Ten-year experience with handmade trileaflet polytetrafluoroethylene valved conduit used for pulmonary reconstruction

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Objective: The objective of this study was to investigate the results of handmade polytetrafluoroethylene trileaflet conduits implanted in the pulmonary position since 1997.

Methods: One hundred thirty-nine patients underwent pulmonary reconstruction with a polytetrafluoroethylene conduit. Conduit function was investigated by means of review of serial echocardiographic studies.

Results: Mean age and body weight were 12.7 ± 12.0 years and 30.9 ± 20.6 kg. Mean size of the conduit was 21.0 ± 3.8 mm (12–28 mm). The z score of the conduit was +0.5 ± 0.8 for patients older than 15 years (n = 43), +1.2 ± 0.7 for patients 5 to 15 years old (n = 48), and +2.4 ± 0.5 for patients younger than 5 years (n = 48). Conduits were used for the Ross procedure in 21 patients and for repair of complex congenital heart disease in 118 patients. There were 3 (2.2%) in-hospital deaths and 1 late death. Four patients required conduit explantation because of pulmonary artery distortion at a distal anastomotic site (interval, 1.2 years), infection of the polytetrafluoroethylene valve (interval, 1.6 years), midportion angulation of the conduit (interval, 4.9 years), and conduit compression by the ascending aorta (interval, 5.4 years). Estimated freedom from conduit explantation was 88.0% ± 6.8%, and pulmonary insufficiency was less than or equal to mild in 75.0% at 10 years. All valves maintained their motion, and the mean estimated pressure gradient across the conduit was 19.6 ± 11.9 mm Hg at 5 years and appeared to reach a plateau thereafter. The pressure gradient across the conduit was 14.2 ± 8.0 mm Hg at 3 years (P = .0127) and 18.1 ± 7.5 mm Hg at 7 years (P = .0208).

Conclusions: Polytetrafluoroethylene conduits represent a valid option and reliable alternative to homograft and xenograft implantation for pulmonary reconstruction.

Extracardiac conduits of any material used for the pulmonary artery have an inherent tendency toward late failure. Even homografts, the most widely used conduits, do not always ensure the best possible durability1,2 because calcific fibrosis has been noted to occur, particularly in very young patients. Furthermore, homografts are not always available. For these reasons, xenografts or other synthetic conduits have been used as alternatives.

Polytetrafluoroethylene (PTFE) is chemically inert, has low friction, and possesses low tissue affinity. Therefore it is theoretically resistant to degeneration or calcification and has been used as a useful substitute for the pulmonary valve.3 In our institute we have used Dacron conduits that incorporate a trileaflet PTFE valve for pulmonary reconstruction since 1997. The purpose of this study was to analyze the results of this particular PTFE conduit.

MATERIALS AND METHODS

Construction of the Conduit

For more information on construction of the conduit, see Figures 1 to 3. A Dacron conduit (Hemashield; Boston Scientific Corp, Natick, Mass) of an appropriate size is provided first. Then a 0.1-mm PTFE membrane (Gore-Tex; W. L. Gore & Associates, Inc, Newark, Del) is cut in a rectangular shape. Six equally sized rectangular grids are drawn with a marking pen, leaving a 1-mm margin on both sides and a 2-mm margin at the top. The sheet is then folded, leaving the top margin. It is separated by suture lines, using running stitches of 6-0 polypropylene sutures to create 3 pockets, and rolled. Both sides are then sutured together to create a syringe-shaped structure with 3 separate pockets on the inside. The valve is pushed inside and fixed onto the Dacron conduit by suturing the top and bottom ends of the PTFE valve with running stitches of 5-0 polypropylene sutures. After fixing the valve, the outer layer of the PTFE valve (at the midpoint of the sinus portion of the valve) is sutured to the conduit to avoid free-floating material. Commisural sutures (1 mm distant from the commissure) are finally placed to improve valve coaptation.

