CAVOPULMONARY ASSIST DEVICE TO BRIDGE FAILING FONTAN CIRCULATIONS

by

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A thesis submitted in conformity with the requirements for the degree of Master of Applied Science

Department of Mechanical and Industrial Engineering University of Toronto

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Abstract

A novel cavopulmonary assist strategy with a multi-lumen cannula powered by an external centrifugal pump is proposed for use in failing Fontan patients. Steady-state computational fluid dynamics simulations are used to characterize hemodynamic performance in an idealized and two patient-specific Fontan pathway models for a wide range of cardiac outputs and pump intake flows, while further transient simulations are conducted for one of the patient-specific models with a periodic cardiac output and coupled to a Windkessel model. Simulations show that the proposed cannula can provide sufficient pressure gain required for cavopulmonary assist. A rigid 3D printed cannula prototype is also tested inside a mock circulation loop. Improvements in mean Fontan pressures from a typical failing circulation occurred at certain flow cases with cannulated assist while venous return flows were altered significantly in the presence of the cannula.

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Chapter 1 Introduction

1 Introduction

1.1 Motivation and Project Definition

At an early age, patients with congenital heart defects (CHD) such as hypoplastic left heart syndrome and tricuspid atresia [1] are treated with a series of three surgical procedures. In the last intervention, the Fontan procedure [2] creates the total cavopulmonary connection (TCPC) by anastomosing the inferior vena cava (IVC) to the superior vena cava (SVC) and left/right pulmonary arteries (LPA, RPA) into one pathway. Among the different Fontan variations, the extracardiac and lateral tunnel are the most common [3]. In the extracardiac Fontan (Fig. 1.1), a conduit is used to connect the IVC to the pulmonary arteries outside of the right atrium, whereas an internal baffle is used inside the right atrium for the lateral tunnel Fontan.



Figure 1.1. Extracardiac Fontan TCPC.

Congenital heart defects have been reported to occur as often as 6 in 1000 [4] and while the Fontan procedure has been successful at transforming the lives of CHD patients, these patients often develop circulation failure in their mid-twenties or thirties from different causes. A common Fontan failure mode is abnormally high pulmonary vascular resistance downstream [5] which raises the pressure in the Fontan pathway and reduces cardiac output. One study attributed 52% of Fontan deaths to heart failure [6] while another study reported circulatory, multi-organ, and pulmonary failure as the most common causes of Fontan failure deaths [7]. The only current treatment option for Fontan failure is heart transplantation. As a potential short-term alternative treatment, several cavopulmonary assist devices have been proposed, such as the viscousimpeller pump (VIP) [8], [9], dual-membrane umbrella cannula [10], [11], and microaxial pumps [12]–[14] but none have reached commercialization. In the Fontan TCPC, collision and mixing of SVC and IVC flows induce pressure losses which exacerbate the effects of high pulmonary vascular resistances downstream. The goal of cavopulmonary assist is to provide sufficient energy and pressure gain to overcome downstream resistances in the TCPC in order for sufficient flow to reach the heart and improve cardiac output. To achieve this goal, these devices aim to provide 2-6 mmHg pressure gain [8] in the Fontan pathway through mechanical means. Some of these devices, such as the VIP, strive to provide longer-term solutions and require surgery to implant, while others aim for short-term usage as a bridge to transplant and are implanted using minimally-invasive approaches. Left ventricular assist devices (LVAD) have also recently been proposed as a suitable strategy [15], and have been successful in a few patients [16]. A proposed self-powered injection jet shunt (IJS) has also been considered [17].

1.2 Objectives and Thesis Outline

The main research objectives of this thesis are to:

- 1. Design a minimally-invasive multi-lumen cannula for cavopulmonary assist in the extracardiac Fontan using computational fluid dynamics (CFD).
- 2. Characterize hemodynamic performance in:
 - a. Steady-State simulations and
 - b. Transient simulations.

The remaining chapters of the thesis are as follows:

In Chapter 2, the proposed cavopulmonary assist strategy is outlined and introduced. Steady-state CFD simulations with the multi-lumen cannula are conducted to determine pressure gain performance (increase in outlet pressures relative to inlet pressures) for three different TCPC geometries including an idealized model and two patient-specific geometries segmented from MRI (Magnetic Resonance Imaging). Different cardiac outputs and cannulated flow cases are simulated for each of the three geometries. Hemolysis damage, flow structures, and wall shear stress are examined for the most extreme cases.

Chapter 3 builds on the steady-state CFD simulation results by presenting transient CFD simulations with a scaled periodic cardiac output for one of the patient-specific TCPCs examined in Chapter 2. A 3-element RCR Windkessel model is also coupled to the pulmonary arterial outlet boundaries to mimic semi-realistic behavior in the presence of the cavopulmonary assist device. Experiments under varying flows are also conducted in a mock circulation loop with a 3D-printed multi-lumen cannula prototype.

In Chapter 4, contributions of the thesis are summarized. Future work is also discussed with potential strategies for further refinement of the proposed cavopulmonary assist cannula.

1.3 Contributions

Contributions for this thesis were made by Gabrielle Sebaldt who designed and constructed the mock circulation loop used for testing the 3D printed prototype, Elyar Abbasi Bavil who redesigned the compliance chambers as well as other modifications for the flow loop, and lastly Jonathan Adams who conducted all the set-up, testing, and data collection for the mock circulation loop experiments.

Chapter 2 Steady-State Computational Fluid Dynamics Simulations of a Proposed Cavopulmonary Assist Device

2 INTRODUCTION

A minimally-invasive multi-lumen cannula coupled to a commercially available blood pump is proposed as a potential cavopulmonary assist strategy for bridging adult patients with failing Fontan hemodynamics to heart transplantation. Insertion of the proposed device is minimallyinvasive, and the device aims to provide extracardiac Fontan patients with a pressure gain of 2-6 mmHg. As part of this study, the performance characteristics of the proposed cannula design were evaluated using CFD simulations. Several flow cases are examined with a range of nominal physiological flow rates and cavopulmonary assisted flow rates in an idealized adult TCPC as well as two patient-specific TCPC geometries. Blood damage for the most extreme cases is characterized using two power-law variants of the hemolysis index formulation through Lagrangian particle tracking. Additionally, device-induced flow structures are examined to determine any potential drawbacks or limitations of the proposed strategy.

