A Design Feasibility Investigation for a Pulmonary ePTFE Transcatheter Pediatric Heart Valve

Ryan M. Arul[1], McKaila K. Danajka[1], Emily C. Gray[1], Kendall P. Henretta[1], Dr. Olga Pierrakos[2]
arulrm18@wfu.edu, grayec19@wfu.edu, henrkp19@wfu.edu , danamk18@wfu.edu , pierrao@wfu.edu
1. Senior Engineering Students, Department of Engineering, Wake Forest University
2. Founding Professor, Department of Engineering, Wake Forest University

***Abstract* - The most replaced valve in the congenital heart defects population is the pulmonary valve. Current treatments require multiple invasive, open-heart surgeries to replace the pulmonary valve as the patient grows. Minimally-invasive procedures, such as transcatheter pulmonary valve replacement, circumvent open heart surgery, which benefits patients and physicians. ePTFE valves have gained prominence recently because they allow cardiothoracic pediatric surgeons to tailor the valve size to the patient. Clinical studies point to the high patency of ePTFE valves. Currently, there are no FDA-approved transcatheter valves made with ePTFE. The purpose of this paper is to offer a preliminary design feasibility investigation of developing a transcatheter ePTFE pulmonary valve. We used an existing FDA-approved Medtronic Ensemble II delivery system to test and evaluate the feasibility of fitting an ePTFE pediatric valve to this existing deployment system. The prototyping and testing goals were: (1) to evaluate stent expansion, (2) to explore anchoring mechanisms, (3) to collapse the stent with the ePTFE conduit down to a size that would fit into a catheter, and (4) to expand and deploy the ePTFE stent-conduit pulmonary valve. Testing revealed that ePTFE conduits with wall thicknesses of 1 mm and 0.5 mm did not collapse to a small enough diameter to fit in the sheath of the Medtronic Ensemble II delivery system. However, expansion of anchored stents showed that valves upheld circular cross-sections when deployed. For the valve to be widely distributed, the product must follow FDA and ISO 5840 standards to ensure appropriate performance. There remains considerable future work to deliver a well-functioning ePTFE transcatheter pulmonary heart valve solution for pediatric patients.**

I. Introduction

Cardiovascular disease is the most common cause of death in the United States [1]. When it comes to pediatric patients, cardiovascular disease is most directly linked to congenital heart defects (CHDs). Nine babies out of one thousand are born with congenital heart defects (CHDs) leading to abnormal and sometimes fatal heart functions [2]. Up to 20% of these pediatric patients with CHD have deformities involving their pulmonary heart valves and right ventricular outflow tracts (RVOTs), which often require multiple, invasive procedures for treatment [3]. Due to less of a market share, pediatric patients lack equitable treatment options compared to adults, especially for heart valve replacement. The most common cardiac procedure among these pediatric patients is invasive and involves replacing the pulmonary valve as the patient grows [4]. For patients below the age of eighteen, the reintervention rate for bioprosthetic valves is still five times greater than for adults with pulmonary valve replacement [5]. This paper focuses on exploring a novel pulmonary valve replacement solution for pediatric patients that addresses these problems.

The current solutions for pediatric patients who need a pulmonary valve replacement involve both open heart surgery (surgical valve options) and minimally invasive options (transcatheter valves). Among surgical pulmonary valves, there are currently multiple materials used such as titanium, animal tissue, and expanded polytetrafluoroethylene (ePTFE) [6]. However, the number of viable materials is significantly reduced for pediatric patients due to size constraints. Among materials used for pediatric valves, ePTFE valves have been found to have the highest patency rates due to less calcification and infection [7]. The challenge with ePTFE valves though is that there are over 20 unique ePTFE valve designs and most have not been tested by engineers towards the goal of meeting FDA requirements and ISO standards. Currently, no ePTFE valve is FDA-approved nor has undergone FDA-approval. Minimally invasive procedures, such as transcatheter pulmonary valve replacements, circumvent open heart surgery, which benefits patients and physicians, but do not come in sizes small enough to benefit the youngest of pediatric patients [8]. A transcatheter valve is a device that can be intravenously entered into a patient, maneuvered into position using a guidewire and catheter, and deployed using balloon expansion into an area of interest within the heart to replace a faulty heart valve. At least five separate transcatheter valves are FDA-approved for adult heart valve replacement. The sizing of these valves ranges from 18 to 30 mm. However, there are no FDA-approved transcatheter valves smaller than 16 mm, leading to a need for patients with this pulmonary valve size [8].

