Long-term outcome of right ventricular outflow tract reconstruction using a handmade tri-leaflet conduit

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Abstract

Objective: Since 1985, we have implanted handmade tri-leaflet conduits made of heterologous pericardium or expanded polytetrafluoroethylene (ePTFE), as an alternative to homograft for right ventricular outflow tract reconstruction. This report assesses the long-term outcome of these prostheses. Methods: From 1985 to 2003, 216 handmade tri-leaflet conduits were implanted in 191 patients. Forty-two patients had previous conduit repairs. The mean age at operation was 8.1 ± 7.7 years (range: 15 days–44 years). The underlying diagnoses were pulmonary atresia with ventricular septal defect in 83 patients, atroventricular discordance in 36, transposition of the great arteries in 26, double outlet right ventricle in 14, and truncus arteriosus in 17. Whole heterologous pericardial tri-leaflet conduits were implanted in 169 patients, in the early series (porcine: 85; equine: 58; bovine: 26); bovine pericardial conduits containing ePTFE leaflets were implanted in 26 patients since 1996; whole ePTFE tri-leaflet rolls were employed in the most recent 21 patients. The conduit size was 21.1 ± 3.1 mm (range: 12-27 mm), 147.4 ± 21.4% (range: 82.6-202.6%) of the anticipated diameter of the pulmonary valve. Follow-up was complete. Results: There were 28 early deaths and 24 late deaths. The indication for conduit replacement was a peak instantaneous pressure gradient of greater than 50 mmHg. Sixty-five conduits required reoperation for conduit obstruction at 8.6 ± 3.3 years after implantation. The freedom from reoperation at 5, 10, and 15 years was 93.9 ± 1.9, 61.4 ± 4.5, and 35.5 ± 5.6, respectively. Patients with smaller conduit size and young age at operation were predisposed to reoperation. None of the 47 ePTFE tri-leaflet conduits developed significant obstruction. The freedom from important pulmonary valve regurgitation (PR) as assessed by echocardiography was 68.3 ± 3.7% at 5 years, 33.0 ± 4.5% at 10 years, and 21.6 ± 4.9% at 15 years. No patient required reoperation due to PR or right ventricular dysfunction. Conclusions: Handmade tri-leaflet conduits provide a reliable alternative for RVOT reconstruction in children, yielding as good a long-term outcome as do homografts. Longer follow-up is needed to determine how well ePTFE leaflets will fare.

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Keywords: Right ventricular outflow tract reconstruction; Homograft; Pulmonary valved conduit; Polytetrafluoroethylene

1. Introduction

Valved conduits are frequently used for right ventricular outflow tract reconstruction (RVOTR) for a wide range of congenital heart diseases. The ideal choice for a valved conduit, however, has yet to be found. Desired characteristics include availability, ease of implantation, and longevity. From the early 1970s, commercially available porcine-valved Dacron conduits had been used in many institutes, including our own [1,2]. However, the results were disappointing, characterized by poor handling, excessive intimal fibrocalcific peel formation, and degeneration of the porcine valve—particularly when implanted in children [3,4]. Eventually, the porcine-valved Dacron conduit gave way to the cryopreserved homograft conduit [5]. Although homograft conduits remain the popular choice, certain disadvantages—such as lack of sufficient availability, the requirement of sterilization and preservation, and late complications due to degenerative processes and calcifications—have led us to search for other alternatives. Commencing in 1985 we developed a hand-made tri-leaflet conduit made of glutaraldehyde-fixed heterologous pericardium, which we call the "valved pericardial roll (VPR)", as a potential alternative to homograft conduits [6-8]. Then, in 1996, we introduced expanded polytetrafluoroethylene (ePTFE) leaflets in order to avoid the degenerative characteristics of heterologous pericardium. In this study we reviewed the long-term outcome of 216 handmade tri-leaflet conduits. We assessed the long-term durability, valve function, and risks of reoperation, in order to clarify the optimal surgical strategy for better outcome. In addition, the intermediate characteristics of the ePTFE leaflets were reviewed.