2.1 MATERIALS AND METHODS

2.1.1 Cavopulmonary Assist Device

The proposed cavopulmonary assist device is a multi-lumen cannula consisting of two extruded discharge lumens and one suction lumen located in the center (Fig. 2.1). The discharge lumens have an internal diameter of 4.5 mm and tapered inner nozzle diameter of 3 mm while the suction lumen has a rectangular cross-section measuring 10 mm by 3.75 mm. The exterior cross-sectional dimensions of the cannula are 11 mm by 15.75 mm which translates to a 33-47 Fr size. In the proposed strategy, the cannula is inserted through the right internal jugular vein into the TCPC, where two guidewires are then used to guide the discharge lumen nozzles towards their respective pulmonary arteries. Flows from the SVC and IVC are siphoned through the suction lumen into an external centrifugal blood pump, such as the ROTAFLOW centrifugal pump

(Maquet, Rastatt, Germany), before being pumped back into the TCPC through the discharge lumens. Each discharge lumen nozzle contains a set of two helical protrusions in the interior to induce a slight swirl (Fig. 2.1) to stabilize the flow. Intake flow from the SVC and IVC can be diverted through the blood pump and into the pulmonary arteries to provide a positive pressure gradient in the Fontan TCPC. In this study, the pressure gain is defined as the difference between the average LPA and RPA pressures and the average IVC, SVC and left jugular vein pressures.



Figure 2.1. A) Cross-sectional and B) isometric views of the proposed multi-lumen cannula, and C) side view of the helical protrusions.

2.1.2 Idealized and Patient-Specific TCPC Geometries

An idealized adult Fontan TCPC (Fig. 2.2) was created in SolidWorks (Dassault Systèmes Solid Works Corp., Waltham, MA, USA) based on typical diameters used in literature [18]. The idealized TCPC is composed of cylindrical sections with diameters of 22 mm and 18 mm for the IVC/SVC and pulmonary arteries, respectively, with 10 mm fillets at the anastomosis

intersections. Both the IVC and the SVC were taken to be 60 mm in length while the pulmonary arteries were 100 mm long. Due to symmetry, only half of the TCPC was used for the CFD simulations.



Figure 2.2. Symmetric idealized adult TCPC geometry.

Following institutional research ethics approval, MRI of two Fontan patients were obtained. Patient A is a 21 years old male with a typical extracardiac TCPC while patient B is an 18 years old female with a bilateral SVC and extracardiac TCPC. Patient-specific TCPC geometries were segmented with centerline generation and contour lofts using SimVascular [19]. The geometries were then imported into MeshLab [20] for surface smoothing and decimation. Using SolidWorks, boundary truncations were performed along with circular lofted extensions of the outlet boundaries. Artificial inflation of the SVC branches was done to simulate elastic expansion of the vessel in the presence of the cannula. Figure 2.3 shows the TCPC models for patients A and B during segmentation and after final smoothing. Patient A's LPA has a mild constriction prior to bending towards the rear (Fig. 2.3B) while patient B's LPA bifurcates into two branches near the left SVC (Fig. 2.3D). Also, for patient A, the left jugular vein was included in the model due to its proximity to the TCPC.



Figure 2.3. A) Patient A segmentation with MRI rendering, B) patient A with surface smoothing and boundary extension/truncation, C) patient B segmentation with MRI rendering, and D) patient B with surface smoothing and boundary extension/truncation.

2.1.3 Cannula Insertion

The cannula was inserted virtually in SolidWorks. Cannula positions inside the three TCPC cases are shown in Figure 2.4. In the idealized model, the cannula is located along the SVC centerline with the suction lumen entrance situated 25 mm above the TCPC center. The discharge lumen was modelled to bend 90° into the centerline of the pulmonary artery. In the patient-specific models, the suction lumen entrance is situated at a distance away from the anastomosis junction. Care was taken to align the discharge lumens and pulmonary arteries as close to parallel as possible to avoid jet flow from impinging on the vessel walls. In Patient A, the left discharge lumen section is modelled longer to follow the sharp LPA bend as shown in Figure 2.4B. In Patient B, the left discharge lumen is terminated at a short distance before the LPA bifurcation as shown in Figure 2.4C. Furthermore, the nozzle is modelled to aim directly at the LPA bifurcation to avoid skewing cannula flow towards one of the LPA branches. Cannula dimensions are kept identical for all TCPC geometries except for the discharge lumen lengths and slight fillet radii differences on the internal helical protrusions.



Figure 2.4. Cannula inserted inside TCPC for A) idealized geometry, B) patient A, and C) patient B.

2.1.4 Computational Fluid Dynamics Simulations

The commercial finite volume software Fluent (ANSYS, Inc., Canonsburg, PA, USA) was used to conduct computational fluid dynamics (CFD) simulations. Simulations were conducted in steady-state as a first study for the proposed cavopulmonary assist strategy. Blood was assumed to be a Newtonian fluid with a density of 1060 kg/m³ and a viscosity of 0.0035 kg/m·s. Varying flow conditions were conducted to assess the cannula performance with cardiac outputs (COs) ranging from 1 to 4 L/min. Different pump flow rates through the cannula were conducted equal to 70%, 80%, and 90% of the total cardiac output. In Patient B, the pump flow rates are based on 70%, 80%, and 90% of the IVC and right SVC flow only to avoid flow intake from the distal left SVC.

The transition k-kl- ω turbulence model with second-order upwind scheme for the continuity equation and first-order upwind scheme for the remaining equations was used for all cases. The first-order upwind scheme for the remaining equations was chosen due to difficulties with convergence for the second-order scheme on patient-specific cases. However, as pressure gain is the primary variable of interest in these simulations, first-order schemes were deemed sufficient based on an approximately 2% change in pressure gain between first- and second-order schemes for simulations with the idealized TCPC. Residual convergence criteria for all equations was 1×10^{-5} . Three different mesh sizes for each geometry were used to ensure mesh independence. Final mesh sizes for the idealized and patient-specific cases (Patients A & B) were 6.7, 8.9 and 7.9 million elements respectively to ensure that pressure gain errors did not exceed 2.6%.

2.1.5 Boundary Conditions

Fully-developed velocity profiles were prescribed for all inlet boundaries and uniform pressure was prescribed for all outlet boundaries. Pressures at the LPA and RPA outlets were assumed to be equal. A symmetric boundary was used for the idealized adult TCPC due to symmetry of the geometry. An IVC:SVC flow split of 65:35 was assumed for the idealized TCPC case [21]. For Patient A, 65.0% of the CO was prescribed to the IVC, 17.5% to the SVC, and 17.5% to the left jugular vein. For Patient B, 60.6% of the CO was prescribed to the IVC, 19.0% to the right SVC and 20.4% to the left SVC based on data from the MRI report. For all cases, the pump flow intake at the suction lumen outlet boundary was implemented as a pressure outlet with a target mass flow condition. Equal flow splits of the pump flow were assigned to each discharge lumen. All wall boundaries were set as rigid walls. A summary of the inlet boundary flow rates as a percentage of patient cardiac output is given in Table 2.1.

