1257	2225	991	1843

Conclusion: Timely use of short-term VADs for PGF after HTx allows for recovery of graft function. This immediate benefit is extended as shown by the excellent long-term survivals. Increased use of VAD support PGF may explain in part the time-dependent improved survival post-HTx if our findings can be extrapolated to a broader experience.

INITAL EXPERIENCE WITH THE IMPELLA 2.5 DEVICE FOR TEMPORARY LEFT VENTRICULAR SUPPORT

AL Raymond, AG Kfoury, AJ McCormick, BY Rasmusson, GE Thomsen, DG Renlund, BB Reid, JR Revenaugh. *Utah Artificial Heart Program, Intermountain Medical Center, Murray, UT.*

Introduction: The Impella 2.5 (Abiomed, Inc.) is a relatively new, minimally invasive percutaneous LVAD. The small size and ability for rapid deployment in the cardiac cath lab represent significant advances in percutaneous VADs. We report our initial experience with the Impella 2.5 device in a heterogeneous group of patients. **Methods:** Records of patients implanted with the Impella 2.5 from August-December 2008 were reviewed. Data included demographics, indication and duration of VAD support, and various clinical outcomes. **Results:** Six patients were implanted with the Impella 2.5 during the study period. Mean age was 56 years and 67% were male. Cardiogenic shock (CS) was the result of acute MI in one patient and acutely decompensated heart failure in another patient with peripartum cardiomyopathy. PCI patients all received stents while undergoing support by the Impella 2.5 device. No serious complications were noted (Table 1).

Table 1.

	Impella 2.5
Mean age	56±26 years
Male	4
Female	2
Indication	
CS	2
Support during PCI	4
Mean support duration CS	3.5 days
Mean support duration PCI	1 hr, 36 min
Mean pump output	2.2 L/min
Mean time to pump start	27 min
Mean hospital length of stay	7.6 days
Survival to discharge	100%
30-day survival	83%

Conclusion: Initial results with the Impella 2.5 are encouraging and demonstrate that this device can be implanted in a timely fashion to provide safe and effective temporary circulatory support for a variety of cardiac applications. This favorable experience needs further validation on a broader scale.

EXCELLENT HEMOCOMPATIBILITY OF THE VENTRASSIST LVAD IS ASSOCIATED WITH A LOW HEMOLYTIC AND THROMBOEMBOLIC RISK

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Purpose: VentrAssist (VA) LVAD has a hydrodynamically suspended centrifugal pump designed to minimize flow stresses, thereby potentially decreasing blood cell damage. Despite the advantages, hemolytic and thromboembolic (TE) complications remain a concern. **Methods:** 32 patients received VA LVAD at a single center; 25 bridge to transplant; 7 destination therapy. The mean age was 57.5±14.1 years, and mean LVAD support was 215±121 days. 29 were male (90.6%) and 26 had an ischemic etiology (62.5%). Postoperatively all patients received warfarin and aspirin and monthly INR, PTT, hemoglobin, platelets, fibrinogen, d-dimer, and lactate dehydrogenase (LDH) were recorded. **Results:** Of 25 patients, 12 had a mean INR<2. 3 patients with significant gastrointestinal bleeding (9.4%) had warfarin discontinued without adverse effects. There was one pump thrombosis (3.1%) and 3 transient ischemic attacks (9.4%). Platelet count, hemoglobin, fibrinogen and LDH at 6 months after LVAD placement was not statistically significant compared to baseline (Table 1).

Table 1. Laboratory Values Over Time

	Baseline	Month 1	Month 6
INR	1.2 ± 0.1	2.3 ± 0.8	2.3 ± 0.5
PTT	35 ± 9.2	42 ± 5.9	40 ± 6.3
Hemoglobin	12.5 ± 1.8	10.8 ± 1.3	12.1 ± 2.3
Platelets	218 ± 96	353 ± 114	254 ± 75
Fibrinogen	346 ± 97	520 ± 119	385 ± 86
d-dimer	1.1 ± 1.2	4.7 ± 2.7	1.6 ± 0.7
LDH	589 ± 125	672 ± 154	670 ± 171

Conclusions: Preliminary single center analysis suggests that the VA LVAD is associated with a low risk of hemolysis and TE based on biochemical and clinical evidence. These properties favor the use of this device for longer-term support.

POST-TRANSPLANT PULMONARY HEMODYNAMICS REMAIN NORMAL AFTER SUPPORT WITH CONTINUOUS-FLOW LVAD

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Purpose: Continuous flow LVADs have been shown to decrease pulmonary pressures prior to transplantation, however it has yet to be determined if pulmonary hemodynamics continue to be normal after heart transplantation in these patients. **Methods:** 40 patients received HMII LVAD as a bridge-to-transplant (BTT) at a single center. Hemodynamics were evaluated with right heart catheterization at baseline, prior to transplantation, 1 month and 1 year post-transplant. **Results:** Demographic data of these patients were as follows: mean age 53.0±13.4 years, 67.5% male, and 55% ischemic etiology. Mean duration of support was 270±219 days. There was a significant decrease in mean pulmonary artery pressure (MPAP), pulmonary vascular resistance (PVR), and transpulmonary gradient (TPG) (all $p < 0.001$) at the time of pre-transplant evaluation from baseline. At 1 month post-transplant there was no significant change in MPAP, PVR, or TPG from pre-transplant ($p = 0.65, 0.68, 0.41$ respectively). Similarly MPAP, PVR, and TPG at 1 year post heart transplantation did not change from pre-transplant LVAD support values ($p = 0.08. 0.59, 0.60$ respectively) (Table 1).

Table 1. Pulmonary Hemodynamics Over Time

	Baseline	Pre-Transplant	1 mo Post Transplant	1 yr Post Transplant
MPAP (mmHg)	37 ± 8	22 ± 7	23 ± 6	20 ± 5
PVR (WU)	3.7 ± 1.8	2.1 ± 0.8	1.9 ± 1	1.9 ± 0.8
TPG (mmHg)	13 ± 5	9.4 ± 3	9.9 ± 4	9.4 ± 4

Conclusions: Continuous flow LVADs are efficacious in optimizing hemodynamics in BTT patients with favorable post-transplant hemodynamics at 1 year. Further studies in patients with severe PH are necessary to expand application of this therapy.

NON-INVASIVE BEAT-TO-BEAT EVALUATION OF CARDIAC OUTPUT DURING WEANING OFF-TEST IN PATIENTS AIMING BRIDGE TO RECOVERY FROM LVAS SUPPORT

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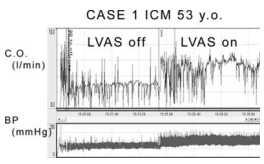
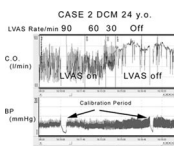
Background: Because of the extreme shortage of donor heart in Japan, the average waiting period on LVAS is over 3 years. Bridge to recovery (BTR) is essential. We investigated the usefulness of the non-invasive cardiac output (C.O.) measurement as an alternative to the invasive method as a tool during LVAS off-test. **Method:** Non invasive beat to beat measurement of C.O. and arterial blood pressure was performed using a finger photoplethysmographic device (Finapres, Ohmeda, Englewood, CO) in two patients with pulsatile LVAS (Toyobo). Case-1: ICM 53-year-old male. During the LVAS off period, C.O. measured using non invasive method was nicely correlated with the thermodilution method (2.0 to 3.0 L/min) and this improved right after the LVAS was on (Figure 1).



Case-2: DCM 24-year-old male. During the weaning of BPM of LVAS, C.O. fluctuated and decreased due to the conflict between the LVAS and the patient's heart. After the LVAS was off, significant improvement of blood pressure and C.O. was nicely shown (Figure 2).



Conclusion: The non-invasive method might be useful to determine the indication for BTR.

PERFORMANCE EVALUATION OF THE ENSION REV 7 PEDIATRIC CARDIOPULMONARY ASSIST SYSTEM

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The pump performance of the Ension Rev 7 pediatric cardiopulmonary assist system (pCAS) was evaluated on a mock circulation approximating the hemodynamics and key anatomic features of a small infant. The mock circulation was instrumented with ultrasonic flow probes and high fidelity pressure catheters. Clinically relevant inflow/outflow cannulae combinations (8–10, 10–12, and 12–14 Fr) were inserted into the right atrium and aortic arch and connected to the pCAS by 60 cm lengths of ¼" tubing. Performance was assessed by establishing a net zero flow through the pCAS and then incrementally increasing RPM. Pump-off reverse flow was also recorded. Test solutions of 25, 35 and 45% glycerin/water were used to create a clinically relevant range of viscosity (2.2, 3.1, 4.6 cP). The aortic pressure was regulated to 75 mm Hg. Flow rates were inversely proportional to viscosity and directly proportional to cannulae size. At 5000 RPM, the maximum pCAS flow was 2.5 L/min for the lowest viscosity and largest cannulae combination and 0.84 L/min for the highest viscosity and smallest cannulae combination. Pump-off reverse flow ranged from −.20 to −.78 L/min depending on the viscosity and cannulae combination. For a pCAS flow of 1 L/min, the pressure drop across the pCAS ranged from 169 mm Hg for the lowest viscosity and largest cannulae combination to 619 mm Hg for the highest viscosity and smallest cannulae combination. These data demonstrate that the pCAS delivers adequate flow to support neonates and small infants. (Supported by NHLBI Contract HHSN268200449189C)

NUMERICAL STUDY OF THE FLOW DESIGN OF THE TWO-STAGE CENTRIFUGAL PUMP FOR CARDIOPULMONARY SUPPORT

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The centrifugal blood pump consisting of the two-stage impeller has been developed as a blood pump for cardiopulmonary support system aiming at generation of high pressure (> 500 mmHg). The pump possesses the two-stage impeller with the vaned return channel, which enables high pressure generation at the relatively low rotational speed. The present study deals with the analyses of the flow field of the initial prototype of the device and the design modifications based on the numerical analyses on the shear stress distribution and the regions with low flow velocities. The 1st prototype was designed based on the conventional design theories, and was able to generate 560 mmHg at the flow rate of 3 L/min at approximately 4200 rpm. The numerical flow studies indicated that the local shear stresses exceeds the thresholds for mechanical blood trauma, and also that there are stagnant regions in the impeller passages. The 2nd prototype designed in consideration with these results of CFD analyses. The summary of the modified design of the 2nd prototype are; 1) Use of the shrouded impeller 2) The enlarged clearance of the tips of the return channel and the double volute 3) Use of the shrouded return channel 4) The profiles of the impeller and the return channel The performance tests have shown that the 2nd prototype maintained the same hydrodynamic performance as the 1st prototype while reducing the maximum shear stress and the area of low-flow regions. In conclusion, the numerical results were useful for modification of the design of the newly-developed multistage impeller.

