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A novel, low cost, disposable, pediatric pulsatile rotary ventricular pump (PRVP) for cardiac surgery that provides a physiological flow pattern

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Abstract

Research is underway to develop a novel, low cost, disposable pediatric pulsatile rotary ventricular pump (PRVP) for cardiac surgery that provides a physiological flow pattern. This is believed to offer reduced morbidity and risk exposure within this population (1,2). The PRVP will have a durable design suitable for use in short- to mid-length prolonged support after surgery without changing pumps. The design is based on proprietary MC3 technology which provides variable pumping volume per stroke, thereby allowing the pump to respond to hemodynamic status changes of the patient. The novel pump design also possesses safety advantages that prevent retrograde flow, and maintain safe circuit pressures upon occlusion of the inlet and outlet tubing. The design is ideal for simple, safe and natural flow support.

Computational methods have been developed that predict output for pump chambers of varying geometry. A scaled chamber and pump head (diameter=4 inches) were prototyped to demonstrate target performance for pediatrics (2 L/min at 100 rpm). A novel means of creating a pulsatile flow and pressure output at constant RPM was developed and demonstrated to create significant surplus hydraulic energy (greater than 10%) in a simplified mock patient circuit.

Keywords

pediatric pump; pulsatile; blood pump; cardiac surgery

Introduction

Over the past decade, mortality rates associated with pediatric open heart surgery procedures have been significantly reduced (3,4), yet morbidity remains a significant clinical problem with patients suffering cerebral, myocardial, or renal dysfunction following cardiopulmonary bypass (CPB). Many factors associated with the extracorporeal circuit technology have been associated with these complications. The un-physiologic, non-pulsatile flow produced by a standard heart-lung machine has been a concern during the operation of cardiopulmonary bypass. Undar and associates have recently published a significant series of papers documenting the benefits of maintaining a physiologic flow in pediatric patients (5-9). A recent comparative study in pediatric open heart surgery patients concluded that pulsatile perfusion improved patient outcomes in preserving significantly better cardiac, renal, and pulmonary function in the early postoperative period compared to non-pulsatile perfusion (10).

Roller pumps, first used in perfusion studies in 1935 (11), are still relied on in 98% of centers performing pediatric CPB today (12). Risks associated with their use are well documented and include risks related to: occlusion, air embolism, generation of either excessive outlet or suction pressure, and raceway tubing failure. Finally, the waveform of the output pulse from a roller pump is considered far from physiologic and can obscure the benefits of pulsatile flow.

Hemodilution is a further concern in pediatric bypass patients. A typical infant can reach a dilution factor of 2:1 to 3:1, contributing visibly to systemic edema. Attempts have been made to reduce the volume of the ECC circuit, yet edema related to these systems remains a concern.

One post operative complication is low cardiac output syndrome (LCOS) that affects an estimated 25% of pediatric patients approximately 6 -18 hours post surgery. Inotropic intervention with Milrinone has been shown to reduce the risk of LCOS by 55% in a select group of patients, while leaving others more susceptible to morbidities related to LCOS (13). There are limited options available for post surgical support in pediatric patients related to size limitations and flow requirements with current devices.

A low cost, inherently safe pump could provide a physiologic pulse output, operate with a low circuit volume, and support the circulation to a recovering heart during the first 24 hours post surgery when the risk of LCOS is high. The pediatric pulsatile rotary ventricular pump, (PRVP) is a scaled embodiment of previously described MC3 pump technology designed for continuous flow cardio-respiratory support. The pump (Figure 1) consists of a collapsible conduit (A) called the pump chamber, wrapped under tension around freely rotating rollers (B) mounted on a simple, three roller pump head (C). The benefits of this design include startling principle operation, pressure limited output, and suction limited input and an inability to pump air or drain a venous reservoir. Pump operation is intuitive like a roller pump, with inherent safety features that are beyond those of a centrifugal pump. These features are described in detail in the literature (14-16).