TCPC Case	IVC Flow	SVC Flow	Left Jugular or Left SVC Flow	Cannula (Pump) Flow (70%, 80%, 90%)	Cannula Discharge Lumen Flow Split
Idealized	65.0%	35.0%	-	IVC + SVC	50:50
Patient A (Left Jugular Vein)	65.0%	17.5%	17.5%	IVC + SVC + Left Jugular	50:50
Patient B (Left SVC)	60.6%	19.0%	20.4%	IVC + SVC	50:50

Table 2.1: Inlet boundary flow rates as percentage of cardiac output

2.1.6 Hemolysis

Blood cell damage is a common concern in biomedical devices especially in regions with high shear stresses or long residence times. Hemolysis index was used as a measure of hemoglobin damage based on particle histories in the flow field. In the symmetric idealized TCPC case, 300 massless particles were injected at each inlet boundary (IVC, SVC, and one cannula inlet) for a total of 900 tracked particles. For Patients A and B, 200 massless particles were injected at each inlet boundary (IVC, SVC, and two cannula inlets) for a total of 1000 tracked particles per case. Injection locations at each inlet boundary were first chosen in a pseudorandom distribution such that locations were not unnecessarily close to boundary walls and avoided areas with low velocity magnitudes. This was done using the boundary face mesh nodes as the selection set with filtering to prevent numerical tracking error in the Lagrangian discrete phase model in the Fluent solver. The same injection points were then used for all flow cases for a single geometry to maintain consistency in the final analysis. Hemolysis index (*HI*) was calculated from the particle trajectory histories based on the following power-law

$$HI = \frac{\Delta Hb}{Hb} = C\tau_s^{\ \alpha} t_{exp}^{\ \beta},\tag{2.1}$$

where α =1.991, β =0.765 and *C*=1.8×10⁻⁵ based on Heuser and Opitz [22], τ_s is the scalar shear stress, and t_{exp} is residence time. Two variants of the power law [23], [24] were used to calculate the hemolysis index

$$HI_{1} = \sum_{inlet}^{outlet} \beta C t_{exp}^{\beta - 1} \tau_{s}^{\alpha} \Delta t_{exp}, \qquad (2.2)$$

$$HI_2 = C \left[\sum_{inlet}^{outlet} \Delta t_{exp} \tau_s^{\alpha/\beta} \right]^{\beta}.$$
 (2.3)

The shear stress [25], [26] in the equations 2.2 and 2.3 was calculated as

$$\tau_{s} = \frac{1}{\sqrt{3}} \left[\tau_{xx}^{2} + \tau_{yy}^{2} + \tau_{zz}^{2} + 3 \left(\tau_{xy}^{2} + \tau_{yz}^{2} + \tau_{xz}^{2} \right) - \left(\tau_{xx} \tau_{yy} + \tau_{yy} \tau_{zz} + \tau_{xx} \tau_{zz} \right) \right]^{1/2}.$$
(2.4)

The two *HI* variants and particle history analysis were conducted using a custom MATLAB (MathWorks, Natick, MA, USA) script which was validated against a benchmark case by Hariharan et al. [23]. Hemolysis contributions of each particle were weighted for each outlet boundary and flow-averaged using

$$HI_{outlet,i,j} = \frac{1}{Q_j} \int_{A_j} HI_{i,k} \cdot u_k \, dA_j, \tag{2.5}$$

where i=1,2, k is the index of each particle exiting outlet j, Q_j is the volumetric flow, A_j is the cross-sectional outlet area, and u_k is the corresponding exit velocity magnitude. The overall hemolysis index of the TCPC domain was calculated using the following expression for the flow-weighted *HI* averages of each outlet

$$HI_{TCPC,i} = \frac{\sum \left[Q_j \cdot \left(\int_A HI_{i,k} \cdot u_k \, dA \right)_j \right]}{Q_{total}}.$$
(2.6)

2.2 RESULTS

2.2.1 Pressure Gains

Pressure gains as a function of cardiac output and cannula assist rate are shown in Fig. 2.5. Positive pressure gains were achieved for all flow cases with maximum pressure gains occurring at the highest cardiac outputs and cannula assist flow rates. For the idealized and Patient B cases, up to 4 mmHg of pressure increase was attained while over 9.2 mmHg was achieved in Patient A. The pressure gain curves for Patient A and the idealized TCPC show comparable behavior with proportional pressure gain increases between different pump flow rates. Patient B however shows a dramatic increase in pressure gain starting at 2.5 L/min cardiac output. Table 2.2 summarizes the pressure differential between the suction and discharge lumens as well as between pulmonary arteries and 5 mm in front of the suction lumen entrance. A maximum pressure differential of 95 mmHg in the idealized TCPC case is needed to pump 90% CO, not including pressure losses in the tubing connecting the cannula to the external blood pump. Maximum pressure difference between the LPA/RPA boundaries and suction lumen entrance was 9.9 mmHg in patient A, 4.9 mmHg in patient B, and 4.6 mmHg in the idealized TCPC.



Figure 2.5. Pressure gains as a function of cardiac output and cannula assist rate curves for A) idealized TCPC, B) patient A, and C) patient B.

TCPC Case	Max. ΔP between Suction- Discharge Lumens [mmHg]	Max. ΔP between Suction Lumen Entrance-pulmonary artery outlet(s) [mmHg]	
Idealized	94.8	-4.6	
Patient A	93.2	-9.9	
Patient B	60.3	-4.9	

Table 2.2: Summary of pump pressure requirements

2.2.2 Flow Fields

Velocity and pressure contours for 4 L/min cardiac output and 90% cannula assist are shown in Fig. 2.6 for all three TCPC cases. In the idealized case, symmetric flow structures including vortices near the cannula nozzle can be observed in the velocity contours (Fig. 2.6A) while the pressure contours illustrate the increased pressure gradient downstream of the cannula nozzle flow. The region of low pressure near the TCPC center and suction lumen is artificially separated by the interaction of cannula nozzle flow with the slower surrounding flow. Similarly, Figures 2.6B and 2.6C show velocity contours in the RPA and LPA for Patient A with asymmetric vortices. In the RPA side, the nozzle was misaligned and jet flow impinged on the top vessel wall, while the nozzle in the LPA side was positioned parallel. In both pulmonary arteries, high pressure regions were also created downstream of the nozzles. Velocity contours for Patient B also show formation of vortices near the cannula nozzles. Two vortices are present between the LPA birfucation and the nozzle entrance with the one closer to the larger LPA branch being greater in size. Figure 2.7 shows pathlines colored by velocity magnitude for all three TCPC geometries. Major portions of blood flow from the IVC are directed into the central suction lumen with the remaining flow going into the RPA and LPA while almost all the flow from the SVC is siphoned through the suction lumen.



Figure 2.6. Contours for 4 L/min CO with 90% CO pump flow in A) the idealized TCPC, B) patient A RPA, C) Patient A LPA, D) Patient B RPA, and E) Patient B LPA.



Figure 2.7. Velocity pathlines for 4 L/min CO and 90% CO for A) patient A, B) Patient B, and C) the idealized TCPC.

Figure 2.8 shows the velocity magnitude distributions along the pulmonary artery for the idealized TCPC case. As the cannula nozzle is aligned colinearly with the vessel centerline, the velocity profiles at each plane are all symmetric with smaller velocity variation downstream. Furthermore, flow structures near the cannula nozzle are dampened out at a short distance away.