EXPERIMENTAL HEMODYNAMIC PERFORMANCE OF THE PEDIATRIC VENTRICULAR ASSIST DEVICE InCor (PedVAD-InCor)

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Objective: to evaluate the hemodynamic performance of the PedVAD-InCor in pigs. Methods: Anestethized "Large White" pigs (n=14; 10–12 Kg body weight) were studied acutely. Biventricular assistance with PedVAD-InCor was initiated after left ventricular apical and innominate artery cannulation in 7 animals (G_{VAD}) and hemodynamic parameters were compared to cannulation alone (G_C; n=7). Cardiac rate, mean arterial pressure (MAP), mean pulmonary artery pressure, mean left atrium pressure (LA) and thoracic aortic flow (AoF) were recorded continously. Cardiac output was measured with a Swan-Ganz catheter. The Cardiac Index (CI), systemic vascular resistance and pulmonary vascular resistance indexes were determined. All parameters, except AoF and LA, were measured before sternotomy (T_{basal}), after cannulation (T_0) and at 20 minutes intervals for 120 (T_{20} to T_{120}). Results: All animals in G_C died before T_{80} while all animals in G_{VAD} survived at T_{120}. Compared with T_{basal}, the CI decreased 23,33% in G_C and 17,33% in G_{VAD} after sternotomy and cannulation (T_0). In G_C the CI and MAP decreased progressively until the animal died. The CI in G_{VAD} was mantained between 3,14 and 4,11 $l.min^{-1}.m^{-2}$ with biventricular assistance. Conclusion: the PedVAD-InCor provided a satisfactory ventricular assistance, maintaining the CI in clinical acceptable ranges in the animals studied.

VENTRICULAR ASSIST DEVICE FOR TODDLERS WITH HYBRID MAGNETIC-MECHANICAL BEARINGS

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A new mixed-flow turbodynamic blood pump (TBP) for toddlers having a combined mechanical-magnetic bearing is presented. The hybrid design was motivated to capitalize on biocompatibility advantages of magnetic suspension, while avoiding the complexity of feedback-controlled levitation. The fundamental flow path resembles the PediaFlow™ maglev pump, with 14 mm diameter impeller, but replaces the active magnetic axial actuator with a mechanical support at the aft of the impeller. Several mechanical bearing designs, including a three-point support, onventional hydrodynamic thrust bearing, and ball-cup support were fabricated and tested. High-speed tracer particle flow visualization on the three-point bearing revealed unacceptable flow disturbance by the supporting rods, eliminating it from further consideration. The hydrodynamic bearing, comprised of a ceramic cone and mating carbide pin, was found to partially occlude the flow path and also cause excessive friction, thus heat generation and power consumption. A ball-cup bearing was devised that minimally intruded into the flow path and provided acceptably low friction torque. In vitro tests conducted in both steady state and pulsatile conditions demonstrated a maximum flow rate of 3.0 lpm at 20.2kRPM. Preliminary in-vitro tests in blood demonstrated hemolysis comparable to the BP80 Biopump. In-vivo tests will soon be performed to evaluate thrombogenicity; and additional design optimization is ongoing to further reduce friction, thereby improving hemocompatibility.

A SUCTION DETECTION BASED CONTROL SYSTEM FOR ROTARY BLOOD PUMPS

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A control system for rotary ventricular assist devices was developed to automatically regulate the pumping speed of the device to avoid ventricular suction. The control system is comprised of a suction detector and a fuzzy logic controller (FLC). The suction detector can correctly classify pump flow patterns, using a discriminant analysis (DA) model that combines several indices derived from the pump flow waveform, to classify the pump status as one of the following: No Suction (NS), Moderate Suction (MS) and Severe Suction (SS). The discriminant scores, which are the output of the suction detector, were used as inputs to the FLC. Based on this information, the controller updates pump speed, providing adequate flow and pressure perfusion to the patient. This controller has been tested in simulations showing the ability of autonomously adjusts pump flow according to the patient's level of activity, while sustaining adequate perfusion pressures. The performance of the system (suction detector and controller) was tested for several levels of activity and contractility state of the left ventricle, using a lumped parameter model of the circulatory system coupled with a left ventricular assist device. The controller was able to maintain cardiac output and mean arterial pressure within acceptable physiologic ranges, while avoiding suction, demonstrating the feasibility of the proposed control system.

HOW MUCH OF THE IAB VOLUME IS DISPLACED TOWARDS THE CORONARY CIRCULATION?

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Background: The hemodynamic benefits of intra-aortic balloon pumping (IABP) are achieved via blood volume displacement towards the heart during inflation (V_{infl}) and away from the heart during deflation (V_{defl}). V_{infl} leads to diastolic aortic pressure augmentation (P_{aug}) while V_{defl} causes end-diastolic aortic pressure (EDP) reduction. It is usually presumed that V_{infl} and V_{defl} correspond to approximately half of the balloon volume, but this has never been verified *in vivo*. We examined this assumption in patients. **Methods:** Simultaneous ascending aortic pressure and flow rate were recorded in 25 patients during IABP with assistance frequency 1:2. V_{infl} and V_{defl} were calculated by integrating aortic backflow during early diastole and forward flow during late diastole, respectively, over time. **Results:** P_{aug} was 19.1±2.3 mmHg during IABP, while EDP decreased from 49.6±2.5 to 45.9±2.9 mmHg ($p<0.01$). On average V_{infl} was 9.3±1.4% of the nominal balloon volume and V_{defl} 10.8±2.3%. A relation between volume displacement and IABP hemodynamic benefit expressed in terms of pressure parameters was found only during deflation, in the form of a negative correlation between V_{defl} and EDP ($r = 0.65$, $p<0.05$). **Conclusions:** The unexpectedly small volumes displaced by IABP and the absence of a correlation between V_{infl} and P_{aug} suggest that there are unaccounted for factors involved in the interaction between the balloon and the aorta. The geometry and resistances of the arch vessels, which lie between the balloon and the heart, could be implicated in this interaction. CK was supported by BHF grant PG/06/120.

PULSATILE MECHANICAL CIRCULATORY SUPPORT WITH THE HeartMate II

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It has been suggested that pulsatile mechanical circulatory support (MCS) is superior to continuous MCS in DCM patients. Model studies have shown counterpulsating MCS to be most beneficial. Continuous devices, however, tend to have better long-term integrity than pulsatile ones. To establish the application possibility of the HeartMate II (HMII), by Thoratec, in pulsatile MCS, we measured its pump characteristics in terms of flow rate (Transonic, Ithaca, NY), pressure difference (Beckton Dickinson, Belgium) and power uptake (generic ammeter), in static and dynamic conditions, from 15 up to 240 BPM, at different mean rotational speeds and different peak-to-peak speed values. In all cases, the HMII was driven by a commercially available brushless DC motor controller (Maxon motor, Switzerland), and data were sampled at 1kHz using LabVIEW software. The H-Q curves we measured were similar to the ones published by Thoratec, indicating a properly working test rig. Under dynamic conditions, the mean flow and pressure at mean speed are the same as under static conditions, so the static H-Q curves may serve as H-Q estimate under dynamic conditions. The power uptake, however, is larger under pulsatile conditions, probably due to acceleration/deceleration effects. Although the flow response amplitude drops a little at higher heart rates, the HMII can generate pulsatile flows up to 240 BPM. Our study indicates the feasibility of pulsatile control of the HMII. This opens the way to e.g., animal studies, to evaluate whether pulsatile operation of the HMII really is superior.