The opportunity exists to deliver a new FDA-approved pulmonary prosthetic heart valve for pediatric patients, and this is the focus of this paper. Less than 12% of the National Institute of Health's (NIH) budget is directed toward pediatric research and less than 10% of healthcare spending goes towards pediatrics in general [9]. The low budget for pediatrics leads to fewer options and accessibility to medical devices for pediatric patient treatment. This can have a major adverse impact on pediatric patients with specific, uncommon diseases. Typically, medical devices are scaled down for adolescents from adult device options, but younger pediatric patients are still completely overlooked. According to pediatric medicine specialist Dr. Juan Espinoza, "another common refrain in the health care innovation world is, 'Healthcare is hard; medical devices are harder; pediatric medical devices are the hardest'" [9].

The purpose of this paper is to showcase the progress of a Design Feasibility investigation for an ePTFE transcatheter pulmonary pediatric heart valve and building on the work of previous preliminary testing of a quadleaflet ePTFE pediatric pulmonary valve [10]. A Design Feasibility is a process that examines how well a new design direction

can deliver on requirements and goals. It is a preliminary attempt at a technical confirmation of the technical feasibility of a novel solution towards meeting constraints, such as existing infrastructure and approaches (e.g., current use of transcatheter deployment systems, current methods cardiothoracic surgeons use, etc.). Some of our preliminary design goals were: (1) to use a catheter-based prosthetic heart valve deployment system that is applicable for pediatric patients, (2) to target the needs of patients from five to twelve years old, and (3) to align with ISO 5840 standards for potential FDA approval and commercial use. The ability to deliver a catheter-based ePTFE pediatric pulmonary heart valve will positively impact both pediatric patients and physicians as it is a minimally invasive procedure compared to open heart surgery. Pediatric patients will benefit directly by not needing open heart surgery if a minimally invasive option is available to them. Physicians will benefit by having a less invasive option to address tissue degradation and helping their patients who would ultimately need multiple open-heart surgeries over their lifetime.

II. Background

The human heart contains four major valves that control the flow of both oxygenated and deoxygenated blood into and out of the heart: the mitral valve, aortic valve, pulmonary valve, and tricuspid valve. These valves, shown in Figure 1, contain either two or three leaflets and divide the heart into four chambers. On the left side of the heart where oxygenated blood flows, the mitral valve separates the left atrium and ventricle while the aortic valve controls the flow between the left atrium and the aorta. On the right side of the heart with deoxygenated blood, the tricuspid valve separates the right atrium from the right ventricle while the pulmonary valve controls the flow between the right ventricle and the pulmonary artery [11].

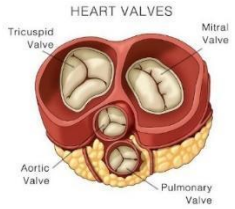

Figure 1. Top view of heart valves [12].

Due to the number of CHD patients with RVOT deformities, the main area of concern for this project is the pulmonary valve through which deoxygenated blood flows. The pulmonary valve is a trileaflet valve (i.e. three cusps) that controls flow towards the lungs by which blood can become oxygenated once again. Without proper blood flow through the pulmonary valve, lower levels of oxygenated blood return through the heart and are pumped out through the body which leads to fatigue, shortness of breath, and right-sided heart failure [13]. Therefore, the function of this valve is of the utmost importance.

