Modification of expanded polytetrafluoroethylene valved conduit using the thin-type leaflets

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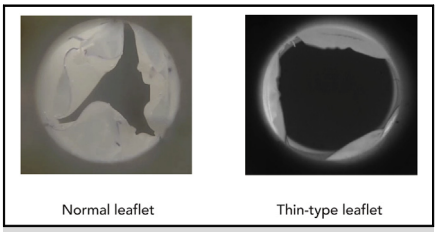
ABSTRACT

Objectives: The expanded polytetrafluoroethylene conduit with fan-shaped leaflets and bulging sinuses for right ventricular outflow tract reconstruction was modified with a newly developed thin-type expanded polytetrafluoroethylene leaflet. The purpose of this study was to evaluate the clinical outcomes and hemodynamic performance of the modified conduit.

Methods: From January 2010 to December 2013, 149 patients underwent definitive right ventricular outflow tract reconstruction using the expanded polytetrafluoroethylene conduit; the 55 patients receiving a conventional conduit (group N) were compared with the 94 patients receiving a modified conduit (group T).

Results: There were no conduit-related deaths, operative deaths, or reimplantations for conduit failure. The overall survival and freedom from reintervention for conduit-related reasons at 3 years were 98.2% versus 95.6% ($P = .438$) and 94.7% versus 97.9% ($P = .954$) for groups N and T, respectively. The mean peak pressure gradients were 22.6 ± 15.6 mm Hg versus 18.2 ± 11.5 mm Hg ($P = .161$), and in the subanalysis within small-sized conduits, they were 30.2 ± 16.5 mm Hg versus 20.4 ± 10.7 mm Hg ($P = .034$). Regarding conduit insufficiency, the modified conduit showed a significantly worse grade of insufficiency ($P = .014$) only in the subanalysis within large-sized conduits.

Conclusions: Although the clinical outcomes did not differ within midterm observation, the thin-type expanded polytetrafluoroethylene leaflet was considered to be suitable for the small-sized conduits, but not for large-sized conduits, based on the comparison of the hemodynamic performance. Long-term follow-up is necessary to address the appropriate sheet type for middle-sized conduits and to estimate the durability of the thin-type leaflet. (J Thorac Cardiovasc Surg 2018;■:1-8)



Comparison of maximum valve opening between the 2 types of leaflets.

Central Message

The thin-type ePTFE sheet as a leaflet material of the ePTFE valved conduit provides reduction of pressure gradient in the small-sized conduit, but increased regurgitation in the large-sized conduit.

Perspective

In the midterm observation, clinical outcomes of the 2 types of ePTFE conduits were equivalent regardless of the significant difference of hemodynamic performance. Further follow-up study will reveal the chronologic changes of the thin-type leaflets and the significance of this modification on the clinical outcomes in the long-term, and it will help improvement of the ePTFE conduit.

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Although several materials are used as an artificial valve in right ventricular outflow tract (RVOT) reconstruction for congenital heart disease, no material is ideal in terms of availability, hemodynamic performance, and, in particular, durability.[1-3] In 2002, we developed the expanded polytetrafluoroethylene (ePTFE) conduit with fan-shaped leaflets and bulging sinuses for RVOT reconstruction and started clinical application and supply to other institutes in Japan. In the past 15 years, more than 1000 conduits have been used in 65 institutes in Japan, and follow-up studies have revealed good valve function and durability as described previously.[4,5] The positive contribution of

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Abbreviations and Acronyms
CI = confidence interval
ePTFE = expanded polytetrafluoroethylene
RVOT = right ventricular outflow tract

bulging sinuses and fan-shaped leaflets to valve function has been demonstrated in an experimental study.[6]

We aimed for further improvement of the hemodynamic performance of the conduit, especially with regard to the material of the leaflet. Conventionally, the leaflet of this valved conduit was made from a 0.1 mm–thick ePTFE sheet, and although this sheet is thinner than the native pulmonary valve (mean thickness 0.39 ± 0.11 mm),[7] it might be slightly stiff as a leaflet material. We developed a new thin-type ePTFE sheet (mean thickness 0.040 ± 0.008 mm) by an original drawing process and manufactured a modified ePTFE conduit with this sheet as leaflet material.

The purpose of this study was to evaluate the clinical outcomes and hemodynamic performance of the modified conduit with thin-type leaflets in comparison with the conventional conduit with normal leaflets.

