Design of a continuous flow centrifugal pediatric ventricular assist device


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ABSTRACT: Thousands of pediatric patients suffering from cardiomyopathy or single ventricular physiologies secondary to debilitating heart defects may benefit from long-term mechanical circulatory support due to the limited number of donor hearts available. This article presents the initial design of a fully implantable centrifugal pediatric ventricular assist device (PVAD) for 2 to 12 year olds. Conventional pump design equations, including a nondimensional scaling approach, enabled performance estimations of smaller scale versions (25 mm and 35 mm impeller diameters) of our adult support VAD. Based on this estimated performance, a computational model of the PVAD with a 35 mm impeller diameter was generated. Employing computational fluid dynamics (CFD) software, the flow paths through the PVAD and overall performance were analyzed for steady state flow conditions. The numerical simulations involved flow rates of 2 to 5 LPM for rotational speeds of 2750 to 3250 RPM and incorporated a k-e fluid turbulence model with a logarithmic wall function to characterize near-wall flow conditions. The CFD results indicated best efficiency points ranging from 25% to 28%, which correlate well with typical values of blood pumps. The results further demonstrated that the pump could deliver 2 to 5 LPM at 70 to 95 mmHg for desired physiologic conditions in resting 2 to 12 year olds. Scalar stress levels remained below 300 Pa, thereby signifying potentially low levels of hemolysis. Several flow regions in the pump exhibited signs of vortices, retrograde flow, and stagnation points, which require optimization and further study. This CFD model represents a reasonable starting point for future model enhancements, leading to prototype manufacturing and experimental validation. (Int J Artif Organs 2003; 26: 1015-31)

KEY WORDS: Blood pumps, Pediatric ventricular assist device, Pediatric circulatory support, Left ventricular assist device (LVAD)

INTRODUCTION

Approximately 1% of the 4 million live births per year in the United States suffer from debilitating congenital heart defects (1). These heart defects include hypoplastic left/right heart syndrome and univentricular failure, which may lead to dilated cardiomyopathy and heart failure (1-4). These defects normally warrant immediate corrective surgery and may ultimately result in cardiac transplantation. Postoperative complications often require mechanical circulatory support until full recovery or a donor heart becomes available. Only a limited number of donor hearts (~400) become available each year, thus intensifying the need for effective, longer-term pediatric circulatory support for bridge to transplant (BTT) or bridge to myocardial recovery (BTR).
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Currently the most common method of mechanical circulatory support for pediatric cardiac failure patients is extracorporeal membrane oxygenation (ECMO) (5-9). Pediatric patients can also be hemodynamically supported by intraaortic balloon pumps (IABPs). While each of these techniques provides a certain degree of success, neither method appears effective for longer-term (>2 weeks) mechanical support as BTT or BTR (5).

Ventricular assist devices (VADs) are a valid option for longer-term circulatory support in pediatric patients suffering from dilated cardiomyopathy and single ventricular physiologies secondary to debilitating congenital defects (3, 5-9). Clinical experience with pediatric circulatory support systems to date has only been for short time periods, days to a couple of weeks at most. These trials included a number of pediatric mechanical circulatory support systems such as the Medos-HIA system, Berlin Heart, Biomedicus pump, Abiomed BVS 5000, Hemopump, ECMO units, and the IABP systems. These pumps and support systems have shown promise in providing adequate circulatory support to pediatric cardiac failure patients (3, 5-9). Many of these systems, however, encompass a large number of instruments, elaborate plumbing, and finite capacity or stroke volume capabilities. These extracorporeal assist devices further require larger quantities of anticoagulants, continuous monitoring, and patient immobility for effective operation. Despite these drawbacks, the assist systems proved successful for short-term support and encourage the belief that longer-term support is possible (3, 5-9). We hope to satisfy the growing need for long-term pediatric circulatory support by developing a fully implantable PVAD. Statistics suggest that 10,000 to 20,000 pediatric patients each year may benefit from a reliable PVAD for BTT or BTR (2, 5, 9).

We have already developed several successful prototypes of continuous flow left ventricular assist devices (LVADs) for long-term use in the adult population. One of these centrifugal prototypes, the CF3-LVAD measured approximately 103 mm in diameter by 37 mm in height and was the world's first magnetically levitated pump (10-12). The CF3 pump was scaled down with a few additional design enhancements to produce the CF4-LVAD (currently in animal testing), the fourth and final prototype to support adult patients. The CF4 continuous flow pump measures approximately 67 mm in diameter by 34 mm in height with a 47 mm impeller (size of a hockey puck) (10-12).