For pulmonary heart valve replacements, there are currently multiple materials used - titanium, animal tissue, and ePTFE [6]. However, for pediatric patients, the size of the valve places constraints on the types of materials that can be used for surgical valves. The most common materials used in FDA-approved transcatheter pulmonary heart valves for pediatric patients are porcine and bovine tissue. However, these tissues have lower patency rates than clinically approved ePTFE valves [14]. ePTFE is a linear polymer consisting of fluorine and carbon molecules that is expanded, creating a microporous structure. This is to improve the properties of the material including a high strength-to-weight ratio, biocompatibility, and high thermal resistance. ePTFE does not adhere to body tissue because it is hydrophobic and oleophobic. This leads to less calcification and stenosis risk [7].

In previous studies, ePTFE material has had the capacity to stretch in graft applications. The Gore-Tex stretch vascular graft, which is made of ePTFE, is known to have a median diameter dilation of over 15% in all aspects of the graft after 12-36 months [15]. This is important for the target population as valve longevity within the patient's body is important. Considering the valve will be oversized (to delay replacement) and will have the ability to expand its diameter by about 15%, ePTFE valves have a significantly longer patient lifespan than other valves [14]. This expandability coupled with higher patency rates was the justification behind choosing ePTFE as the valve material.

Transcatheter valves are made up of various components, including a catheter, an expandable balloon, a stent, and a valve. The commonly used transfemoral retrograde procedure consists of only a few steps [16]. To access the left ventricle, a small incision is made near the femoral vein and a catheter is inserted [17]. From there, physicians advance the catheter to the heart with the use of X-ray guidance. Once the correct location has been established, a guidewire is inserted, allowing for the transcatheter valve to reach the correct position. Once this has been done, the physicians implant the artificial pulmonary valve in place of the old one [18].

Transcatheter pulmonary valve replacement (TPVR) allows for faster recovery times and fewer surgical procedures in the future compared to surgical valves that are inserted via open-heart surgery [17]. While the hemodynamics for this procedure is usually excellent, residual paravalvular regurgitation is frequent [19]. This is when the artificial valve does not close properly, thus causing blood flow to leak back into the chambers of the heart. This is harmful as it may cause failure within the ventricle as well as reduce blood flow to the heart and lungs [18]. Moreover, there are risks with the procedure as well, such as periprocedural stroke, vascular and conduction disturbance complications, and relatively high midterm mortality [19]. Existing FDA-approved transcatheter valves for adult populations are often too large of a caliber to be utilized in procedures [16].

As an invasive medical device, an ePTFE Transcatheter Pulmonary Heart Valve, will need to undergo FDA approval. The FDA-approval ensures the efficiency and safety of medical products used in the United States. The

relevant standards to be followed are ISO 5840 Standards for Cardiovascular Implants — Cardiac Valve Prostheses [20]. As part of this Design Feasibility investigation, the following are important ISO 5840 related standards:

TABLE I
HEMODYNAMIC PERFORMANCE ISO STANDARDS [20].

ISO Parameter	Description	Target Range
Heart Rate	Number of heart contractions over time	60 to 140 beats/minute
Cardiac Output	Ventricular volumetric flow rate	2 to 5 liters/minute
Peak Differential Pressure Gradient	Maximum pressure loss across valve	10 mmHg minimum
Effective Orifice Area	Minimal cross-sectional area of downstream flow [21]	0.70 cm^2 minimum
Regurgitation Fraction	Percentage of back flowing blood volume divided by forward flow volume	10% forward flow volume maximum

TABLE II
STRUCTURAL PERFORMANCE ISO STANDARDS [20].

Testing Method	Assessment
Accelerated Wear Testing	Wear of valve in accelerated-time conditions
Dynamic Failure Mode Testing	Potential durability-related failure modes
Real-Time Wear Testing	Wear of valve in real-time conditions
Device Structural Component Assessment	Structural fatigue and biocompatibility

III. BENCHMARKING

I. Existing Transcatheter Heart Valves Benchmarking

Benchmarking of existing transcatheter valves has been an important part of our feasibility investigation. Table 3 showcases transcatheter heart valves that are FDA approved or not, as well as those used in pediatric patients or not.

