Performance of a 3-Bladed Propeller Pump to Provide Cavopulmonary Assist in the Failing Fontan Circulation

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Purpose. **We hypothesized that a propeller pump design would function optimally to provide cavopulmonary assist in a univentricular Fontan circulation.**

Description. **The hydraulic and hemolysis performance of a rigid three-bladed propeller prototype (similar to a folding propeller design) was characterized. Pressure and flow measurements were taken for flow rates of 0.5 to 3 liters per minute (LPM) for 5,000 to 7,000 revolutions per minute (RPM) using a blood analog fluid. Hemolysis testing was performed using fresh bovine blood for 2 LPM at 6,000 RPM for a 6-hour duration.**

Evaluation. **The prototype performed well over the design operating range by producing a pressure rise of 5 to 50 mm Hg. Plasma free hemoglobin concentration remained less than 15 mg/dL. The normalized index of hemolysis peaked during the first hour, and then remained less than 10 mg/dL thereafter.**

Conclusions. **A propeller pump has the pressure-flow characteristics and minimal risk of hemolysis and venous pathway obstruction which make it ideal for temporary cavopulmonary assist. This type of device has the potential to provide a new therapeutic option for patients with failing univentricular Fontan physiology as a bridge-to-recovery or transplantation.**

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Patients with a univentricular Fontan circulation are at high risk of circulatory insufficiency not only at the time of repair, but also as they age. This is presumably due to the combined sequelae of elevated systemic venous pressure, reduced pre-load to the single ventricle, and increased afterload. A blood pump specifically designed to augment cavopulmonary flow would address these problems and improve circulatory status by producing conditions more similar to the normal two-ventricle circulation [1, 2]. This is supported by the clinical improvement observed in patients who undergo Fontan conversion from atriopulmonary to total cavopulmonary connections [3]. Hydraulic efficiency in their cavopulmonary circulation is improved by a seemingly trivial, yet highly significant, 2 to 5 mm Hg, which reduces systemic venous pressure, and improves transpulmonary flow and cardiac output.

Technology

Folding propellers have relatively flat pressure flow characteristics that can ideally provide the modest pressure boost and high-volume flow necessary to gently augment cavopulmonary flow. We have previously demonstrated that a relatively simple two-bladed propeller will function within the desired pressure and flow range to provide this type of support [4]. We now present the hydraulic and hemolysis performance of a more highly advanced (nonfolding) three-bladed prototype.

Technique

Prototype

Pump scale and ideal operating range were specified to provide unidirectional cavopulmonary assist in adults with univentricular Fontan circulations (Table 1). Computational fluid dynamics software (ANSYS Inc, Canonsburg, PA) was used to numerically optimize blade hydraulic performance and minimize flow irregularities

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Table 1. Design Specifications for the Propeller Pump

Specification	Adult
Flow (LPM)	0.5 to 4
Pressure rise (mm Hg)	5 to 20
Rotational speed (RPM)	3 to 9,000
Design flow (LPM)	1.5
Vessel diameter (mm)	30

LPM = liters per minute; RPM = revolutions per minute.

and shear stress. From this, computer-aided design drawings (Solidworks Inc, Concord, MA) were used to manufacture a stereolithography prototype (Accura 25 resin [Aircom Manufacturing Inc, Indianapolis, IN]). Tip-to-tip diameter is 20 mm with maximal blade width of 6 mm and hub diameter of 6 mm (Fig 1).

