MECHANICAL ASSISTANCE FOR THE FONTAN CIRCULATION USING AN INTRAVASCULAR AXIAL FLOW BLOOD PUMP

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Motivation

- The incidence of patients born with functional univentricular physiology is approximately 2 per every 1000 births. Without surgical intervention, the combination of cardiac anomalies is fatal within the first 2 weeks of life.
- The Fontan procedure has remained the prominent means of surgical palliation for these patients with modifications and staging evolving over the past three decades.
- The total cavopulmonary connection (TCPC) is an example of the extracardiac Fontan first described by de Leval et al. This procedure connects the inferior vena cava (IVC) and superior vena cava (SVC) directly to the main right pulmonary artery. The resulting Fontan configuration of the univentricular anatomy leads to an increased workload on the systemic ventricle due to a loss of kinetic energy from the lack of a subpulmonary ventricle.
- Improved management strategies and continued research of the Fontan physiology and its response to treatment may reduce the risk of developing late stage morbidity. Research indicates that an afterload reducing agent, such as a blood pump, improves ventricular-vascular interactions and Fontan hemodynamics. Few therapeutic alternatives exist for the failing Fontan patient beyond medical therapy and ultimately heart transplantation.
- To address this need for novel therapeutic options, we are developing a collapsible, percutaneously inserted, magnetically levitated axial flow blood pump to support the TCPC of a failing Fontan in adolescent and adult patients. Our intravascular pump is designed to provide mechanical pressure augmentation of blood flow from the IVC to the lungs, thus enhancing cardiovascular hemodynamics through improved systemic pressure, increased ventricular filling, and augmented cardiac output. The blood pump could serve as a bridge-to-transplant, bridge-to-recovery, or bridge-to-surgical reconstruction.
- In order to assess the interactive dynamics between the pump and Fontan physiology, we constructed a numerical model of the idealized TCPC and incorporated the intravascular pump into the IVC. This work builds upon the idealized geometry of the TCPC as provided by Ryu *et al*. and previous studies.
- The following three models were analyzed: 1) an idealized TCPC with 1-diameter offset without a blood pump, 2) an idealized TCPC with a 1-diameter offset and an axial flow blood pump having only impeller blades, and 3) an idealized TCPC with a 1-diameter offset and an axial flow blood pump having a set of impeller and diffuser blades. Placement of the blood pump for models 2 and 3 were in the IVC.
- The numerical analyses included the generation of pressure-flow characteristics, fluid streamlines, and energy assessment calculations. We also examined performance conditions having five left and right pulmonary arterial pressures (10 *mmHg*, 14 *mmHg*, 18 *mmHg*, 22 *mmHg*, and 26 *mmHg*), a range of pump rotational speeds as dependent upon the model under evaluation, and flow rates ranging from 1 to 4 L/min. A blood damage analysis was also performed to determine the probability of blood trauma for 350 particles released at the inlet and tracked through the pump.

Numerical Results and Discussion

- Numerical predictions indicate that the pump with an impeller and diffuser blade set produces pressure generations of 1 to 16 *mmHg* for rotational speeds of 2,000 to 6,000 RPM and flow rates of 1 to 4 L/min. (**Figure 3** and **4**)
- In contrast, the model with the impeller only in the IVC demonstrated pressure generations of 1 to 9 *mmHg* for flow rates of 1 to 3 L/min for 10,000 to 12,000 RPM.
- The model with the diffuser blades significantly outperformed the pump design without the diffuser blades by operating at much lower rotational speeds while generating more than twice as much pressure rise.

Table 1: Blood damage estimations for the intravascular blood pump

Damage Cases	RPM	Viscosity (cP)	Mean DI	Max. DI	Mean Residence Time	Max. Res. Time
Case 1	5000	5	0.110%	0.990%	0.2724	0.3740
Case 2	5000	3.5	0.130%	0. 800%	0.3754	0.3990
Case 3	4000	3.5	0.0549%	0.280%	0.4222	0.5160

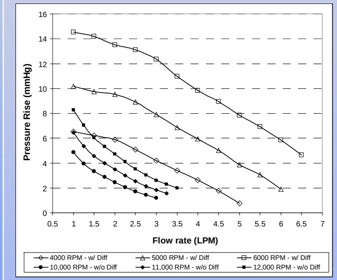

Figure 3:CFD predictions of the hydraulic performance of the blood pump models. Two blood pump designs were considered. One model had the protective cage, catheter, and an impeller blade set only. The other model included a set of diffuser blades at the outflow of the pump. The model having the diffuser blades outperformed the pump design not including the diffuser blades. The model with the diffuser blades operated at much lower rotational speeds and generated more than twice as much pressure head across the pump.

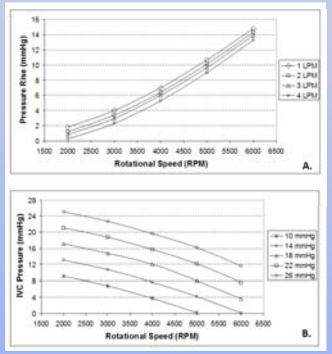

Figure 4: CFD predictions of the pressure rise across the axial blood pump and the IVC pressure (pump inlet side) as a function of increasing rotational speed. A. The pressure rise across the pump increases with higher rotational speeds, as would be expected. **B.** The IVC pressure decreases as the pump is rotated faster, as would be expected.

