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Original Article

Valve Template Design and Applications

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Abstract

Background and Objective: **To evaluate the results of autologous pericardial valve-conduit reconstruction, made with the help of metallic valve-conduit templates of various sizes specifically created for Thai patients.**

Methods: **Metallic valve-conduit templates were made based on the diameters of the aortic root at the levels of the aortic annulus, the sinus of Valsalva and the sino-tubular junction derived from cine-angiography measurements in 20 Thai subjects. The average diameters at the3 levels were to the ratios of 1 to 1.50 to 1.13, respectively. These ratios were used in constructing valve-conduit templates of various sizes.**

Results: **From 2001 to 2010, ten children underwent autologous pericardial valve-conduit reconstruction and one adult patient underwent pericardial valve replacement, using the metallic valve-conduit templates in the reconstruction. Of the seven children and one adult who survived the immediate postoperative period, the functions of the valves and conduits as measured by echocardiography were satisfactory. Only mild valvular regurgitation was seen postoperatively, although the regurgitation worsened with longer follow-up.**

Conclusion: **Autologous pericardial valve-conduit reconstruction using metallic templates is a suitable alternative to other types of repairs.**

Keywords: **Valve conduit; pericardium; aortic root; valve template**

Introduction

Correction of abnormal valves and outflow tract obstruction often requires prosthetic valves or the construction of valve-conduits[1]. Such valve-conduits can be constructed freehand using fresh autologous pericardium[2]. A valve-conduit template for such constructions, closely resembling the actual shape of the aortic root, should be extremely useful especially for repairs in very young children.

Patients and Methods

A valve-conduit template was created and used in the reconstruction of valves and conduits for the correction of cono-truncal malformations in children with congenital heart disease, and in adults with aortic stenosis. A retrospective review was done of the results of valve-conduit reconstruction during the years 2001 and 2010 in which the templates were used.

The valve-conduit template was constructed as follows: A triangular template was fabricated from stainless steel, with the outer perimeters of the template equal to the circumferences of the actual aortic root. The ratios of the perimeters of the template representing the circumferences of the aortic root at the levels of the annulus, the sinus of Valsalva and the sinotubular junction were 1 to 1.5 to 1.13, which were as the ratios of the respective diameters. The detail of

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the derivation of these ratios will be outlined below. The triangular form of the template (Figure 1, template model 1), instead of a cylindrical form, was to facilitate the placement of sutures in the freehand construction of a new valve. A second template type was also constructed, which was essentially a "core" of the first template model (Figure 2, template model 2). Both types of templates were equally useful in the freehand reconstruction of valves and conduits. Various sizes of the templates were made corresponding to the various sizes of the aortic annulus that could be found from infants to adults.

For any given patient the valve and conduit reconstruction began with the selection of a template of appropriate size. During surgery, when the chest has been opened, a large piece of pericardium was harvested. Three pieces were cut for the construction of valve leaflets. All pericardium pieces were used fresh, with no chemical pretreatment. They were then sutured to the template. A large portion of the remaining harvested pericardium was wrapped around the template to form the conduit, which was sutured to the reconstructed leaflets at each valve commissure using 5-0 polypropylene. A small piece of Gore-tex® was sutured to the reconstructed annulus to strengthen it.

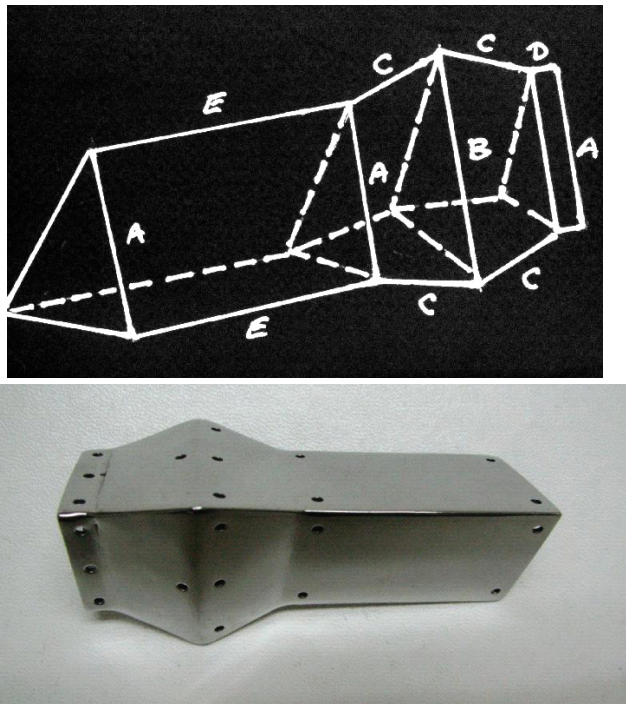

Figure 1 Template model 1: schematic diagram (above); photograph of actual stainless steel model (below).