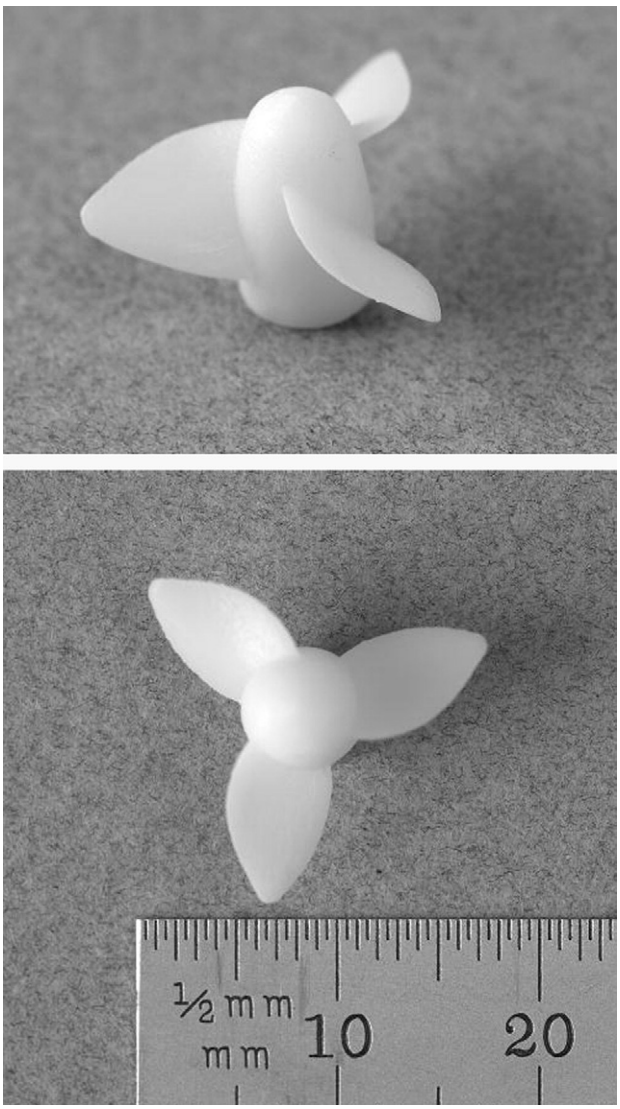

Fig 1. (Top) Plastic propeller prototype. (Bottom) Shows size.

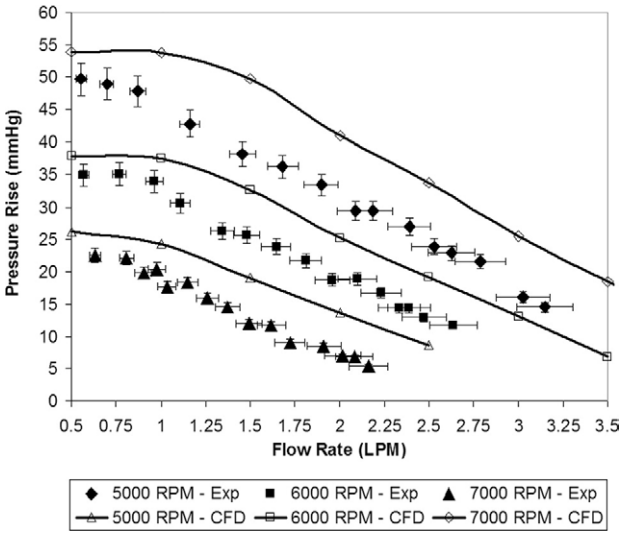

Fig 2. Hydraulic performance. (Exp = experiment number; CFD = computational predictions; LPM = liters per minute.)

Clinical Experience

Hydraulic Testing

The prototype was mounted within a pipe conduit (30-mm internal diameter) of a hydraulic flow loop for pressure-flow performance measurement. A blood analog fluid (water/glycerin, 60/40; viscosity, 3.34 ± 0.152 cP; specific gravity, 1.08 ± 0.002) was used to match the properties of blood. Flow rates were varied by increasing and decreasing resistance in the loop. The pressure differential was determined using a diaphragm pressure transducer. Pressure rise and flow rate were simultaneously measured under steady-flow conditions.

Hemolysis Evaluation

Blood bag studies (n = 2) were performed using the same hydraulic flow loop in accordance with American Society

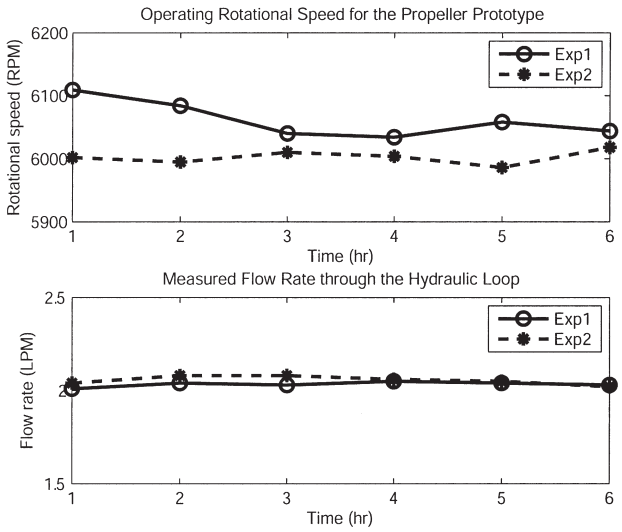

Fig 3. Rotational speed, flow rate, and temperature. (Exp = experiment number; LPM = liters per minute.)

