Applicability of handmade expanded polytetrafluoroethylene trileaflet-valved conduits for pulmonary valve reconstruction: An ex vivo and in vivo study

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ABSTRACT

Objective: The handmade expanded polytetrafluoroethylene (ePTFE) trileaflet-valved conduit could potentially be used as a substitute pulmonary valve replacement material, especially in children. The current study investigated (1) the function of the ePTFE trileaflet-valved conduits in an ex vivo experimental system and (2) the short-term performance of the conduit in a porcine model to verify its clinical applicability.

Methods: The competency of the ePTFE trileaflet-valved conduits was estimated through ex vivo (using a pulmonary mock circulation loop) and in vivo (in a porcine model with a damaged pulmonary valve) experiments. Explants were examined by gross morphology and histopathologic examination.

Results: In the ex vivo experiment, the ePTFE trileaflet-valved conduits were determined to effectively increase mean pulmonary pressure from 10.2 to 14.4 mm Hg compared with defective silicon-valved conduits. In addition, the regurgitation fraction value of ePTFE trileaflet-valved conduits was 15.9% to 18.1%, which was significantly better than the defective valve conduits (regurgitation fraction = 73.5%-85.7%). In the in vivo experiment, the valved conduits were confirmed to be with good valve position maintenance, and the valve and leaflets showed no signs of thickening or peeling after a short-term implantation period. There were also no significant signs of inflammation reaction on histopathologic examination.

Conclusions: The ePTFE trileaflet-valved conduits for pulmonary valve reconstruction showed acceptable performance and outcomes in the ex vivo and in vivo experiments. The ePTFE trileaflet-valved conduit may be clinically useful, although additional studies in animals should be conducted to determine its long-term outcomes. (*J Thorac Cardiovasc Surg* 2018;155:765-74)

The expanded polytetrafluoroethylene trileaflet-valved conduit is able to effectively reduce regurgitation.

Central Message

Handmade expanded polytetrafluoroethylene trileaflet-valved conduits for pulmonary valve reconstruction demonstrated acceptable performance and outcomes in the ex vivo and in vivo experiments in this study.

Perspective

The handmade expanded polytetrafluoroethylene valved conduit described herein may be clinically useful and could be developed into additional commercial products for open or percutaneous treatment strategies.

See Editorial Commentary page 775.

Right ventricle to pulmonary artery (RV-PA) continuity reconstruction has become one of the most common surgical procedures for treating children with complicated congenital heart disease, specifically for those with the right ventricular outflow tract obstruction.¹⁻³ After

reconstruction (and in part due to patients' growth), pulmonary valve and right ventricular function can worsen in some patients over time, warranting a pulmonary valve re-replacement.⁴ This re-do open heart surgery for pulmonary valve implantation or replacement

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Abbreviations and Acronyms

CT	= computed tomography
ePTFE	= expanded polytetrafluoroethylene
MCL	= mock circulation loop
RF	= regurgitation fraction
ReV	= regurgitation volume
RV-PA	= right ventricle to pulmonary artery
SV	= stroke volume

Scanning this QR code will take you to the supplemental video, appendix, table, and figure for the article.

incurs certain greater surgical risks, including a greater risk for operative morbidity and more severe pain, than the first operation.⁵ Various conduits, including homografts and xenografts, are used as reconstruction materials, but with limited source availability.¹ Furthermore, if needed, the use of commercial mechanical or tissue valve conduits might need sufficient sizes of pulmonary artery and thoracic capacity to accommodate them.^{1,6}

To circumvent or minimize the surgical risks associated with multiple cardiopulmonary bypass surgeries, expandable cardiac valves have been proposed as alternative conduits for use in these children.⁶ Catheter-based valve implantation allows the definitive surgery to be delayed until (near) adulthood or even allows for no further treatment in some individuals.⁶ Notably, although some commercialized products, such as the Melody valve (Medtronic, Minneapolis, Minn), the Edwards SAPIEN valve (Edwards Lifesciences Inc, Irvine, Calif), and the Venus P-valve (Venus Medtech, Shanghai, China), are approved for transcatheter implantation into the right ventricular outflow tract for valve placement with acceptable short/mid-term durability, they are not readily available in many regions or countries.^{7,8}