ASSESSMENT OF HEMOCOR HEMOCONCENTRATOR IN CONTRAST MEDIA CLEARANCE

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Diagnostic procedures with radiocontrast agents are often associated with adverse chemotoxic and idiosyncratic reactions. In fact, contrast media has become the third leading cause of hospital-acquired acute renal failure (ARF). Realizing that hemoconcentration results in better survival of patients with ARF after cardiac surgery, we conducted a series of ex vivo experiments with Hemocor HPH®1400 (Minntech Corp.) to evaluate its usefulness in Optiray®350 (Ioversol Injection 74%; Mallinckrodt Inc., St. Louis, MO) clearance from saline, human albumin, packed RBC and whole human blood. All experiments mimicked a 2 hr cardiopulmonary bypass, scaled down to a 1 L model, using standard blood and ultrafiltrate flow rates with sampling times at: 0, .25, .5, 1 and 2 hrs. Hemocor showed to be highly biocompatible with all blood components. After 30 min of dialysis, the Optiray level was reduced by 99.8% y=674.4 * x^1.932 R^2=0.991) in saline, 96.2% (y=615.2 * x^1.920 R 2=0.993) in albumin, 97.8% (y=645.4 * x^1.926 R 2=0.992) in RBC, and 84.7% (y=530.5 * x^1.898 R^2=0.993) in whole blood. Optiray was not detectable at the 1 hr interval in all tested solutions. This data indicates that Hemocor can be an effective therapeutic strategy in preventing contrast-induced toxicity.

AUTOMATIC ADAPTATION OF A PHYSIOLOGICAL CONTROLLER FOR ROTARY BLOOD PUMPS IN PATIENTS WITH ARRHYTHMIAS

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Purpose: Arrhythmias are a common complication in patients with heart failure requiring circulatory assist. A method for controlling implantable rotary LVAD's based on the pulsatility of the pressure difference signal (Δp) is extended to automatically detect and to tolerate arrhythmias. **Methods:** On the basis of the Δp measured by the INCOR pump, a pulsatility index (PI) is calculated. The gradient of the PI with respect to pump speed is estimated via a recursive least squares method (RLS). A cascaded control loop is used to run the pump either at a stable operating point with high pump output and closed aortic valve or in partial assist mode with opening aortic valve. Both, the estimation method and the regulators are optimized for rapid control action under rhythmic conditions. In the arrhythmia case high noise variances σ^2 would lead to a relatively large control effort. This in turn, results in unwanted speed variations. The residuals of the RLS method are used to estimate σ^2 which corresponds to the degree of arrhythmia. If the estimated σ^2 rises above a threshold, the estimation time constant is increased and the regulators are detuned to accommodate to higher fluctuation of the PI due to arrhythmias. **Results:** The method has been tested in a computer simulation. By detecting the degree of arrhythmia, a proper parameterization of the estimator and the regulators of the control loop is selected automatically. Fast regulation of disturbances like variations of venous return is achieved for the rhythmic case. Arrhythmias require a more attenuated control action, thus sacrificing control performance.

AN IMPLANTABLE ELECTRONIC SYSTEM WITH FUZZY ALGORITHM FOR THE AUXILIARY TOTAL ARTIFICIAL HEART (ATAH): ITS RELIABILITY ASPECTS

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A miniaturized artificial heart was developed, the Auxiliary Total Artificial Heart (ATAH). The dimensions of this pump are reduced being capable to be implanted in the abdominal cavity of average sized patients without removing their natural heart. ATAH is an electromechanical pulsatile blood pump with left and right chambers. This device operates in left master alternate mode (LMA), with the left auxiliary ventricle, the master, setting the ATAH pumping rate. An implantable electronic system have been developed and tested, applying reliability concepts in order to improve the Hardware and Software and to minimize risks. Reliability calculus are developed and the results are adequated to the purposes (bridge to cardiac transplant).

Key Words: Total artificial heart, Cardiac assist device, Fuzzy System, Reliability.

DEVELOPMENT OF AN ARTIFICIAL PLACENTA II: PUMP-DRIVEN AV-ECLS IN A NEONATAL SHEEP MODEL

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Background: Development of a pumpless artificial placenta—umbilical arteriovenous extracorporeal life support (AV-ECLS) demonstrated hemodynamic instability and low device flow. We hypothesized that use of a pump and aortic cannulation via the umbilical arteries would improve device flows and hemodynamics. **Methods:** Twelve fetal sheep(127–138 days;term=145) were exposed by hysterotomy and flow probes placed. Two umbilical arteries and one vein were cannulated with 8–12Fr catheters and attached to a pump-driven AV-ECLS circuit. The fetus was supported for 4 hours in a fluid bath. **Results:** Average device flow was 163±9ml/min/kg with at least one cannula in the aorta (n=6 with two, n=3 with one) and 122±20ml/min/kg with no cannulas in the aorta (n=3, p=0.05). Despite improved device flow, initial pH was closer to normal with no cannulas in aorta (pH 7.38 v. 7.29, p=0.03) and remained higher (avg pH 7.26 v.7.20). Average mean arterial pressure was higher (47±5 mmHg v. 38±3 mmHg) with no cannulas in the aorta. Device flow as a percentage of cardiac output was higher than physiologic (42%) for both groups (63% no cannulas, 64% at least one cannula in aorta). **Conclusion:** Although placing arterial cannulas in the aorta facilitates stable device flows, it led to hypotension due to an AV steal phenomenon. Further work is required to determine optimal artificial placental device flows to maintain normal fetal physiology.

IN VITRO EVALUATION OF A NEW RESILIENT HARD CARBON THIN FILM COATING AS A VENTRICULAR ASSIST DEVICE BEARING MATERIAL

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Purpose: Our aim was to evaluate the potential use of BioMedFlex™ (BMF), a new resilient hard carbon thin film coating, as a blood journal bearing material in the DexAide and SmartHeart™ continuous flow right and left ventricular assist devices (VADs). BMF differs from other thin film carbon coatings by its high flexural strength, radio opacity, and wear resistance. **Methods:** A 2–4 microns thick BMF adhesion layer was deposited on the VAD journal bearing surfaces without changing the remaining pump components. A commercial diamond-like carbon (DLC) coating used in other blood pump applications was used as a control. Durability and reliability of the BMF coating was verified in severe pump start/stop testing using 20 BMF-coated journal bearing pairs. **Results:** The BMF-coated pumps showed no coating failures, while 50% of the commercial DLC bearing pairs developed scratches through the carbon coating, documenting that BMF can provide a durable coating in our blood journal bearing application. **Conclusion:** BMF has qualities that support its significant advantages as an alternate journal bearing material in both the DexAide and SmartHeart VADs due to microns-thick thin film coating and bearing reliability. Our plan includes biocompatibility testing with ongoing VAD animal studies, endurance testing with submerged pumps running in saline at body temperature, and assessment of batch coating processing capability.

INDUCED FEVER IN THE TREATMENT OF HEART FAILURE

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Objective: Thermal therapy utilizing slight intermittent increases in body core temperature has been anecdotally reported to have beneficial outcomes in patients with heart failure. The objective of this work was to conduct an analysis of literature regarding the impact of this type of induced fever, with a specific focus on measurements of heart failure related indicators and markers. **Methods:** Reviews including articles up to and including 2008 were conducted utilizing the Medline and Embase databases. Studies were included only if quantitative assessments were made on specific heart failure related indicators. English papers covering all age groups, gender and disease severity were included in these reviews. **Results:** 1) Induced fever was associated with clinically significant benefits for heart failure patients, 2) Significant improvements were noted across a wide range of indicators including; a) ejection fraction, b) systemic vascular resistance, c) cardiac index, d) systolic and diastolic blood pressures, e) premature ventricular contractions, f) cardiac geometry and g) brain natriuretic peptides. 3) Benefits were noted across multiple studies and a wide range of patients (NYHA Class II-IV). 4) Improvements were observed across a wide cross section of patients including those of all ages and genders. **Conclusions:** Thermal therapy may provide an important low cost and non-invasive modality in heart failure. Existing evidence while compelling is from a relatively small number of typically single centre studies. A well controlled multi-centre clinical study is planned to assess the potential of this approach in a scientifically rigorous manner.

SCHEDULED IMPLANTATION OF VADs FOR TREATMENT OF TERMINAL HEART FAILURE IN PATIENTS WITH ADVANCED AGE: SINGLE-CENTER EXPERIENCE

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Background: Heart failure is a leading cause of death in developed nations despite medical management. Ventricular assist device (VAD) implantation is accepted therapy in patients with end-stage heart failure. Although advanced age is considered a relative contraindication to heart transplantation, there is no published consensus–on critical age in the case of mechanical circulatory support (MCS). **Methods:** Thirty-one heart failure patients in advanced age (above 65 years of age at the time of surgery) in whom an VAD was implanted between January 2006 and September 2008 at our institution were retrospectively evaluated. Demographic information, hemodynamic and laboratory data gathered immediately before VAD insertion were analyzed. **Results:** Overall 30-day survival was 77%. There were 28 patients supported with an LVAD and 3 patients supported with a BVAD. Mean age at time of implantation was 69 (range 66–80) years. Mean time of support was 196 (range 4 - 915) days. Presence of cardiogenic shock was associated with higher perioperative mortality. Eighteen (58%) patients were discharged home. Conclusion: Our experience shows that permanent mechanical circulatory support may be a successful therapy option in selected elderly patients with terminal heart failure.

