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

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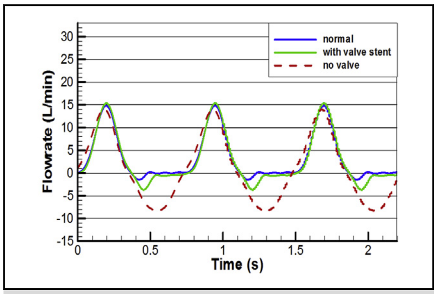
ABSTRACT

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.

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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 purposes[10]; 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, $D = (1.1\sim1.2) \times D'$;
- 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, $\theta1$ and $\theta2$, 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.