TABLE III
MATRIX OF TRANSCATHETER BENCHMARKS

	Transcatheter Valves FDA Approved	Transcatheter Valves Not FDA Approved
Transcatheter Valves Used in Pediatric Patients	Melody Valve (Medtronic) [8] Harmony Valve (Medtronic) [22]	ePTFE Valves (Lin et al.) [23] Chang et al. [24]
Transcatheter Valves Not Used in Pediatric Patients	SAPIEN 3 Ultra (Edwards) [25]	Venus-P Valve (Venus Medtech) [26]

The ***Edwards SAPIEN 3 Ultra Transcatheter Valve*** is considered to be the gold standard of replacement transcatheter heart valves. This is one of the limited FDA-approved transcatheter valves and has been successfully implemented in replacing heart valves. This design allows for an expandable and collapsible sheath, which is important when it comes to determining the correct size, and is accompanied with an open stent geometry. A limitation of this design is that it is neither re-sheathable nor repositionable, so once the artificial valve has been removed from the sheath, it's in its final position. The largest limitation of this device is the size range which limits use for pediatric patients. The average size of a pediatric pulmonary valve is smaller than 16 mm, whereas the Sapien is available in diameters of 23-29 mm fully expanded [19].

The ***Melody Transcatheter Valve*** is another one of the limited FDA-approved designs for transcatheter valve replacements. One of the largest advantages of this device is its use in pediatrics, as the sizing options (16 and 18mm) are suited for older pediatric patients [8]. An additional option is the ***Harmony Medtronic transcatheter valve***. The valve leaflets have advantageous kinematics across the full range of pressures within the right side of the heart due to the material of choice: porcine pericardium [27]. Moreover, it has been shown to have faster recovery times and less pain for patients compared to other procedures and valve replacements [8], [22].

Lin et al. has demonstrated the feasibility of ePTFE based valves being delivered via a transcatheter system. While it is used in pediatric patients, it is not FDA approved. Moreover, these valves are made from aortic stent grafts which may have differences to pulmonary grafts[23].

Finally, the ***Chang et al.*** points to a valve that combines hand-made ePTFE valves with transcatheter delivery options. These valves are made using the "flip over" method and have been used in both benchtop testing and been implanted clinically in 42 patients. Trials demonstrated satisfactory results and it was determined that this design would be one of the most feasible for further BIB transcatheter pulmonary valve replacement [28].

II. Existing ePTFE Pulmonary Heart Valves Benchmarking

Benchmarking of existing ePTFE pulmonary heart valves was important to our Design Feasibility investigation as well. Several studies have been conducted (from 2005 to 2020) on ePTFE pulmonary valves involving over 100 pediatric patients per study. All studies with over 100 patients except Dr. Koh's study which had a patency rate of greater than 90%. A comprehensive review of ePTFE studies before 2020 found that ePTFE pulmonary valves have a 95.1% 10-year freedom of reintervention while porcine xenografts only have an 86.5% 10-year freedom of reintervention. The same study also found that porcine xenografts have an 81.3% 15-year reoperation-free rate while bovine pericardial valves only have a 60.6% 15-year reoperation-free rate [7].

While survival rates of different ePTFE valves is important, we desired to understand the design differences among these ePTFE valves. Benchmarking highlighted the need for smaller diameter sizes as well as the accessibility of the procedure, which impacted system requirements. Moreover, benchmarking provided key design details of FDA-approved solutions that could then be utilized in the device concept generation and design.

IV. DESIGN CONSIDERATIONS

In our Design Feasibility investigation, we identified a set of design requirements to guide the team. These system requirements are primarily driven through the examination of the stakeholder's needs and influenced by benchmarked solutions. The ePTFE transcatheter pulmonary heart valve should:

(1) *Be compatible with pre-existing delivery systems.*

If the system is compatible with pre-existing catheter delivery systems, engineers can cut down on design time, allow for ease of testing the system, and physicians will not have to be trained on a novel delivery system. This reduces the time for the system to increase accessibility for the use of the system globally.