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2. Materials and methods

Between October 1985 and June 2004, 216 handmade tri-leaflet conduits were implanted in 191 patients in order to re-establish continuity between the pulmonary ventricle and the pulmonary arteries, at National Cardiovascular Center in Osaka, Japan. One hundred and seventy-four were primary conduit repairs; 42 had had previous conduit implantation: porcine-valved Dacron conduit in 17, and handmade tri-leaflet conduit in 25 (Table 1).

2.1. Patient characteristics

The mean age at operation was 8.1 ± 7.7 years old (range: 15 days–44 years); 7.2 ± 7.6 years old for initial implantation, and 14.3 ± 5.0 years old for reoperation. There were 18 infants including one neonate. The diagnostic categories are summarized in Table 1. There was pulmonary atresia and ventricular septal defect with major aortopulmonary collateral arteries (PA-VSD with MAPCAs) in 50 patients, PA-VSD without MAPCAs in 33, atrioventricular discordance (AVD) in 36, transposition of the great arteries in 26, double outlet right ventricle in 16, and truncus arteriosus in 12. In nine of the 36 patients with AVD, functional biventricular repair using a left ventricle—pulmonary artery conduit was performed [9]; the other 27 patients underwent anatomical biventricular repair, double switch operation, in which a conduit was inserted between the anatomical right ventricle and the pulmonary artery [10]. As preparative procedures, 41 patients with aplasia or hypoplasia of intrapericardial pulmonary arteries required intrapulmonary pulmonary artery reconstruction with heterologous pericardial roll, prior to definitive conduit repair [11–13].

2.2. Handmade tri-leaflet conduits

Prior to the operation, a tri-leaflet conduit was manufactured on the operating table. Conduit size was determined to be almost always larger than the anticipated pulmonary valve diameter, if the sternum allowed. Mean conduit size was 21.1 ± 3.1 mm (range: 12-27 mm), 147.4 ± 21.4% (range: 82.6-202.6%) of the anticipated diameter of the pulmonary valve (Fig. 1).

2.2.1. Original style: "Whole heterologous pericardium" (1985–1996)

A piece of heterologous pericardial rectangular patch, with a width of approximately three times the conduit diameter, was prepared (Fig. 2). The base of the rectangle was turned up and each trichotomy line was sutured with 5-0 or 6-0 polypropylene sutures so as to create three leaflets. In general, the height and the width of the leaflets were the same as the conduit diameter, as determined by our laboratory studies [8]. Then, the rectangle with the tri-leaflet was wrapped around the corresponding Hagar’s dilator and the conduit was closed with 5-0 polypropylene continuous sutures—so as to create a pericardial roll containing a valve structure. An additional conduit of the same size was constructed which was to be inserted between the ventriculotomy and the valved pericardial roll. The upper and lower ends of the conduit were left open, to allow the surgeon to tailor these to each patient’s needs. Originally, we used glutaraldehyde-fixed porcine pericardium (Rygg; Polystan AS, Copenhagen, Denmark) as the material in 82 consecutive conduits. In the pursuit of optimal valve function, we changed the material of the tri-leaflet

![Fig. 1. Correlation between conduit size and body surface area.](https://academic.oup.com/ejcts/article-abstract/27/5/807/503823)
conduit, sequentially (Table 2). Equine pericardium (Xenomedica; Baxter, Chicago, IL) was employed in 58 conduits, from 1990 to 1993, followed by bovine pericardium (No React; Shelhigh, Millburn, NJ, or PeriGuard; BioVascular, Inc., St Paul, MN) in 26, from 1993 to 1996.

2.2.2. Modified style "ePTFE leaflets" (1996–)

In November 1996 we abandoned glutaraldehyde-treated heterologous pericardial leaflets and employed ePTFE leaflets. A 0.1 mm-ePTFE sheet (Gore-Tex Pericardial Membrane; W.L. Gore and Assoc., Newark, DE) to be used for the leaflets was cut in a nearly semi-oval shape with the base measuring approximately 140% of the conduit diameter, and the height equal to the conduit diameter. In practice, we cut the leaflets to be more generous than the actual measurement—with a seam allowance of 3 mm. Then, the edge of each ePTFE leaflet was secured to a rectangular piece cut from bovine pericardium, or, from 2000 to present, a piece cut from ePTFE prosthetic vascular graft (Gore-Tex stretch vascular graft) using 5-0 polypropylene continuous sutures. Care was taken not to make undesirable folds in the leaflet patch. Then, a small piece of radiopaque marker (A/C Locator graft marker; Scanlan International, St Paul, MN) was attached, using 6-0 polypropylene sutures at the center of the free edge of each ePTFE leaflet, to imitate the natural thickening of the edge of the normal human semi-lunar valve imitating the nodule of Arantius. We expect this ploy to assist natural motion of the leaflet. In addition, this marker allows postoperative radiological assessment of leaflet function. Pairs of horizontal mattress sutures were placed at each commissural portion, producing a mildly bulging profile similar to the sinus of Valsalva, to encourage natural blood-flow patterns and leaflet motion.