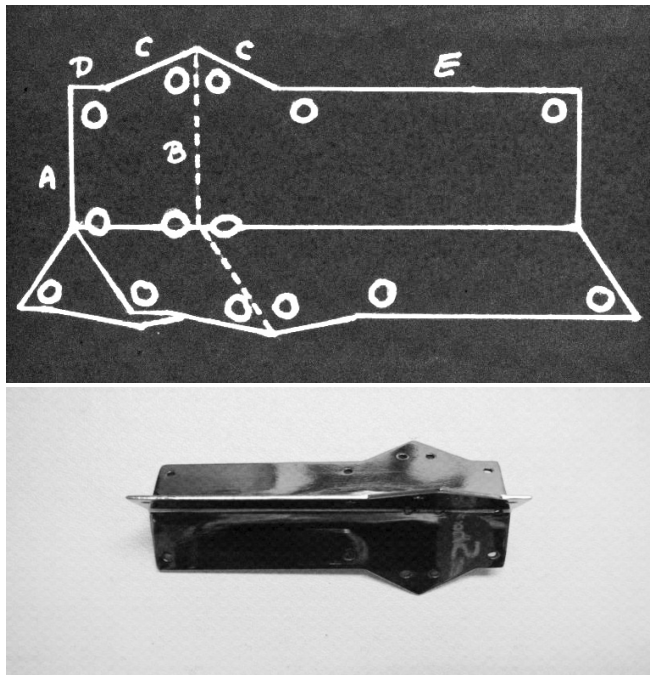

Figure 2 Template model 2 - the "core" of template model 1: schematic diagram (above); photograph of actual stainless steel model (below).

Continuous data in the study were summarized as mean (SD) and/or median (range) as appropriate. Categorical data were summarized as counts and percentages. Comparison and tests between two independent groups were done using unpaired *t*-test or rank test for continuous and ordinal data as appropriate. Tests for continuous data measured on the same subjects were done using repeated measures ANOVA or sign tests (Friedman's test) as appropriate. Significant *p*-values were defined as a two-tailed *p*-value of 0.05 or less.

The derivation of the aortic root ratio used for template construction

The shape and measurements of the aortic root were obtained from cine-angiography of 20 subjects with no cardiac diseases. There were 16 adults, with age ranging from 14 to 75 years (mean, 58.8 years, SD, 15.0 years), and 4 children, with age ranging from 2 to 3 years (mean, 2.75 years; SD, 0.5 years). The shape of the aortic root was simply a cylinder with a bulge in the middle (at the sinus of Valsalva region) as depicted schematically in Figure 3. The shape of the aortic root could thus be defined by the diameters at three levels: at the annulus, the sinotubular junction (STJ) and at

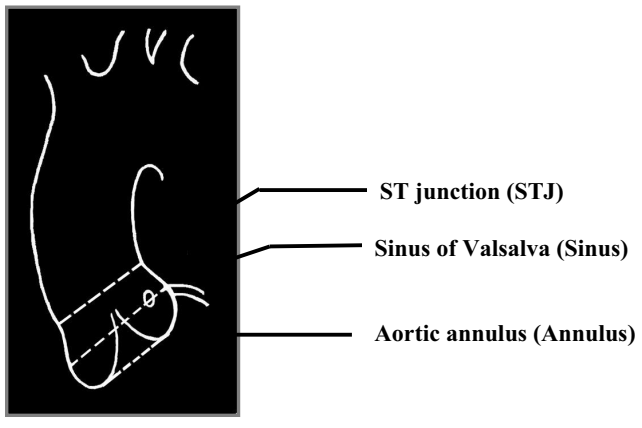

Figure 3 Schematic representation of the three levels of the aortic root: Sinotubular junction (STJ), Sinus of Valsalva (Sinus), Aortic annulus (Annulus)

the sinus of Valsalva (Sinus) levels.

The mean of the ratio of the STJ diameter to annulus diameter was almost identical to the ratio of the mean STJ diameter to mean annulus diameter. Similarly, the mean of the ratio of the sinus diameter to annulus diameter was almost the same as the ratio of the mean sinus diameter to mean annulus diameter (Table 1). There were no significant differences in the mean diameters or the mean ratios between the adults and children, as determined by both the t-test and the rank-sum test (Table 1). Thus the two groups were combined. The three mean diameters were, however, significantly different from one another (12.9 mm versus 14.6 mm versus 19.3 mm; repeated measures ANOVA p-value < 0.001). There was also a statistically significant difference between the two mean ratios (1.5 versus 1.13), whether determined by the paired t-test (p-value < 0.001) or the signed-rank test (p-value < 0.001). The ratio of the diameters of the annulus to the STJ to the sinus of Valsalva was therefore taken to be 1 to 1.5 to 1.13, the average over all subjects, and used for the valve template construction.