The “energy equivalent pressure” (EEP) is defined by Shepard (17) to quantify pulsatile pressure and flow waveforms. EEP is the average energy content of the fluid (energy/ unit volume) expressed in terms of pressure. It is calculated as the area under the hemodynamic power curve divided by the area under the flow curve. The following formula is used for defining EEP, the units are mmHg:

$$EEP (mmHg) = \frac{\int Q \cdot P dt}{\int Q dt}, \text{ where } Q = \text{pump flow (L/min)} \text{ and } P = \text{arterial pressure (mmHg)}$$

During pulsatile perfusion, EEP is always higher than the mean arterial pressure (MAP).(18) The pulsatile flow from the human heart produces an average 10% increase in EEP over MAP. The “surplus hemodynamic energy” (SHE) is calculated by multiplying the difference between EEP and MAP by 1332 and represents the extra energy required to generate pulsatile flow in terms of energy units.(19)

$$SHE (ergs/cm^3) = 1332 \times \left[\frac{\int Q \cdot P dt}{\int Q dt} - MAP \right]$$

The goal for the pediatric PRVP pump is to achieve a flow rate to 2 L/min at < 100 rpm, with a physiologically significant pulsatile output characterized over MAP (greater than 10%). (20).

Materials and Methods

Computational Modeling

A generalized model of the pump chamber was created to predict the effects of changes in design parameters on flow/pressure performance. The physical problem was modeled in a finite-element based software package, ADINA (ADINA R&D, Inc., Watertown, MA). ADINA allowed modeling of both the fluid dynamics and solid mechanics required to capture deformations resulting from fluids-structure interactions (FSI). Stroke volume for the pump was determined by considering the internal chamber volume resulting from deformations predicted by the FSI model under specific conditions of fluid pressure, chamber tension, chamber geometry and material properties. The predicted maximum flow can be approximated as: $Q = \nabla \times n \times r$, where ∇ is the stroke volume (cc), n is the rotation rate of the rotor (rpm), and r is the number of rollers on the rotor, which determines the number of strokes per revolution of the rotor. Initial efforts were focused on modeling an adult-sized pump head (diameter=6.25 inches). The model was validated using a physical model and a blood analogue of 40:60 glycerin to water and predicted the pump output as a function of RPM within 10% error.

Downsize Pump

Initial studies were undertaken to design and test a pump rotor and pump chamber for pediatric bypass application. A prototype pump was constructed with a rotor diameter=4 inches. An RF welded pump chamber (width = 0.7 inch) with a biased inlet section was constructed to fit onto the small pump head. A 3/8 inch inlet tube and a 1/4 inch outlet tube was RF welded to the prototype chamber. The prototype chamber was connected to a Terumo Capiiox-RX 05 hard shell reservoir (Terumo Cardiovascular, Ann Arbor, MI). The reservoir was placed at the height of the pump and filled with tap water maintained at various levels to create desired inlet pressure at the pump. Figure 2 shows an image of the downsized pediatric PRVP.

Pulsatile Pump Chamber for PRVP

The pump chamber was modified to produce a physiologic pulse waveform (Figure 3). The pump head contains three rollers and rotates at constant RPM. A first roller passes over the fill region of the pump chamber, drawing fluid under low pressure from the venous reservoir until a second roller contacts and occludes the chamber isolating the fluid between the rollers. Fluid is forced from the fill region into the delivery region remaining isolated between the rollers. The delivery region is characterized by a tapering cross section which results in pressurization of the advancing fluid. As the lead roller disengages the tubing, an initial pressurized discharge into the extracorporeal circuit (ECC) results, followed by a period of steady reduced flow as the roller passes over the smaller cross section portion of the discharge region. The resulting flow and pressure are pulsatile and periodic with each roller pass.