In recent years, researchers have indicated that a handmade pericardial patch sutured on a prosthesis graft can be used as a valved conduit as an alternative strategy for RV-PA continuity reconstruction in children; notably, the results of these studies have been excellent.^{1,9} Thus, in a previous study, we designed a cost-effective, handmade trileaflet stent graft by suturing a bisemilunar tricuspid-shaped expanded polytetrafluoroethylene (ePTFE) PRECLUDE pericardial membrane (W. L. Gore & Associates, Inc, Flagstaff, Ariz) onto a commercial transcatheter stent graft. Our results suggested that the conduit can be used for clinical purposes¹⁰; moreover, a follow-up study was conducted

by Lin and colleagues, who performed a successful transcatheter implantation.¹¹

However, the valve function, hemodynamic status, and the follow-up of the handmade ePTFE trileaflet-valved conduits were suboptimal. More data about the design, ex vivo hemodynamic evaluation, valve function, and in vivo performance of ePTFE trileaflet-valved conduits are therefore required to facilitate optimal clinical usage and development. In response, in the present study we demonstrated the function and hemodynamics of the handmade ePTFE trileaflet-valved conduits by performing ex vivo and in vivo experiments and noting the short-term outcomes in porcine model study.

MATERIALS AND METHODS

Optimal Design of Handmade ePTFE Trileaflet-Valved Conduits

We propose a formula for designing handmade, trileaflet-valved conduits with different diameters. The formula is derived from a trigonometric function and can be used to estimate the optimal parameters for handmade ePTFE trileaflet-valved conduits for young adults and children. As shown in Figure 1, the optimal design procedure can be summarized as follows:

- Step 1: The diameter (D') of the patient's main pulmonary artery is determined through computed tomography (CT) angiography and is used to ensure that the diameter of the conduit (D) is oversized: therefore, $D = (1.1 \sim 1.2) \times D'$;
- Step 2: The width (W) of each leaflet is one-third of the perimeter (P);
- Step 3: A semilunar cup, as the connecting junction in each leaflet, is determined by length (H_1); subsequently, the 2 isosceles angles, θ_1 and θ_2 , are used to estimate the isosceles length (D_1);
- Step 4: The hemline ($L = L_1 + L_2$) is used to reconstruct the pulmonary valve according to the radius (D_1) of the conduit chamber;
- Step 5: A general formula is used to design the handmade trileaflet-valved stents by varying diameter (D) and length (H_1 and H_2); and
- Step 6: A leaflet template is drafted using computer-aided design software (MATLAB plotting; MATLAB, MathWorks, Natick, Mass).

For diameters < 25 mm, the terms W_1 and θ_2 are the variable parameters. This formula is used to design trileaflet-valved conduits for children. In addition, for a fixed length of 5 mm, the formula can be approximated as $H \approx H_1 + 0.2887 \times \pi D$ for adult patients. Hence, the lengths of the curved structure and semilunar cup can be estimated (Step 6; Figure 1). The optimal design algorithm of these detailed formulas is presented in Appendix E1.

Valved-Stent Conduit Assembling

The proposed general design formula for each leaflet was implemented with LabVIEW programming software (National Instruments, Austin, Tex) (Figure 2, A); this template can provide the estimation parameters for modifying the leaflet shape in clinical practice. In addition, a leaflet template can be drafted with MATLAB plotting software (MathWorks, Natick, Mass), (Figure 2, B). In clinical practice, the graphic user interface for windows applications has reproducibility and flexibility to enable quick designing and drafting of leaflet templates. We trimmed an ePTFE pericardial membrane into designed bi-semilunar tricuspid leaflets. The trileaflet piece was sutured onto an inside-out flipped stent graft by using 6-0 polypropylene continuous sutures. Next, the sutured stent graft was flipped right side out to construct the valved conduit (Figure 2, C and D). The valved conduits were further folded and reloaded into the Medtronic thoracic stent-graft delivery device (Medtronic, Minneapolis, Minn) for the in vivo experiments.