The pump design for each of these VADs sets them apart from currently available devices in that the impeller is suspended entirely by magnetic bearings, not conventional mechanical (pivot or fluid) bearings (13-15). This suspension allows the impeller to avoid any contact with the pump's internal housing. This design also reduces regions of stagnant and high shear flow that normally surround a fluid or mechanical bearing by allowing for larger clearances between the rotor and housing. Table I details design parameters and operating conditions for the CF3 and CF4 pumps. Applying a similar design technique as for the CF3 and CF4 pumps, we developed an implantable VAD for the pediatric population.

This article presents a preliminary design of the pediatric pump, including the exploration of traditional pump design equations and nondimensional (ND) scaling techniques. These equations assisted in estimating design characteristics of smaller scale versions of our CF4-LVAD for the adult population. Additionally, more detailed studies by computational fluid dynamics (CFD) enabled the performance estimation of a full computational pediatric VAD model. In the past, we successfully applied AEA Technology's CFD software to design and optimize the CF3 and CF4-LVAD. Furthermore, CFD has been widely used at institutions all over the world in the design and optimization of numerous blood pumps (16-19). This previous design experience aided in developing and evaluating a computational flow model of a PVAD.

Operating conditions and target age

Dr. Thomas Spray and colleagues at the Children's Hospital of Philadelphia presented the results of a demographic study of the pediatric population at the American Society of Artificial Internal Organs (ASAIO) conference in June of 2001. This study indicated that

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>CF3-LVAD</th>
<th>CF4-LVAD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall diameter</td>
<td>104 mm</td>
<td>67 mm</td>
</tr>
<tr>
<td>Overall height</td>
<td>37 mm</td>
<td>34 mm</td>
</tr>
<tr>
<td>Impeller diameter</td>
<td>61 mm</td>
<td>47 mm</td>
</tr>
<tr>
<td>Number of blades</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Blade height</td>
<td>2.3 mm</td>
<td>1.9 mm</td>
</tr>
<tr>
<td>Design rotor speed</td>
<td>2000 RPM</td>
<td>2500 RPM</td>
</tr>
<tr>
<td>Design flow rate</td>
<td>6 LPM</td>
<td>6 LPM</td>
</tr>
<tr>
<td>Design pressure rise</td>
<td>100 mmHg</td>
<td>100 mmHg</td>
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pediatric patients between 2 and 12 years old would most benefit from the availability of a VAD for long-term use (20). Upon learning of this demographic study and after discussions with pediatric cardiologists at the University of Virginia Medical Center, our design team focused on developing a PVAD for this age range. Table II describes normal hemodynamic conditions for pediatric patients at rest, a reasonable starting point for the first design step (1, 2, 4, 21). The pressure values correspond to averages between systolic and diastolic left ventricular pressures in pediatric patients. Using this data for 2 to 12 year olds, the VAD’s output was expected to range from 2 to 5 LPM at pressures of 73.5 to 81 mmHg for resting conditions (1, 2, 4, 21). The PVAD’s design point was selected to be 3 LPM at approximately 76 mmHg for rotational speeds of 3000 to 5000 RPM.

**Conventional pump design equations**

Karassik et al (22) and Stepanoff (23) put forth a useful approach to designing centrifugal pumps. At lower specific speeds and smaller pump sizes, as is the case here, the conventional design equations must be extrapolated well beyond the range of capacity and impeller sizes upon which they are based. Hence, these equations were tested for accuracy and applicability to smaller capacity pumps. Since we have already developed a VAD for the adult population, these conventional design equations were used to calculate the known head of the CF4 pump. This analysis demonstrated the poor estimating capabilities of the conventional equations over this size and capacity range, particularly values for the hydraulic efficiency and slip coefficient.

Experimental flow measurements from laser particle image velocimetry (PIV) helped to better estimate a slip coefficient and provide a more representative prediction of the hydraulic efficiency (24, 25). This optical technique involved measuring the instantaneous velocity field in a laser illuminated plane inside of the VAD. Since performance results for 6 LPM at 2100 RPM were available, this operating point was used to determine a hydraulic efficiency and compare the results to the predictions of the conventional design equations.