MATERIALS AND METHODS

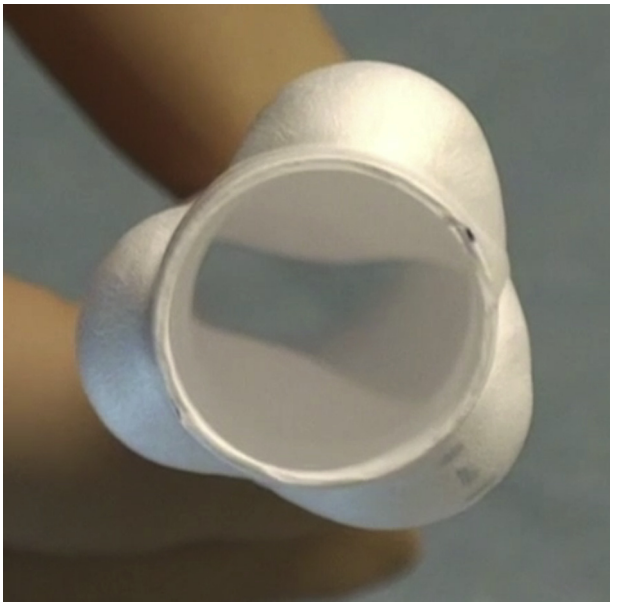
Patients

The present study was a retrospective, observational, cohort study conducted at Kyoto Prefectural University of Medicine and Fukuoka Children's Hospital. The clinical application of the ePTFE tricuspid-valved conduit and the study protocol were approved by the ethics boards, and written informed consent was obtained from 1 or both parents of all patients.

A total of 149 consecutive patients who underwent definitive RVOT reconstruction using the ePTFE conduit at both institutes from January 2010 to December 2013 were included in this study. Since the clinical application of the modified conduit with thin-type leaflets was launched in June 2011, all patients received conventional conduits with normal leaflets from January 2010 to May 2011, and all patients received the modified conduits from October 2011 to December 2013. In the 4 months of the transitional period from June to September 2011, both types of conduit were used, with preference for the conventional one until its stocks ran out. No patient was excluded during this period for any reason.

Expanded Polytetrafluoroethylene Tricuspid-Valved Conduit

The ePTFE tricuspid-valved conduit is a handmade valve manufactured through 2 major processes: molding of bulging sinuses and sewing the leaflets to the inner surface of the conduit (Video 1).[8] The diameter of the conduit ranges in 2-mm increments from 10 to 24 mm according to the size of the selected ePTFE graft (STRETCH Vascular Graft, WL Gore & Associates, Inc, Flagstaff, Ariz); thus, it can be applied to a wide range of patients. Although conduits of 6 and 8 mm in diameter are also available, they are not tricuspid and therefore excluded from this study.



VIDEO 1. Manufacturing process of the ePTFE conduit with bulging sinuses and fan-shaped tricuspid valves. Video available at: http://www.jtcvs.org.

The leaflet of the conventional conduit was made from a 0.1 mm–thick ePTFE sheet (Preclude Pericardial Membrane, WL Gore & Associates, Inc) cut in a fan-shape with a long free margin intended to accommodate a sufficient coaptation zone. On the other hand, the leaflet of the modified conduit was made of the thin-type ePTFE sheet with the same fan-shaped configuration (Figure E1 and Table E1). This thin-type sheet was made from a 0.1 mm–thick ePTFE sheet by an original drawing process under heat application, with a mean thickness of 0.040 ± 0.008 mm. Tension testing of the 2 types of ePTFE sheet revealed that there was no significant difference in the ultimate tensile strength, that is, the maximum stress that a material can withstand while being stretched (Figure 1), and both values were far higher than that of the native pulmonary valve

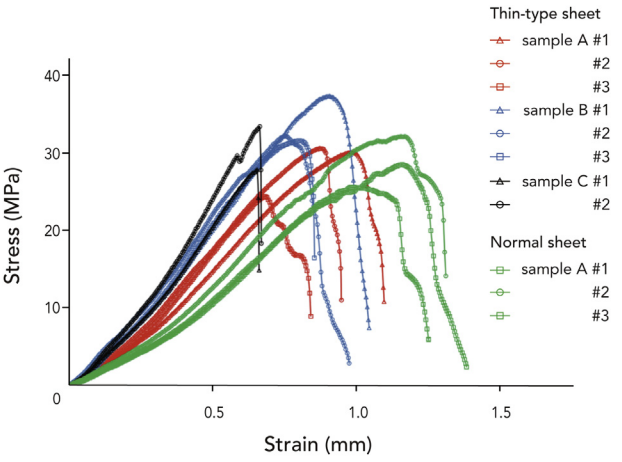


FIGURE 1. Stress-strain curve of the 2 types of ePTFE sheet. A total of 8 specimens obtained from 3 thin-type ePTFE sheets (samples A, B, and C) were examined. As a control, 3 specimens obtained from 1 normal ePTFE sheet were also examined.

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