FIGURE 1. Step 1, Axial slice of a CT angiogram at the level of the pulmonary trunk for measurement. Steps 2-6, Design procedure for shape modification of the leaflets. CT, Computed tomography.

Same as most instructions for use of the current aortic stent graft recommendation, the ePTFE trileaflet-valved conduit was implanted 10% to 20% oversized with respect to pulmonary artery. For example, for a pulmonary artery with an inner diameter of 23 mm, we used 26 × 30 mm or 28.5 × 30 mm stent grafts (EXCLUDER AAA Endoprosthesis Aortic Extender; W. L. Gore & Associates) to assemble and prepare valved conduits.

Valve Competency Testing Using a Mock Circulation Loop (MCL)

The competency of our handmade ePTFE trileaflet-valved conduits was estimated by using a mock pulmonary circulation system at the National Cheng Kung University Heart Science and Medical Research Center. An MCL is a mechanical representation of the human circulatory system. Typically, the lumped-parameter concept has been used for MCL designs, in which flow rate and pressure are considered important aspects while accurate wave phenomena are ignored. Pulmonary arteries were modeled and constructed via the use of silicone rubber casts with simplified T-shape geometric and compliance properties that are similar to those seen in the pulmonary circulation system.

In this study, pulmonary circulation was simulated with a hybrid 1-dimensional and lumped-parameter MCL that can mimic pulse-wave

propagation phenomena, as shown in Figure 3. This MCL consisted of one artificial right ventricle and a main pulmonary artery with right and left pulmonary branches; returning blood flow was deposited into the right atrium. The artificial right ventricle was made of silicone rubber with a heart-like appearance, and stroke volume (SV) was installed in an aluminum chamber. Two silicone rubber trileaflet valves were installed in the inflow and outflow of the right ventricle, respectively, to direct the flow direction similar to the function of the normal tricuspid and pulmonary valves.

Right ventricular function was simulated by using a digitally controlled hydraulic piston SuperPump (ViVitro Labs, Victor, British Columbia, Canada), which generated a pulsating flow to drive the chamber and send it into a compliant pulmonary artery. The artificial pulmonary artery was made of 2-mm thick, inner diameter 25 mm, silicone rubber with a T-shaped geometry. The volume compliance of the T-shaped artery was about 0.2 mL/mm Hg, and it was connected to the right and left lung compliance chambers. Two sets of compliance chambers and pinch valve resistors were designed and attached to the distal ends of the right and left pulmonary arteries to mimic the resistance and compliance characteristics of the distal vasculature. A reservoir compliance chamber also was connected to the left and right pulmonary branches with back flow to a right atrium compliance chamber. The measured segmental compliance and resistance values are

FIGURE 2. Gross picture of the handmade ePTFE trileaflet-valved conduits. A, The design formula for each leaflet was implemented with LabVIEW software (National Instruments, Austin, Tex). B, A leaflet template can be drafted with MATLAB software (MathWorks, Natick, Mass). C, Leaflets outlet side. D, Leaflets back inlet.

presented in Table 1. The pulmonary valve was substituted with handmade ePTFE trileaflet-valved conduits or with defective trileaflet silicon valve to test valve competency.

Measurements and Data Processing of the MCL

Data acquisition and filtering. The pulmonary artery flow rate was measured with a Transonic clamp-on flow sensor (ME16PXL; Transonic Systems, Ithaca, NY), and all blood pressure measurements were obtained with pressure transducers (81A 006G Sensormate, Chang Hau, Taiwan). All acquired pressure and flowrate data were

transmitted into a data acquisition card (PCI-6259; National Instruments, Austin, Tex) that was operated by LabVIEW (National Instruments). Postprocessing filtering was then performed with MATLAB. We set 3 heartbeats as one period, and the data were phase-averaged across 30 beats (10 periods) to establish a stable MCL with periodicity.

Valve stent performance index. Valve stent efficacy was evaluated with the regurgitation fraction (RF) (%), which was calculated as the ratio between backward and forward flow across the silicon pulmonary valve or ePTFE trileaflet-valved conduit.