ELUCIDATION OF THE INTERACTION BETWEEN AN IMPLANTED ROTARY LEFT VENTRICULAR ASSIST DEVICE AND THE NATIVE LEFT VENTRICLE BY ACOUSTIC WAVEFORM ANALYSIS

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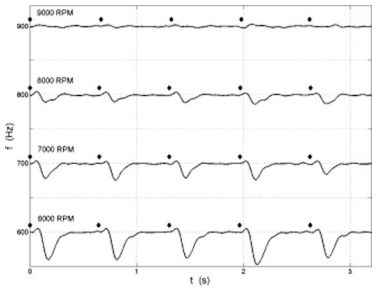
Elucidation of the interaction between rotary LVADs (rLVADs) and the native left ventricle (LV) is likely to confer clinical benefits, particularly in bridging to recovery (BTR). We recently showed that the acoustic signal from rLVADs implanted in patients is determined by impeller geometry and rotation speed. Here we examined the rLVAD/LV interaction using the acoustic signal from Heartmate II dilated cardiomyopathy patients at pump speeds from 9K to 6K rpm during BTR investigations. The ECG was also recorded to allow the acoustic data to be related to the cardiac cycle. Instantaneous frequency of the acoustic waveform was calculated using Hilbert transformation of the bandpass-filtered signal (filter centred on the spectral complex at 6 x rotation frequency, bandwidth 100Hz). Representative results are presented at different pump speeds with the ECG R-wave depicted by a diamond. A dip in frequency of increasing magnitude is seen during ventricular systole as the pump speed is decreased (increased ventricular loading). In summary, the frequency dip occurs in response to LV systole, and may be used to optimise LV loading and assess LV performance during BTR (Figure 1).



RIGHT VENTRICULAR SPARING TECHNIQUE FOR LEFT VENTRICULAR REPLACEMENT WITH A CONTINUOUS FLOW ASSIST DEVICE

OH Frazier, Egemen Tuzun, Cuneyt Narin, Jo A Winkler, Kelly Harms, Steven Parnis, William Cohn. *Texas Heart Institute, Houston, TX.*

Despite advances in ventricular assist device (VAD) and total artificial heart technologies, patient/device size mismatching and pulmonary hypertension pose a major problem in patients awaiting heart transplantation. To overcome this problem, we developed a right ventricular (RV) sparing technique for replacing the left ventricle with a continuous flow VAD. We then performed a pilot study of this technique in a healthy bovine model. We excised the left ventricular free wall of an 87-kg calf with on beating heart. Extreme care was taken to protect the left anterior descending coronary artery and its septal branches and, thus, to avoid ischemia. We attached a sewing ring to the mitral annulus and inserted a HeartWare HVAD into the left atrium. We then anastomosed the device's 10-mm Dacron outflow graft to the descending thoracic aorta. The calf was uneventfully weaned from CPB. During the 2-hour follow-up period, pump and hemodynamic parameters were recorded at varying pump speeds. The aortic valve remained competent during and after surgery. Sinus rhythm was sustained after left ventricular removal, and no blood was seen regurgitating from the valve. The RV cardiac output and pump flow ranged from 4.8 to 9.0 L/min, and RV function remained normal. Arterial blood gases and pressures were maintained within physiologic limits. The study was successfully completed without hemodynamic or pump problems. Long-term experimental studies to test the feasibility of this technique are ongoing at our institution.

TEN MONTHS OF BIVENTRICULAR BERLIN HEART EXCOR SUPPORT IN A 4 KG PATIENT MANAGED WITH SINGLE WARFARIN THERAPY

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Purpose: In infants on EXCOR biventricular assist device (BVAD) the anticoagulation can be safely managed with warfarin administration. **Methods:** A 4 kg patient was referred to our hospital with dramatic heart failure and dilatative cardiomyopathy diagnosis. Patient was immediately unscripted in urgent list of heart transplant. After two months, patient's conditions decreased and became resistant to pharmacological therapy and a Berlin Heart EXCOR Pediatric BVAD was implanted. In the early days after surgery the anti-coagulation therapy was performed with continuous heparin infusion; aPTT value was maintained between 65 to 88 seconds. When patient was extubated heparin infusion was switched to oral warfarin administration. We started with a first dose of 0.2 mg/Kg/die to join the target of international normalized ratio (INR) fixed to 2.5–3.5. We combined warfarin with subcutaneous heparin administration until the INR target was higher than 2. We didn't combine warfarin administration with ASA and dipirydamole. 300 days after BVAD implantation patient underwent heart transplantation. **Results:** During the EXCOR assistance the pumps were monitored, and neither small or large thrombi were detected. The BVAD didn't require pump exchange. The child didn't present any episodes of bleeding or thromboembolism. **Conclusions:** We successfully managed the anticoagulation of an infant on a BVAD only with warfarin administration without any adverse event.

PLATELET ACTIVATION IN OVINES IMPLANTED WITH THE Levitronix® PediVAS™ USING CUSTOM CANNULAE

Carl Johnson Jr.,[1] Peter Wearden,[2] Joshua Woolley,[1] Sang Ho Ye,[1] J. Scott Richardson,[3] Barry Gellman,[3] Harvey Borovetz,[1] Kurt Dasse,[3] William Wagner.[1] *[1]McGowan Insitute and Bioengineering, PA; [2]Cardiothoracic Surgery, PA; [3]Levitronix LLC, MA.*

Purpose: The objective in this study was to characterize blood biocompatibility of a new pediatric ventricular assist system (Levitronix® PediVAS™) and custom designed cannulae by quantifying circulating activated platelets in 20–25 kg lambs. **Methods:** Serial platelet activation was measured during five PediVAS™ left ventricular support studies using flow cytometric platelet activation assays previously developed for ovines. Flow was maintained in the range of 0.5–1.5 LPM over 30 days duration. Coumadin and heparin were used to maintain an INR > 2.0 and an ACT between 180 and 200 sec. **Results & Conclusions:** In two of the five studies platelet activation was persistently elevated for the duration of the 30 day study. In the remaining three implants platelet activation, while initially elevated, returned to low or baseline levels by 30 days. The level of activation generally related to necropsy findings (i.e.; presence/lack of infarcts). The platelet activation assays demonstrated utility in assessing the modified cannula design for the Levitronix® PediVAS™ system. Overall, we conclude that the blood biocompatibility of the Levitronix® PediVAS™ and custom cannulae, as represented by a low level of platelet activation observed in the majority of studies, is encouraging. Supported by SBIR Phase II award R44 HL071376.

PLATELET ACTIVATION IN OVINES IMPLANTED WITH THE PediaFlow™ VAD

Carl Johnson Jr., Joshua Woolley, Sang Ho Ye, Harvey Borovetz, William Wagner. *McGowan Institute and Bioengineering, PA.*

The PediaFlow™ VAD is an implantable, magnetically levitated mixed flow rotary blood pump being developed to provide cardiac support for up to 6 months in infants. Our current year PediaFlow™ prototypes boast a number of improvements over our original design including improved cannula connections and rotor stability over the entire flow rate range, which might impact biocompatibility. Therefore we sought to characterize temporally blood biocompatibility of our current PediaFlow™ prototypes in terms of circulating activated platelets. Flow cytometric assays to detect ovine platelet activation were applied in 3 chronic implants of 16, 30, and 70 d duration. In each study, platelet activation rose following surgery, eventually returning to low or baseline levels. In the first study however, mechanical fatigue of the driveline led to premature study termination and on the final day platelet activation rose after pump stoppage. Improved strain relief was added to the driveline and in subsequent studies platelet activation remained low or at baseline for the duration of the study. These platelet activation results represent a marked improvement over evaluations with our original PediaFlow™ VAD, where all three chronic studies concluded with a rise in platelet activation. We conclude that the developed platelet activation assays were able to discern trends among the post-operative courses of our current year PediaFlow™ implanted ovines. Furthermore, these assays discerned differences in our current year and original PediaFlow™ VADs, demonstrating improved biocompatibility of our current design.

FLOW PERFORMANCE MODELING AND EXPERIMENTAL VALIDATION OF LIFEFLOW CARDIAC ASSIST DEVICE

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Background: A considerable effort has been dedicated to the design of an axial flow blood pump with a magnetically levitated impeller, and its subsequent flow path refinements in order to achieve a streamlined and unobstructed blood flow path. This report details the current flow path design configuration and includes a thorough CFD analysis of device performance as well as the experimental validation of flow performance. **LifeFlow** VAD has a design point of 4.5*l pm* at 100 *mmHg* to meet full physiologic needs of adult patients with congestive heart failure. It measures approximately 85 *mm* in length by 35 *mm* in outer diameter and delivers flows from 2 to 8*lpm* at rotational speeds varying from 5,000 to 8,000 *rpm*. **Methods** The pump design included the extensive use of conventional pump design equations and computational fluid dynamics modeling for predicting pressure-flow curves, hydraulic efficiencies, scalar fluid stress levels, exposure times to such stress, and axial fluid forces exerted on the impeller for the suspension design. Flow performance testing was completed on a plastic prototype of the **LifeFlow** for comparison to the CFD predictions. **Results:** No obvious signs of irregular flow patterns were identified in the CFD analyses. The pressure-flow performance predictions demonstrated the **LifeFlow**'s ability to deliver adequate flow over physiologic pressures for reasonable rotational speeds. The CFD numerical estimations generally agree within approximately 10% of the experimental measurements over the entire range of rotational speeds tested.