(2) Have a diameter of 16 mm when fully expanded.

The 16 mm expanded diameter of the system fits the size of the orifice of pulmonary heart valves of children aged 5 to 12 years old. This became our target pediatric population

primarily as a result of communicating with stakeholders Dr. Ross Ungerleider and conducting background research on existing heart valves.

(3) *Collapse down to 4.1 mm.*

The valve must collapse down to 4.1 mm, which is the diameter of the sheath on our delivery system, the Ensemble 20mm transcatheter delivery system, which is inserted through the femoral vein. The femoral vein diameter in children ages 5-12 years old is 6.6 mm to 7.4 mm [29] so we know that a catheter must be smaller to allow for clearance.

(4) *Include a conduit to provide structural support for the pulmonary artery.*

Pediatric pulmonary valve replacements need to be structurally supported and reinforced due to physical deformities of the vessel. A conduit is the cylindrical tube that enables the leaflets to be secured and positioned appropriately. The stent is positioned on the outside of the cylindrical tube. To minimize adverse hemodynamic effects, a conduit can provide structural integrity for the vessel and serve to secure and position the leaflets appropriately.

Figure 2. Hand-sutured PTFE Conduit.

(5) Deliver trileaflet ePTFE valve.

A natural pulmonary valve in humans is a trileaflet valve, which means that the valve has three cusps. Thus, the design requirement is that a trileaflet ePTFE heart valve should be designed. With regards to the specific shape and dimensions of the leaflets to be used for the system, we decided to target an ePTFE valve design from a collaborator (Dr. Otaki) as illustrated in Figure 3.

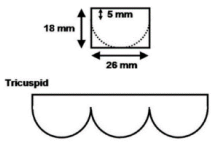

Figure 3. Dr. Otaki's stent template [30].

(6) Uphold a circular cross-section when deployed.

Considering the physical deformities of the pulmonary artery that pediatric patients have, it is important for any valve replacement solution to uphold a circular cross-section in order to ensure appropriate hemodynamic performance.

(7) Meet ISO 5840 performance standards.

ISO 5840 are the regulatory standards that are required by the FDA to ensure the safety and effectiveness of heart valve systems and provide guidance for system testing. The ISO 5840 "Standards for Cardiovascular implants — Cardiac valve prostheses — Part 1: General requirements" outline and provide guidance on technical requirements as well as testing requirements. Requirements are based on the age of the patient which the system is targeted for. ISO 5840 standards provide target performance ranges for pressure gradient, peak differential pressure, and flow rates, which have also been provided previously.

V. Conceptual Design

The critical components of FDA approved transcatheter heart valves include: (1) the heart valve, (2) a deployment system, and (3) a stent. The ePTFE valve we selected for use in our design feasibility investigation is Dr. Yoshio Otaki's trileaflet ePTFE valve which has been implemented in many patients [30]. Dr. Otaki is currently Professor of Surgery at Oregon Health and Science University (OHSU). Dr. Otaki provided a 20-mm ePTFE trileaflet valve that we used in our prototyping and testing Upon deciding which ePTFE valve will be the valve of choice in our Design Feasibility investigation for developing a transcatheter pulmonary valve solution, we focused on deciding the appropriate deployment system and stent.

To support the implantation of a transcatheter ePTFE valve, two types of deployment systems were considered: a balloon expandable system and a self-expandable system. Ultimately, a balloon expandable deployment system was determined to be the preferred deployment system for an ePTFE valve. Balloon expandable deployment is more suitable for smaller diameter valve sizes than self-expandable deployment. Research shows that the use of self-expandable deployment was associated with a higher risk of paravalvular regurgitation, higher in-hospital, and 2-year mortality compared with the use of balloon expandable deployment [31].