We were particularly interested in the absolute tangential velocity components at the leading edge of the CF4 impeller. The theoretical or ideal value of $c_{a2}$ was estimated from the well-known pump flow velocity triangles as given by:

$$c_{a2} = u_2 - w_{a2}$$  \[1\]

$$c_{a2} = \omega r_2 - \frac{c_{a2}}{\tan (\beta_2)}$$  \[2\]

<table>
<thead>
<tr>
<th>TABLE II - HEMODYNAMIC PARAMETERS FOR HEALTHY PEDIATRIC PATIENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (given)</strong></td>
</tr>
<tr>
<td>1 day</td>
</tr>
<tr>
<td>5 days</td>
</tr>
<tr>
<td>10 days</td>
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<tr>
<td>50 days</td>
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<tr>
<td>100 days</td>
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<tr>
<td>1.37 yr</td>
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<tr>
<td>1.42 yr</td>
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<tr>
<td>2.7 yrs</td>
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<tr>
<td>5 yrs</td>
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<td>9 yrs</td>
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<td>15 yrs</td>
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<tr>
<td>17 yrs</td>
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<tr>
<td>18 yrs</td>
</tr>
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</table>

$W = $ Weight, BSA = Body surface area, HR = Heart rate, CO = Cardiac output, LV = Left ventricle.
where \( u \) signifies the tangential velocity component, \( w \) is the tangential relative velocity component, \( c_{in} \) represents the absolute tangential velocity component, \( r \) is the radius of the impeller, \( 2 \) corresponds to the trailing edge position at the end of each blade (outlet of the impeller), \( c_{m} \) is the meridional or normal absolute velocity component, \( \omega \) symbolizes the angular rotational speed and \( \beta \) denotes the blade angle. The theoretical or ideal value of \( c_{m} \) was calculated to be 4.8 m/s. The PIV measurement results for 2100 RPM and 6 lpm demonstrated an average actual \( c_{m} \) velocity of 3.4 m/s (25). Hence, taking the ratio of actual to ideal, the slip coefficient was determined to equal approximately 0.7. Experimentally measured in a flow loop, operating the pump at 2100 RPM and 6 LPM produced a head of 61 mmHg. For these conditions and a slip coefficient of 0.7, the hydraulic efficiency as estimated by the conventional pump design equations to generate 61 mmHg was approximately 50%. Measuring the electrical torque applied and accounting for mechanical efficiency (due to motor losses and disk friction in the clearance regions) and volumetric efficiency (due to leakage flow in the back clearance region), the hydraulic efficiency for this pump at 2100 RPM and 6 LPM was in fact approximately 50%. The design equations effectively estimated the actual hydraulic efficiency, but only based on measurements of the actual slip factor, leakage flow through the back clearance region, and mechanical efficiency. These measurement values are not usually known during the initial design stages, and the pump performance is very sensitive to all of these parameters.

Accurate prediction of the pump performance depends on accurate estimation of the hydraulic efficiency, flow leakage, and slip coefficient. Because of the inaccuracy introduced by extrapolating data from larger capacity pumps to our miniature blood pump, we considered using a nondimensional scaling technique for the pediatric VAD, based on the adult pumps.

**Nondimensional scaling approach**

In a study of over 40 miniature rotary blood pumps, Smith et al (26) illustrated how to scale test data from one pump impeller to another impeller size for the same pump configuration. Many texts also discuss pump scaling and similarity laws, which support this approach (22, 23, 26). The procedure involves collapsing experimental pump data from one pump into affinity coefficients, such as the following pressure coefficient and flow coefficient, respectively (26):

\[
\psi = C_\psi \frac{\Delta P}{\rho N^2 R^2} \tag{3}
\]

\[
\varphi = C_\varphi \frac{Q}{NR^3} \tag{4}
\]

where \( \psi \) represents the pressure coefficient, \( \varphi \) is the flow coefficient, \( \rho \) denotes the fluid's density in kilograms per cubic meter, \( R \) signifies the impeller's radius in millimeters, \( N \) indicates the rotational speed (RPM), \( Q \) denotes the flow rate in LPM, \( \Delta P \) is the pump’s pressure rise in millimeters of mercury, \( C_\psi \) is a pressure factor equal to 1.2157 x 10^10, and \( C_\varphi \) symbolizes a flow factor equal to 1.5915 x 10^5. Once experimental data have been collapsed into the ND terms, the pressure coefficient is plotted versus the flow coefficient; a polynomial trendline is then fit to the data. This trendline gives a mathematical relationship between the pressure and flow coefficient; for different impeller radii and operating conditions, a reasonable estimation for smaller versions of the pump can then be made. This analysis accounts for the effects of varying pressure rise, fluid density, rotational speed, impeller radius, and flow rate.