FIGURE 3. Scheme and photo of the pulmonary circulation mock loop. PV, Pulmonary vein; RA, right atrium; RV, right ventricle.

Stroke volume. SV was defined as the volume of blood ejected per heartbeat. Specifically, it reflected the ejected blood volume that was delivered from the right ventricle and is calculated as follows:

$$SV = \int_{1 \text{ beat}} PAF dt. \quad (1)$$

where PAF, or the pulmonary artery flow rate (L/min), represents the flow rate recorded at the pulmonary artery.

Regurgitation volume (ReV). ReV was defined as the volume of blood that flowed backward across the pulmonary valve in one beat cycle, and is calculated as follows:

$$ReV = \frac{1}{2} \int_{1 \text{ beat}} |PAF| |PAF| dt. \quad (2)$$

Regurgitation fraction. The RF was estimated as the volume ratio between backward and forward blood flow across the pulmonary valve in one beat cycle and is calculated as follows:

$$RF(\%) = \frac{ReV}{SV + RV} \times 100\% \quad (3)$$

where ReV and SV are the regurgitation and stroke volumes, respectively.

Functional and Morphology In Vivo Tests in a Porcine Model

Our animal experiments were approved by the National Cheng Kung University Hospital ethics committee (MOST 104-2314-B-006-090). All of the animals received care in compliance with the Guide for the Care and Use of Laboratory Animals (www.nap.edu/catalog/5140.html).

Four healthy piglets, aged 4 to 6 months with an average weight of 40 kg, were used to evaluate the in vivo functions and morphologic changes that occurred in the implanted valves. The piglets' original pulmonary valves were destroyed by repeated traction from a Coda balloon catheter (Cook Medical, Bloomington, Ind), which was passed through from the right femoral vein sheath to create the pulmonary valve regurgitation model. One month later, the valved-stent conduits were implanted in the piglets' pulmonary valve regions via a percutaneous transvenous approach

via the femoral vein. In brief, a 6-French pigtail catheter (Cordis; Johnson and Johnson, New Brunswick City, NJ) was introduced through the femoral vein sheath to identify the route. A long, stiff wire was inserted to replace the catheter, then the whole delivery system (Medtronic) was advanced to deploy the valved-stent conduits under C-arm, fluoroscopy-guided assistance; transthoracic echocardiography was then performed to confirm the success of the implant (Video 1). After surgery, chest radiography and transthoracic echocardiography were performed every 2 weeks. After 1 month, the piglets' chests were scanned via CT, and the ePTFE trileaflet-valved conduits were retrieved to evaluate the morphology and determine whether thrombi were present.

RESULTS

Valve Competency Mock Test

Figure 4 depicts sample pressure and flow rate waveforms at the mock pulmonary artery. The right ventricle pumping SV and pumping rate were set at 40 mL and 80 bpm, respectively. The solid blue line, solid green line, and dashed red line represent the intact valve (silicone rubber trileaflet valve), handmade ePTFE trileaflet-valved conduits, and the defective silicon valve, respectively. Figure 4, A, reveals that the ePTFE trileaflet-valved conduit increased the mean pulmonary pressure from 10.2 to 14.4 mm Hg compared with the defective silicon valve (although not as perfectly as can an intact valve). The flow rate results in Figure 4, B, also show that the ePTFE trileaflet-valved conduit is able to effectively reduce regurgitation. The experimental results of the valve efficacy mock test at different heart rates and SVs are presented in Table 2; in particular, they indicate that the RF of the handmade ePTFE trileaflet-valved conduit was significantly improved compared with that of the defective trileaflet silicon valve (RF = 15.9%-18.1% vs 73.5%-85.7%, respectively).