Figure 4 shows the original chamber (no pressure build region, no delivery region) and the new pulsatile chamber. Roller pumps are known to be naturally pulsatile in their pressure and flow outputs. In order to assess the level of pulsatile augmentation achieved with the new pressure build and delivery regions, both pulsatile and non-pulsatile chambers were constructed to fit onto the 4 inch prototype pump head. Each pump chamber was attached to a pediatric reservoir with 3/8" inlet tubing, and the test circuit was filled with water at room temperature. A screw clamp was placed on the outlet to set the pump outlet pressure to an average of 50 mmHg. The reservoir was filled to ~600 ml to ensure proper filling, and the pump speed was set to achieve a target 1 L/min flow rate.

Mock Loop Test

To assess the feasibility of creating elevated EEP in a patient during extracorporeal circulation, the pulsatile pump chamber was tested in a simplified mock loop intended to simulate patient resistance, and aortic compliance. A simplified mock patient was assembled (Figure 5) and consisted of lengths of 1/2 inch I.D. PVC tubing joined together with a rigid polycarbonate Y connector. One branch of the connector served as an input from the ECC circuit. A second branch of the Y leads to a rigid air-filled tube serving as a compliance chamber. Air volume in the chamber was adjusted to achieve a compliance of 0.1 ml/mmHg to represent the pediatric aorta (21). The third segment of the Y connected to a fluid reservoir through an adjustable resistance clamp to provide adjustment of the mean arterial pressure.

The PRVP was connected to the mock through an extracorporeal loop representative of pediatric bypass circuits (22) and included a Terumo Capiiox RX 05 oxygenator (Terumo Cardiovascular, Ann Arbor, MI) and Medtronic, DLP 10 French arterial cannula (DLP 77010) (Medtronic, Minneapolis, MN) connected with 1/4 inch I.D. PVC tubing.

The system was primed with tap water, de-aired and the pump was operated at average flow rates of 0.5 and 1.0 L/min. Outlet resistance and fluid reservoir height were adjusted to achieve a 40 mmHg MAP. The system was allowed to stabilize at the selected flow rate for 2 minutes prior to collecting data. Pressure and flow values were captured and recorded once every millisecond for 10 seconds at each flow condition. Instrumentation included disposable pressure transducers (Utah Medical, DPT200, Salt Lake City, UT), amplifiers (AMP9991, Vivitro systems, Victoria, Canada), Transonics T110 flowmeter with Pediatric flowprobe 6XL135 (Transonic, Ithaca, NY). Data recording software was proprietary data acquisition software (Heart Beat, Tylman Software, Laguna Niguel, CA). Each 10 second data sample was analyzed for mean arterial pressure (MAP), energy equivalent pressure (EEP), average percentage increase in EEP over MAP, and surplus hydraulic energy (SHE).

Results

Sizing confirmation results

Initial studies were undertaken to design and test a pump rotor and pump chamber under pediatric bypass conditions. Computational efforts were made to determine a pump head diameter and pump chamber geometry (*i.e.*, width, length, thickness) that would produce flow performance suitable for a pediatric application. With a pump rotor diameter=4 inches (only 60% of the original size), a pump chamber thickness of 0.02 inch, and width of 0.7 inch, the pump can readily produce the flow required for pediatric bypass surgery (2 L/min).(22,23).

An RF welded pump chamber (width = 0.7 inch) with a biased inlet section was constructed to fit onto a prototype pump head. A 3/8 inch inlet tube and a 1/4 inch outlet tube were connected to the pump head, and the prototype chamber was tested on the 4 inch diameter pump head. The pump was operated over a range of speeds and inlet pressures and flow rate was recorded. Data is summarized in the Figure 6. The maximum target flow rate of 2 L/min was achieved at 100 rpm, 10 mmHg inlet pressure. The prototype pump chamber with biased inlet section achieves the maximum flow requirement for pediatric cardiac surgeries.