To assess the applicability of this approach, experimental performance data for the CF3 pump from a benchtop flow loop using a water / glycerine (60/40) mixture to model blood viscous properties was collapsed and scaled using this ND technique to predict the known measured performance of the CF4 LVAD. Using the CF3 ND relationship between the pressure and flow coefficients, Figure 1 illustrates that the ND approach predicts the performance of the CF4 pump fairly well. The deviation between the ND prediction and experimental measurements was less than 15% due to experimental variance and the inherent linear correlation technique. In contrast to conventional design equations, this ND scaling analysis demonstrated acceptable prediction of pump performance for scaling the CF3 impeller to the CF4 impeller size. Hence, this method was employed to estimate the performance of a PVAD based on scaling the CF4 impeller diameter.

Following the same procedure executed for the CF3 scaling to the CF4, the ND coefficients for the CF4 pump
were calculated from experimental data recorded from flow loop measurements for flows ranging from approximately 0 LPM to 12 LPM for 2000 RPM to 3000 RPM. Figure 2 displays a plot of the pressure coefficient and the flow coefficient yielding the following trendline:

$$\psi = -305.47 \phi^2 + 1.5123 \phi + 0.5152 \quad [5]$$

The $R^2$ value for this polynomial fit is 0.97, which indicates an acceptable correlation. This mathematical relationship enabled the performance estimation of smaller CF4 VADs by varying the impeller diameter.

**Varying the impeller diameter**

Equation 5 was expanded to give pressure values for a specific rotational speed and impeller radius or diameter. In particular, the ND analysis allowed for the performance prediction of two geometrically similar scaled-down CF4 pumps with impeller diameters of 25 mm and 35 mm. The
subsequent sections detail the performance predictions for each impeller size.

25 mm impeller diameter design

Figure 3 illustrates the predicted performance for a 25 mm impeller diameter at rotational speeds of 3500, 3750, and 4000 RPM. The results shown in Figure 3 demonstrate that the 25 mm impeller would be able to deliver adequate blood flow and pressures for newborns and infants. Based on previous design experience, the overall pump dimensions would likely be approximately 50 mm in diameter by 30 mm in height (14-15, 24-28). Pediatric cardiologists at the University of Virginia Medical Center agree that this pump size would be small enough for permanent implantation into the abdominal cavity of a newborn or infant with other components placed external to the body (2). This smaller sized 25 mm impeller pump, however, would require much higher rotational speeds, on the order of 6000 RPM, to achieve the necessary flows and pressures for older pediatric patients. It may be possible to operate the pump at these speeds, but substantially higher rotational speeds increase the risk of blood damage and may pose challenges for the magnetic bearing suspension design. Since the pump must be as compact as possible, the bearings, motor, and corresponding electrical components must also be small enough to produce a pump for implantation. More compact magnetic bearings may not be able to generate enough force for successful suspension of the impeller at these higher rotational speeds (bearing size α flux capacity). In summary, this 25 mm impeller size limits the VAD’s abilities to sufficiently deliver higher flow rates for older pediatric patients.

35 mm impeller diameter

The performance of a 35 mm impeller for 3000, 3250, and 3500 RPM was also predicted using the ND analysis as shown in Figure 3. This figure illustrates that the larger impeller diameter would enable the pump to deliver 2 to 5 LPM at a pressure of 70 to 100 mmHg, depending on the
rotational speed. The 35 mm impeller would work well for patients approximately 2 to 12 years old based on hemodynamic data in Table II. The overall pump dimensions would be approximately 60 mm in diameter by 35 mm in height.

If a pump with a 25 mm impeller can be fully implanted into an infant, then a 35 mm impeller diameter would be compact enough to implant into an older and, likely more than twice as large, pediatric patient (2). Therefore, this impeller diameter appears to be the most promising for implant considerations in older pediatric patients of 2 to 12 years old with reasonable rotational speeds; thus, we selected this impeller diameter to generate a full computational model of the PVAD.