Figure 2.8. Velocity contours at CO = 4L/min and 90% CO pump flow in the idealized TCPC.

Several velocity contour slices at fixed distances away from the RPA and LPA outlet boundaries are shown in Figs. 2.9 and 2.10 for Patients A and B. The RPA contours for Patient A (Fig. 2.9) show a faster decay of vortices with a mainly uniform flow profile at the RPA outlet boundary, whereas the LPA section shows a slower decay with a non-uniform flow profile at the LPA outlet boundary. For Patient B (Fig. 2.10), the RPA and main LPA branches also have slower decay of vortices while the smaller LPA branch returns to a uniformly distributed velocity profile by the end of the outlet boundary.



Figure 2.9. Velocity contours at CO=4L/min and 90% CO pump flow for Patient A. Top row are RPA contours and bottom Row are LPA contours.



Figure 2.10. Velocity contours at CO=4L/min and 90% CO pump flow in patient B. Top row are RPA contours, middle row are main LPA contours, and bottom row are secondary LPA contours.

2.2.3 Hemolysis

The total flow-weighted hemolysis indices, $HI_{TCPC,1}$ and $HI_{TPCP,2}$ were calculated for the idealized TCPC geometry and are shown in Fig. 2.11. Both hemolysis indices show increased damage with higher CO and pump flow rates, as expected. Estimates for $HI_{TCPC,2}$ were consistently higher than $HI_{TCPC,1}$ for the same flow cases with a maximum $HI_{TCPC} = 1.95 \times 10^{-5}$. Both flow-weighted *HI* show a slight increase starting at 3 L/min CO as shown in Fig. 2.11.



Figure 2.11. Hemolysis Indices for the idealized TCPC.

For patient A, the distribution of accumulated hemolysis index HI_1 and HI_2 was calculated for the 4 L/min at 90% CO pump rate case and sorted by magnitude for each particle based on which inlet boundary they originated from, as shown in Fig. 2.12. Both variations of HI showed the highest accumulated damage for particles originating from the left and right discharge lumens. Particles originating from the SVC, IVC and left jugular vein had lower accumulated damage in general. There are a few particles originating from the IVC boundary with higher accumulated hemolysis index than the SVC and left jugular boundaries. It should be noted that the particles shown in Fig. 2.12 include those with incomplete trajectories.



Figure 2.12. Left) Accumulated HI₁ by particle and right) accumulated HI₂ by particle for patient A with 4 L/min CO at 90% CO cannula assist.

2.2.4 Wall Shear Stress

Contour plots of wall shear stress (WSS) (Fig. 2.13A) on the RPA and LPA for patient A show localized areas of high WSS from jet flow impinging on the vessel walls. In the RPA, the nozzle was aimed at an angle towards the upper vessel wall which resulted in WSS up to 55 Pa. In the LPA, where the nozzle was positioned in a near-parallel alignment, WSS up to 34 Pa occurred at the vessel wall near the nozzle. Wall shear stress plots for the LPA bifurcation (Fig. 2.13B) show small regions with WSS exceeding 130 Pa where the left cannula nozzle is aimed directly at the junction wall. Wall shear stress contours for cannula nozzle walls and suction lumen lip entrance are shown in Fig. 2.14 for patient A for 4 L/min CO at 90% pump flow. In the inner cannula nozzle walls, minute areas on the innermost portion of the helical protrusion and nozzle entrance had WSS of up 369 Pa with most of the inner nozzle experiencing 240 Pa or less. Miniscule portions of the fillet corner on the suction lumen entrance experienced WSS up to 504 Pa due to the high flow rate diverted through the external pump.



Figure 2.13. Wall shear stress contours for 4 L/min CO at 90% CO assist for A) patient A RPA & LPA and B) patient B LPA.



Figure 2.14. Patient A cannula WSS for 4 L/min CO at 90% CO assist for A) suction lumen entrance and B) right cannula nozzle interior.

2.3 DISCUSSION

Pressure gain is one of the main goals in developing cavopulmonary assist strategies either as a short-term or long-term solution for patients with failing Fontan circulations [8]. CFD results for our proposed multi-lumen cannula show that pressure gain of up to 4 mmHg is possible when the cardiac output is at 4 L/min in an idealized adult TCPC geometry with a 22 mm diameter pulmonary artery. In our patient-specific cases, pressure gain up to 9.2 mmHg was achieved in Patient A and 4 mmHg for Patient B. At lower cardiac output flow rates, the pressure gains in all three TCPC cases were substantially lower and highly dependent on the CO and pump assist flow rates. The pump pressure requirement is not an issue as the maximum pressure differential needed to siphon blood into the pump is less than 95 mmHg excluding pressure losses in the tubing sections not modelled in the simulations. Pressure measured at a point 5 mm outside of the cannula suction lumens was a maximum of 9.9 mmHg from the pulmonary arteries and should not cause vessel collapse in a typical elevated failing Fontan pathway. Velocity contours and flow field pathlines showed vortices near the cannula nozzles due to mixing of high velocity flow. Depending on the cannula nozzle position and alignment with respect to the vessel centerline, varying types of flow structures were observed with localized areas of high wall shear stress. Flow-weighted hemolysis analysis of tracked particles in the idealized TCPC showed hemolysis index estimates of $1.14-1.95 \times 10^{-5}$ for the most extreme flow case using the two power-law variants HI1 and HI2, respectively. This result shows that hemoglobin damage in the red blood cells is much less than a 2% threshold used in literature [12] and is not expected to be a significant concern in the TCPC region. Lower physiological flow rate cases yielded lower estimates of hemolysis index as expected.

While our results show that pressure gains up to 9 mmHg are attainable in the most ideal flow cases, the pressure gain drops substantially at lower cardiac output flow rates. Other proposed cavopulmonary assist devices such as the microaxial pump and viscous impeller pump have been shown in both CFD simulations and experimental flow loops to operate for higher pressure gains with performance more akin to traditional pump pressure curves [8], [12]. The lower pressure gain performance of the multi-lumen cannula stems from the strategy of delivering pressure gain without physically separating high and low-pressure zones (as in the case with the double-membrane cannula) or using driven impellers to directly induce the pressure gradients. Advantages of our approach are the lack of moving components to avoid blockage of the

circulation in the event of pump failure and the ease of insertion with a minimal invasive technique. Also, in our proposed cannula design, the discharge lumens inject flow into the pulmonary arteries directly which reduces energy loss and prevents flow from being recirculated back through the suction lumen. Furthermore, left and right discharge lumen lengths can be tailored to patient-specific geometries to maximize cavopulmonary assist.

An unexpected behavior in the pressure gain curve for Patient B is observed (Fig. 2.5). In cardiac output flows of 1 to 2 L/min the pressure gain behaves in a linear fashion at different pump flow rates, but at 2.5 L/min CO and higher the differences between different pump flow rates are greater. These differences might be caused by the LPA branching or by the bilateral superior vena cava geometry. In the flow-weighted hemolysis index curves (Fig. 2.11) for the idealized TCPC, a similar increase occurs at 2.5 L/min CO and higher. Further investigation is needed to determine the cause of the increase.