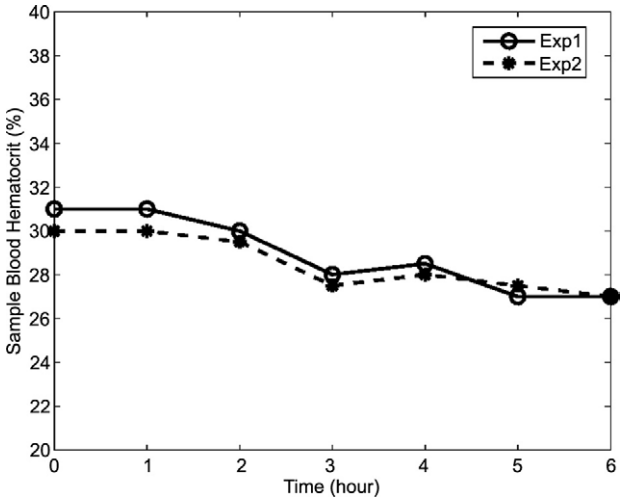

Fig 4. Hematocrit during blood bag experiments. (Exp = experiment number.)

for Testing and Materials standards F1841-97 (Standard Practice for Assessment of Hemolysis in Continuous Flow Blood Pumps), F1830-97, and F756-00 under guidelines from International Workshops on Rotary Blood Pumps in 1988 and 1991 [5]. Fresh bovine blood was collected in standard 500 mL citrate phosphate dextrose adenine blood bags and stored at 4C during transport. Blood was filtered with a 150 micron filter. Sodium heparin 500 units and gentamicin 50 mg were added to the circuit, and temperature was maintained at 37°C.

After baseline samples were collected, pump rotation was initiated and a flow rate of 2 LPM and rotational speed of 6,000 RPM was maintained for 6 hours. Samples were collected hourly. Fresh donor blood was reintroduced into the loop to replace the minimal volume collected at each time point. For each interval, 2 cc was used to measure hematocrit. In addition, 2 cc was placed in a tube containing ethylenediaminetetraacetic acid and centrifuged for 20 minutes at 4,000 RPM. Plasma was transferred into a 1.5 mL polystyrene cuvette for spectrophotometric analysis (Genesys 5 [Thermo Scientific, Waltham, MA]). Optical density was determined at three different wavelengths (ie, 576.5 nm, 596 nm, and 560 nm). Plasma free hemoglobin was calculated based on the weighted difference in absorbance. The normalized index of hemolysis was calculated.

Hydraulic Performance Results

Pressure rises were observed in the desired range of 5 to 50 mm Hg and flow rates of 0.5 to 3.25 LPM at rotational speeds of 5,000 to 7,000 RPM (Fig 2). Compared with numerical estimates, observed hydraulic performance was approximately 20% less than predicted, but closely correlated, especially at lower flow rates. This is explained by a difference in conditions between the numerical model and the experimental configuration. The blade tip clearance was 5 mm as tested, as opposed to 0.2 mm in the numerical model. Although the larger experimental gap clearance contributed to hydraulic energy loss, it more accurately reflects conditions that would be encountered in the clinical setting.

Hemolysis Evaluation Results

Rotational speed, flow rate, and hydraulic loop temperature for the duration of the experiments are shown in Figure 3. Hematocrit remained between 27% and 30%, with a slight decline in the 6-hour period (Fig 4). Plasma free hemoglobin concentration rapidly increased in the first hour and then steadily, but much more slowly, increased in hours from 1 to 6 (Fig 5). Similarly, normalized index of hemolysis values spiked in the first hour and then remained consistently less than 10 mg/dL during hours 1 to 6. The rapid increase in plasma-free hemoglobin and normalized index of hemolysis values during the first hour are attributed to lysis of red blood cells due to rapid pump start-up secondary to instrumental limitations. Free hemoglobin levels less than 50 mg/dL are acceptable for device-related hemolysis, and levels less than 10 mg/dL are excellent.