**CFD analysis**

The computational model of the PVAD consists of a flat inlet volute, exit volute, 35 mm in impeller diameter, and clearance regions surrounding the impeller, as illustrated in Figure 4. Specifically, the 35 mm in diameter, scaled CF4, impeller consisted of 4 blades with a blade height of 1.6 mm. The software packages from AEA Technology provided useful programs, such as Bladegen (impeller geometry), Turbogrid (impeller mesh), and Build (volute and clearance geometry and mesh) to create a full computational model of the PVAD. After successful mesh generation with acceptable element aspect ratios and no negative grid volumes, the computational flow model was implemented in the numerical solver, TascFlow (AEA Technology).

CFX-TascFlow utilizes the equations for conservation of mass and momentum in terms of the dependent variables, velocity and pressure. TascFlow employs a process of Reynolds-Averaging to determine the mean flow and fluctuating flow values. It does not directly solve for the fluctuating component, but, rather, expresses this component in terms of its mean values. For incompressible fluids, the Reynolds-Averaging form of conservation of mass equation can be reduced to:

$$\frac{\partial U}{\partial x} = 0$$  \[6\]

where U represents the velocity, x is the spatial component, i corresponds to the universally-accepted Einstein summation convention, and the bar denotes a mean value. Applying the Reynolds-Averaging process for
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incompressible fluids derives the conservation equation describing the mean momentum:

\[
\frac{\partial}{\partial t} \left( \rho \overline{U} \right) + \frac{\partial}{\partial x_i} \left( \rho \overline{U} \overline{U}_i \right) = -\frac{\partial}{\partial x_i} \left( \overline{P} \right) - \frac{\partial}{\partial x_i} \left( \tau_i + \rho \overline{U}_i \overline{U}_i \right) \quad [7]
\]

where \( \rho \) is the fluid density, \( P \) represents the pressure, and \( \tau \) corresponds to the shear stress. The Reynolds stress tensor, \( \rho \overline{U} \overline{U}_i \), results from the averaging procedure due to the nonlinear convection term. This tensor is considered one of the most difficult quantities to determine in turbulence flow modeling. TascFlow relates the Reynolds stresses and turbulent fluctuating terms to the mean flow variables according to:

\[
\rho \overline{U}_i \overline{U}_j = -\mu_l \left( \frac{\partial \overline{U}}{\partial x_i} + \frac{\partial \overline{U}}{\partial x_j} \right) + \frac{2}{3} \rho \overline{U}_k \delta_{ij} \quad [8]
\]

where \( \mu_l \) is the turbulent viscosity, \( \delta_{ij} \) represents the Kronecker delta, and \( k \) signifies the turbulent kinetic energy term. The Reynolds-Averaging viscous stress tensor for an incompressible fluid is as follows:

\[
\overline{\tau}_{ij} = -\mu_l \left( \frac{\partial \overline{U}}{\partial x_i} + \frac{\partial \overline{U}}{\partial x_j} \right) \quad [9]
\]

where \( \mu_l \) signifies the dynamic fluid viscosity. The turbulent viscosity and turbulent kinetic energy term are estimated by selecting a turbulence model.

Turbulence model

Since turbulent flow conditions are present in the cutwater region and exit diffuser of our adult centrifugal VAD models (27, 28) (substantiated by laser flow measurements (27-29)) and likely in the PVAD, we selected a standard turbulence model coupled with a logarithmic wall function to characterize near-wall flow conditions. With Re numbers of \( \sim 10^6 \), turbulent flows are expected in the PVAD; these flow conditions are further evident by increased vorticity and flow separation occurring in the exit diffuser of the PVAD, as shown in the results section.

The \( k-\varepsilon \) turbulence model has been used for several years in designing our adult heart pump prototypes and in the design of numerous other blood pumps (18, 27-28, 30-32). In further support of the \( k-\varepsilon \) model, PIV measurements in the back clearance regions of the CF3 pump resulted in the acquisition of fluid velocity components, which correlated within 15% of CFD results using the \( k-\varepsilon \) model (24, 25). PIV measurements for the impeller and clearance regions of the CF4-LVAD are currently being completed, but are not available for direct comparison to CFD results. Therefore, the CFD analysis of the pediatric VAD applied the \( k-\varepsilon \) turbulence model in each simulation to initiate the design phase, but this choice will be subject to further scrutiny after the CF4 and pediatric prototype flow measurements are completed.