Our CFD results for the highest flow cases show that nozzle alignment, vessel geometry, and pump flow rates impact flow stability inside the pulmonary arteries with unwanted effects such as localized high WSS and vortices. In the presence of pulmonary arterial branching, high velocity jet flow directed at the junction wall produces high WSS and similarly for angled nozzles on the surrounding vessel walls. In this study, minor pulmonary vascular branches were not included in the patient-specific segmentation with only one major LPA branch kept in the Patient A TCPC cases. These misalignment concerns can be further investigated by characterizing performance effects of nozzle position, alignment angle, ratio of nozzle diameter to vessel diameter and different flow rates as a simplified jet flow inside distinct types of wallbounded vessels in future studies. This will aid in creating a framework for customization of cannula sizes and optimal cannula placement tailored to each patient-specific case, because, in the present study, cannula lumen diameters were kept consistent and were not optimized based on patient vessel diameters. A framework to determine the optimal cannula placement would also allow us to test how deviations from this optimum affect the cannula performance. Sensitivity of suction lumen distance from the TCPC center or the cannula discharge lumen lengths were not examined in this study. During preliminary work, partial flow recirculation from the cannula nozzle back into the suction lumen was noted under certain flow conditions when the cannula nozzle was too close to the suction lumen entrance. Further experimental work is also needed to ensure that vortices generated in the pulmonary arteries will not induce

thrombosis. The cannula nozzle geometry also requires further modifications to reduce areas of high WSS as well as the suction lumen entrance. Finally, the dependency of the performance on patient TCPC geometry and the amount of flow siphoned through the cannula/pump may limit the number of patients who can use this strategy. Future work will be conducted to address the shortcomings and limitations identified in the present study including refinement of the nozzle and suction entrance design, characterization of more realistic nozzle placement/effects of misalignment and customization to individual patient geometries. Work to include transient CFD studies, flow loop experiments with a 3D printed prototype, and animal testing will also be done in the future.

2.4 CONCLUSIONS

A novel cavopulmonary-assist device in the form of a multi-lumen cannula coupled to an external blood pump was presented as a strategy in bridging Fontan patients to heart transplant. Steady-state CFD simulations were undertaken for three different TCPC cases; an idealized TCPC, a typical extracardiac TCPC, and an extracardiac TCPC with bilateral superior vena cava for different cardiac outputs and pump flow rates. Positive pressure gains up to 9.2 mmHg were achieved which meets the general range of cavopulmonary assist needed to overcome resistances in the downstream vascular pulmonary bed. Higher pressure gains were achieved in the two patient-specific cases compared to the idealized TCPC on average, with the pressure gain performance limited by the amount of flow that can be physically diverted to the external blood pump. Blood damage was also quantified using two variants of hemolysis index which showed that blood damage was much less than 2% and is not a significant concern in the TCPC and cannula regions. Overall, our results show potential for a minimally-invasive cavopulmonary assist strategy to serve as a method for bridging failing Fontan patients with high pulmonary vascular resistance to heart transplant. Pressure gains were achieved by siphoning blood from the superior and inferior vena cava into an external blood pump and injected through two discharge lumens positioned in the pulmonary arteries. With careful surgical planning, a custom-sized multi-lumen cannula may provide a viable short-term solution to overcoming high pulmonary vascular resistance until a donor heart is available for transplant.

Chapter 3 Transient Computational Fluid Dynamics Simulations and *in vitro* Flow Experiments

3 INTRODUCTION

A multi-lumen cannula, with a central suction lumen and two discharge lumens, coupled to an external centrifugal blood pump was previously shown to provide pressure gains in the TCPC in steady-state CFD simulations. The objective of this study is to investigate the pressure gain performance of the multi-lumen cannula in a patient-specific case using transient CFD simulations with a typical physiological periodic cardiac output for a Fontan patient and 3-element Windkessel models coupled to the pulmonary artery outlets to mimic the downstream responses. Two different pump flow rates were simulated to determine the pressure gain under realistic *in vivo* scenarios. Velocity contours and pathlines are used to examine the formation of vortices at four instances in the cardiac cycle. A pump failure case is also simulated to determine pressure losses in the event the pump fails during operation. To test how failing TCPC pressures respond to cavopulmonary assist, a mock circulation loop mimicking the full-body physiological response was built to test a 3D printed rigid cannula prototype.

3.1 METHODS

3.1.1 Computational Model

3.1.1.1 Patient-Specific Geometry

Following institutional research ethics approval, MRI scans were obtained for a 21 years old male extracardiac Fontan patient. The TCPC geometry was then segmented from the MRI scans in SimVascular [19] and the cannula was virtually inserted in SolidWorks (Dassault Systèmes SolidWorks Corp., Waltham, MA, USA), using the approach described previously in Chapter 2. Surface smoothing and boundary extensions were then done with MeshLab [20] and SolidWorks. The LPA and the RPA measure approximately 10.9 mm and 10.5 mm, respectively.

The LPA had a mild narrowing just before a sharp bend to the anterior as shown in Figure 3.1A and 3.1B, while Figure 3.1C shows the cannula position inside the final smoothed geometry.



Figure 3.1. A) Front view of MRI segmentation, B) back view of MRI segmentation and C) smoothed geometry with cannula inserted.

3.1.1.2 Simulations Setup

Unsteady CFD simulations were conducted using Ansys FLUENT (ANSYS, Inc., Canonsburg, PA, USA) with blood assumed to be a Newtonian fluid with density of 1060 kg/m³ and viscosity of 0.0035 kg/m·s. Transient simulations were performed to simulate the effects of different pump flow rates including a worst-case scenario with pump failure (cannula inserted but no pump flow). Compared to the previous steady-state simulations, the transient simulations are more physiological, at the expense of increased computational costs, and allow for more accurate assessment of vortices formation downstream of the cannula. The transition k-kl- ω turbulence model was used for cases with pump flow while the laminar model was used for the pump failure case, due to lower Reynolds numbers with no pump flow. The first-order upwind scheme was used for all equations, except for the continuity equation, which used the second-order upwind scheme. The first-order implicit time formulation was used, and the residual convergence criteria was set to 1×10^{-4} for all equations. Three cardiac output (CO) cycles were first simulated to wash out any initial transient effects and the data from the fourth cycle was used. The unstructured

mesh consisted of 8.9 million cells with mesh independence determined based on previous steady-state simulations.