TABLE 1. Mock loop components and their measured compliance and resistance

Name	Theoretical compliance, $\text{g}^{-1} \times \text{cm}^4 \times \text{s}^2$	Measured compliance, $\text{g}^{-1} \times \text{cm}^4 \times \text{s}^2$	Measured resistance, mm Hg/LPM
Left lung	2.3×10^{-3}	2.47×10^{-3}	240
Right lung	2.3×10^{-3}	2.4×10^{-3}	240
Right atrium	4×10^{-3}	4.2×10^{-3}	N/A

LPM, Liters per minute; N/A, not available.

Functional and Morphologic In Vivo Tests

After being implanted with the handmade ePTFE trileaflet-valved conduit (Figure 5, A and B), the piglets were housed for 1 month at a veterinary hospital to observe their general condition. Follow-up chest radiographs indicated that the artificial valves did not noticeably migrate (Figure 5, C), and the echocardiographs and cardiac CTs also revealed no evidence of valve stent dislocation or deformation; indeed, normal valvular and cardiac functionality was maintained (Figure 5, D-F). After 1 month, the piglets were killed to enable examination of the valve conditions and gross morphology. The gross morphology of the handmade ePTFE trileaflet-valved conduits demonstrated good valve position without migration, and both the valve and leaflets seemed grossly intact without significant thrombosis (Figure 6, A). Finally, histologic examination of the adjacent area of the valved stent revealed no significant signs of inflammatory reaction (Figure 6, B-D).

DISCUSSION

Right heart failure is not uncommon in patients after treatment for complicated congenital heart diseases

involving the right ventricular outflow tract, who can present with chronic pulmonary insufficiency, right ventricular dilatation, and ventricular arrhythmias.¹ Several materials have been used for repeated RV-PA continuity reconstruction, including homografts, bovine jugular vein conduits, the Hancock porcine-valved polyester conduit (Medtronic), and various brands of mechanical valves.⁴ However, availability, durability, and size limitations are the major concerns, along with limited use and applicability. Homografts are the preferred conduits of choice because of their superior handling characteristics and longevity; however, accessibility and size mismatching present considerable challenges to their use.¹ Moreover, one half of all patients who underwent a homograft operation may require a conduit exchange surgery within only 10 years after implantation.¹² The repeat open heart surgery revealed that the recipient's immune response and accelerated calcium turnover had caused graft wall calcification, and valvular annulus thickening was evident.^{1,13}

Although the Contegra bovine jugular vein graft (Medtronic) is available in a number of different sizes, reintervention rates remain significantly greater for younger patients or those with smaller conduits, with neointimal peel at the distal anastomosis perhaps occurring as the result of xenograft rejection.¹⁴ In addition, a graft infection rate of 11.3% has been reported with Contegra grafts.¹⁵ The major concerns for porcine-valved polyester conduits and mechanical-valve conduits are conduit kinking, sternal compression, and body size problems.¹ Because of the restricted availability and unsatisfactory durability of current conduits, alternative materials are being developed. For example, commercialized transcatheter stent-mounted

Trileaflet semilunar cusp design

VIDEO 1. 1. Applicability of the handmade ePTFE trileaflet valved conduits for pulmonary valve reconstruction: An ex vivo and in vivo study. 2. Design and output of the optimal trileaflets. 3. Optimal design of trileaflet valved stents. 4. Optimal design procedure. 5. Input the parameters $D = 28.5$, $H_1 = 4$ and computer programming. 6. Output the trileaflets design. 7. Trileaflet semilunar cusp design. 8. Preparation of ePTFE membrane. 9. Trileaflet rapid-design template. 10. Release the graft stent from the EXCLUDER AAA Endoprosthesis Aortic extender stent graft system. (Preparation/inside-out flipped stent/suturing semilunar ePTFE membrane.) 11. Release the stent graft from EXCLUDER AAA Endoprosthesis stent graft system. 12. Inside-out flipped stent graft. 13. Hegar dilator assistance. 14. Suturing the semilunar ePTFE membrane. 15. Flipping right side out to construct the valved conduits. 16. Assembly of the valved stent graft. 17. Valved stent deployment. 18. In vivo functional and morphologic tests. Video available at: [http://www.jtcvsonline.org/article/S0022-5223\(17\)31967-0/fulltext](http://www.jtcvsonline.org/article/S0022-5223(17)31967-0/fulltext).