Blood properties

As mentioned, PIV flow measurements are being completed on the CF4 adult VAD to validate the CFD predictions. The fluid being used in the PIV experiments has a viscosity and density that correspond to those properties of blood, and the fluid also has the same index of refraction as the experimental plastic pump. No non-Newtonian fluid has, however, been found that has all of these characteristics and is suitable for PIV measurements. Hence, for validation of the CFD model, the fluid properties used in the PIV experiments are also used in the numerical studies with Newtonian flow characteristics. Once the CFD validation studies are completed, non-Newtonian effects on the flow field will be investigated.

Blood behaves as a Newtonian fluid for conditions of high shear stresses (\( > 0.7 \text{ Pa} \)) and shear rates above 100 s\(^{-1} \) (33, 34). The shear stresses dominating the flow paths in this computational model are large enough that the assumption of Newtonian fluid properties is acceptable to begin the design process. Hence, a constant viscosity value of 0.0035 kg/m/s was used for each CFD simulation, corresponding to a hematocrit of approximately 33%, which is reasonable for PVAD candidates. Additionally, for each simulation, an average constant density fluid was applied with a value of 1,050 kg/m\(^3\) (24, 25, 27, 28, 35).

Blood trauma

The prospect of VADs as long-term support devices in pediatric patients depends on excellent blood compatibility. TascFlow includes the ability to determine the Reynolds and viscous stresses at any nodal location in the computational domain.

Blud...
the computational flow field. This capability allows designers to estimate levels of high shear and possible fluid stagnation (low shear). Under turbulent flow conditions, as expected in the PVAD, Reynolds stresses tend to be much larger than viscous stresses generated during laminar flows. Bludszuweit completed a computational flow study of blood damage in an Aries Isolflow Pump using TascFlow (30). A considerable part of this study involved the development of a scalar stress value, which is based on comparative stress theory of fluids and is analogous to the Mises yield criterion for solid materials. The scalar stress value involves the six components of the stress tensor, including viscous and the dominating Reynolds stresses, and represents the level of shear experienced by the blood. We adopted this approach to account for the three-dimensional shear field and calculated the scalar stress \( \sigma \) according to Bludszuweit's stress formula (30):

$$\sigma = \left( \frac{1}{6} \sum (\sigma_i - \sigma_j)^2 + \sum \sigma^2_{ij} \right)^{\frac{1}{2}}$$ [10]

**CFD results**

Figure 4 shows the full computational model consisting of approximately 400,000 elements and 43 regions. This number of grid elements resulted in convergence times of 72 hours for each individual simulation on a Sun Dual 450 MHz Microsystems Workstation. Previous grid convergence studies aided in the determination of regional grid densities, especially in the impeller region. Additionally, a maximum residual convergence study demonstrated less than 5% difference in bulk performance parameters and velocities at selected grid points for convergence cutoff levels ranging from \(1 \times 10^{-3}\) to \(1 \times 10^{-4}\). For this reason, a maximum residual convergence criterion of \(5 \times 10^{-4}\) was applied for each CFD simulation. Flow through the pump was assumed to be steady, which ensures constant boundary conditions and velocities in time for these simulations. The no-slip boundary condition was applied to the stationary walls so that the fluid velocity values along the boundary would equal zero. A stationary wall boundary was applied to the internal housing regions of the pump; whereas, the impeller or rotor (blades, hub, bearing region) was specified as rotating walls in the counterclockwise direction according to the blade orientation. The frozen rotor interface was applied to link regions of differing reference frames. A uniform inflow mass flow rate and rotational speed were specified for each simulation. Similarly, the outflow pressure was specified to be constant at 20,000 Pascals to establish the outlet boundary condition.

Figure 5 illustrates a cross-sectional slice of the pump with dimensions. The fluid regions of the pump measure 22 mm in height by 54 mm in total diameter. As suggested by the ND analysis, flow rates of 2 to 5 LPM and rotational speeds of 2750 RPM to 3250 RPM were simulated to produce physiologic conditions for pediatric patients at rest. The subsequent sections discuss the results of the CFD analysis for these operating conditions.

