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Physics-driven impeller designs for a novel intravascular blood pump for patients with congenital heart disease

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Mechanical circulatory support offers an alternative therapeutic treatment for patients with dysfunctional single ventricle physiology. An intravascular axial flow pump is being developed as a cavopulmonary assist device for these patients. This study details the development of a new rotating impeller geometry. We examined the performance of 8 impeller geometries with blade stagger or twist angles varying from 100° to 800° using computational methods. A refined range of blade twist angles between 300° and 400° was then identified, and 4 additional geometries were evaluated. Generally, the impeller designs produced 4–26 mmHg for flow rates of 1–4 L/min for 6000–8000 RPM. A data regression analysis was completed and found the impeller with 400° of blade twist to be the superior performer. A hydraulic test was conducted on a prototype of the 400° impeller, which generated measurable pressure rises of 7–28 mmHg for flow rates of 1–4 L/min at 6000–8000 RPM. The findings of the numerical model and experiment were in reasonable agreement within approximately 20%. These results support the continued development of an axial-flow, mechanical cavopulmonary assist device as a new clinical therapeutic option for Fontan patients.

1. Introduction

In normal cardiovascular physiology, the heart consists of two main ventricles or pumping chambers. The left ventricular chamber drives blood through the body and end-organs, while the right ventricle pumps blood to the lungs for gas exchange. Thousands of infants, however, are born each year with abnormal physiology due to heart defects and structural disorders. The incidence of congenital heart defects is reported to be approximately 4–10 of every 10,000 live births [1]. Those defects having the highest complexity, such as hypoplastic left heart syndrome and tricuspid atresia, lead to single ventricle physiology (SVP), requiring invasive heart surgery in the first year of life. These patients utilize healthcare resources disproportionate to their numbers with treatment costs exceeding $1.4 billion annually [1,2].

Patients exhibiting SVP typically undergo three, staged palliative cardiac surgeries. Each surgery progressively offloads the single ventricle while allowing time for growth, development, and adaptation to the altered physiology. The culminating Fontan procedure separates the pulmonary and systemic circulations and creates a total cavopulmonary connection (TCPC) where the inferior vena cava (IVC) and superior vena cava (SVC) are joined directly to feed the pulmonary arteries [2]. In this configuration blood flows passively from the venous system into the lungs without a subpulmonary power source or right ventricle to provide a pressure boost to push blood to the left atrium. After the Fontan, elevated central venous pressures have been linked to mounting complications, such as liver disorders, cardiac arrhythmias, and thrombosis or clot formations [3,4]. Few therapeutic alternatives exist, except for a heart transplant if patients survive the waiting period. Clinically-approved blood pumps or ventricular assist devices (VADs) are not ideal treatment options since these have been designed for patients with normal anatomy, not for patients having dysfunctional or failing SVP [5,6]. As a new treatment strategy for Fontan patients, we are designing a collapsible, percutaneously-inserted, axial flow blood pump to support the cavopulmonary circulation of adolescent and adult Fontan patients. The development of such a medical device involves consideration of biophysical factors, such as hemolysis, biocompatibility, implantability, pump performance, biomaterials, and thrombosis [7]. For Fontan patients, the target

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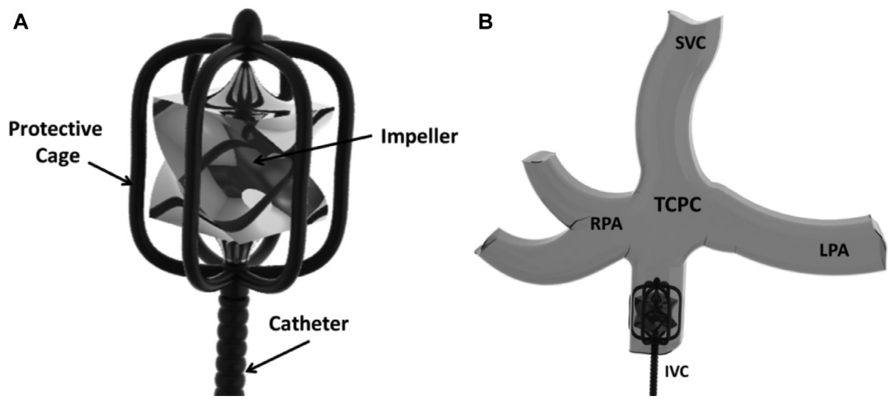