Results

During the period between 2001 and 2010, the valve-conduit template was used for the reconstruction of aortic or pulmonary valves and conduits in 10 children with congenital heart disease[3,7] and in one adult with aortic stenosis. Clinical characteristics of these patients are shown in Table 2. Operations performed and their outcomes are shown in Table 3. All 10 children underwent autologous pericardial valve conduit reconstruction at the pulmonary valve position. One adult underwent autologous pericardial aortic valve replacement. Three children died after surgery. Two newborn children with truncus arteriosus died from myocardial failure and prolonged cardiopulmonary bypass. One child who had absent pulmonary

Table 1 Age of subjects and aortic root measurements

Age & aortic root measurements	All patients (n=20)	Adult group (n=16)	Children group (n=4)	*p*-value*
Age (years)				
Mean (SD)	47.6 (26.6)	58.8 (15.0)	2.8 (0.5)	<0.001
Diameter at annulus (mm.)				
Mean (SD)	12.9 (2.2)	13.0 (2.1)	12.5 (2.9)	0.699
Median (range)	13 (8-16)	13 (8-16)	12.5 (10-15)	0.703
Diameter at STJ (mm.)				
Mean (SD)	14.6 (2.6)	14.8 (2.3)	13.8 (3.9)	0.480
Median (range)	15 (9-18)	15 (9-18)	13.5 (10-18)	0.736
Diameter at Sinus (mm.)				
Mean (SD)	19.3 (3.2)	19.5 (3.1)	18.3 (3.8)	0.494
Median (range)	20 (13-25)	20 (13-25)	18 (15-22)	0.599
Ratio of STJ to annulus				
Mean (SD)	1.13 (0.08)	1.14 (0.07)	1.09 (0.08)	0.245
Median (range)	1.14 (1-1.29)	1.15 (1-1.29)	1.08 (1-1.20)	0.254
Ratio of Sinus to annulus				
Mean (SD)	1.50 (0.07)	1.50 (0.07)	1.47 (0.05)	0.321
Median (range)	1.50 (1.33-1.63)	1.52 (1.33-1.63)	1.48 (1.40-1.50)	0.180

* Comparison between the adult and children groups; p-values by *t*-test or rank-sum tests as appropriate

Table 2 Clinical characteristics of patients

Patient	Sex	Age	Diagnosis
1	Male	4 months	Absent PV
2	Male	9 months	Truncus arteriosus
3	Male	9 years	Tetralogy of Fallot (SDL)
4	Male	13 years	Pulmonary atresia; ventricular septal defect
5	Male	4 years	Absent PV
6	Male	10 years	Absent PV; bronchomalacia; prior classical BT shunt
7	Female	7 days	Truncus type I; interrupted aortic arch
8	Female	10 days	Truncus type II; right & left pulmonary artery stenosis
9	Male	6 years	Pulmonary atresia; ventricular septal defect
10	Male	14 years	Pulmonary atresia; tricuspid stenosis; small rt ventricle
11	Male	50 years	Severe AS & AR; small aortic annulus

PV: pulmonary valve; BT: Blalock-Taussig; AS: aortic stenosis; AR: aortic regurgitation

Table 3 Operations and outcomes

Patient	Operation	Follow-up results (echocardiography)			
		1st FU	2nd FU	3rd FU	4th FU
1	Closure of VSD & conduit replacement	Mild PS,PR (1 yr)	Mod PS, PR (5 yrs)	Severe PS	-
2	Closure of VSD & conduit replacement	Mild PR (4 mo)	Mild PR (2 yrs)	Mod PR	-
3	Closure of VSD & conduit replacement	Mild PS,PR (2 mo)	Mild PS,PR (6 mo)	Mild PS,PR (2 yrs)	Mod PS
4	Closure of VSD & conduit replacement	Mild PS,PR (2 mo)	Mild PS,PR (2 yrs)	Mild PS,PR PR (5 yrs)	Mod-severe
5	Closure of VSD & conduit replacement	Mild PS (1 yr)	Mod PS,PR	-	-
6	Closure of VSD & conduit replacement & RPA plication	Pulmonary sepsis & death			
7	Repair aortic arch & conduit replacement	Myocardial failure & death			
8	Repair truncus & Rt & Lt pulmonary arterioplasty & conduit replacement	Prolonged cardiopulmonary bypass & death			
9	Closure of VSD & conduit replacement	Mild PR	-	-	-
10	Conduit replacement	Mild PR	Mild PS, mod PR (4 yrs)	-	-
11	Pericardial valve replacement	Mild AR	Mod AR (6 yrs)	-	-

