Performance evaluation of a pediatric viscous impeller pump for Fontan cavopulmonary assist

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Objective: The anatomic and physiologic constraints for pediatric cavopulmonary assist differ markedly from adult Fontan circulations owing to smaller vessel sizes and risk of elevated pulmonary resistance. In this study, hemodynamic and hemolysis performance of a catheter-based viscous impeller pump (VIP) to power the Fontan circulation is assessed at a pediatric scale (~15 kg) and performance range (0-30 mm Hg).

Methods: Computer simulation and mock circulation studies were conducted to assess the hydraulic performance, acute hemodynamic response to different levels VIP support, and the potential for vena caval collapse. Computational fluid dynamics simulations were used to estimate VIP hydraulic performance, shear rates, and potential for hemolysis. Hemolysis was quantified in a mock loop with fresh bovine blood.

Results: A VIP augmented 4-way total cavopulmonary connection flow at pediatric scales and restored systemic pressures and flows to biventricular values, without causing flow obstruction or suction. VIP generated flows up to 4.1 L/min and pressure heads of up to 38 mm Hg at 11,000 rpm. Maximal shear rate was 160 Pa, predicting low hemolysis risk. Observed hemolysis was low with plasma free hemoglobin of 11.4 mg $\cdot$ dL^{-1} $\cdot$ h^{-1}.

Conclusions: A VIP will augment Fontan cavopulmonary flow in the proper pressure and flow ranges, with low hemolysis risk under more stringent pediatric scale and physiology compared with adult scale. This technology may be developed to simultaneously reduce systemic venous pressure and improve cardiac output after stage 2 or 3 Fontan repair. It may serve to compress surgical staging, lessening the pathophysiologic burden of repair. (J Thorac Cardiovasc Surg 2013;145:249-57)

Despite advances, palliative repair of functional single ventricle remains an enigmatic challenge.[1] Intractable morbidities in the interim-staged palliative approach include severe hypoxemia, ventricular hypertrophy, sudden hemodynamic instability, and neurocognitive dysfunction. Late sequelae have been linked to prior repair in which a shunt source of pulmonary blood flow was used.[2] Furthermore, recent studies question the benefit of interim staging with respect to late Fontan ventricular function and functional status.[3] It would appear that a physiologic cost incurred early in repair is reflected in suboptimal late functional status.

In the setting of preserved systolic ventricular function, modest augmentation of cavopulmonary blood flow would shift the univentricular Fontan circulation toward a ''biventricular Fontan'': single-ventricle anatomy with the physiologic attributes of more stable 2-ventricle physiology.[4] Development of a safe and reliable means to apply cavopulmonary assist in younger patients as a bridge to Fontan may permit compression of surgical staging of Fontan conversion.[5] It may ultimately obviate dependence on use of a systemic arterial shunt source of pulmonary blood flow and resolve the associated hallmarks of hypoxemia, ventricular volume overload, unstable parallel circulations, and impaired diastolic coronary perfusion. A clinical device to accomplish this does not currently exist.

To address these problems, we are developing an expandable viscous impeller pump (VIP) to provide temporary cavopulmonary support.[6] The VIP is a catheter-based, biconical, vaned rotary pump that can be inserted percutaneously using a modified Seldinger technique and advanced to the cavopulmonary junction via either the superior or inferior vena cava and expanded (Figure 1). The biconical design of the VIP allows for simultaneous pumping of blood from both the superior and inferior venae cavae to each of the pulmonary arteries using only a single pump head. The VIP is designed to fit within the cavopulmonary junction of a pediatric patient and is stabilized inside the cavopulmonary junction by an expandable nitinol cage.

In pediatric patients, the anatomic and physiologic constraints for cavopulmonary assist are more stringent than for adults with failing Fontan circulations. Chief among these are smaller vessel size and risk of elevated pulmonary vascular resistance. This study was performed to assess

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Abbreviations and Acronyms
ASTM = American Society of Testing and Materials
CFD = computational fluid dynamics
H-Q = pump hydraulic performance
TCPC = total cavopulmonary connection
VIP = viscous impeller pump

performance feasibility of a VIP within the anatomic and physiologic limitations of pediatric Fontan using computer simulation, a mock circulatory system, and computational fluid dynamic (CFD) methods.

METHODS

Computer Simulation Study

A previously reported computer simulation model of the pediatric biventricular cardiovascular system[7] was modified to simulate single-ventricle Fontan physiology of a 4-year-old (~15 kg) child. The biventricular computer simulation model has been used in previous studies to develop and test physiologic control algorithms for mechanical circulatory support devices.[8-10] In brief, the computer model subdivides the Fontan circulatory system into 2 heart valves and 8 blocks, which include common atrium, single ventricle, pulmonary and systemic circulations, vena cava, aorta, and coronary circulation. The volume of blood in each block is described by a differential equation as a function of volume (V), pressure (P), compliance (C), and resistance (R), which is an expression for the macrosopic material balance for the block given by:

$$\frac{dV_n}{dt} = F_n^{in} - F_n^{out}, \frac{dV_n}{dt} = \frac{V_{n-1}}{C_{n-1}R_{n-1}} - \frac{V_n}{C_n}\left(\frac{1}{R_{n-1}} + \frac{1}{R_n}\right) + \frac{V_{n+1}}{C_{n+1}R_n}.$$

where dV_n/dt is the rate of change of volume in block n, F_{in} is the blood flow rate into the block, and F_{out} is the blood flow rate out of the block.