Furthermore, balloon-expandable deployment has a lower risk and intervention rates with valve replacements [31]. The feasibility of a balloon expandable transcatheter ePTFE valve has been investigated before [Zhang et al. 2014] and this further justified our decision to select a balloon expandable deployment system. For purposes of prototyping and testing, which will be detailed in the next section, we purchased and used the FDA approved Medtronic Ensemble II Delivery System.

Regarding stent selection, sizing limitations due to the patient population reduced the number of available stents that could work with the Medtronic Ensemble II Delivery System. The NuMed CP-Stent was the only stent that had a suitable length to anchor to a conduit and was designed to collapse to within 4.1 mm to fit in the sheath of the Medtronic Ensemble II delivery system. In addition, the NuMed CP-Stent was chosen due to its similarities in the stent's open-cell geometry to both the Lin et al. transcatheter ePTFE valve replacement study [23], and the FDA approved Edwards Sapien Heart Valve [19]. The NuMed CP-Stent also fits the appropriate diameter range of the patient population and is made of platinum-iridium. Lastly, the BIB catheter was bought and used with a crimping system to expand and collapse the stent and valve system. As a result of this research, it was determined that each of the components could be used together to make a prototype to be tested.

Table 4 serves to summarize the key designs that guided our conceptual design and informed our prototyping and testing work described in the section that follows.

TABLE IV
DESIGN OF PROTOTYPE FOR NON-INVASIVE REPLACEMENT HEART

Component	Prototype Design	Summary of Rationale
Stent	NuMed CP Stent	Open-cell Geometry, collapsibility, expandability, and suitable diameter
Balloon-in-Balloon Catheter	NuMed BIB017	Compatible with expanding the NuMed CP Stent
Valve Material	ePTFE Conduit	Higher Patency Rates, Less Calcification, Less Infection [7]
Deployment System	Ensemble II Delivery System	Lower mortality rates, Lower chance of complications [31]

VI. Prototyping & Testing

The goal of prototyping was to demonstrate we can successfully (1) expand the stent, (2) anchor to the ePTFE conduit to the stent, (3) collapse the stent with the ePTFE conduit down to 4.1 mm, and (4) use an existing FDA approved transcatheter delivery system to expand and deploy the ePTFE stent-conduit pulmonary valve.

Expansion and Collapsing of the Stent

The NuMed CP stent was expanded to 20 mm in diameter using the BIB catheter system. According to the chart of pressure to diameter values provided by NuMed, the inner balloon was expanded using 5 atm of pressure and the outer balloon was expanded using 4 atm of pressure using a pressure gauge.

Fitting of the 1 mm ePTFE Conduit with the Stent

The 20 mm ePTFE valve provided by Dr. Otaki was placed inside the expanded 20-mm NuMed CP stent to gauge fit. The valve fits perfectly inside the stent. The ePTFE valve conduit length was longer than the NuMed CP stent length. Length of ePTFE conduit would be something that a surgeon would determine based on patient specific information. Separate conduits of the same thickness were used for testing to preserve Dr.Otaki's valves.

Collapsing of the 1 mm ePTFE Conduit with the Stent

Collapsing the ePTFE valve with the stent revealed that the valve did not collapse in a uniform manner. The collapsed stent with the ePTFE valve could not fit in the sheath for the catheter, shown in Figure 5 below. This revealed that the ePTFE valve thickness of 1 mm is too thick to be used with the Medtronic Ensemble II delivery system.

Figure 4. Collapsed NuMed CP Stent and 1-mm ePTFE Conduit.

For deployment testing the following procedure is followed. The valve is collapsed as shown in Figure 4. Two balloon catheter pumps are filled with water and attached to the inner and outer balloon hubs on the delivery system. The inner balloon is expanded to 5 atm pressure with one balloon catheter pump. Once the inner balloon is expanded, the outer balloon is immediately expanded to 4 atm pressure with the other balloon catheter pump. This leaves the fully expanded system as shown in Figure 5. The stent's structural integrity was compromised due to non-uniform expansion. In the image on the left of Figure 5, the correct stent geometry is retained on one side of the stent-valve system, but on the right, the stent geometry is warped.