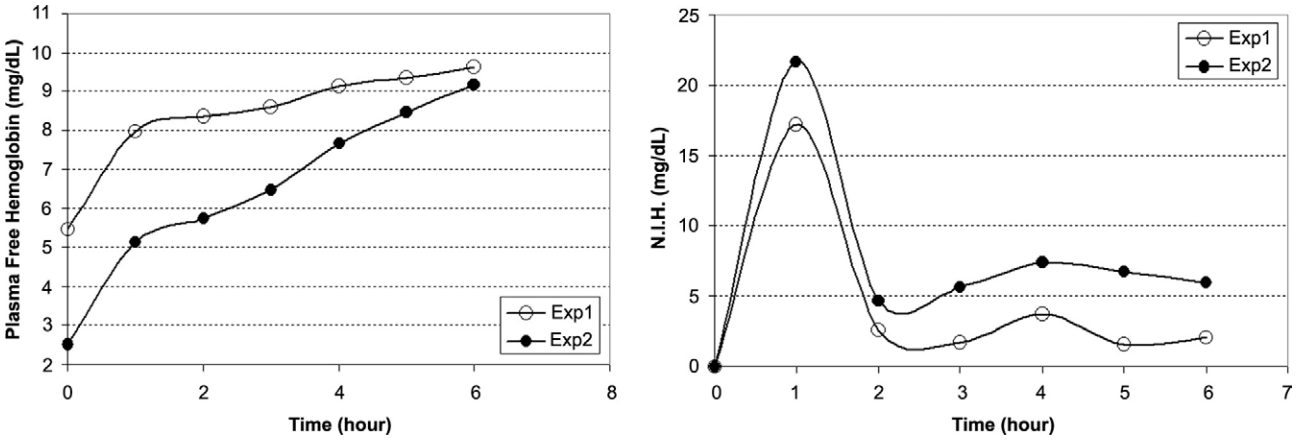

Fig 5. Plasma free hemoglobin (left) and normalized index of hemolysis (NIH) (right) during blood bag experiments. (Exp = experiment number.)

Comment

Clinical management of "Fontan failure" is challenging. Predictable morbidities after Fontan include low cardiac output, peripheral edema, ascites and effusions, protein-losing enteropathy, and diminished exercise tolerance, many of which are direct consequences of elevated venous pressure in the inferior vena caval distribution. Medical therapy can only address secondary sequelae, and cardiac transplantation is an end-stage treatment option if patients can be medically stabilized and survive the waiting period for a donor organ. Intermediate therapeutic options for these patients are limited.

Although patients with failing Fontan physiology exhibit features typical of congestive heart failure (decreased tissue and organ perfusion, increased tissue and organ water), the causative factor is not necessarily a reflection of intrinsic myocardial dysfunction. Doppler myocardial echocardiographic studies in Fontan patients (with normal systolic function) demonstrate that diastolic dysfunction is a result of chronically reduced filling rather than primary myocardial dysfunction [6]. Stated otherwise, it can be argued that other segments of the circulation are actually failing the Fontan heart. The position of the "failing Fontan" heart on the Starling curve is a critical distinction, because cavopulmonary assist is based on the tenet that a modest (2 to 5 mm Hg) increase in ventricular filling will improve myocardial performance and cardiac output. Cavopulmonary assist can be applied unidirectionally in the inferior vena cava (IVC) alone for adult patients with failing Fontan physiology, because the majority of their morbidity arises from the IVC territory and IVC flow accounts for the majority of systemic venous return. In theory, it could also be applied as bidirectional support (both superior vena cava and IVC territories), including the potential for combined-stage Fontan repair in younger patients in whom superior vena cava pressure and flow are more critical [2].

Mechanical Circulatory Support in the Univentricular Fontan Circulation

Cavopulmonary assist is conceptually unique; a device temporarily supports the circulation in a location where no ventricle will recover to assume its function. For a pump to safely augment cavopulmonary blood flow, unique anatomic, physiologic, and bioengineering issues must be considered. Relative to the systemic circulation, blood pressure within the cavopulmonary connection of a univentricular Fontan circulation is very low. Furthermore, a pressure boost of only 2 to 5 mm Hg may be all that is necessary (or ideal) to augment cavopulmonary flow and significantly improve hemodynamic status. The upstream source of inflow is steady-flow systemic venous return; there is no volume reservoir for the pump inlet to draw from. Thus, there is higher than usual risk of vessel collapse and cavitation due to pump suction. In addition, no natural occlusive mechanism (valve) is present within a cavopulmonary connection to prevent recirculation around the pump body. Finally, it is imperative that the venous pathways remain unobstructed during pump deployment and after withdrawal. These challenges are significant, and they are new to the circulatory support field.