THE OPTIMAL SURFACE FOR CARDIAC ASSIST DEVICE INFLOW CANNULAE

Johannes Mueller,[1] Barbara Kapeller,[2] Kurt Graichen,[1] Kersten Brandes,[1] Doris Moser,[2] Karin Macfelda.[2] *[1]Berlin Heart, Berlin, DE; [2]Medical University Vienna, Vienna, Austria, AT.*

The movement of the cannula in the apex of the LV stimulates proliferation of fibroblasts. The cannula is responsible for unfavourable flow which may induce thrombus formation in the LV. To avoid suction of thrombi or cell tissue into the pump the surface of the cannula should see for a proper adhesion of cells and thrombi to their surface. We investigated the degree of growth and adhesion of fibroblasts to different titanium surfaces in vitro. 9 titanium test discs (25 mm diameter) were coated with biomaterials: silicone, spongy silicone, polished titanium, sintered titanium (150 and 300 μm roughness), velour, silver coated velour, plasma injected titanium and titanuim/HA. Polystyrole served as control. Human fibroblasts were isolated and cultured in DMEM-culture medium. After 2 weeks specimens and ongrowing cells were prepared for electron microscopical analysis. Cell layers on the discs were exposed to shears stress to test adhesion of the cells. Only silver coated velour did not show any cell growth. The cellular overgrowth of the other materials was of varying intensity. The most densely cell layer was observed on polished titanium followed by sintered titanium. Under shear stress the best cell growth and optimal adhesion of the cell to the surface was obtained on sintered titanium (300) followed by plasma injected titanium and titanium/HA. Sintered titanium (300) can be suggested as appropriate material for optimal adhesion of thrombi and cells to the cannula surface and in-growth of the cannula into the LV.

CONTINUOUS-FLOW VENTRICULAR ASSIST DEVICE SUPPORT IN PATIENTS WITH MECHANICAL MITRAL VALVE

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Purpose: Mechanical prosthetic valves in patients receiving mechanical circulatory support increases the risk for thromboembolic complications and therefore have been considered a relative contraindication to LVAD therapy. However, the safety of continuous-flow support in such patients has not been established. **Methods:** We reviewed our experience with continuous-flow (Heartmate II) support in 74 patients between June 2005 and Jan 2009 (bridge to transplant (BTT) n=54 or destination therapy (DT) n=20). Of these patients, 3 had prior mechanical mitral valve replacement. **Results:** Two patients received LVAD as a BTT and one as DT. Mean age of the patients was 66 (range 57–74). One BTT patient has been transplanted after support of 206 days; support for the other BTT patient and the DT patient is currently at 148 and 722 days. The total mean duration of support was 359 days +/− 316. GI bleeding occurred in 2 patients (66%). The mean INR in these patients were 1.82, 2.36, and 2.55. There were no thromboembolic events and no deaths. **Conclusions:** End-stage heart failure patients with pre-existing mechanical mitral valves can safely and effectively undergo placement of continuous-flow devices with careful clinical management. The increased incidence of GI bleeding warrants further studies into the etiology of bleeding in patients with continuous-flow devices. A lower INR requirement (2 to 2.5) may be sufficient to prevent adverse thromboembolic complications than what is required for mechanical mitral valves alone.

THE AVALON Elite™ Bi-CAVAL DOUBLE LUMEN CANNULA PREVENTS DRAINAGE LUMEN COLLAPSE AND SEPTUM SHIFT

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The newly patented Avalon Elite™ Bi-Caval Double Lumen Cannula (DLC) was developed to prevent drainage lumen collapse and septum shift, and to eliminate recirculation. The membrane sleeve infusion lumen forms a firm round membrane tubing due to the pressure difference between the more positive infusion lumen relative to the negative drainage eliminating septum shift toward the drainage side. Stainless steel wire outer reinforcement prevents DLC wall collapse at high drainage pressures. Our goal was to compare the Avalon DLC to the Origen DLC for lumen collapse during drainage side suctioning to enhance circuit flow. **Methods:** An Origen DLC (18 Fr) and Avalon DLCs (19 Fr and 27 Fr) were tested with a CentriMag Pump in 40% glycerin at 38°C. Pressure and flow were measured and recorded by NI Data Acquisition System and analyzed by MATLAB Real Time Workshop. **Results:** The18 Fr Origen DLC had drainage lumen collapse with a suction pressure of 96 mmHg; Avalon DLCs showed a smooth P/Q curve up to 400 mmHg (19 Fr) and 120 mmHg (27 Fr) drainage pressure without evidence of drainage lumen collapse and septum shift. Flow increased up to 5 l/min with the 27 Fr at 120 mmHg suction and 2.5 l/min with the 19 Fr DLC at 400 mmHg suction. **Conclusion:** The Avalon DLC remains firm and intact at elevated drainage suction pressures with enhanced flow of up to 2.5 l/min for the19 Fr and up to 5 l/min for the 27 Fr cannulae.

LEVACOR VAD MAGNETIC LEVITATION SYSTEM PERFORMANCE

Gill Bearnson,[1] Phil Miller,[1] Jim Lee,[1] Gordon Jacobs,[1] Darwin Mullins,[1] James Malmstrom.[2] *[1]World Heart Inc, Salt Lake City, UT; [2]Eclipse Product Dev, Salt Lake City, UT.*

The Levacor(TM) ventricular assist system (VAD) is an implantable, centrifugal pump intended for later stage heart failure patients, including bridge to cardiac transplant, bridge to recovery and for destination therapy. The rotor, the pump's only moving part, is magnetically levitated using a combination of passive permanent magnets and single active axis electromagnetic control. Final preclinical testing of the system has included levitation tests, mock circulation performance testing, controller performance evaluation and human factors assessment. The levitation system was tested under 1) nominal pumping conditions, 2) maximum pumping conditions, and 3) extreme acceleration conditions. Under nominal pumping conditions the performance of the pump was tested to at least 6 g of acceleration in all orientations with no rotor touchdown. At maximum pumping conditions, the performance was tested to at least 4.5 g of acceleration in all orientations with no rotor touchdown. Under exteme acceleration conditions, which includes situations likely to result in serious injury to the patient such as an auto accident, the system was tested to greater than 24 g acceleration. At extreme accelerations, the pump may stop, but was tested to restore cardiac output within 30 seconds. A total of 69 different test conditions were documented. Test results showed that the Levacor VAD levitation system performs over the full range of acceleration and pumping conditions expected to be seen in clinical use.

TandemHeart PERCUTANEOUS VENTRICULAR ASSIST DEVICE AS A BRIDGE TO DEFINITIVE SURGICAL THERAPY

Igor D Gregoric,[1] Pranav Loyalka,[1] Rajko Radovancevic,[1] OH Frazier,[1] Biswajit Kar.[1] *[1]Center for Cardiac Support, Texas Heart Institute, Houston, TX; [2]Texas Heart Institute, TX; [3]Texas Heart Institute, TX; [4]Texas Heart Institute, TX; [5]Texas Heart Institute, TX.*

The TandemHeart (TH) (Cardiac Assist, Inc, Pittsburgh, PE) percutaneous ventricular assist device has been used successfully in patients with severe refractory cardiogenic shock (SRCS). In 64 patients (54±15 years old, 45 men, 19 women) with cardiopulmonary resuscitation (CPR) or SRCS the TH was used as a bridge to cardiac surgery: heart transplantation (N=5); left ventricular assist device (LVAD) implantation (30); aortic valve replacement (10 [2 combined with CABG]): mitral valve replacement (11 [6 combined with CABG, 2 with tricuspid valve repair {TVR} and 2 with CABG and TVR]); CABG (5), post-infarction ventricular septal defect (2) and left ventricular aneurysm repair (1). Twenty-eight patients (44%) had previous open heart procedures. Twenty (31%) were undergoing CPR at the time of TH implant. Average EF of the other 44/64 patients was 20±7%. All patients were on maximal pressor support and 44 (69%) were on IABP before TH implant. Average duration of TH support prior to surgery was 8.6±4.9 days. Creatinine level before surgery was significantly lower in comparison to the level before TH support, 1.94±1.2 vs 1.34±0.6 mg/dL, p=0.0006. Thirty day survival was 80% (51/64). Two patients are still in hospital and 49/62 (79%) patients went home. In patients with refractory cardiogenic shock or circulatory collapse, the TandemHeart proved to be successful bridge to definitive surgical therapy.

NEW TOOLS FOR FACILITATING OFF-PUMP INSERTION OF A LEFT VENTRICULAR ASSIST DEVICE

William Cohn, Jo Winkler, Egemen Tuzun, OH Frazier. *Texas Heart Institute, Houston, TX.*

Introduction: This study was done to test new tools and techniques for off-pump insertion of implantable left ventricular assist devices (LVADs). **Methods:** A HeartMate II or Jarvik LVAD was implanted in 7 pigs without cardiopulmonary bypass (CPB). The LVAD sewing ring (SR) was threaded coaxially over a specially designed vacuum cup attached to a self-retaining arm that both exposed the LV apex and held the SR in the desired location. After suturing the SR in place, a guidewire was introduced through the LV apex and fluoroscopically guided across the aortic valve, around the arch, and to the aortic bifurcation. The distal end of the wire was captured with a endovascular snare and externalized through a 14F arterial sheath in the right femoral artery; the proximal end of the guidewire continued to exit the LV apex. A 34-cc balloon was advanced over the distal end of the wire, up the abdominal aorta, around the arch, and to the LV apex where it was inflated with contrast. An over-the-wire, vacuum-assisted ventricular coring device was then advanced over the proximal end of the wire and used to remove a cylindrical core from the LV apex. This tool is designed to ensure complete plug excision while preventing the blade from contacting the balloon. The LVAD inflow cannula was inserted through the sewing ring. The balloon was deflated and removed through the femoral artery. **Results:** In each case, the LVAD was implanted without CPB with minimal blood loss and little hemodynamic instability. All apical cores were completely removed. **Conclusion:** LVAD insertion without CPB may improve clinical outcomes in some patients.