Implantation of the Conduit

All patients underwent a standard first-time or redo median sternotomy. Cardiopulmonary bypass was established with ascending aortic and bicaval cannulations. If present, the ventricular septal defect was first closed. After creation of the openings in the pulmonary artery and the right ventricle (left ventricle in 11 patients with corrected transposition of the great arteries), the
Abbreviation and Acronym

PTFE = polytetrafluoroethylene

Conduit was cut to the appropriate length. The distal end of the conduit was trimmed off at approximately 0.5 to 1 cm from the distal margin of the PTFE valve. The distal anastomosis of the conduit with the pulmonary artery was first performed with a running suture. The proximal end was then trimmed to an appropriate shape, and the proximal anastomosis with the ventricle was performed with a running suture and reinforced with an autologous pericardial strip.

Echocardiographic Measurements

We collected data regarding conduit function, including the degree of pulmonary insufficiency and estimated pressure gradient across the conduit, from the echocardiographic studies performed every year after conduit implantation by our cardiologists. If flow velocity was clearly detected inside the conduit, the pressure gradient was estimated by the highest maximum flow velocity with the cursor pointed toward the direction of the conduit. There was an average of 3.4 studies per patient, with a total of 477 studies. Of these, 60 (12.6%) were not available for review. In some cases (n = 22, 4.6% of all studies) the flow velocity was not obtained inside the conduit, but the tricuspid regurgitation jet was identified. In that case the pressure gradient was estimated by using the following formula: [(Predicted right ventricular pressure from the maximal flow velocity of tricuspid regurgitation flow) – 20]. This formula assumes that the right atrial pressure was 10 mm Hg and the systolic pulmonary pressure was 30 mm Hg. Pulmonary insufficiency was graded as none to trivial, mild (regurgitation flow confined within the lumen of the conduit, central deficiency during closure of leaflets not visible), moderate (regurgitation flow extending beyond the proximal conduit–right ventricular anastomosis), and severe (massive regurgitation flow through a visible central deficiency at the time of diastole with restricted or absent leaflet motion).

Data Analysis

StatView statistical software for Windows (version 5.0; SAS Institute, Inc. Cary, NC) was used for data analysis. Values were expressed as means ± standard deviation or median. Time-dependent outcomes were assessed with Kaplan–Meier analysis, with the log-rank test used to evaluate group differences. All probability values were 2-tailed. Locally weighted polynomial (Lowess) regression line was drawn based on a weighted linear least squares regression over the span of values of the y-axis scattergram criterion variable.

The study was approved by the Institutional Review Board of Sakakibara Heart Institute, and the procedures were in accordance with institutional guidelines for protection of patient confidentiality. The need for patient consent was waived.

RESULTS

Basic Demographic Information

One hundred thirty-nine patients underwent pulmonary reconstruction with the PTFE conduit. Follow-up was complete in 127 (91.4%) of 139 patients as of November 2007. The mean follow-up period was 2.7 ± 2.4 years. There were 55 female patients. Mean age and body weight at the time of the operation were 12.7 ± 12.0 years (0.07–62.5 years) and 30.9 ± 20.6 kg (3.4–101 kg), respectively.

Anatomic diagnosis and surgical status are listed in Table 1. Conduits were placed from the left ventricle to the pulmonary artery in 11 patients (conventional Rastelli procedure) and from the right ventricle to the pulmonary artery in 4 (double-switch operation) for patients with corrected transposition of the great arteries, ventricular septal defect, and left ventricular outflow tract obstruction. Four patients with ventricular septal defect, left ventricular outflow tract obstruction, and well-developed ventricles underwent conduit replacement after former Norwood-type arch repair and biventricular repair.

Preexisting cardiac problems included severe hypoplasia or discontinuous branch pulmonary arteries in 8 patients, severe hypoplasia or complete absence of the right or left pulmonary artery in 5 patients, complete atrioventricular block requiring pacemaker implantation in 3 patients, residual ventricular septal defect after previous repair in 2 patients, severe tricuspid regurgitation in 2 patients, and ventricular tachyarrhythmia in 1 patient.
First-time complete repair (Rastelli procedure) was performed in 58 (41.7\%) patients, and a nonreoperative Ross procedure was performed in 19 (13.7\%) patients. Forty-one (29.5\%) patients underwent conduit replacement after previous Rastelli or Ross procedures, and 21 (15.1\%) patients underwent conduit placement after previous intracardiac repair by using right ventricular outflow reconstruction.