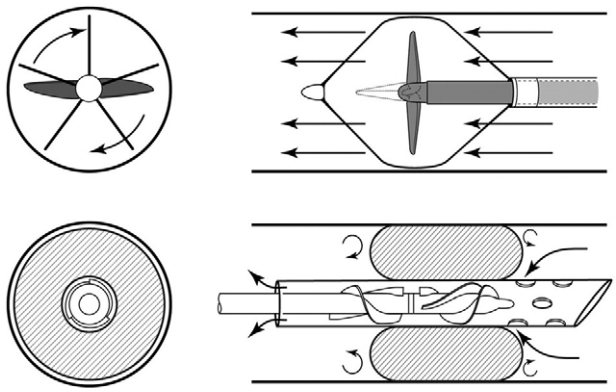

Fig 6. Propeller pump versus microaxial flow pump. (Top) A folding propeller pump occupies minimal vessel cross-sectional area and is not obstructive. Flow is noncompressive across the entire vessel lumen. The vessel wall serves as the "housing" for the pump. (Bottom) Micro-axial pumps require an occlusive mechanism to prevent recirculation around the pump (balloon illustrated). Combined with the pump, this is obstructive to flow in the event of device failure. Flow rate is inherently higher in the inflow and outflow regions to deliver equivalent volume. There is significant potential for flow stasis.

Micro-axial flow pumps are highly efficient, can be placed percutaneously, and have been clinically applied for systemic support [7]. Although we have successfully used micro-axial flow pumps to provide cavopulmonary flow in a univentricular Fontan circulation [1], they have limitations in this circulatory support role in that they may require surgical placement and removal, they have a relatively high preload and afterload dependence, they have high rotational speed, they require a physical barrier to recirculation, and they are obstructive to flow (Fig 6) [8].

A Folding Propeller Pump

A percutaneous, expandable, folding propeller pump with a protective cage may represent an ideal solution. It could be relatively easily applied in the catheterization lab or intensive care unit with femoral or jugular venous insertion and heparin anticoagulation, and managed similar to an intra-aortic balloon pump. As a bridge-to-recovery, it would reduce systemic venous pressure (2 to 5 mm Hg) and improve ventricular filling (2 to 5 mm Hg), which would, in turn, reduce capillary and interstitial hydrostatic pressure and improve end-organ perfusion. As a bridge-to-transplant, it would increase the likelihood of surviving the wait for a donor organ and improve physiologic status at the time transplant occurs.

Folding propellers are used in marine applications; the blades fold flat to a low profile to minimize drag under sail. A folding propeller blood pump has, in fact, been described for systemic circulatory support [9]. As applied in the descending thoracic aorta, however, this device has limitations: (1) it augments systemic arterial pressure by only 20 mm Hg, which is marginal for systemic support;

(2) it reduces upstream pressure, thereby reducing cerebral and coronary perfusion pressure. For cavopulmonary assist, a pressure gradient in the 20 mm Hg range (or less) is ideal. Furthermore, a reduction in upstream systemic venous pressure is desirable and has no deleterious consequences, with the exception of negative pressure.

Folding propellers may be less efficient from a hydraulic standpoint due to limited blade width and surface area. A high degree of fluid slip is desirable; however, because it reduces preload and afterload dependence, thereby reducing risk of excessively negative upstream pressure (ie, suction, vein collapse, cavitation) or excessively positive downstream pressure (ie, perfusion lung injury). It also eliminates the critical problem of venous pathway obstruction. Furthermore, an artificial barrier to prevent recirculation is not required; the propeller blades provide a functional rather than physical barrier to backflow, which spans the vessel lumen.

This study has several limitations. The prototype was a nonfolding rather than folding blade design. It was, however, otherwise similar in dimension to a folding blade design (ie, narrow blade width, relatively wide hub). Pump performance was not characterized in the presence of the expandable protective cage, which may significantly influence hydraulic performance. Interaction of the pump and protective cage will be evaluated in subsequent studies. Future direction will involve optimization of blade and hub geometry, development of protective cage, flow-field visualization and interaction with the cage, and in vivo testing of a folding prototype. Given the low-pressure environment in which this support will be provided, risk of thrombogenicity must be carefully considered.

Disclosures and Freedom of Investigation

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