THE ESTIMATION OF PRESSURE DIFFERENCE ACROSS AORTIC VALVE AND AORTIC FLOW DURING VENTRICULAR ASSISTANCE WITH A ROTARY BLOOD PUMP

Akira Tanaka,[1] Yusuke Kanno,[2] Makoto Yoshizawa,[3] Telma Keiko Sugai,[2] Yasuyuki Shiraishi,[4] Atsushi Baba,[5] Tomoyuki Yambe,[4] Shin-ichi Nitta.[4] *[1]Faculty of Symbiotic Systems Science, Fukushima University, Fukushima-shi, Fukushima, JP; [2]Graduate School of Biomedical Engineering, Tohoku University, Sendai, JP; [3]Cyberscience Center, Tohoku University, Sendai, JP; [4]Institute of Development, Aging and Cancer, Tohoku University, Sendai, JP; [5]Faculty of Systems Engineering, Shibaura Institute of Technology, Tokyo, JP.*

It is desirable to control the ventricular assist devices (VADs) adapting to the conditions of circulatory system, including the native heart, for further improvement of the patient's QOL and recovery of own heart. It is very important to know not only pump flow but aortic flow in order to achieve the effective control. Many research groups have tried to estimate flow rate and head pressure of rotary blood pumps using pump rotational speed and supplied electric power. The aim of this study is to estimate pressure difference across aortic valve (*PD*) and aortic flow (*AoF*) using pump rotational speed, supplied electric power and pump flow. *PD* was estimated by auto-regressive exogenous (ARX) models with supplied power, rotational speed and pump flow rate as inputs. And the aortic flow is estimated by another simple linear model which expresses dynamic character between pressure and flow at aortic valve. RMSE and correlation between measured and estimated value of *PD* were under 10 mmHg and over 0.9, respectively. This result indicates the possibility of obtaining the information of the aortic valve opening/closing. However the accuracy of AoF estimation was not sufficiently high. RMSE and correlation of AoF estimation were about 5L/m and 0.8. The main reason of the error is that the model cannot express the dynamic change of pressure loss of cannula. In future studies, this dynamic characteristic of pressure loss must be also modelled.

ACUTE LEFT VENTRICULAR UNLOADING BY THE IMPELLA LD CARDIAC ASSIST DEVICE

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Background: In clinical practice, acute left ventricular unloading using a ventricular assist device is often needed to reduce heart workload and at the mean time, increase cardiac output. The Impella LD cardiac assist device (Ambiomed, Inc., Danvers, MA) was designed to meet such a clinical need, with less invasivity as well as easy placement and management. In this study, the acute ventricular unloading effect of an Impella LD device was investigated quantitatively in a large animal model. **Methods:** The Impella device, together with 16 sonomicrometric crystals for left ventricular deformation tracking, were implanted in four adult Dorsett hybrid sheep weighing 45–65 kg, following an apical myocardial infarction of about 25% of the left ventricular free wall mass. The device was operated at various speeds from 10,000–22,000 rpm. Echocardiographic exam and sonomicrometric measurement were performed without and with the device running. **Results:** As measured by echocardiography, the end-diastolic and end-systolic volumes were 90±5 ml and 42±1 ml, respectively, when the device was off. The corresponding values decreased to 74±6 ml and 34±2 ml when the device was turned on. The end-systolic strain (contraction) calculated from sonomicrometric data was 10.4±0.3% with device support, as compared to 13.1±2.8% without device support. **Conclusion:** The Impella LD cardiac assist device could effectively unload the left ventricle. Both the pre-load (end-diastolic volume) and the contraction (end-systolic strain) were notably decreased.

TandemHeart LVAD IN PATIENTS WITH CRITICAL AORTIC VALVE STENOSIS SUFFERING FROM CARDIOPULMONARY COLLAPSE

Igor D Gregoric, Pranav Loyalka, Rajko Radovancevic, Sylvia Carranza, OH Frazier, Biswajit Kar. *Texas Heart Institute, TX.*

Patients with aortic stenosis in severe refractory cardiogenic shock (SRCS) or undergoing cardiopulmonary resuscitation (CPR) who require emergent surgical aortic valve replacement (AVR) have very high mortality rates. We report 10 patients with critical aortic stenosis who had CPR or SRCS. Eight of them received TandemHeart (TH) (Cardiac Assist, Inc, Pittsburgh, PE) support prior to AVR surgery and 2 patients received TH in the operating room for postcardiotomy cardiogenic shock. Six men and 4 women, age 62±12 years, had aortic valve area 0.69±0.17 cm^2. Seven were undergoing CPR (6 for >20 min) at the time of TH implant. The other 3 patients had EF 16.7±5.8%. All patients were intubated, on maximal pressor support and 7 on IABP before TH implant. Six patients had previous open heart surgery. STS surgical mortality risk before TH was 74±24%. Average TH support for 8 patients before AVR was 6.4±3.8 days and resulted in significant improvements in the levels of Cr (p=0.002) and BUN (p=0.023). One of these 8 patients died 34 days later of sepsis and 7 patients were discharged home (EF=42±14%). They are alive 3–20 months later. Two patients who received TH during surgery died on the postoperative days 8 and 21. In these critically ill patients TH seems promising rescue therapy prior to AVR. It appears that better outcome may be achieved if patient's end organ function on TH support normalizes and the patient undergoes surgery under elective and not emergent conditions.

MECHANICAL CAVOPULMONARY ASSIST USING AN INTRAVASCULAR AXIAL FLOW BLOOD PUMP

Jugal Kapadia,[1] Sonya Bhavsar,[1] Steven Chopski,[1] Scott Gullquist,[1] William Moskowitz,[1] Ajit Yoganathan,[2] Amy Throckmorton.[1] *[1]Virginia Commonwealth Univ, VA; [2]Georgia Tech, GA.*

Purpose: We are developing a collapsible, percutaneously-inserted, axial flow blood pump to support the cavopulmonary circulation in adolescent and adult patients. This blood pump will augment flow from the vena cavae through the lungs and ameliorate the poor physiology of the univentricular circulation. **Methods:** An initial design of the impeller for this axial flow blood pump was performed using numerical analysis, including pressure-flow characteristics, scalar stress estimations, blood damage indices, and fluid force predictions. An impeller prototype was constructed for hydraulic performance testing, and these experimental results were compared to the numerical predictions. Hemolysis testing was also performed. **Results:** The numerical predictions and experimental findings of the pump performance demonstrated a pressure generation of 2 to 16 *mmHg* for 0.5 to 5 LPM over 4000 RPM to 6000 RPM. Fluid forces and blood damage indices were within acceptable ranges. The normalized indices of hemolysis remained below 40 mg/dL for six experiments. **Conclusions:** These results support continuing the development of this device, including the design of a protective cage. The objective is to produce a new therapeutic alternative for the clinical treatment of patients with failing Fontan physiology.

SUCCESSFUL IMPLANTATION OF VENTRICULAR ASSIST DEVICE SUPPORT IN PATIENTS WITH PREVIOUS REPAIR OF LEFT VENTRICULAR ANEURYSM

Ryan C Shelstad, Lyle D Joyce, Kenneth K Liao, Ranjit John. *Cardiothoracic Surgery, Univerisity of Minnesota, MN.*

Background: Previous repair of LV aneurysm could complicate LVAD inflow cannula placement resulting in cannula malposition and poor LVAD flow. Thus, the resulting technical challenges from prior repair has resulted in this being a relative contraindication to LVAD placement. The aim of this study is to report our single-center experience with HeartMate (HM) II LVAD placement as bridge-to-transplant (BTT) therapy in patients with prior LV aneurysm repair. **Methods:** 74 patients received HM II LVADs at our center between June 2005 and Dec 2008; 54 as BTT, 20 as destination therapy. Of the BTT patients, 3 patients had a previous LV aneurysm repair. **Results:** Of the 3 patients with prior LV aneurysm repair, 2 were successfully bridged to transplant after a mean duration of support of 199.5 days (range 197–202). The third BTT patient is currently at 119 days of support and awaiting transplantation. The mean age was 61.3 years (range 56–66). In all three cases, the ventricular apex was successfully cannulated through the previous patch repair. Surgical techniques in all 3 patients included partial excision of the LV apical repair patch. No major complications were experiencedincluding pump related complications (e.g. inflow obstruction, cannula malposition or bleeding related to the LV apex). **Conclusions:** End-stage heart failure patients with previous LV aneurysm repair can safely undergo placement of continuous-flow devices LVAD. Preoperative imaging studies including echocardiography and CT chest are essential in determining feasibility of LVAD placement.

VAD PUMP MODELING AND PROGNOSTICS

Rafik Borji,[1] Hassene Jammoussi,[1] Matthew Franchek,[1] Ralph Metcalfe,[1] Cedric Benkowski,[2] Bob Benkowski,[2] Steve Parnis,[3] William Cohn,[3] Howard Frazier,[3] Egemen Tuzun.[3] *[1]Mechanical Engineering, University of Houston, Houston, TX; [2]MicroMed Cardiovascular, Inc. MicroMed Technology, Inc., Houston, TX; [3]Texas Heart Institute, Houston, TX.*

Continuous flow pumps are being widely used for cardiac replacement. Numerous efforts have been made to enhance the performances of these pumps. In this research work Parametric Models of the VAD pumps are developed based on experimental results. These models will be used to perform real time diagnostics of the VAD for error free prognostics of the TAH, estimate in real time the effective blood viscosity and facilitate the design of the multivariable control system. The parametric models are built up using the Orthogonal least Squares Algorithm that identifies the most significant regressors for which accuracy of the model output is reached. The data sets are obtained from dry and wet tests for different viscosities to allow a wider range collection of data mimicking the pump performances. The identified parametric models are evaluated through a comparison to the physics based models.