One patient with complete transposition of the great arteries, ventricular septal defect, and left ventricular outflow tract obstruction had undergone a palliative Senning operation previously. This patient underwent takedown of the Senning baffle, closure of the ventricular septal defect, and morphologic left ventricle–pulmonary artery conduit placement. Other concomitant procedures included tricuspid repair or replacement in 11 patients, extended pulmonary...
TABLE 1. Anatomic diagnosis and operative status

<table>
<thead>
<tr>
<th>Anatomic diagnosis</th>
<th>First-time operation</th>
<th>S/P ECR</th>
<th>S/P RVOTR</th>
<th>Total</th>
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<tbody>
<tr>
<td>VSD with pulmonary atresia</td>
<td>30</td>
<td>14</td>
<td>1</td>
<td>45</td>
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<tr>
<td>TOF/DORV + PS</td>
<td>10</td>
<td>8</td>
<td>15</td>
<td>33</td>
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<tr>
<td>AS/AR/AS + AR (Ross procedure)</td>
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<td>2</td>
<td>0</td>
<td>21</td>
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<td>2</td>
<td>0</td>
<td>11</td>
</tr>
<tr>
<td>Corrected TGA (RV–PA conduit)</td>
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<td>2</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>TGA + LVOTO</td>
<td>3</td>
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<td>7</td>
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<td>5</td>
<td>0</td>
<td>7</td>
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<tr>
<td>PS/PA without VSD</td>
<td>2</td>
<td>0</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td>VSD+LVOTO</td>
<td>0</td>
<td>4</td>
<td>0</td>
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S/P ECR, Status after extracardiac conduit repair; S/P RVOTR, status after right ventricular outflow tract obstruction; VSD, ventricular septal defect; TOF, Tetralogy of Fallot; DORV, double-outlet right ventricle; PS, pulmonary stenosis; AS, aortic stenosis; AR, aortic regurgitation; TGA, transposition of the great arteries; LV–PA, left ventricle–pulmonary artery; RV–PA, right ventricle–pulmonary artery; LVOTO, left ventricular outflow tract obstruction; PA, pulmonary atresia.

arterial plasty in 7 patients, mitral valve plasty or replacement in 3 patients, aortic valve plasty or replacement in 3 patients, resection of subaortic stenosis in 2 patients, pulmonary unifocalization in 2 patients, the Senning procedure (double switch) in 2 patients, and pacemaker implantation in 1 patient.

The size of the conduit used was 12 mm in 2 patients, 14 mm in 4 patients, 16 mm in 20 patients, 18 mm in 22 patients, 20 mm in 16 patients, 22 mm in 26 patients, 24 mm in 24 patients, 26 mm in 24 patients, and 28 mm in 1 patient, with a mean conduit size of 21.0 ± 3.8 mm (12–28 mm). The z score of the conduit was +0.5 ± 0.8 for patients older than 15 years (n = 43), +1.2 ± 0.7 for those 5 to 15 years of age (n = 48), and +2.4 ± 0.5 for patients younger than 5 years (n = 48).

Operative and Late Mortality

There were 3 (2.2%) in-hospital deaths and 1 late death. The first patient, who underwent the Ross procedure for congenital aortic stenosis, had severe left ventricular dysfunction after the operation. Despite maximal effort to resuscitate the ventricle, the patient died on the first day after the operation. This death was thought to be attributable to the imperfect myocardial protection in the setting of severe left ventricular hypertrophy.

The second patient underwent an operation for repair of ventricular septal defect and pulmonary atresia. After weaning from cardiopulmonary bypass, multiple communications between both ventricles were found. Unsuccessful attempts were made to close these additional defects. The patient had severe cardiac dysfunction and died on the day after the operation.

The third patient, with a ventricular septal defect and pulmonary atresia, underwent an uneventful operation, and the postoperative course in the intensive care unit was also uneventful. After transfer to the ward, the patient had sudden respiratory arrest followed by cardiac arrest. Despite resuscitation, the patient died on day 2 from the operation. The cause of death was not identified.