The heart rate, resistances, and compliances were modified to reproduce hemodynamic pressure and flow waveforms of the univentricular Fontan physiology of a 4-year-old child based on literature[11-13] and clinical guidance. A model of the VIP was integrated at the cavopulmonary junction. Simulations were conducted to predict acute hemodynamic responses from 0 to 3.5 L/min of VIP support in 0.25-L/min increments. Ventricular, aortic, and cavopulmonary pressures, aortic, coronary, and cavopulmonary flows, and ventricular volume and external work were calculated. These parameters were compared with normal biventricular physiologic values.

Mock Circulation Studies

Acute hemodynamic performance. A mock circulation system consisting of a silicone ventricle, aorta, systemic and pulmonic resistances and compliances, and a cavopulmonary junction was used to simulate the univentricular Fontan circulation (Figure 2, *A*). The cavopulmonary junction is rigid with 11-mm diameter superior and inferior venae cavae and 9-mm diameter pulmonary arteries that are connected to flexible silicone tubing. The prototype pediatric VIP measures 9.75 mm in height and 9.5 mm in diameter (expanded). Ventricular pressure, heart rate, systemic and pulmonary resistances, and compliances were adjusted to reproduce hemodynamic waveforms of univentricular Fontan physiology of a 4-year-old child. Baseline hemodynamic pressure and flow data were collected for the univentricular Fontan circulation (no VIP support). The VIP was introduced at the cavopulmonary junction and data were collected at VIP rotational speeds of 3000 to 11,000 rpm. The venae cavae were partially clamped (60%) to test for risk of vena caval collapse (negative vena caval pressure) with the VIP operating at its maximum operational speed of 11,000 rpm. The potential of the VIP to impede Fontan cavopulmonary flow during pump failure was studied by stopping VIP rotation while leaving the fully deployed device in place in the midst of the cavopulmonary junction. The hemodynamic effect of off-center alignment of the VIP along the axis of the venae cavae in the cavopulmonary junction was studied by placing the VIP at 20%, 40%, 60%, 80%, and 100% offset conditions along the axis of the inferior vena cava. A 20% offset implies that the VIP was placed 20% of the radius of the pulmonary artery away from the optimal location in the total cavopulmonary connection (TCPC) along the axis of the inferior vena cava.

Hydraulic performance. A mock circulation consisting of a cavopulmonary junction with VIP and a resistor was used to characterize hydraulic performance of the VIP. The VIP was operated at 3000 to 11,000 rpm and against 5 different resistances at each pump speed. Steady state pressure head and flow rates generated by the VIP were recorded for each operational condition and plotted (H-Q curve) to characterize hydraulic performance.

Data collection and analysis. Hemodynamic data were collected using a clinically approved good laboratory practices (GLP)-compliant data acquisition system.[14,15] All transducers were precalibrated and postcalibrated against known standards to ensure measurement accuracy. In hemodynamic studies, pressure and flow waveforms were used to calculate heart rate, stroke volume, cardiac output, mean aortic pressure, cavopulmonary pressures, left atrial pressure, and aortic and cavopulmonary flows on a beat-to-beat basis by using the HEART program[16] developed in Matlab (MathWorks, Natick, Mass) and averaged to obtain a single mean value. In hydraulic performance characterization studies, pressure and flow waveforms were used to calculate average pressure head across the VIP and average flow rates.

CFD Study

Fluent (ANSYS Inc, Canonsburg, Pa) was used to model and estimate VIP shear stress as a predictor of hemolysis. The laminar solver was applied for no VIP and stationary VIP conditions. The rotating VIP cases were solved using the transient realizable k-ε model. Blood viscosity of 3.5 cP and a density of 1060 kg/m^3 were assumed. The grid was generated using Solid Edge to create the solid model and Gambit (preprocessor for Fluent) to generate the mesh (2 million tetrahedral elements). Motion was modeled using the sliding mesh method. CFD analyses were performed for no vena caval offset and 20% vena caval offset conditions. The flow and the pressure head developed by the VIP were calculated to plot the H-Q curve for the device. The maximum scalar stress was calculated as an indicator of blood damage.[17]

Hemolysis Study

Fresh whole bovine blood (<48 hours) was used in an in vitro blood loop to quantify VIP hemolysis (Figure 2, *B*). Blood was heparinized to an activated clotting time greater than 300 seconds, and hematocrit value was adjusted to 28% ± 2% with plasma buffer solution. VIP was operated at 9000 rpm against a pressure head of 15 ± 2 mm Hg resulting in a flow rate of 2.2 ± 0.3 L/min. Total blood volume in the in vitro loop was 1 L. In vitro blood damage was assessed by measuring plasma free hemoglobin, hematocrit, red blood cell, white blood cell, and platelet counts before device operation (baseline) and every hour thereafter for 6 hours. The plasma free hemoglobin was quantified using a Plasma Photometer (HemoCue, Mission Viejo, Calif). Platelet count and hematocrit were measured using CDC Mascot (CDC Technologies, Oxford, Conn). Normalized index of hemolysis was calculated using American Society of Testing and Materials (ASTM) standards. The hemolysis study parameters and protocols comply with Food and Drug Administration guidelines for 510(k) submission and ASTM standards.[18,19]

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