2.3. Operative techniques

All patients were approached by median sternotomy. Hypothermic extracorporeal circulation with cold antegrade crystalloid cardioplegia was used. If the operation was confined to the right side of the heart, the aorta was not cross-clamped. In 37 patients with non-confluent central pulmonary artery, reconstruction of the central pulmonary artery with heterologous pericardial roll was carried out concomitantly [13]. Surgical correction of the pulmonary artery branches was necessary in 18 patients. The stenotic area was enlarged mostly with a piece of autologous or heterologous pericardial patch, followed by distal anastomosis of the conduit. The distal end of the conduit was trimmed and beveled, and an end-to-end anastomosis between the distal conduit and the proximal pulmonary bifurcation was performed using continuous 6-0 polypropylene sutures. Care was taken to tilt the conduit plane to the pulmonary artery and to create a large anastomosis. We expect this maneuver to not only prevent compression of the valve between the heart and the sternum but to minimize turbulent blood flow. An additional conduit was inserted between the tri-leaflet conduit and the ventriculotomy, tailoring its proximal end in an S-shaped manner so as to avoid a gradient at the transition of the ventriculotomy.

2.4. Patient follow-up

There were 28 early deaths; AVD in 7, VSD and PA with MAPCAs in 6, TGA in 5, DORV in 4, and others in 6. All surviving patients had periodic follow-up at our institution. Follow-up was 100% complete and ranged from 1 month to 18 years, with a mean of 8.5 ± 5.9 years. All were given warfarin sodium and low-dose antiplatelet drugs for at least 1 year after conduit implantation.

Table 2
Changes of material

<table>
<thead>
<tr>
<th>Original style “Whole heterologous pericardium”</th>
<th>Modified style “ePTFE leaflets”</th>
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<tr>
<td>10/1985—Porcine valved pericardial roll 85</td>
<td>11/1996—ePTFE leaflets + Bovine pericardial conduit 26</td>
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<td>5/1993—Bovine valved pericardial roll 26</td>
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Fig. 2. Construction of handmade tri-leaflet conduit (A–C: original style, D–E: modified style). (A) A rectangular patch of heterologous pericardium with a width of three times the conduit diameter is prepared. Its base is turned up and divided into three parts. Each trichotomy line is sutured to the confronting patch to create the leaflet. As a rule, the height of the leaflet is equal to the conduit diameter. (B) The rectangular patch containing the tri-leaflet assembly is rolled up and closed. (C) An additional conduit is inserted between the valved conduit and the ventriculotomy. (D) A 0.1 mm-thick ePTFE sheet is trimmed to become a semi-oval shaped leaflet. The height is equal to the conduit diameter and the width is 140% of the conduit diameter. A small piece of radiopaque marker is attached to the center of the edge of each leaflet. (E) Each commissure is plicated with pairs of horizontal mattress stitches. This ploy produces the mildly bulging profile of the sinus.
Recently, routine postoperative catheterization was carried out in most cases at approximately 1 year after the operation. During catheterization, the radiopaque markers attached to the ePTFE leaflets could be easily visualized, allowing convenient assessment of leaflet motion. We assessed the motion of the ePTFE leaflets in 25 conduits.

The indication for reoperation was persistent pressure gradient across the conduit of greater than 50 mmHg.

2.5. Echo examinations

All patients were examined in the immediate postoperative period and reexamined serially with transthoracic echocardiograms every 6–12 months. Pulmonary valve regurgitation (PR) was assessed by looking at the regurgitant jet with pulsed color-flow Doppler; of particular interest was the width of the jet at its source and its penetration depth into the ventricle. PR was graded subjectively as follows: none, slight, mild, moderate, or severe. If PR was equal to or greater than moderate, it was considered to be important. For seven patients the echocardiographic windows were inadequate to allow comment on valve function, and for another three patients serial analysis was unavailable; the echocardiographic follow-up was therefore complete in 206 conduits (95.4%).