Figure 5. Expanded NuMed CP Stent and 1-mm ePTFE Conduit (Left) and Warped NuMed CP Stent and 1-mm ePTFE Conduit. (Right)

Expansion and Collapsing of an 0.5-mm ePTFE Conduit

Thinner ePTFE (0.5-mm) was acquired and a circular conduit with an inner diameter of 20 mm was mocked up to attach to the stent. The ePTFE conduit length was sized down to match the stent length. The ePTFE valve conduit was anchored to the stent as shown in Figure 6, by suturing knots between the conduit and the stent along their shared circumference to facilitate uniform expansion and collapsing.

Figure 6. Conduit of ePTFE anchored to Expanded CP Stent.

Testing of the Deployment System with the 0.5-mm ePTFE Conduit Anchored to the Stent

Upon replacing Dr. Otaki's 1-mm thick 20-mm diameter ePTFE valve with the thinner ePTFE conduit (0.5-mm), the valve and stent were crimped onto the Ensemble II Delivery system using a handheld crimper as shown in Figure 7.

Figure 7. Prototype: Collapsed NuMed CP Stent & 0.5-mm ePTFE Conduit Crimped on Ensemble II Delivery System.

After crimping the system, the ePTFE again folded in an uneven pattern as shown in Figure 7 and did not collapse to a diameter that would fit within the sheath. For deployment testing the same procedure is followed as the one for the 1-mm ePTFE conduit, but this time deployment was tested into a tube instead of into air. After the system is expanded inside of the tube the water in the inner and outer balloons is withdrawn and, collapsing the balloons and leaving the deployed valve system as shown in Figure 8.

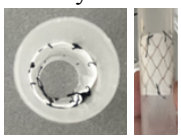

Figure 8. Expanded Stent & ePTFE Conduit deployed into clear tube.

Figure 8 shows that despite uneven collapsing due to folding in the ePTFE the circular cross-section was mostly upheld when expanded due to the anchoring of the conduit to the stent. The delivery system functioned as intended in deployment and was able to successfully deploy the valve with minimal structural damage into a "landing zone" like those that accompany a Medtronic Melody Valve.

VII. Conclusions & Future Work

This design feasibility investigation outlined important design requirements that would be needed in delivering a transcatheter ePTFE pulmonary valve, but only

focused on sizing and fit. Prototyping and testing revealed that current ePTFE surgical valves are too thick to collapse down and fit within a catheter (4.1 mm in diameter) that could be deployed for pediatric patients. Preliminary testing revealed that both a 1 mm and 0.5 mm thick ePTFE conduit would not be able to collapse down to 4.1 mm to fit in the catheter. The 1 mm ePTFE conduit of 20 mm in diameter collapsed to a diameter of 10.2 mm and the 0.5-mm ePTFE conduit of 20 mm in diameter collapsed to a diameter of 9 mm. Assuming reducing the thickness by 50% causes the collapsed diameter of an ePTFE conduit to reduce by 1.2 mm then the ePTFE conduit would need to be around 0.05 mm in thickness to reduce the collapsed diameter to 4.1 mm. This is unfeasible as the current ePTFE valve designs use 0.1-mm leaflets and the conduit needs more structural integrity to survive the environment of the heart[30].However, the expansion testing of the ePTFE conduits was promising. This is because the 0.5-mm ePTFE conduit expanded uniformly when anchored to the NuMed CP-Stent with minimal visible structural damage.

Future work should focus on testing thinner ePTFE conduits, hemodynamics, and material testing in line with FDA requirements and ISO standards. In conclusion, the clinical promise of ePTFE pulmonary valves offer surgeons and patients a unique opportunity to be implanted via minimally-invasive, transcatheter approaches. Current ePTFE surgical valve designs need to be redesigned to fit within a catheter. Valves with conduit thicknesses greater than 0.5 mm will not work.

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