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Design of an Implantable Blood Pump for Mechanical Circulatory Support in Pediatric Patients

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1 Background

While the use of pulsatile- and continuous-flow ventricular assist devices (VADs) has become widely accepted as an acceptable treatment for end-stage heart failure in adults over the last three decades, the technology development for pediatric-specific patients is lagging behind that of adult devices. Only one pulsatile-flow VAD has been approved for use in pediatric patients in the U.S., just five years ago [1]. One continuous-flow device was approved specific to this population under Humanitarian Device Exemption (HDE), but is not in clinical use today [2]. As continuous-flow rotary blood pumps (RBPs) have become commonplace for mechanical circulatory support (MCS) in adults due to smaller size and greater reliability, significant resources have gone into the development of RBPs for pediatric use [3]. Further, RBPs designed for adult MCS have been used off-label in pediatric patients [4]. Development of an implantable device specific to a pediatric population includes challenges of anatomic placement and fixation.

We have developed a RBP for adult MCS specific to right heart failure using computational fluid dynamics (CFD) and flow visualization [5]. The miniaturized device includes a rotating impeller and a vaned-diffuser in a 7 mm axial hydraulic diameter. As seen in Figure 1, the hydrodynamic characteristics suitable for a right-VAD (RVAD) may also be suitable for pediatric patients. Currently, the only approved device is placed extracorporeal due to size constraints in the intended population [1]. This report shows results of computational simulations for anatomic fit and fluid flow studies of our device geometry in pediatric patients.

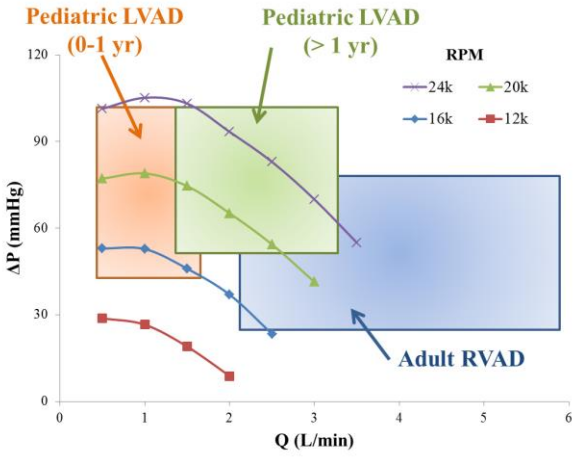

Fig. 1. Characteristic curves for a single device platform that may be able to serve multiple clinical product needs showing hydraulic performance data for differential pressure (ΔP) against flow rate (Q) for multiple rotor speeds (12000-24000 RPM) as measured in vitro.

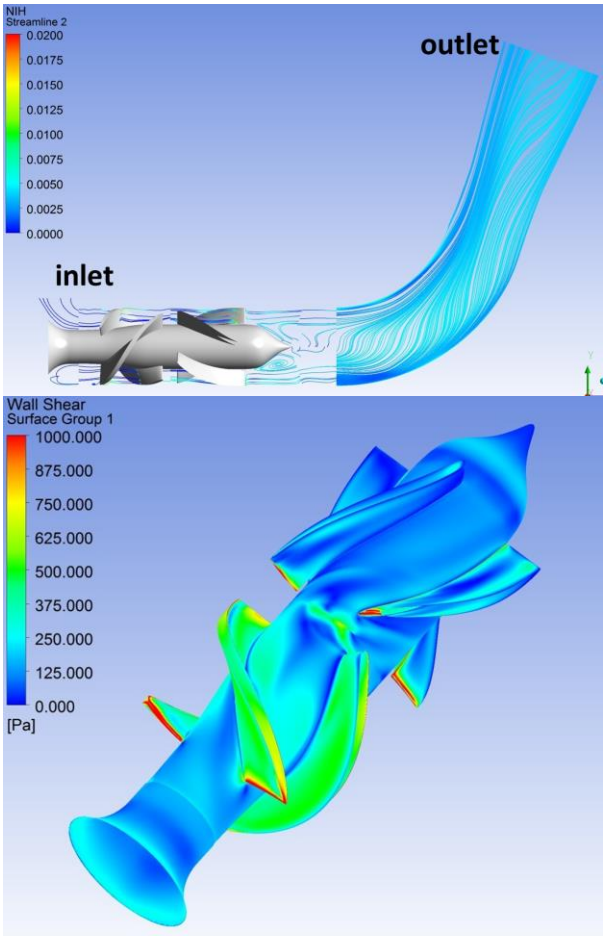

Fig. 2. CFD-predicted normalized index of hemolysis (NIH, g/100L) streamlines (top), and wall shear stresses [Pa] (bottom) at 22000 RPM and 4 L/min flow rate.