3.1.1.3 Boundary Conditions

A physiological CO waveform (Fig. 3.2) was derived from literature [27]. This waveform was scaled to match a mean CO of 2.4 L/min with a 55 BPM heartrate. Four instances during the cardiac cycle, denoted as T1, T2, T3 and T4, representing points near the minimum, mid-stage, maximum, and end of the CO waveform, respectively are shown in Fig. 3.2 and are the times for which results will be presented. Two pump flow rates were used based on 70% (1.3 L/min) and 90% (1.7 L/min) of the minimum CO. Flow at the IVC, SVC, and left jugular vein inlets were assumed to make up 65%, 17.5%, and 17.5% of the total CO, respectively (Fig. 3.3) based on a typical IVC to SVC ratio of 65:35 [21] and the assumption of equal flow in the SVC and left jugular vein. All inlet boundaries were set as fully-developed velocity profiles except for a uniform mass inlet boundary on the SVC which was necessary because of the irregular cross-sectional profile at this boundary with the cannula. All wall boundaries were assumed to be rigid. A pressure outlet with target mass flow was set on the cannula suction lumen boundary to ensure balanced flow rates for the two cannula discharge lumens.



Figure 3.2. Cardiac output cycle scaled to patient-specific case.



Figure 3.3. Transient boundary conditions.

A 3-element RCR Windkessel model [28]–[31], which simulates downstream physiological behavior using analogies between fluid mechanics and electrical circuits with two resistors and a capacitor, was coupled to the RPA and LPA outlets as follows

$$C\frac{dP}{dt} + \frac{P(t)}{R_P} = R_C C \frac{dQ}{dt} + Q(1 + \frac{R_C}{R_P})$$
(3.1)

where *C* is compliance, P(t) is the pressure at time *t*, R_P and R_C are resistances, and *Q* is the outlet flow rate. Equation 3.1 can be rearranged to solve for P(t)

$$P(t) = R_P R_C C \frac{dQ}{dt} - R_C C \frac{dP}{dt} + Q(R_P + R_C).$$
(3.2)

The Windkessel parameters were set to C = 0.5 L/mmHg, $R_C = 13.37$ mmHg/(L/min), and $R_P = 6.93$ mmHg/(L/min) using a semi-brute force fitting script in MATLAB (MathWorks, Natick, MA, USA) for a given range of typical physiological values. The parameters were fit to RPA pressure catheter measurements from a different Fontan patient with an intra-lateral TCPC because catheter pressure data for this extracardiac Fontan patient was not available. A comparable CO waveform was scaled and adjusted for the intra-lateral RPA flow and used as the input for fitting the parameters.

3.1.2 Experimental Model

3.1.2.1 Cannula/TCPC Prototype

As a first step in experimentally testing the cannula design, a rigid-walled multi-lumen cannula was printed with a ProJet MJP 5500X 3D printer (3D Systems Corporation, Rock Hill, SC, USA) and a hard polycarbonate-like material (VisiJet CR-CL). The cannula and idealized TCPC were printed as one solid piece with the cannula suspended along the centerline of the SVC with two support struts as shown in Fig. 3.4. The two discharge lumen nozzles individually bend into the left and right pulmonary arteries with the nozzles supported by small struts (Fig. 3.4). The cannula position inside the idealized TCPC is identical to CFD simulations in previous work with 22 mm IVC and SVC diameters and 18 mm LPA and RPA diameters. Four ports are located on each TCPC branch for pressure transducers to measure pressure at the same locations as was done in the CFD simulations. Two ports upstream of the SVC allow for connection to an external ROTAFLOW centrifugal pump (Maquet, Rastatt, Germany) with the suction and discharge lumens.



Figure 3.4. Photo of polycarbonate prototype and renderings showing internal cannula lumens.

3.1.2.2 Mock Circulation Loop

A mock circulation loop was constructed for testing 3D printed prototypes of the multi-lumen cannula. A pulsatile Harvard Apparatus Model 1423 pump (Cambridge, Massachusetts, USA) provides a realistic cardiac waveform with systemic and venous compliance chambers and systemic resistances located downstream to mimic clinical values (Fig. 3.5). Compliance chambers and resistance clamps are also located upstream and downstream of the TCPC region to induce typical clinical hemodynamics of a failing Fontan circulation. Flow rates are measured using ultrasonic flow sensors (Model UF31210) made by Strain Measurement Devices (Wallingford, CT, USA) and pressures are measured using pressure transducers (PX309 series) by Omega Engineering (Norwalk, CT, USA).



Figure 3.5. Experimental flow loop schematic (top) and photographs (bottom).

3.1.2.3 Experimental Testing Conditions

Flow experiments were performed using a Newtonian blood analog fluid made by mixing distilled water and glycerin (36.7% by vol) [32] with a density of 1092 ± 1.475 kg/m³, and a theoretical viscosity of 0.00431 kg/m·s (based on a theoretical density of 1096.7 kg/m³). Batch quantities of 5 L were made to ensure consistency across trials and the density was measured for each batch. Correction factors to account for different fluid properties were also applied accordingly in the data acquisition software as per manufacturer's guidelines. Experiments were performed with mean COs from 2-4 L/min and cannulated flow rates of 0% (pump failure), 70%, 80%, and 90% of the mean CO.

For each set of experiments with a fixed mean CO, a rigid TCPC without a cannula was first used to tune the compliances and resistances to achieve pressures representative of a typical failing Fontan case and a 65:35 IVC:SVC flow split. The rigid TCPC without the cannula was then replaced with the rigid TCPC with the cannula. The cannula was then connected to the centrifugal pump and the flow loop reset to the same compliances and resistances settings as before. The centrifugal pump RPMs and mean pump intake flows were then mapped and calibrated for each CO case. The IVC:SVC flow split was not adjusted from the no cannula case and allowed to change naturally due to the presence of the cannula. Flow cases for pump failure (no flow through cannula), 70%, 80% and 90% pump assist were then recorded for a set amount of time (Table 3.1) before ramping up centrifugal pump RPM to the next flow assist case. Two sets of trials were performed, one in which the pressure was measured in the LPA and one in which the pressure was measured in the RPA. Reported TCPC pressures are mean values from the two tests for each CO case.

Flow assist per CO flow case	Time Elapsed [s]
Pump failure (no pump)	25
70% CO assist	20
80% CO assist	20
90% CO assist	20
Pump failure (no pump)	10

Table 3.1. Cannula flow case data measurement times.

3.2 RESULTS

3.2.1 Computational Results

3.2.1.1 Pressure

Figure 3.6 shows the pump gain curves for the simulations with pump failure, 70%, and 90% pump assist with the cardiac output cycle shown for comparison. In the pump failure case with no flow through the pump, the presence of the cannula induces a pressure loss of less than 2 mmHg. The 90% pump assist case provides a pressure gain ranging from approximately 1.25-2.25 mmHg while the 70% pump assist case provides a pressure gain up to ~1 mmHg with a brief period of pressure loss at the minimum. Figure 3.7 depicts the computed LPA and RPA pressures for all three flow cases. The RPA pressure was higher than the LPA pressure for all cases with the greatest difference in the pump failure case. The pressure difference between LPA and RPA decreased with increased cannula flow with the 90% assist case having near identical LPA and RPA pressures.



Figure 3.6. Computational pressure gain curves.



Figure 3.7. Computational pressures in the left and right pulmonary arteries.