1st FU: first follow-up was within one month of operation; VSD: ventricular septal defect; RPA: right pulmonary artery; Mod: moderate; PS: pulmonary stenosis; PR: pulmonary regurgitation; AR: aortic regurgitation

valve syndrome and bronchomalacia died from pulmonary sepsis. Postoperative echocardio-graphy was performed on all survivors (8/11) within 30 days after surgery. The length of follow-up for the children was from one month to five years. The only adult patient was followed for six years. Information gathered on follow-up was by clinical observation supplemented with echocardiography as indicated. Short-term results showed that all patients had only mild valvular regurgitation of the reconstructed valve, although this tended to worsen with time.

Discussion

The results of the present study showed that autologous pericardial valve-conduit replacement,

constructed freehand over a metallic template as described, was reasonably effective in the correction of various congenital heart anomalies as well as in adult aortic stenosis. Short-term results (within five years) were good, according to echocardiograms, which showed mild pulmonary stenosis or regurgitation in most cases. However, since the number of patients in the study was rather small (seven children and only one adult were available for review), no conclusions can be made with certainty, especially for adult patients. Nonetheless, we consider these results to be encouraging and warrant further investigation and longer follow-up. Although a tendency to worsening valvular function with time can be seen in the present series, this tendency is common to all studies on pericardial valve replacement[4-6].

A freehand pericardial valve and conduit can be made from either glutaraldehyde-treated or fresh autologous pericardium. Batista et al. reported the use of stentless pericardium aortic monopatch made from glutaraldehyde-treated bovine pericardium shaped to fit and stitched to the aortic annulus to replace the aortic valve. They divided a large rectangular bovine pericardium into three equal portions corresponding to each aortic leaflet and sutured in place to the annulus and commissure. The native valve remained intact and its contour functioned as a framework for reconstruction[4]. But in many cases of congenital heart disease, such as pulmonary atresia, truncus arteriosus or absent pulmonary valve syndrome, the native valve does not exist or exists only in rudimentary form. The use of a valve-conduit template is then necessary to reconstruct a valve and conduit which is of right size and shape and has satisfactory competency.

Other studies using the pericardium to reconstruct or replace heart valves have reported similar results to the present study. The pericardium can be used for cusp extension in aortic valve reconstruction with good outcomes, as in the study of Duran et al., who used both autologous and glutaraldehyde-treated bovine pericardium[5]. Al Fagih et al. also used tailored bovine pericardial extensions to the native cusps in 20 patients with severe rheumatic aortic valve incompetence, and observed good short-term outcomes[6]. Satisfactory outcomes can also be seen in patients with tetralogy of Fallot, in whom the enlargement of the right ventricular outflow tract makes the construction of a monocusp using the pericardium especially suitable. We have also previously reported satisfactory experience with autologous pericardial valve-conduit reconstructions[3,7].

The tendency to worsening regurgitation of the reconstructed pulmonary valve-conduit in the long-term can be of considerable concern. Regurgitation of the pericardial valve-conduit is an important factor in the deterioration and calcification of the valve tissues, from shear stress on the valve leaflets[8]. The use of intraoperative biomechanical tests in order to select the pericardium with the right thickness, strength and stress properties can help in constructing autologous pericardial valves which may be more durable[9]. Vascularized pericardial grafts, which may grow in size along with the child, may also be similarly beneficial in pediatric patients[10]. Nonetheless, in the child who has undergone pericardial valve-conduit reconstructions, redo surgery may be necessary after a number of years. The ideal material for reconstructing the diseased valve-conduit does not currently exist, and the pericardium - whether autologous or bovine, fresh or chemically pretreated - offers a suitable and reasonably effective alternative material in such repairs.

Conclusion

A new metallic valve-conduit template was presented, with shapes and proportions based on measurements made using cine-angiography on subjects with no cardiac diseases. The template was used for reconstructing the valve-conduit, from autologous pericardium, in a small group of children with congenital heart disease, and in one adult with aortic stenosis. Short term results (within five years) were seen to be satisfactory, with only mild valvular regurgitation and stenosis in most patients. Autologous pericardial valve-conduit reconstruction, using metallic templates, is a suitable alternative to other types of repairs.

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