- **Figure 6** illustrates the energy losses of the TCPC without a pump in the IVC in comparison to the energy gains of the TCPC with the intravascular pump (impeller and diffuser blade set) in the IVC. A steady increase in energy as a function of flow is observed from 1 to 3.5 L/min for the 4,000 RPM operating conditions. Upon reaching 4 L/min, the energy performance curve at 4,000 RPM ceases to increase in slope; the inherent hydraulic losses from this higher flow rate through the TCPC and the lower head produced by the pump begin to inhibit energy augmentation. For the 5,000 RPM operating condition, the pump is able to continuously improve energy gains over the entire 1 to 4 L/min flow range.
- Blood damage analyses were performed for 3 cases or operating conditions using 350 particles and a flow rate of 3.5 L/min. This damage model was selected to examine a combined effect of fluid stresses and exposure time to those stress levels in the fluid domain. All three cases resulted in a maximum damage index (DI) of less than 1% and maximum residence time of less than 0.52 seconds indicating a low probability of blood damage due to interaction with the pump. (**Figure 5**)

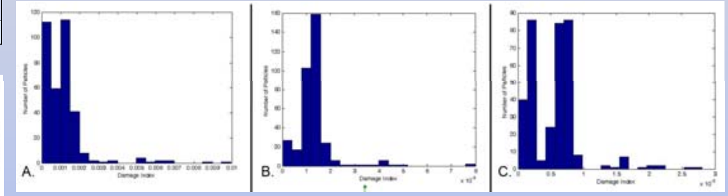

Figure 5: Blood damage indices for the intravascular blood pump for the pump operating conditions, fluid viscosities, and left and right pulmonary arterial pressures as specified in Table II. A) Case I, B) Case II, and C) Case III.

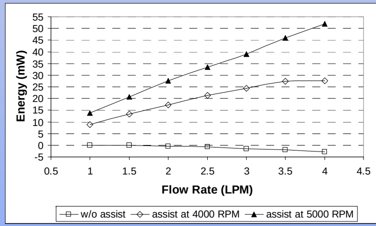

Figure 6: Energy Gain due to Mechanical Assistance of the TCPC with a Blood Pump in the IVC. Mechanical assistance of the IVC pressure enhanced the hydraulic energy within the TCPC as compared to conditions without pump support.

Numerical Methods

CFD Model of Intravascular Pump with Cage

- ~3 million elements; grid quality and convergence study completed
- Blood Properties: Newtonian assumption; fluid viscosity of 3.5 cP (hematocrit of 33%); fluid density of 1050 kg/m^3
- Turbulent flow conditions expected in the pump and TCPC because of the pump
- Standard k-ε turbulence model coupled with scalable wall function to characterize near-wall flow conditions
- Steady flow with constant boundary conditions and velocities in time
- No slip boundary conditions applied to stationary walls (pump housing regions)
- Rotating walls specified for impeller in the counterclockwise direction according to blade orientation; frozen rotor interface linked regions of differing reference frames
- Examined flow range from 1 to 4 L/min, as would be appropriate to support adolescent and adult patients with failing single ventricle physiology
- Outlet boundary conditions, such as the left and right pulmonary arteries (LPA and RPA), defined to have static pressures of 10, 14, 18, 22 and 26 *mmHg*. Vessel walls for the IVC, SVC, and pulmonary arteries modeled as rigid tubes.
- Blood damage analysis calculated the scalar stress of the 3-D flow field. Damage indices determined using the scalar stress level and exposure time.
- Simplified control volume approach determined the energy losses through TCPC configuration with and without the pump. Common approach for estimating the energy loss or gain in the cavopulmonary configuration.

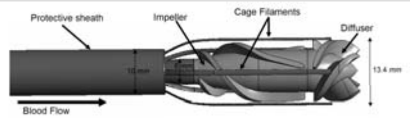

Figure 1: Intravascular Axial Flow Blood Pump for Cavopulmonary Assist. This intravascular cavopulmonary assist device consists of a protective sheath with cage filaments, a rotating shaft and catheter, impeller blades, diffuser region, and inlet and outlet sections

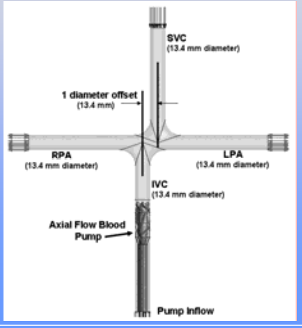

Figure 2:Position of the cavopulmonary assist device in the total cavopulmonary connection (TCPC). The intravascular pump (Model 3) is placed into the inferior vena cava (IVC) for patients with failing single ventricle physiology. It is designed to augment pressure and thus flow into the IVC and subsequently into the left and right pulmonary arteries (LPA and RPA) while supporting the incoming flow from the superior vena cava (SVC).

Conclusions

This study presented a numerical analysis of the interactive fluid dynamics between the cavopulmonary connection and a mechanical blood pump. This blood pump is a percutaneously-inserted, axial flow blood pump in the IVC that is designed to augment pressure in the cavopulmonary circulation for adolescent and adult patients with failing Fontan physiology. It will serve as a bridge-to-transplant, bridge-to-recovery, or bridge-to-surgical reconstruction. A pressure augmentation of as little as 2 to 5 *mmHg* may be sufficient to stabilize and reverse hemodynamic deterioration in Fontan patients. Computational predictions indicate the blood pump would augment pressure acceptably in the idealized TCPC model and result in a hydraulic energy boost or gain for a range of viscosity values, LPA and RPA pressures, flow rates, and pump rotational speeds. These results support the continued design and development of this cavopulmonary assist device, building upon previous numerical work and experimental testing.

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