Fig. 1. Axial Flow Blood Pump for Fontan Patients. A. Design consists of a catheter, protective cage of filaments, impeller blade set, and outlet nose cap; B. Percutaneous placement of the blood pump in the IVC to support a Fontan patient; superior vena cava (SVC), left pulmonary artery (LPA), right pulmonary artery (RPA), inferior vena cava (IVC), and total cavopulmonary connection (TCPC) [36].

performance for this pump is to produce flow rates of 1–4 L/min with pressure rises of 2–25 mmHg for 1000–9000 RPM. Fig. 1 illustrates the conceptual design, which consists of three main components: the rotating impeller which imparts energy to the blood, the protective cage or stent that has radially arranged filaments as touchdown surfaces to protect the vessel wall from the rotating impeller blades, and the support catheter with a specially designed drive cable-fluid seal combination. An infused dextrose solution lubricates the cable and serves as a purge fluid to flush the seal of accumulated blood cells.

In this study, we focused on the design of new impellers with geometric simplicity. Conventional pump design equations based on Newton's second law and computational fluid dynamics (CFD) were readily used for the design of the impellers [8,9]. This study details the computational analyses of the impeller designs. A prototype of these impeller designs was constructed, and hydraulic testing was performed. In addition to hydraulic performance studies, a blood damage analysis was conducted to estimate the fluid shear stresses and the exposure time to such levels of shear in consideration of the biophysical factors of hemolysis and thrombosis. This study contributes a new generation of axial flow impellers based on first principles. These impellers are unique in their design by incorporating a range of helical blade twist angles. We were able to determine the highest performing impeller design with a reasonable blood damage index.

2. Materials and methods

Energy transfer across an axial flow blood pump occurs as the blade imparts rotational energy to the blood. Newton's law of motion, as applied to an impeller in the form of fluid traversing the rotor, states that the torque on the impeller is equal to the changing rate of angular momentum of fluid [9]. Thus, physics-driven, pump design equations were employed to derive the characteristics of the impeller geometry based on operating specifications [10,11]. The geometry of an impeller includes the hub diameter, blade tip, leading and trailing edge angles, blade thickness, pitch, skew, number of blades, and more. The leading and trailing edge angles of the blades are selected to achieve a particular performance. Blade thickness and blade tip clearance is limited in part by clinical implementation and manufacturing tolerances. In contrast to systemic VADs, mechanical cavopulmonary assist requires a lower pressure augmentation; a pressure adjustment of only 1–5 mmHg is likely sufficient to improve Fontan hemodynamics. Optimization of the impeller geometry was performed through parametric analysis of the blade stagger in which computational simulations provided valuable data about the impact on the hydraulic performance [9,12].

2.1. New impeller geometries

To generate the impeller designs in this study, we employed 3-D computer aided design (CAD) software (SolidWorks 2014, Dassault Systems, Concord, MA). We developed 6 axial-flow impeller geometries from first principles and modified the angle of twist or pitch of the impeller blades from 100° to 800° at 100° intervals. We also refined the design with focused iterations between 300° and 400° of blade twist at 20° increments. Fig. 2 displays the impeller geometries. An inlet pipe was placed at the inflow of the impeller models in order to support developed flow profiles entering the bladed region. Fig. 3 illustrates the computational model for the 300° twisted configuration.

2.2. Computational analyses

A commercial CFD software package (ANSYS 15.0, ANSYS, Inc., Canonsburg, PA) was utilized to simulate blood flow conditions across the impeller designs. A tetrahedral element mesh of the impeller domains was constructed having approximately 3.3 million elements, and we placed inflation layers at the surfaces to satisfy the constraints of the turbulence model. A grid density and convergence study were performed. The mesh was systematically refined through incremental adjustments until grid independence was achieved. Turbulent flow conditions are expected to dominate in the impeller domain with high Reynolds. The k-ε turbulence model has been used in the evaluation of prior pump designs with experimental validation [9]. Thus, this turbulence model was employed [8,9,13].

2.2.1. Boundary conditions

Flow through the pump domain was set to be steady flow, and a no-slip boundary condition was applied to the stationary walls of the model. In the stationary reference frame, the inlet and outlet of the impeller were defined as stationary boundaries. The impeller was specified to be in the rotating reference frame with rotation in the counterclockwise direction as required by the impeller blade orientation. The frozen rotor interface connected regions of differing reference frames (i.e. inlet pipe and impeller domain) and maintained flow properties [13]. A viscosity value of 0.0035 kg/m$*$s and a density of 1050 kg/m^3 were used for the fluid properties. A uniform mass inflow rate was specified for each simulation. Rotational speeds were evaluated at 6000–10,000 RPM, and the twisted blade positions were 100°–800° with a refined range of 300–400°