3.2.1.2 Flow

Figure 3.8 shows the computed velocity contours and Fig. 3.9 shows the computed pathlines in the RPA and LPA for both 70% and 90% CO assist cases at different instances during the cardiac cycle. The 70% CO assist case has visibly less pronounced vortices in the pulmonary arteries (Fig. 3.9) compared to the 90% CO assist case. A change in vortex size can be seen in the RPA at 90% CO assist while the RPA vortex at 70% CO assist is dampened out during the same period. The LPA vortex almost dampens out completely at T3 and T4 in the lower flow case while at the higher flow case the vortex remains largely unchanged with a slight decrease at T3.



Figure 3.8. Velocity contours at four selected time points.



Figure 3.9. Velocity pathlines at varying time points.

3.2.1.3 Wall Shear Stress

LPA and RPA wall shear stress contours are shown in Fig. 3.10 for both flow cases at timepoint T3 near the maximum cardiac output. The maximum WSS values were 28.7 and 16.1 Pa for the 90% and 70% CO assist flow cases, respectively, at small regions due to impingement of the jet flow in the RPA. There is substantially less WSS in the LPA because the nozzle was aligned nearly parallel to the vessel centerline.



Figure 3.10. Wall shear stress A) 90% CO assist at T3 and B) 70% CO assist at T3.

3.2.2 Experimental Results

Table 3.2 shows the change in IVC:SVC flow split for both the failing Fontan scenario (no cannula inserted) and cannula assist cases in the mock circulation loop experiments. The cannula created obstruction in the SVC flow which increased the flow in the IVC up to 79.1% of the CO. Overall a 11-13% change in the flow split was caused just by the cannula presence. Varying the centrifugal pump flow intake did not have significant effects on the flow split. Mean Fontan TCPC pressures for all flow cases from the mock circulation loop experiments are shown in Fig. 3.11. For COs of 2.0-2.5 L/min, the presence of the cannula increased the mean TCPC pressures from 7.86-9.38 mmHg to a maximum of 9.25-11.69 mmHg, which occurred without pump assist. For COs of 3.0-4.0 L/min, the presence of the cannula, with or without pump assist, reduced the pressures in the TCPC to approximately 10.28-11.52 mmHg, compared to the no cannula case.

For example, at 90% CO assist, the mean TCPC pressure is lowered by ~1.8 mmHg for CO = 3 L/min and ~0.8 mmHg for CO = 4 L/min.

 Table 3.2. Mock circulation loop IVC:SVC flow split for failing Fontan and cannula assist cases.

CO [L/min]	Failing Fontan IVC:SVC Flow	Mean Cannula Assist IVC:SVC Flow	% IVC Flow Difference
2.0	68.1:31.9	79.1:20.9	+11.0%
2.5	66.4:33.6	78.3:21.7	+11.9%
3.0	66.2:33.8	78.3:21.7	+12.1%
3.5	65.3:34.7	78.6:21.4	+13.3%
4.0	64.8:35.2	78.2:21.8	+13.4%



Figure 3.11. Experimental mean TCPC pressures vs cardiac output.

3.3 DISCUSSION

CFD simulations for a multi-lumen cannula were conducted using a patient-specific TCPC geometry with a generic pulsatile cardiac output for three cannulated assist scenarios. Pressure gains up to 2.25 mmHg were achieved for the 90% assist case (1.7 L/min pump flow) while gains less than 1 mmHg were achieved for the 70% assist case (1.3 L/min pump flow). This is comparable to previous steady-state CFD studies which predicted pressure gains from 1.79 – 3.63 mmHg at 2.5 L/min cardiac output. It should be noted that in this study the percent CO assist was based off the minimum value in the CO cycle instead of the mean value (2.4 L/min) which partially explains the decrease in pressure gain. A simulated pump failure case showed a pressure loss of under 2 mmHg. Pressures at the LPA and RPA also showed smaller differences under cannulated flow with comparable differences in flow rates at both branches. Pathlines and velocity contours also show smaller vortices at the lower flow case and consequently lower wall shear stresses. Similar to findings from previous work, localized regions had high peak WSS in the RPA due to the cannula nozzle being directed at that vessel wall area. The LPA walls had much lower peak WSS in comparison, similar to what was found in previous steady-state

simulations. Experiments with the mock circulation loop showed significant changes in hemodynamics. The flow split between IVC and SVC changed by up to 13.4% while cannula assisted cases reduced the mean TCPC pressures for COs of 3.0-4.0 L/min by up to 1.8 mmHg with 90% CO assist. Flow cases with CO of 2.0-2.5 L/min showed a detrimental increase in mean TCPC pressures with the insertion of the cannula.

Pressure gains from the CFD simulations in the patient-specific TCPC are lower in comparison to other cavopulmonary assist devices currently proposed in literature. Impeller driven devices such as the VIP [8], [33] and microaxial pumps [12] which operate directly inside the TCPC are naturally more efficient in inducing pressure gain without pressure losses associated with cannulation to an external pump at the expense of complexity in moving parts. The most similar device to ours is the double-membrane cannula [10], [11] which was tested in sheep models with self-deploying membranes coupled to commercial centrifugal pumps as well. For our multi-lumen cannula device, we used a mock circulation loop with a pulsatile pump mimicking a single-ventricular heart as a way of simulating the physiological behavior. Future work may include modifying the loop to conduct particle image velocimetry as was done for the VIP [9] or steady flow pressure head tests.

While the mock circulation loop tests showed potential for the cannula to reduce the mean TCPC pressures at certain cardiac output flows, the drastic reduction in SVC flow caused by cannula obstruction may hinder long-term clinical use. The lack of separate upper and lower body venous compliance/resistance components in the loop may have affected the change in IVC/SVC flows. Our use of a pulsatile pump with upstream reservoir also meant that the long-term change in cardiac output could not be properly evaluated without animal testing. At the lower cardiac output cases, it was noted to be difficult in achieving the failing Fontan pressures as the rigid TCPC could not replicate vessel constriction and dilation. The use of support struts in the rigid cannula prototype and large cross-sections also likely induced higher pressure losses. Future improvements may be done to the mock circulation loop including addition of flow straighteners upstream of the TCPC, another pressure transducer and flow sensors. Effects of physiological responses in SVC/IVC boundaries were not modelled in the CFD simulations and would require coupling a full-body lumped-parameter model. Further work is needed to validate a more refined cannula version in animal testing with a properly manufactured flexible cannula prototype.

3.4 CONCLUSION

CFD simulations of a proposed multi-lumen cannula in a patient-specific model with a cardiac output waveform were conducted. Results showed up to 2.25 mmHg pressure increase in the TCPC while a simulated pump failure case showed a maximum pressure loss under 2 mmHg. Pathlines and velocity contour plots showed formation and decay of vortices in the pulmonary arteries at varying stages in the cardiac cycle while wall shear stress contours showed a maximum WSS of 28.7 Pa at the RPA from the misaligned discharge lumen nozzle. Experiments done in the mock circulation loop showed potential for reducing the mean TCPC pressures in a failing Fontan circulation with cannula assistance. The results of this study represent a further step towards refinement of the cavopulmonary assist strategy.