FIGURE 4. A, Pulmonary artery pressure waveform. B, Pulmonary artery flow rate waveform at heart rate = 80 bpm and cardiac output = 3.2 L/min.

pulmonary valves, such as the Melody valve, SAPIEN valve, and Venus P-valve, may present suitable alternative strategies for treating these patients.^{6,7,14-16} However, they are unavailable in some areas or countries, and the major disadvantages are their needing wet storage and assembling in ice water.

Conversely, the ePTFE pericardial membrane has good biocompatibility and low antigenicity, and good outcomes for handmade ePTFE-valved conduits for open right ventricular outflow tract reconstruction surgery have been reported.^{1,9} Previously, we had reported our successful clinical experience of using handmade ePTFE trileaflet-valved conduit for pulmonary valve implantation,¹⁰ and the concept was followed up by Lin and colleagues,¹¹ who performed a successful transcatheter implantation. However, the actual valve functioning and postimplant status of these ePTFE trileaflet-valved conduits are ongoing concerns, necessitating repeat evaluation and analysis for further use and development purposes.

To enable better coaptation, we applied the bisemilunar tricuspid-shaped leaflets by adding a 3- to 5-mm curved structure on each leaflet.¹⁰ In addition, to simplify the

preparation process and minimize the tissue reaction situation, we used an EXCLUDER AAA Endoprosthesis aortic extender stent-graft conduits as our vehicle stent conduits. These conduits had the same advantages as those of the ePTFE pericardial membrane for leaflets with good biocompatibility and low antigenicity. Moreover, they had a low profile, suitable diameter size, and a stent length appropriate for handmade ePTFE trileaflet-valved conduits, with no need to trim, and a preexisting M-shaped edge.

We also developed the optimal design algorithm for clinical application of handmade ePTFE trileaflet-valved conduits, the formula for which is shown in [Appendix E1](#). Specifically, by varying D and H_1 , the estimation parameters of each leaflet can be determined using the proposed algorithm, as revealed in [Table E1](#), which presents the estimated parameters of handmade trileaflets with oversized diameters (15.0-40.0 mm). With this formula, the ePTFE membrane can be trimmed into a semilunar tricuspid-shaped leaflet, which can then be mounted in the stent conduit via hand suturing. To construct different diameters, the leaflet length approaches $P/3$, as seen in [Figure E1](#).

Notably, the proposed formula has more reliable estimation parameters than most instructions for use recommendations. When the diameter sizes of main pulmonary artery are measured by CT, surgeons can rapidly estimate the parameters for handmade trileaflet-valved conduit designs; in addition, the proposed general formula for stents in adults and children can be easily implemented via the use of a portable electronic device application ([Figure 2, A and B](#)). A leaflet template can also be easily drafted using the application and computer-aided design software such as MATLAB plotting, AutoCAD (Autodesk, San Rafael, Calif), or SolidWorks (Dassault Systèmes SolidWorks Corporation, Waltham, Mass) ([Figure 1](#)).

The results of our mock experiment using an ex vivo setup showed that the handmade ePTFE trileaflet-valved conduits were competent, although less perfect as “ideal” normal valve (silicone rubber trileaflet valves). Specifically, our handmade conduits raised the mean pulmonary pressure from 10.2 to 14.4 mm Hg compared with the defective silicone valves and effectively reduced regurgitation. Subsequently, after our in vivo experiment with piglets, we determined that the morphologies of the postimplant handmade ePTFE trileaflet valves were stable with no obvious thrombi or peel formation on the valve leaflets; the adjacent pulmonary artery region also showed no significant inflammatory reaction.

ePTFE is thought to have low tissue affinity and result in less cellular or fibrous deposition, which is advantageous for avoiding calcium deposition and stenosis development as well as for maintaining effective valve functioning over the long term. The use of this handmade ePTFE trileaflet-valved conduit strategy opens up the possibility of using them in open operations or by percutaneous methods.