Pulsatile Chamber Results

Figure 7 illustrates a comparison between the non pulse and pulsatile version of the PRVP chamber. A pronounced increase in the pulse pressure including rise time and amplitude with the pulsatile chamber was observed. A similar steep rise in flow rate and pulsatile flow amplitude also occurred. The EEP was calculated to quantify the hydraulic energy content of

the pulsatile waveforms. The EEP of the pulsatile pump chamber (88 mmHg) was observed to be larger than the original pump chamber (52 mmHg).

Mock Loop Test Results

The flow rate and arterial pressure recorded for average flows of 0.5 L/min and 1.0 L/min using the pulsatile pediatric chamber operating in the simplified mock loop is shown in Figure 8. Table 1 summarizes the numerical calculations derived from these recordings and illustrates significant pulsatility is transferred to the mock patient through the extracorporeal circuit components. Percentage increase in EEP over MAP easily meets or exceeds our objective of a greater than 10% increase seen with the natural heart.

Discussion

Roller pumps were first used as blood pumps in 1935. Risks associated with the use of these pumps are well documented and have been partially addressed by the development of centrifugal blood pumps. Due to a margin of added safety, centrifugal pumps are now used in over 50% of adult heart cardiopulmonary bypass procedures. However, these pumps are largely unsuitable for pediatric use and conventional roller pumps continue to be used in over 98% of pediatric bypass procedures.

The MC3 pump technology has been clinically demonstrated to address the limitations of conventional roller pumps and centrifugal pumps in the adult bypass setting. The benefits include inherent protection against over pressure, excessive suction, reservoir drainage, and backflow. Additionally, the MC3 pump technology offers Starling-like flow and is capable of use in a closed loop ventricular assist setting. These features offer unique advantage in a pediatric bypass setting, in which safe operation in a very low volume extracorporeal circuit is critical and post surgical ventricular support needs are high.

Physiologic pulsatile flow has been shown to aid recovery from deep hypothermia, a common surgical technique used in pediatric congenital heart surgery. Creating an adequate pulsatile flow has proven problematic for conventional roller pumps and centrifugal pumps (24). The PRVP addresses the limitations of existing pump designs and provides a low cost, simple means of generating a physiologically significant pulsatile flow. Future efforts will focus on optimizing the pump chamber to deliver physiologic pulsatile flow when coupled with commercially available circuit components connected to an improved pediatric mock loop.

Conclusions

A novel, low cost, disposable pediatric pulsatile rotary ventricular pump has been described that provides inherent safety and normal physiological pulsatile flow patterns. The PRVP pump promises to provide needed safety and performance improvements to pediatric bypass surgery and post surgical ventricular support.

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Figure 1.

The principles of operation of the MC3 pump technology. (A) shows the pump in its free condition and the cross-sectional shape is collapsed and occluded. (B) illustrates the unique sectional shape of the filled tubing wrapped around the rollers of the pump head. (C) simple three roller pump head design illustrating inlet region (left), isolated fluid volume (center), and outlet region (right).

Figure 2.
Downsized PRVP 4 inch diameter pump head.

Figure 3.
a) Schematic of pulsatile pump chamber for PRVP, b) pump chamber region descriptions.

Figure 4.
Original chamber and pulsatile chamber.

Figure 5.
Simplified mock patient loop.

Figure 6.

Measured flow performance of the pump chamber scaled for pediatrics. This data serves to confirm the performance target of 2 L/min at 100 RPM can be met using a 0.7 inch wide chamber on a 4 inch diameter pump head.

Figure 7. PRVP Pressure (left) and Flow (right) vs. non-pulse (non-pulse (gray) PRVP (black). The EEP=88 mmHg for the PRVP, and EEP=52 mmHg for the non-pulse pump chamber.

Figure 8. Flow rate and arterial pressure recorded for average flows of 0.5 L/min and 1.0 L/min using the pulsatile pediatric chamber operating in the simplified mock loop.

Table 1

Flow rate (Average set point)	0.5 L/min	1.0 L/min
MAP	42.26	40.94
EEP	47.20	55.61
% increase in EEP over MAP	11.68	35.83
SHE	6577	19541