2 Methods

2.1 Computational Analysis. Blade geometries were optimized for hydrodynamic performance specific to left heart failure in a pediatric population while maintaining hemocompatibility using CFD-based design techniques as detailed elsewhere [5]. Virtual anatomic fit studies were carried out with approximate reconstructions and models in MIMICS (Materialise, Leuven, Belgium) and SolidWorks (Dassault Systemes, Vélizy-Villacoublay, France).

2.2 In vitro analysis. Hydraulic performance was quantified in a simple flow loop including a 3.5 L polycarbonate reservoir, Tygon E-3603 tubing, pressure meter and probes (PM-4; Living Systems, Albans City, VT) and flow probe and meter (9XL and T110; Transonic Systems, Ithaca, NY). Hemolysis was quantified in a similar flow loop using 2 L abattoir bovine blood adjusted to 33 ± 3% hematocrit by addition of 5% bovine serum albumin (BSA; Fisher Scientific, Pittsburgh, PA) in phosphate buffered saline (PBS; Fisher). The pumps (n=3) operated for 6 h at each set-point to generate flow from 1 to 3.5 L/min at rotor speeds from 16k to 20k RPM. Pressure was measured using a disposable pressure transducer (Medex Supply, Monsey, NY) connected to an OmniCareCMS 24 Patient Monitor (Hewlett Packard, Palo Alto, CA). Plasma free hemoglobin (PFH) quantified by commercial assay kit (Catachem, Oxford, CT) and used to calculate normalized index of hemolysis (NIH).

3 Results

Hydraulic best efficiency point (BEP) of this model was calculated at 37% at rotor speed of 22000 RPM and 3 L/min with CFD. Hydraulic characteristic performance measured with five devices in vitro shows likely pediatric operation at speeds greater than 20000 RPM (Fig. 1). Blade designs were iterated to optimize hydrodynamic performance and hemocompatibility. CFD predicted NIH at 0.0056 g/100L at hydraulic BEP. In vitro hemolysis conducted with three devices (Fig. 4) shows an average hemolytic burden of 1.1 g/day inclusive to measured conditions. At BEP, NIH calculated as an average of 0.064 g/100L.

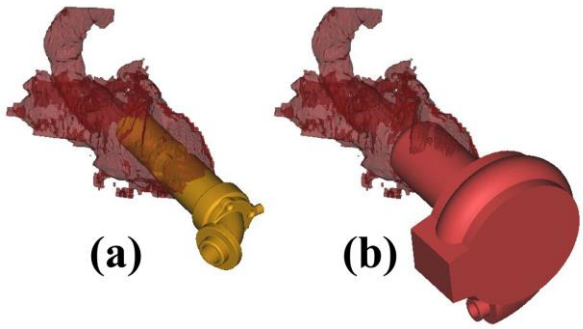

Fig. 3. Side-by-side comparison of virtual anatomic fit of (a) our device, and (b) a hypothetical centrifugal RBP [4] placed at the left ventricular apex of a theoretical 8-10 kg child.

4 Interpretation

Virtual anatomic fit and hemodynamic performance results from this study show promise for a new platform technology with application in a pediatric patient population. Indeed, the most critical operating range for infants is at low flow. Further efforts to develop and optimize device hydraulic performance and hemocompatibility at the ranges specific to pediatric population will be carried out. Without modifying the form factor of the device, designing a custom set of hydraulic blades suitable for low flow ranges in infants may be necessary.

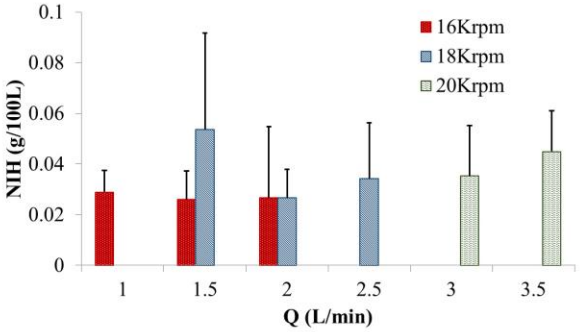

Fig. 4. Normalized index of hemolysis (NIH) calculated from in vitro measurements for various flow rates (Q) and rotor speeds.

Acknowledgement

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