TABLE 2. Summary of the mean RF in each test condition

No.	Heart rate, bpm	Input SV, mL	Silicone trileaflets valve			Defected valve			Handmade trileaflets valve		
			SV, mL	ReV, mL	RF, %	SV, mL	ReV, mL	RF, %	SV, mL	ReV, mL	RF, %
1	60	40	38.8	0.5	1.4	5.3	32.1	85.7	32.8	7.2	18.1
2	60	50	48.8	1.8	3.6	7.3	42.0	85.3	42.7	8.5	16.6
3	60	60	58.7	1.9	3.2	9.0	51.7	85.1	51.5	9.8	15.9
4	80	40	40.3	1.7	4.2	11.6	32.5	73.7	35.3	7.5	17.4
5	80	50	48.9	1.8	3.8	14.4	40.0	73.5	42.9	8.4	16.3
6	80	60	58.9	1.7	2.9	16.9	65.7	74.5	51.4	10.2	16.5

SV, Stroke volume; ReV, regurgitation volume; RF, regurgitant fraction.

Moreover, for patients of low body weight who require a smaller primary ePTFE conduit, we can provide slightly larger valved conduits with good thoracic adaptation capabilities and competent valve function for them, and then it might prevent the development of conduit stenosis and delay repeat intervention time. Finally, by using these proposed valved-conduits, repeated open-heart surgery might be avoided in patients who experience failed pulmonary valve function, which is both cost-effective and has demonstrated a good short- to mid-term follow-up.

Limitations

Because the handmade ePTFE trileaflet-valved conduits needed be folded and reloaded onto the Medtronic thoracic

stent-graft delivery devices, the length discrepancy might need another leg stent graft to be preloaded first to lessen the shortened length problem. Because of this limitation in the process, we need to design and develop a more suitable delivery system in the future. Second, we attempted to create pulmonary valve regurgitation in piglet models through repeated Coda balloon traction. However, because of problems with the equipment, the animal echocardiographs were only able to show the regurgitation flow; thus, the regurgitation flow ratio could not be precisely quantified. Finally, although the handmade ePTFE trileaflet-valved conduits showed acceptable performance over the short term, further in vivo animal experiments are required to determine the mid- and long-term effectiveness of the conduits.

FIGURE 5. A and B, The implantation of the handmade ePTFE trileaflet-valved conduits by percutaneous method under fluoroscopy on the pulmonary valve region. C, Chest radiograph shows the position of the valved-conduit. D, Color echocardiography reveals stent in the RVOT without obstruction. E, Doppler echocardiography reveals normal laminar flow through RVOT stent. F, Computed tomography shows the position of the valved-conduit on the pulmonary valve position.

FIGURE 6. Valved-conduit explants appeared to have good valve and leaflet function and with good coaptation conditions. A, Macro view of cross section of valve stent in the right ventricular outflow tract position. B, Valve stent adjacent area for histopathologic examination. C, Low-power (10 $\times$) field revealed no signs of inflammation. D, High-power (40 $\times$) field revealed no signs of inflammation.

CONCLUSIONS

Handmade ePTFE trileaflet-valved conduits showed acceptable performance for pulmonary valve reconstruction in both mock and animal experiments. The proposed optimal design algorithm was applied to design the handmade trileaflet-valved conduits with an oversized diameter. Notably, the algorithm was easily implemented with a portable electronic device application. We suggest that these conduits may be suitable for clinical purposes, although their long-term in vivo behavior requires further evaluation.

Conflict of Interest Statement

Authors have nothing to disclose with regard to commercial support.

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Key Words: pulmonary valve reconstruction, ePTFE trileaflet-valved conduits, porcine model

APPENDIX E1.