MINIMALLY-INVASIVE LONG TERM PARACORPOREAL ARTIFICIAL LUNG SHEEP STUDY

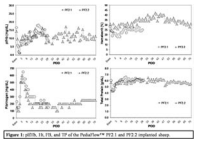
Dongfang Wang, Xiaoqin Zhou, Cherry B Croft, Garry R Pattison, Larry R Sumpter, Joseph B Zwischenberger. *Surgery, University of Kentucky College of Medicine, Lexington, KY.*

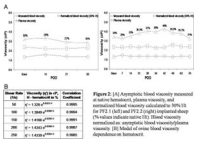
The goal of this study was to test the ability of a minimally-invasive paracorporeal artificial lung (PAL) circuit to provide respiratory support via a single cannulation. Methods and materials: The PAL circuit consists of a 27 Fr Avalon Elite™ Bi-Caval Double Lumen Cannula (formally called the Wang-Zwische catheter), a CentriMag® MegLev Pump, and an Affinity® gas exchanger. Under general anesthesia, the primed system was connected to adult sheep (n=3, 35–44 kg) by a single jugular vein cannulation following femoral vein and artery instrumentation and systemic heparinization. The device was attached to the sheep's back and secured to a metabolic cage with a pulley-system. The sheep were transferred to ICU with free access to food and water after recovery from anesthesia. The activated clotting time was maintained at 180–220 sec. Results: The sheep were alert and ambulatory within the metabolic cage. The experiment was terminated day 3 in sheep 1 due to a broken cannula, day 13 in sheep 2 for gas exchanger failure, and day 26 (gas exchanger replaced on day 12 and day 21) in sheep 3 for a subcutaneous hematoma resulting from falling against the cage. The blood flow for gas exchange was 2–3 l/min with 70–180 ml O2 transfer and 60–210 ml CO2 removal throughout the study. Conclusions: The CentriMag® MegLev Pump, and Affinity® gas exchanger connected to a sheep by one site venous cannulation using a 27 Fr Avalon Elite™ Bi-Caval DLC can achieve long term respiratory support.

HEMORHEOLOGICAL ASSESSMENT OF BIOCOMPATIBILITY OF TWO PediaFlow™ PUMP MODELS IN VIVO

Amanda Daly,[1,2] Salim Olia,[1] Shawn Bengston,[2] Timothy Maul,[1,2] Peter Wearden,[2] Harvey Borovetz,[1,2] Marina Kameneva.[1,2] *[1]University of Pittsburgh, Pittsburgh, PA; [2]McGowan Institute for Regenerative Medicine, Pittsburgh, PA.*

To evaluate biocompatibility of the PediaFlow™ (PF) VAD, pump models PF2.1 and PF2.2 were implanted into ovines for 30 and 70 days, respectively. The pump models differed only in manufacturing variability. Blood parameters including plasma free hemoglobin (plfHb), hematocrit (Ht), fibrinogen (FB) and total protein (TP) concentrations were monitored daily for the duration of each implant. Blood viscosity, elasticity and plasma viscosity were measured at baseline and weekly after implantation. Asymptotic blood viscosity values were calculated to the same 30% Ht with an algorithm developed in our laboratory using blood samples of healthy sheep (shown below). Figure 1 shows that blood parameters in both animals were within normal range except for an anticipated post-surgical reaction (increased FB levels) during the first post-surgical week. As expected, the original blood viscosity shows a strong dependence on Ht while normalized blood viscosity values remain stable indicating very low or no RBC damage (Figure 2). Based on these results, we conclude that the PediaFlow™ VADs demonstrate excellent biocompatibility in an ovine model.





COMPUTATIONAL FLUID DYNAMIC SHAPE OPTIMIZATION OF THE PediaFlow™ VAD

Jeongho Kim, James Antaki. *Biomedcal Engineering, Carnegie Mellon University, Pittsburgh, PA.*

Introduction: CFD was used to modify the third design of the PediaFlow™ VAD (PF3), a miniature magnetically levitated blood pump for infants and small children (3–20 kg). **Methods:** Iterative three-dimensional simulations of the flow path were performed to optimize pump efficiency and minimize NIH. Navier-Stokes equations were solved using ANSYS CFX. Blood was modeled as an incompressible Newtonian fluid (μ=3.5 cP; ρ=1080 kg/m^3). Hemolysis was predicted with an additional transport equation solved throughout the entire flow domain with an Eulerian approach. **Results:** The velocity field of the optimized pump exhibited well aligned flow with the leading edge of the impeller and stator blades. Consequently, inter-blade recirculation was minimized. These can be a source of energy losses affecting pump efficiency. Multi-point CFD simulations produced H-Q performance prediction with reduced droop compared to the previous PF2 design. (See Figure1.) Similar analysis was performed for hemolysis generation, which was found to be acceptable (NIH=0.07 at 1.2 L/min and 11 kRPM) but is likely to be improved with further optimization. **Conclusion:** CFD shape optimization has proven to be an effective and efficient tool for hemodynamic optimization of the PediaFlow™ VAD (Figure 1).

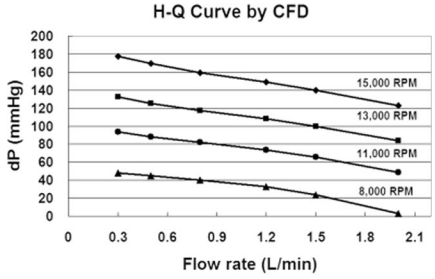


Figure 1: Pressure rise-flow curves predicted by CFD.

SINGLE FLOW PATH AXIAL FLOW LEV-VAD

Steven W Day,[1] Mark W Olles,[1] Arnold D Gomez,[1] Ronald W Kipp,[2] Don B Olsen.[3] *[1]Rochester Institute of Technology, NY; [2]RK Engineering, PA; [3]Utah Artificial Heart Institute, UT.*

The **LEV**itated impeller, left **V**entricular **A**ssist **D**evice (LEV-VAD) is a magnetically suspended axial flow rotary blood pump developed for long term circulatory support using a novel large-gap hybrid passive/active magnetic bearing system. In contrast to currently available rotary VADs, this axial flow LEV-VAD has a single unobstructed blood flow path and no mechanical bearings, thus eliminating retrograde flow, stagnant areas, and high fluid stresses. We have successfully fabricated and assembled functional prototypes of the pump, including all magnetic devices, fluid pumping components, and electronics. These prototypes have achieved and exceeded the design operating point of 6 l/min at 80 mmHg while operating at or slightly above 5,500 rpm. Within this presentation, we will report on several accomplishments: [1] A comparison of the measured hydrodynamic performance of the pump during steady state and pulsatile conditions, and a comparison of this empirical data to numerical simulations used in the design process. [2] Empirical measurements of the power consumption of the motor, bearing system, and electronics over a range of operating conditions. [3] Data supporting the accuracy of a "sensorless" measurement of flow and the pressure rise across the pump. [4] Estimates of the hemolysis caused by the pump over a limited range of operating conditions.

MANAGING AN ANTICOAGULATION NIGHTMARE

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Introduction: This case report describes how a HIT+ patient with gastric & non-responsive to plavix was successfully managed with bivalirudin (Bival), eptifibatide, persantine, and coumadin through an extremely challenging period of risk for both thrombosis and bleeding. A patient supported by Thoratec pneumatic BiVADs presented with septic shock and stroke was managed through a period of high risk for additional embolic events and hemorrhage through the use of TEG, TEG + platelet mapping (TEG-PM), and standard coagulation tests (PT/INR, PTT). Source of septicemia was pedal osteomylitis, requiring eventual amputation. **Methods & Results:** Anticoagulation was achieved with Bival, monitored by PTT. Antiplatelet medications were aspirin, discontinued (d/c'd) for gastric ulcer, and persantine, d/c'd due to headaches nausea. Thus, plavix and eptifibatide to achieve >50% platelet inhibition by TEG-PM were started. Patient was discharged on coumadin for INR of 2.5–3.5, aspirin with misoprostol & esomeprazole for ulcer prophylaxis, and plavix. Plavix was ineffective, so persantine was restarted. 1 wk post-discharge, INR was <1.5 and clots were observed in RVAD, so Bival eptifibatide were restarted until thrombi dissolved. Bival was weaned and eptifibatide reduced for pedal amputation. Patient was then restarted on Bival, aspirin, persantine, with conversion to coumadin for discharge. Patient experienced no additional strokes or significant hemorrhage during this very challenging management period.