**Pressure performance curves**

For each rotational speed, the pressure rise across the pediatric pump was determined for flow rates of 2 to 5 LPM. Figure 6 shows the pressure performance curves for this computational model. Each data point corresponds to a steady state simulation for a given flow rate and rotational speed. The static pressure rise across the pump for a given rotational speed decreased with increasing flow rate as theoretically expected due to flow losses. Additionally, higher rotational speeds generated a larger pressure rise for a given flow, as seen in the results. The pressure performance curves demonstrate the pump's ability to deliver adequate flow with the desired pressure rises of 70 to 95 mmHg at reasonable rotational speeds.

**Fluid efficiency**

The fluid power efficiency also represents an important indicator of performance and was determined for each simulation according to:

$$\eta = \frac{\text{Fluid power output}}{\text{Mechanical power input}} = \frac{\dot{m} \left( P_2 - P_1 \right)}{\rho \left( \frac{M \omega}{\text{Mg}} \right) \omega}$$ [6]

where \(\eta\) is the fluid efficiency, \(\dot{m}\) denotes the mass flow rate, \(\rho\) represents the fluid density, \(P_2\) is the total pressure at the pump's outlet, \(P_1\) represents the total pressure at the inlet, \(M\) is the applied mechanical torque, and \(\omega\) signifies the rotational speed. Figure 7 depicts the efficiency performance curves for the pediatric pump. The best efficiency points (BEPs) for these rotational speeds
and flow rates ranged from 25% to 28% and correlate well with typical efficiencies for blood pumps (36).

ADDITIONAL PERFORMANCE RESULTS

Flow profile

Beyond acquiring the bulk performance parameters, such as efficiency and pressure rise, the flow profile through the pump can be analyzed for each flow and rotational speed. The velocity profile provides information concerning areas of irregular flow patterns. Rather than detailing the results for each operating point, we present the computational results for the pump's design point: a rotational speed of 3000 RPM, a flow of 3 LPM, and a BEP of 27%. Figure 8 demonstrates the relative velocity vectors through a cross-sectional center plane of the pediatric computational model. The velocity speed is proportional to the vector length and shading. The regions highlighted by a box in Figure 8 indicate areas where the velocity vectors show an irregular flow pattern. The fluid velocity in these boxed regions appeared to be very small, which could suggest possible flow stagnation. Figure 9 illustrates a closer view of flow profile in the exit diffuser. The velocity profile indicated that a region of separation may exist in the exit diffuser of the pediatric pump. The region located on the pressure side of the blades was also expanded to examine the slight tendency of retrograde flow toward the pump inlet, as shown in Figure 9.

Figure 10 shows the velocity profile through a center plane of the inlet volute. The dark boxes indicate regions of low fluid velocity and irregular flow patterns, which appear to be symmetric on either side of the inlet volute. Figure 10 demonstrates an enhanced view of this region on one side of the inlet volute and illustrates a possible region of flow separation that may be due to the sudden area expansion. The enhancement of the region also revealed a layer of retrograde flow toward the pump's inlet and a small vortex close to the solid wall boundary. With modifications to the inlet volute design, this irregular flow pattern may be eliminated or greatly reduced.
**Fig. 6** - Static pressure rise for a given rotational speed and flow rate: steady state flow performance results show the pump's ability to deliver 2 to 5 LPM at 70 to 95 mmHg for rotational speeds of 2750 to 3250 RPM.

**Fig. 7** - Fluid efficiency for various rotational speeds and flow rates: The points of highest efficiency for a given rotational speed or best efficiency points range from 25% to 28% for the steady flow operating conditions.

**Scalar stress**

Figure 11 displays the results of this scalar stress analysis along a plane at the blade-tip surface, which intuitively has the highest level of shear. Since the pump is not completely symmetric, the scalar stresses would not be symmetric among the impeller blades, with higher levels of shear rates to be expected near the cutwater region of the pump. For this plane of the pump, the magnitude of stress was found to be approximately 225 Pascals. Blood exposure to scalar stress values less than 250 Pascals for very short time periods should not...
produce deleterious levels of blood trauma (37, 38). According to Forstrom et al (39), the threshold level for blood damage was found to be approximately 4000 Pascals for an exposure time of 0.001 ms. Additionally, other research groups have reported damage threshold levels of 500 Pascals for exposure times of 10 ms and 250 Pascals for 4 minutes (27, 40). Recently, in fact, Paul et al (41) reported threshold levels of 425 Pascals for exposure times of 620 ms for a Couette flow device. While the blade tip region was important to analyze, the clearances raised some concern regarding stress levels because of its narrow thickness. Scalar stresses in the clearance separating the internal housing and the rotor did not exceed 220 Pascals in this region for the design point and did not exceed 300 Pascals for off-design or higher rotational operating speeds.