The fourth patient, with a diagnosis of ventricular septal defect and pulmonary atresia, had undergone bilateral systemic–pulmonary artery shunts before complete repair. The distortion of both pulmonary arterial branches at the site of shunt anastomosis was not successfully relieved and resulted in a high right ventricular pressure with severe dysfunction. This patient died of heart failure at 9.5 months.

Other Postoperative Complications

One patient, who underwent the Ross operation, had sudden cardiac arrest on the day of the operation, presumably because of imperfect myocardial protection during the operation. The patient subsequently recovered, and the remainder of the hospital course was uneventful.

Other postoperative complications included prolonged pleural effusion requiring chest tube placement for 7 days or longer in 5 patients, atrial fibrillation requiring cardioversion in 2 patients, sternotomy wound infection in 2 patients, phrenic nerve paralysis in 2 patients, protein losing enteropathy (present before the operation) in 1 patient, ventricular tachyarrhythmia requiring cardioverter defibrillator implantation in 1 patient, reoperation for bleeding in 1 patient, and complete atrioventricular block requiring pacemaker insertion in 1 patient.

Conduit Explantation

Thirty-one patients underwent a follow-up catheterization after the operation. Indications included suspected pulmonary stenosis in 6 patients, potential intervention for residual branch pulmonary stenosis in 6 patients (for whom angioplasty was done in 2 patients), aortic regurgitation in 3 patients, and decreased left ventricular function in 2 patients. In the other 14 patients, catheterization was performed to generally assess cardiac performance with no suspected abnormality. Among them, conduit stenosis requiring replacement was found in 4 patients.

The first patient had pulmonary artery distortion at the distal conduit–pulmonary artery anastomosis. This patient also had a residual ventricular septal defect and a patent systemic–pulmonary artery shunt. This patient underwent closures of the residual ventricular septal defect and systemic–pulmonary artery shunt and replacement of the pulmonary conduit at 1.2 years.

The second patient had also pulmonary artery distortion at the distal conduit–pulmonary artery anastomotic site, as well as a midportion angulation requiring conduit replacement at 4.9 years.

The third patient had pseudoaneurysm at the proximal suture line of the autograft after a Ross procedure. This caused an extrinsic compression of the pulmonary conduit and

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stenosis. The patient required repair of the pseudoaneurysm and pulmonary conduit replacement at 5.4 years.

The fourth patient, with a ventricular septal defect and pulmonary atresia, underwent conduit replacement with a PTFE conduit. The patient had previously experienced episodes of ventricular tachycardia, which exacerbated after the operation. The patient received implantable cardioverter defibrillator, resulting in the lead infection. After removal of the defibrillator, the patient manifested persistent staphylococcal bacteremia, resulting in infection of the PTFE valve. The patient eventually required replacement of this conduit at 1.6 years.

Estimated freedom from conduit replacement was 97.8% ± 1.6% at 3 years, 93.5% ± 4.4% at 5 years, and 88.0% ± 6.8% at 10 years.

Other Reoperations not Requiring Conduit Explantation

Two patients with ventricular septal defect and pulmonary atresia required aortic valve replacement for progressive aortic valve insufficiency at 1.9 and 7.6 years, respectively. The third patient underwent one and a half ventricle repair for pulmonary atresia with intact ventricular septum. The patient had right heart failure because of the hypoplastic right ventricle and required creation of the atrial septal defect at 4.6 months. The fourth patient, with aortic atresia and a ventricular septal defect, had ascending aortic stenosis and underwent aortoplasty at 1.5 months. Pulmonary conduits were considered to be intact in these patients and were not replaced.