IMPROVEMENT IN TRICUSPID REGURGITATION AND RIGHT VENTRICULAR FUNCTION IN A PATIENT WITH CONTINUOUS-FLOW LVAD FOLLOWING PHARMACOLOGIC AUGMENTATION OF LV AFTERLOAD

Mark R Bonnell, Scott Banuelos, Mark D Plunkett, Chuck Campbell, David Booth, Kevin Hatton. *Cardiothoracic Surgery, Anesthesia, and Cardiovascular Medicine, University of Kentucky, Lexington, KY.*

Purpose: Right ventricular (RV) dysfunction is a common problem during the early perioperative course of patients requiring left ventricular assist device (LVAD) placement. Although the mechanism of RV dysfunction in this setting is not well understood, deformation of the interventricular septum, exacerbated by continuous left ventricular (LV) unloading from continuous-flow LVAD devices, may play a role. Septal shift may result in severe tricuspid regurgitation (TR). The institution of modest LV afterload increases LV end-diastolic volume and pressure with resultant improvement in the LV septal shift, RV dysfunction, and TR. We report a case of near-complete resolution of septal shift and severe TR with institution of increased LV afterload. **Methods:** Serial hemodynamic measurements and echocardiography were routinely performed for optimization of LVAD performance and made prospectively during administration of phenylephrine in a HeartMate II patient (Table 1).

Table 1. Change in Hemodynamics and TR after 200 mcg of Phenylephrine IV

RPM	Flow	Pulsatility Index	HR	MAP	CVP	PAP	TR
8200	4.1	2.8	100	55	15	30/24	3–4+
8200	4.6	3.8	100	71	17	33/26	trace

Results: Modest increase in afterload may be a useful tool in the management of RV dysfunction and TR in patients with a continuous-flow LVAD.

DECREASED HEMOGLOBIN A1C IN DIABETIC PATIENTS FOLLOWING VENTRICULAR ASSIST DEVICE SUPPORT

Ryan C Shelstad, Andrew J Boyle, Frances Martinez, Kenneth K Liao, Lyle D Joyce, Ranjit John. *University of Minnesota, MN.*

Background: Diabetes is a primary risk factor for heart disease and is associated with poorer outcomes after heart transplantation. The aim of this study is to report our institution results of management of diabetic patients receiving LVAD support. **Methods:** Review of our single institution experience with LVAD devices identified 34 patients with history of diabetes. Review of glycosylated hemoglobin, random blood sugars, and medication requirements was performed both before and after LVAD placement. **Results:** The mean age is 61.9 years (range 31–80); Five were female, 28 were male. Analysis of A1C laboratory data demonstrated a mean A1C of 6.75 preoperation and 5.63 at 3–6 month follow up ($p<0.0001$). Random blood sugar data collected preoperatively and at 1, 3, and 6 month follow up were 127, 117, 116, and 118, respectively ($p=NS$). Of the diabetic patients, 30 had medication dosage data at six months follow up. Five required higher dosages and 7 had less medication requirement. **Conclusions:** Diabetic patients receiving left ventricular assist device support demonstrate a statistically significant decrease in hemoglobin A1C levels following implantation. Possible mechanisms for this include improved end organ perfusion, improved pancreatic function, decreased insulin resistance, and shortened RBC lifespan. Further studies are necessary to better understand glucose metabolism in diabetic patients with end-stage heart failure in order to improve their success with circulatory support.

WHY THE SHIFT FROM ROLLER TO CENTRIFUGAL PUMPS FOR ECMO SUPPORT?

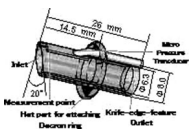
John Marks. *Levitronix LLC, Waltham, MA.*

ECMO support has historically consisted of a reliable roller pump, bladder box, and membrane oxygenator. There is a growing trend toward greater use of centrifugal pumps for ECMO and ECPR support applications. The purpose of this investigation was to study the trends and perceived advantages of centrifugal and roller pump technologies for these applications as reported by experienced clinicians. **Methods:** The Levitronix CentriMag and PediMag Systems were developed to provide improved biocompatibility and reduced risk of complications for ventricular and ECMO support. Both systems are CE Mark approved for 30 days VAD or ECMO use, although the predominant application is ECMO. The technology is in use in 25 countries and >150 centers. Experienced clinicians were surveyed to identify trends and perceived advantages of centrifugal and roller pump systems for ECMO and ECPR applications. **Results:** Advantages of centrifugal ECMO support included: a simplified circuit, no raceway, lower priming volume, reduced blood-material surface area, smaller footprint, portability, lower maximum pressure and management. Advantages of roller pump use were reported as lower cost of disposables, reduced hemolysis at low flow, and a proven technology with an established track record for safety, effectiveness and reliability. **Conclusion:** Both centrifugal and roller pump systems were perceived to provide equivalent hemodynamics, pressures and flows. Centrifugal pump ECMO was preferred for larger patients and conditions requiring transport or emergent support. There is universal agreement of the need for studies to compare and define the clinical advantages, limitations and relative effectiveness of each technology.

DEVELOPMENT OF A NOVEL APICAL DRAINAGE CANNULA FOR VAD WITH A BUILT-IN MICRO-PRESSURE SENSOR

Yoshimasa Yokoyama,[1] Tetsuo Fujimoto,[2] Hideyuki Osawa.[2] *[1]IBB, Tokyo Medical and Dental University, Tokyo, JP; [2]Shibaura Institute of Technonlogy, Tokyo, JP.*

Because of shortage in donor hearts particularly , recovery of the heart has been actively pursued in combination with drug therapy The assessment of heart function is important to control VAD flow. This study has designed novel apical drainage cannula with a built-in micro-pressure sensor to assess heart function through LV pressure measurement during VAD assistance. Fig. 1 shows a prototype apical drainage cannula tip made of acrylic resin with a micro-pressure sensor. The pressure sensitive diaphragm was exposed to the blood stream inside the cannula lumen. The external electronic circuit is a bridge type to balance the off-set current generated by the deformation of the silicon diaphragm by the applied pressure. The static and dynamic responses of the micro-sensor were obtained in the mock circulatory loop against Millar catheter type pressure transducer while the pressure measurement remained stable for 5–300 mmHg pressure levels. The pressure measurement by the micro-sensor showed high correlation against Miller Catheter with $r = 0.999$ and excellent stability for environment temperature (35–42 degree C). Additionally, frequency response was similar to that of Millar pressure transducer. Since this study, it can give continuous assessment of heart function through LV pressure measurement.



BEARING WEAR AND PUMP PERFORMANCE ANALYSIS AFTER 4-YEAR ENDURANCE STUDY OF THE CENTRIFUGAL GYRO PUMP

T Motomura, S Oshima, Y Sugita, H Miyamoto, Y Nosé. *Baylor College of Medicine, Houston, TX.*

Background: PI710 pump comprised of a "double pivot" impeller suspension design principal was developed for long-term VAD. Eight pumps passed 3-month animal studies without thrombus formation. Endurance characteristic has been evaluated in parallel since 2004. This report aims to focus on a pivot bearing wear of the PI 710 pump and the final performance testing after 4-year endurance studies. **Materials and Methods:** Eight systems were subjected to the endurance studies by mimicking LVAD condition with a master pulsatile pump. The testing pump flow was maintained at 5 L/min against 100 mm Hg of pressure head. The pump, actuator, cannulae, and controller were all immersed into saline solution simulating a physiological environment. The pump flow and motor parameters were recorded every 2 weeks. Then in-depth pump performance tests were conducted at each anniversary year. After completion of the 4-year study, the pumps were removed for the final performance tests and bearing analysis. **Results:** All of the 8 pump system revealed no device failure on the 1^{st}, 2^{nd}, and 3^{rd} anniversary year. Six out of 8 pumps reached the 4^{th} anniversary and 2 demonstrated device failure. Average P max and Q max at 1,800 RPM were 102.6 mm Hg and 5.12 L/min, respectively. However, device failure was detected (no flow) in the remaining 2 pumps. These 2 pumps were disassembled, and a visual inspection indicated that the pump failure was due to the impeller dislodgement. The average amount of the HPMWPE bearing wear in the failed pumps was 394 μm, in contrast to that of normal operating pumps (average wear: 119 μm). **Conclusion:** A practical bearing wear to allow secure double pivot bearing suspension should be less than 350 μm. PI 710 bearing system is durable enough to deliver over three year application.

POSTCARDIOTOMY EXTRACORPOREAL LIFE SUPPORT IN ADULTS: THE OPTIMAL DURATION OF BRIDGING TO RECOVERY

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Purpose of Study: Mortality due to postcardiotomy Extracorporeal life support (ECLS) often results from failing to recognize appropriate patients and bridge them to the next therapy before onset of complications. This study try to suggests a strategy to detect patients with ECLS-refractory heart failure within a short period of ECLS. **Methods Used:** From January 2003 to January 2008, 72 patients (mean age, 59 years) received ECLS for postcardiotomy cardiogenic shock were reviewed . Perioperative EuroSCOREs, bypass times, and postoperative systemic responses to ECLS were analyzed for in-hospital mortality. Indicators of cardiac recovery were identified from the hemodynamic performances in the first 24h of ECLS, and the length of the appropriate support time was defined as the ECLS time of survivors. **Summary of Results:** The ECLS weaning rate was 53% and the discharge rate was 40%.The mean duration of ECLS was 130 h (25624, median 99). 95% (28/29) of the survivors were weaned within 7 days. Age $>$ 60 years, operation other than isolated CABG, and an inotropic equivalent score(IES) $>$ 35 after 24 h of ECLS were the independent risk factors of non-weaning. Age $>$ 60 years, operation other than isolated CABG, requirements of renal dialysis, and ECLS $>$ 100 h were independent risk factors of in-hospital mortality. Persistent hypotension (mean arterial pressure $<$ 70 mmHg) with a high adrenergic demand (IES $>$ 35) under a sufficient ECLS (flow $>$ 50 cc/kg/min, SvO_2 $>$ 80%) more than 24h was common in the non-survivors.