2.6. Data analysis

Data are presented as the mean ± the standard deviation. All statistical tests were conducted with JMP 5.1.1 software (SAS Institute, Inc., Cary, NC). The cumulative survival estimates were made by the Kaplan-Meier method. The log-rank test was applied for comparison between time-related variables. Values of $p<0.05$ were considered significant.

3. Results

3.1. Mortality and morbidity

Four patients developed postoperative mediastinitis, probably due to prolonged sternal splintage in three and unexpected esophageal rupture in one. Three died and one was successfully treated by conduit renewal with omental flap closure. Four patients developed late conduit infection; antibiotic therapy was effective in 3. One patient who developed fulminating fungal infection 10 months after implantation required urgent conduit replacement. Eventually, he died of refractory fungal infection. One patient died from thrombus formation in the conduit. Twenty-four patients died late. There were 14 sudden deaths or arrhythmia-related deaths. Three patients died at reoperation. Overall survival after initial conduit implantation was 79.2 ± 3.0% at 5 years, 74.0 ± 3.3% at 10 years, and 70.4 ± 3.8% at 15 years.

3.2. Reinterventions

Of the 193 survivors, 24 (12.4%) underwent balloon dilatation and 68 (34.2%) required reoperations. Two patients required replacement of an infected conduit. One patient with PA-VSD with MAPCAs, who had an ePTFE tri-leaflet conduit, developed severe aortic valve regurgitation 2 years after the operation. She underwent aortic valve replacement concomitant with conduit replacement using a porcine stentless valve. Although the ePTFE leaflets were pliable and utterly unobstructive in this particular patient, we exchanged the conduit because a more competent valve would be advantageous in the presence of elevated
pulmonary vascular resistance and deteriorated ventricular function. Eventually, 65 conduits were replaced due to obstructive disease within 5 months–17 years after the primary operation (mean: 8.6 ± 3.3 years). All of these were original valved pericardial rolls (porcine: 37; equine: 21; bovine: 7). The most stenotic portion was associated with calcified pericardial leaflets in 55 conduits and excessive peel formation in 10. Virtually all 47 ePTFE tri-leaflet conduits have been free from calcification or important obstruction over a follow-up period that ranged from 1 month–7 years (mean: 3.1 ± 0.3 years).

Regarding the techniques of reoperation, the anterior patching method using autologous tissue, as described by Danielson et al. [4,14], was carried out in 38 cases. A second hand-made tri-leaflet conduit was inserted in 25 cases, a non-valved tube in 4, and a stentless porcine valve in 1. There were three mortalities associated with reoperation (4.4%). Two patients died from severe neurological complications. One patient died from massive postoperative bleeding due to detachment of the distal anastomosis.

Fig. 3 plots the estimates of freedom from reoperation. At 5, 10, and 15 years this was 93.9 ± 1.9, 61.4 ± 4.5, and 35.5 ± 5.6%, respectively. The freedom from reintervention, including balloon dilatation or reoperation for conduit obstruction, was 92.6 ± 2.1, 52.6 ± 4.6, and 23.3 ± 4.8% at the respective time points.

Cases with smaller conduit size and young age at operation were predisposed to reoperation. With regard to the leaflet material, no detectable difference was observed between the three kinds of heterologous pericardial leaflets.

3.3. Pulmonary valve regurgitation

The echocardiographic analysis showed that freedom from important PR was 68.3 ± 3.7% at 5 years, 33.0 ± 4.5% at 10 years, and 21.6 ± 4.9% at 15 years. No significant difference was detected between the leaflet materials (Fig. 4).

3.4. Motion of ePTFE leaflets

Of the 75 ePTFE leaflets comprising 25 conduits, 69 (92%) were functioning well 1 year after the operation (Fig. 5). Four leaflets were completely fixed in the open position and two leaflets had restrictive motion. No ePTFE leaflet had detectable calcification.