Conduit Function on Echocardiographic Analysis

The mean estimated pressure gradient across the conduit was 9.4 ± 6.5 mm Hg immediately after the operation, 14.2 ± 8.0 mm Hg at 3 years, and 19.6 ± 11.9 mm Hg at 5 years and appeared to reach a plateau thereafter (Figure 4). When divided by the size of the conduit, the mean pressure gradient of a conduit sized greater than 20 mm (solid circles), 16 or 18 mm (open circles), and 12 or 14 mm (solid squares). The solid lines were derived by the locally weighted polynomial (Lowess) regression of the data. Numbers in parentheses indicate patients at risk for conduit size 12/14 mm (top row), 16/18 mm (middle row), and greater than 20 mm (bottom row).

Histological Findings on the Explanted Specimen

For more information on histologic findings on the explanted specimen, see Figure 8.

In the PTFE valve specimen of the explanted conduit at 5.4 years, the surface of the valve was smooth, and the valve itself was pliable. On microscopic evaluation, there was no structural deterioration of the PTFE membrane, cellular infiltration, or calcification noted.

DISCUSSION

The extracardiac conduit placed in the pulmonary position is almost always subject to functional deterioration. Even
homografts, the most widely used material for pulmonary reconstruction, are not exempt from failure, and replacement might become mandatory at some point in the patient’s life.

In general, results of homografts used for pulmonary reconstruction in the Ross procedure have been excellent, with reported freedom from reintervention of greater than 90% at 5 years.\(^4\) In the non-Ross population, however, some report poor performance of homografts.\(^1\) According to another report, somatic outgrowth is seldom a primary reason for homograft conduit replacement, but rather conduit obstruction with thickening and shrinkage at the annular area is more frequently responsible for failure.\(^5\) Especially when aortic homografts are used in young patients, accelerated aortic homograft fibrocalcification can occur. Blood group incompatibility between receiver and homograft donor also seems to play an important role in the development of accelerated fibrocalcifications in cryopreserved homografts.\(^6\) Some even report the inferior longevity of homografts when compared with porcine valved Dacron conduits.\(^1\)

Commercially available glutaraldehyde-preserved xenograft pericardial valved conduits (Hancock valved conduit, Medtronic, Minneapolis, Minn; Carpentier–Edwards valved conduit, Edwards Lifesciences, Irvine, Calif) have been widely used since the 1970s. These conduits are known to be associated with a disturbing incidence of late failure,\(^7,8\) with 1 report showing a total incidence of 30% xenograft conduit failure in a 6-year follow-up.\(^9\) More recently, a xenograft valved conduit using a decalcification process to mitigate tissue degeneration and calcification associated with glutaraldehyde (Shellhigh conduit; Shellhigh, Inc, Union,
Glutaraldehyde-preserved bovine jugular vein (Contegra; Medtronic, Inc) conduits are now considered a sound alternative to homografts for pulmonary reconstruction, with reported freedom from graft dysfunction and reoperation of greater than 90% at 7 years postoperatively. This particular conduit might be especially useful for right ventricular outflow tract reconstruction in neonates and infants. However, distal conduit stenosis is frequently seen among younger patients and patients with small pulmonary arteries. Also, significant graft dilatation was observed in patients with pulmonary artery branch obstruction or pulmonary hypertension. Some advocate cautious use of these conduits in patients with predicted high right ventricular/left ventricular pressure ratios.

PTFE has very low tissue affinity. Because of this property, cellular or fibrinous deposition is unlikely, and for these reasons, it is the most reliable material for small-caliber vascular grafts. Moreover, because of its chemical inertness, tissue degeneration or destruction is unlikely or very slow to progress. These properties make PTFE an ideal biomaterial for valve replacement, especially in the pulmonary position. Brown and colleagues reported excellent results with right ventricular outflow tract reconstruction by using a PTFE monocusp valve. They did not witness significant calcification or pulmonary embolization, and the only antithrombotic agent used was low-dose aspirin. According to our results, PTFE conduits have comparable longevity when used in the pulmonary position when compared with the reported results of blood-compatible homografts or Contegra conduits, particularly with respect to larger-sized conduits. In some countries, such as Japan, the access to homografts or xenograft products of Western countries (ie, Contegra) is limited. The PTFE conduit is inexpensive and always available and therefore could be the conduit of choice in these circumstances. Even in Western countries, homografts are not always available in an ideal size. In this context the PTFE conduit might be a good choice, especially if the patient has a high pulmonary artery pressure, for which the Contegra conduit might not be an optimal choice. The follow-up of smaller-sized PTFE conduits is currently limited, with the longest observation period of the smallest size (12 mm) being only 1.5 years. Longer follow-up is required to assess the performance of the smaller-sized PTFE conduit to extrapolate meaningful comparative data with homografts and Contegra conduits.