The magnitude of the stress and the time of exposure to such shear are essential parameters to consider in determining blood damage levels (37, 38). Even though blood may be exposed to a maximum scalar stress of 220 Pascals in the back clearance region, the velocities in the clearance regions average approximately 1 to 2 m/s. Therefore, the fluid only undergoes this shear for a very short amount of time (milliseconds), assuming no unusual flow events to increase the residence time. Nevertheless, if design modifications can be made to reduce the magnitude of the stress level in these regions, then those optimizations should be considered. This situation, however, leads to a trade-off scenario. A wider gap, for example, would reduce pump efficiency (increase
Fig. 9 - Flow profile (m/s): a) Exit diffuser - signs of flow separation b) Pressure side of the blades - slight tendency of retrograde flow and possible vortex.

Fig. 10 - Flow profile through a center plane in the inlet volute (m/s): Possible retrograde flow toward inlet region and vortex.
Design of a continuous flow centrifugal pediatric ventricular assist device

CONCLUSIONS

Currently, in the United States there are only a few options available specifically designed to support pediatric cardiac failure patients suffering from cardiomyopathy and single ventricular physiologies secondary to debilitating heart defects (3). The complex ECMO and IABP mechanical circulatory support systems assist pediatric patients only for a short period of time (3). Miniaturization of our adult LVAD for pediatric use will provide an alternative means for pediatric mechanical circulatory support with potential longer-term benefits.

In designing our PVAD, conventional design equations were first used to estimate the potential performance of the PVAD. These design equations, however, are intended for larger capacity pumps where inertial forces, not viscous effects, dominate the flow field. A nondimensional scaling technique based on existing blood pump designs was then explored and included scaling down of our CF4-LVAD for the adult population to operate as a PVAD. The nondimensional design approach enabled the performance prediction of scaled-down CF4-LVADs (25
mm and 35 mm impeller diameters). The 25 mm impeller performance indicated that this VAD would provide adequate circulatory support for newborns and infants. It would be possible to increase the rotational speed of this impeller to generate larger pressure rises and flow rates, but this would lead to an increased risk of blood damage and larger bearing component sizes. For our target age range, the higher output for resting conditions required by 2 to 12 year olds could be satisfied with a VAD having a 35 mm impeller diameter; thus, a full computational model was created to explore a pediatric pump design based on this impeller diameter.

The computational flow regions of the pediatric VAD measure 22 mm in height by 54 mm in diameter in the current configuration with projected dimensions of 35 mm by 65 mm. The steady state CFD flow simulations demonstrated that the pump could deliver 2 to 5 LPM at a pressure of 70 to 95 mmHg for rotational speeds of 2750 to 3250 RPM, which corresponds well with desired physiologic conditions for 2 to 12 year olds. Scalar stress levels throughout the VAD remained below 300 Pascals, thereby signifying relatively low levels of hemolysis. At the design point, however, the inlet volute, blade regions, and exit volute exhibited signs of possible irregular flow patterns for steady state flow conditions.

This first generation design illustrates the potential of this system to support pediatric patients and represents a reasonable starting point for future model enhancements. The next step will include many different optimization stages. For the immediate future, refinement of the grid is needed to study those regions that demonstrated potential irregular flow patterns, including the impact of Newtonian flow assumptions. While the steady state flow conditions provide a reasonable initial assessment of pump performance, transient simulations may be more physiologically realistic. These simulations would involve initial boundary conditions that reflect the pulsatility of natural blood flow and the periodic beat of the native heart. Additionally, experimental methods, such as PIV measurements and oil streaking, would provide insight into actual velocity values and shear stresses (24, 25, 29, 42). These methods would require that a prototype be built for testing. A prototype will also facilitate performance testing in a mock loop and animal fit trials to ensure ease of implantation into pediatric patients. PIV measurements will also aid in determining which turbulence model would be appropriate to characterize the flow conditions in the pump. Other turbulence models may prove to be more suitable for these viscous dominated flow paths rather than the k-ε model.

This research serves as the foundation from which to begin the design optimization process and to consider other aspects in this circulatory support system. In due time, this pediatric circulatory support system will be a viable option for thousands of pediatric patients.

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