![Fig. 4. Freedom from PR.](image)

![Fig. 5. Postoperative angiography of ePTFE tri-leaflet conduit.](image)
4. Discussion

Homograft conduits have become the most widely used conduit type in RVOTR. However, the short supply of homografts is a considerable problem. Particularly in Japan, there have been difficulties in popularizing of allotransplantation because of cultural background. Although we have our own tissue bank, the availability of homografts remains limited. Porcine-valved Dacron conduits have been another common option. However, although they are convenient to use and easily available, their handling is problematic and they are vulnerable to secondary obstruction [2–4].

The difficulty of utilizing homografts and the unsatisfactory results of previous porcine-valved Dacron conduits led us to produce handmade tri-leaflet conduits made of heterologous pericardium. Pericardial conduits have clear advantages in comparison with porcine-valved Dacron conduits. The biological characteristics of the pericardial tissue match quite well with the pulmonary arteries, allowing easier handling and excellent hemostasis at the suture lines. The pericardial conduits are less bulky in the children’s chest than are prosthetic valved conduits. Handmade tri-leaflet conduits are, obviously, available in any sizes. The quality of the handmade tri-leaflet conduit was investigated in our earlier series, demonstrating favorable valve function and potential longevity, and we have adopted handmade tri-leaflet conduits as our standard technique for RVOTR, since 1985 [6–8].

Our present study reveals that long-term durability of our handmade tri-leaflet conduit is comparable to that of the pulmonary homograft conduit; 84–94% at 5 years, 80% at 8 years, and 58% at 10 years according to recent literatures. [15–17].

With regard to the leaflet material, we initially used porcine pericardium. To obtain better valve function and longer conduit life, we have varied the leaflet material with time. Equine pericardium was employed for the second generation, from 1990, and bovine pericardium for the third generation, from 1993. However, it appeared that no significant improvement was obtained. In general, glutaraldehyde-fixed heterologous pericardium was revealed to have a prominent inflammatory reaction, with calcification and shrinkage. Consequently, in 1996, we quit using heterologous pericardium as the leaflet material and employed ePTFE instead. This material has been used in the form of vascular conduits or to fill defects in many parts of the human body. Experimental and clinical experience indicates that ePTFE causes less calcification, thrombus formation, or intimal hyperplasia than does glutaraldehyde-fixed pericardium [18,19]. These advantages led some groups to employ an ePTFE monocusp in RVOTR [20,21]. Our experience indicates that an ePTFE tri-leaflet conduit can be expected to possess flexible valve behavior along with favorable durability. In early results, the ePTFE leaflets were moving freely and were well tolerated hemodynamically. Conversely, we found that the glutaraldehyde-fixed heterologous pericardial leaflets generally became fixed in the semi-closed or closed position, because of degeneration and calcification, eventually causing significant conduit obstruction. By contrast, when ePTFE leaflets became non-functional, they adhered to the conduit wall and became fixed in the open position without causing significant obstructive deterioration. We believe that ePTFE tri-leaflet conduits may be able to avoid leaflet-related stenotic complication for a lengthy period, if not definitely.

PR has been another concern with the valved conduit [22]. In our study, although the tri-leaflet conduits obviously functioned satisfactorily in the early postoperative phase, PR is ultimately inevitable. The incidence of PR was unrelated to the leaflet material. Certainly PR is malevolent, but it appears that PR was hemodynamically less significant in our study. There was no case that necessitated reoperation due to progressive PR or right ventricular dysfunction. In all cases in need of conduit replacement, conduit obstruction was the dominant lesion and PR was well tolerated. We believe that, although they may be imperfect in the long run, the use of a tri-leaflet conduit is beneficial—particularly for patients with elevated pulmonary vascular resistance or ventricular dysfunction, for whom competent valve function is helpful in the early postoperative period.

Our results show that younger age and smaller conduit size are risk factors for reoperation, as for pulmonary homograft conduits [15–17]. In infants or young children, valved conduits inevitably deteriorate and obstruct within the intermediate term. Accordingly, non-conduit repair using autologous tissue has become popular particularly in Japan. This technique may reduce the requirement for reoperation, although right ventricular dysfunction owing to PR might adversely influence the outcome [23–25]. Since 1992, our primary techniques of RVOTR for infants and young children have involved autologous tissue reconstruction, such as direct anastomosis between the pulmonary ventricle and the pulmonary artery. We reserve the use of handmade tri-leaflet conduits for older children and adults.