Another group reported the results of handmade trileaflet conduits made of heterologous pericardium or PTFE for right ventricular outflow tract reconstruction. The reported freedom from important pulmonary valve regurgitation was 68.3% ± 3.7% at 5 years, 33.0% ± 4.5% at 10 years, and 21.6% ± 4.9% at 15 years. Conduits included whole heterologous pericardial trileaflet conduits in 169 patients and bovine pericardial conduits containing PTFE leaflets in 26 patients. Whole PTFE trileaflet rolls were used in only 21 patients. It is important to note that when materials with different tissue affinities are sutured together, tissue pannus might form at the junction. An example of this is the intimal peel formation leading to valve dysfunction observed in xenograft valved Dacron conduits. Because PTFE has very low tissue affinity, intimal or pseudointimal ingrowths from the adjacent tissue can easily be peeled off and form a pannus. If the PTFE valve is directly sutured to the heterogenous substance, such as xenograft pericardium, a similar phenomenon can occur, which can lead to valve dysfunction. Therefore it is especially important that the outer wall of the PTFE valve leaflet (sinus portion) should be a PTFE substance. To achieve this, one can suture the PTFE membrane directly to the PTFE conduit. It is also possible to fold the PTFE membrane before suturing it inside the outer conduit, as we presently do. We prefer to use a Hemashield conduit (St Jude Medical, St Paul, Minn) for several reasons, including the ease of hemostasis, the stiffness of the conduit (making itself resistant to external compression), and its inherent structure, which is resistant to angulation. It should be also noted that the PTFE membrane is folded, leaving a few millimeters excess at the top end, which gives some space between the suture line with the Dacron conduit and the sinuses of each valve. We believe the pannus, even if formed, can be peeled off before it intrudes into the sinus, preserving the function of the valve.

Our results confirmed that the long-term results of the Rastelli operation for management of patients with transposition of the great arteries, ventricular septal defect, and pulmonary stenosis are still somewhat suboptimal. Aortic translocation and biventricular outflow tract reconstruction might be an alternative for the management of these patients to reduce postoperative right ventricular outflow tract failure.

Conduits are routinely oversized to account for somatic growth in children requiring right ventricle–pulmonary artery continuity. However, there is an increasing awareness of the fact that excessive oversizing of the conduit placed in the pulmonary position results in decreased longevity in children. Pulmonary conduit durability and hemodynamic function in patients undergoing initial conduit insertion at less than 2 years of age can be improved by using pulmonary conduits with z scores between +1 and +3. The target z score of the conduit in our cohort was +2 in the small children aged less than 5 years, +1 for those aged 5 to 15 years, and the normal size for those aged 15 years or older. The distal end of the conduit was cut off, leaving only a 1/2- to 1-cm margin from the top end of the PTFE valve. Because the conduit usually forms an acute-angled curve after arising from the ventricle to be oriented toward the pulmonary
artery, positioning of the valve renders itself to distortion. This technique allows the valve to be positioned in the straight portion of the conduit, leading to the maintenance of its intact shape.

The limitations to this study include the retrospective nature of the study design and that echocardiograms had been obtained by one of our 7 attending cardiologists. Therefore each study might be highly subjective to the bias of each investigator.

In summary, PTFE valved conduits showed acceptable functional durability and maintained valve motion for up to 10 years in all patients in this series. As is shown in this study, late valve fixation in the semiopen position did not occur. Because of this, development of the pressure gradient reached a plateau in conduits with a size of greater than 20 mm, and there was no reoperation because of structural deterioration during this time period. In our opinion PTFE conduits represent a valid option and a reliable alternative to homograft and xenograft implantation for pulmonary reconstruction.

References