The procedure of the proposed optimal design formulas is delineated to follow:

- The width (W) of each leaflet is P/3 and is defined as

$$Perimeter(P) = \pi \times D \quad (4)$$

$$W = \frac{\pi D}{3}, W_1 = W_2 = \frac{1}{2}W = \frac{1}{2} \times \frac{\pi D}{3} = \frac{\pi D}{6} \quad (5)$$

- Two isosceles angles, θ_1 and θ_2 , are used to estimate the isosceles lengths, D_1 and L, as

$$\begin{aligned} \theta_1 &= \tan^{-1} \left(\frac{W_1}{H_1} \right), \theta_2 = 180^\circ - 2 \times \theta_1 \\ &= 180^\circ - 2 \times \tan^{-1} \left(\frac{W_1}{H_1} \right) \end{aligned} \quad (6)$$

- The isosceles lengths, D_1 and L, are

$$D_1 \times \sin(\theta_2) = W_1 \Rightarrow D_1 = \frac{W_1}{\sin(\theta_2)} \quad (7)$$

$$L_1 = L_2 = D_1 \times \sin(\theta_2), L = L_1 + L_2 = 2D_1 \sin(\theta_2), \quad (8)$$

- The length, H_2 , of the semilunar cups is

$$\begin{aligned} H_2 &\approx \sqrt{(L)^2 - (W_1)^2} = \sqrt{(2W_1)^2 - (W_1)^2} \\ &\Rightarrow H_2 = \sqrt{\left(\frac{\pi D}{3}\right)^2 - \left(\frac{\pi D}{6}\right)^2} \quad (9) \\ &\approx 0.2887 \times \pi D \end{aligned}$$

The length of the curved structure and semilunar cup can be designed for children and adult patients.

$$H \approx \begin{cases} H_1 + H_2 \\ H_1 + 0.2887 \times \pi D \end{cases} \quad (10)$$

- Two curved structures are drafted as follows:

$$\text{Lower Curve: } C_1(x) = \frac{x^2}{8 \times (D/20) \times H_1}, x \in [-W_1, +W_1] \quad (11)$$

$$\begin{aligned} \text{Upper Curve: } C_2(x) &= \frac{x^2}{-k \times (D/20) \times H_1} + |\min(C_2(x))| \\ &\quad \times | + 2 \times H_1 \end{aligned} \quad (12)$$

$$k \approx 1.9 - 1.75 \text{ for children, } k \approx 1.75 - 1.40 \text{ for adults} \quad (13)$$

Based on the 20-mm diameter in children, 2 terms, $(8 \times [D/20])$ and $(-k \times [D/20])$, can be used to modify the lower and upper curves for different size leaflets.

TABLE E1. Estimation parameters for handmade trileaflets

<i>D</i> , mm	<i>P</i> , mm	<i>W</i> ₁ , mm	θ_1 , degrees	θ_2 , degrees	<i>D</i> ₁ , mm	<i>L</i> , mm	<i>H</i> ₂ , mm	<i>H</i> ₁ , mm	<i>P</i> /3, mm	Estimation, mm
15.0	47.10	7.85	63.00	53.99	9.70	15.70	13.59	4.00	15.70	17.59
17.5	54.95	9.16	66.41	47.17	12.48	18.32	15.86	4.00	18.32	19.87
20.0	62.80	10.47	69.09	41.82	15.69	20.93	18.13	4.00	20.93	22.12
22.5	70.65	11.78	66.09	41.82	17.66	23.55	20.39	4.50	23.55	24.89
25.0	78.50	13.08	69.09	41.82	19.62	26.17	22.66	5.00	26.17	27.66
27.5	86.35	14.39	70.85	38.30	23.21	28.78	24.92	5.00	28.78	29.92
30.0	94.20	15.70	72.34	35.32	27.16	31.40	27.19	5.00	31.40	32.19
32.5	102.05	17.00	73.62	32.75	31.44	34.02	29.49	5.00	34.02	34.46
35.0	109.90	18.31	74.73	30.52	36.06	36.63	31.73	5.00	36.63	36.72
37.5	117.75	19.63	75.71	28.57	41.03	39.25	33.99	5.00	39.25	38.99
40.0	125.60	20.93	76.57	26.86	46.34	41.87	36.26	5.00	41.87	41.26

D, Diameter; *P*, perimeter; *W*₁, width 1; *D*₁, isosceles length; *L*, hemline; *H*₂, length; *H*₁, length; *P*/3, leaflet width.

FIGURE E1. Oversized diameters versus the leaflet lengths.