Our anticoagulant regimen for handmade tri-leaflet conduit, warfarin sodium and low-dose antiplatelet drugs for at least 1 year, is experimental. We sometimes found small old clots inside the fixed leaflets of extirpated conduits. However, we have no case that developed clinically significant pulmonary embolism.

We are still seeking the optimal leaflet material as well as the optimal design, in order to obtain better valve function and longer conduit life. We have made some modifications in the design of the ePTFE tri-leaflet conduit, such as imitation of the natural bulges of the sinuses of Valsalva and the natural thickening of the nodules of Arantius. Although the efficacy of these modifications is not yet determined, we optimistically believe such modifications could make the handmade tri-leaflet conduit even more favorable.

In conclusion, our results show that RVOTR using a handmade tri-leaflet conduit is an acceptable alternative when homograft conduits are not always available. Although questions about long-term durability of the ePTFE leaflets remain unanswered, the intermediate outcomes are encouraging.
References

Appendix A. Conference discussion

Dr S. Deobritz (Munich, Germany): I have just two questions. Obviously, the ePTFE grafts did very well. What was your mean follow-up for these?

The other question: did you use any anticoagulation therapy postoperatively, particularly if you inserted these ePTFE grafts in neonates operatively, particularly if you inserted these ePTFE grafts in neonates? Do you see any increased risk of thrombosis?

Dr Koh: All patients are administered warfarin plus low dose of antiplatelet agent for at least one year. For infant, our preferred procedure has been non-conduit repair since 1992. There is no infant having ePTFE tri-leaflet conduit in this series.

And please repeat the first question

Dr Deobritz: It was only about the mean follow-up of the ePTFE graft.

Dr Koh: Mean follow-up of ePTFE tri-leaflet conduits is 2 or 3 years. From 1996, we employed ePTFE leaflets.

Dr R. Deac (Targu-Mures, Romania): I have two questions. First one is, what was the reason to use equine pericardium as the material. And during the utilization have you seen calcification?

Dr Koh: At first we used porcine pericardium for the leaflet material. Next generation was equine pericardium and third generation was bovine pericardium. We were disappointed at the degenerative change of porcine pericardium; but equine pericardium had similar result, so we abandoned the use of glutaraldehyde-fixed pericardium and employed ePTFE sheet for the leaflet material.

Dr Deac: And the second question, if I may, have you seen in the long-term results in the conduit a kind of neointima deposition, a thickening of the conduit?

Dr Koh: Yes, thickening formation was found in all cases to some extent, but main cause of conduit obstruction was calcified leaflets.

Dr H. Lindberg (Oslo, Norway): I would like to ask you a question about what was the quality of the ePTFE leaflets, is that 0.1, 0.4? And what is the porosity of those leaflets?

Dr Koh: We employ 0.1 mm ePTFE sheet.

Dr Lindberg: With no porosity? Because the 0.1 Gore-Tex that we have available in Europe is no porosity, in contrast to the cardiovascular patches which has 50 micron porosity.

Dr Koh: I don’t understand your question. You’re asking about the thickness of the leaflet?

Dr Lindberg: And if they are expanded. Because that 0.1 in Europe is not expanded, it’s a solid membrane.

Dr Koh: We use expanded one.

Dr Edmunds: You’re talking about the porosity?

Dr Lindberg: The usual porosity of the Gore-Tex membrane is 50 microns and the surgical membrane that is available in Europe is no porosity at all.
Dr Koh: Gore-Tex membrane we usually used for pericardial patch.

Dr V. Tsang (London, United Kingdom): I noticed you have gone through three different types of animals for your handmade valve. As we know, the only thing constant in life is change. What would you use conduit wise for your reoperations?

Dr Koh: Indication for the operation?

Dr Tsang: No. What conduits are you going to use for your reoperations?

Dr Koh: Are you asking about the kind of conduit in reoperation?

Dr Tsang: Yes.

Dr Koh: There were 68 reoperations in this series and half of them underwent anterior patching as described by Dr Danielson. The other patients underwent second implantation of tri-leaflet handmade conduit.