Chapter 4 Conclusions

4 Contributions

A new minimally-invasive cavopulmonary assist strategy was outlined as an alternative shortterm solution for Fontan patients waiting for heart transplantation. Hemodynamic performance was characterized and investigated using computational fluid dynamics for typical Fontan TCPC as well as patient-specific geometries for bridging patients to transplantation. Results showed that pressure gain in the range required for cavopulmonary assist was achievable even for a bilateral SVC TCPC where available pump flow intake is substantially lower. Flow-weighted hemolysis index was also calculated for the idealized case using Lagrangian particle tracking and showed that hemoglobin damage was not significant in the TCPC region. Issues with elevated wall shear stress were identified in regions downstream of the cannula nozzle as well as in the nozzle protrusions and suction lumen entrance. Vortices propagating along the pulmonary arteries were also evident in varying flow cases.

Transient CFD studies were conducted for one of the patient-specific cases in Chapter 2 with realistic cardiac output flow and downstream outlets coupled to a Windkessel model. Results showed pressure gain performance in a similar range as that of the steady-state analysis with differences between LPA and RPA pressures decreasing at higher pump assist flows. A pump failure (no pump flow) case was also simulated which showed an induced pressure loss of under 2 mmHg. Mock circulation loop tests demonstrated a potential for decreasing mean TCPC pressures of a failing Fontan circulation at a limited range of physiological flows.

Overall, the work conducted in this thesis provides a first step towards a final design for commercialization. Hemodynamic performance in different TCPC geometries were investigated and potential design issues were identified in the CFD studies. Testing of a rigid prototype in a mock circulation loop also highlighted further considerations to be addressed.

4.1 Future Work

In its current form the proposed cavopulmonary assist strategy requires further work to address a few considerations and issues. The most pressing concerns are the cannula sizing and implications for customization to each individual patient, performance validation and related practical problems, and determination of blood damage for allowable duration of operation. These issues and possible future research directions are outlined in more detail below.

4.1.1 Cannula Sizing to Patient

Initially, the multi-lumen cannula was designed as a one-size fits all device using an idealized TCPC geometry as a basis for the design work. The current size was reached based on the ideal 22 mm SVC diameter and a maximum diameter of 16 mm based on input from the collaborating cardiac surgeon. The available adult Fontan patients TCPC geometries all had smaller SVC diameters which may be problematic from a clinical perspective. Furthermore, branches in the pulmonary artery were shown to complicate flow structures downstream of the nozzles. Customization of the cannula to patient-specific cases will either require pre-planning through a robust CFD optimization or by selecting an appropriate cannula size from a catalog based on vessel geometry.

A predefined catalog can be accomplished with an in-depth CFD study to find optimal sizes and pump intake. Parameters of interest may include ratio of lumen to vessel diameters, ideal pump intake flow for a given cardiac output, nozzle position and angle with respect to centerline for several types of pulmonary arterial ends (e.g., gradual converging ends common in RPA with multiple side branches, or bifurcation of two or more branches). This study could be modelled as a jet flow inside a wall-bounded cylinder to reduce computational cost.

4.1.1.1 Cannula Design

Further refinement of the cannula nozzles and potentially design iterations is necessary before reaching commercialization stage. Initial CFD results showed that separate nozzle directions into the pulmonary arteries were required instead of a single discharge port at the center of the TCPC

due to recirculation of flow back into the pump. With the two discharge lumens this issue is greatly reduced but not eliminated completely. One potential design alternative which was considered was using an outer nozzle cone with an exterior inflatable balloon to fix the nozzle location at the LPA and RPA centerlines while still allowing for IVC and SVC flow to pass through. This design greatly enhances the pressure gain performance and solves the nozzle misalignment problem. The downside is design complications in inflating the balloons for two nozzles and difficulty in cost-effective prototype testing.

Lastly, the current cannula suction lumen entrance and internal helical protrusions in the nozzles need to be refined to further reduce the wall shear stress at peak cardiac output and flow intake. The protrusions may also be unnecessary as they were included to avoid near-infinitely long residence times when particle tracking was done in the perfectly symmetrical idealized TCPC model.

4.1.2 CFD Resolution and Patient-Specific Geometries

Due to the complex flow conditions and vastly different velocities involved, the first-order upwind scheme was primarily used to resolve the momentum equations and avoid convergence issues. Most of the flow cases had Reynolds numbers that are considered transitional in the discharge lumen. Combined with the converging nozzle and much slower velocities in the pulmonary artery, turbulent-like structures may be present and the use of k-kl-ω transition model with first-order upwind may not be adequate in resolving the flow field accurately. As such, a less numerically diffusive model such as the LES-WMLES (large eddy simulations – wall modeled large eddy simulation) or SAS (scale-adaptive simulation) models will provide better resolution of flow structures essential for estimation of particle residence times and hemolysis damage. The computational requirement for these schemes can be greatly reduced for the jet flow and wall-bounded vessel simplification. Incorporation of fluid-structure interaction (FSI) with CFD will also improve the modelling of vortices formation and WSS results.

This study only simulated two patient-specific TCPCs due to lack of patient MRIs with sufficient contrast and resolution. In future work, more patient-specific TCPCs should be segmented and simulated with CFD to identify any further potential geometry-induced problems with the multi-

lumen cannula. Further work could also be done to improve the quality of patient-specific models as certain vessel surfaces were less than ideal due to software limitations. The high WSS in Patient A's RPA and Patient B's LPA may have partially been caused by unsmooth wall surfaces as a result of surface mesh decimation and artificial boundary extension. Hemodynamic data from 4D MRI and catheter measurements for these patients can also be collected and used to create more complex lumped parameter models to better simulate physiological responses to cavopulmonary-assist. At present, the Windkessel model may not be the most accurate way of representing the downstream pulmonary response.

4.1.3 Mock Circulation Loop and Animal Trials

Further prototype testing of the cannula is needed prior to proceeding with animal trials. Issues with clinical usage cannot be identified using a 3D printed rigid-wall prototype in the mock circulation loop. Limitations in available 3D printing facilities did not allow for a flexible cannula to be used in the experiments. New manufacturing methods for making flexible prototypes should be examined in the future. The manufacturing should be cost-effective and be suitable for rapid design iterations. Partnership with a commercial biomedical device company would provide better resources and manufacturing know-how which would greatly expedite the progression from academia to industry. Improvements to the mock circulation loop can also be conducted to improve ease of use and flow stability.

Animal testing using a properly manufactured cannula prototype will be required to further identify clinical-related problems and validate the performance as a cavopulmonary assist device. Testing with animal blood in a mock circulation loop or through animal testing is needed to characterize the accumulated blood damage as this determines how long the cavopulmonary-assist device can be safely used as a bridge to transplant device.

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