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Early Failure of the Shelhigh Pulmonary Valve Conduit in Infants

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Background. The ideal valved conduit for right-sided (pulmonary) reconstruction in infants and children remains elusive. Desired characteristics include availability, ease of implantation, and longevity. Cryopreserved homografts are most commonly used, but availability of small sizes and limited durability remain problematic. The Shelhigh porcine-valved conduit (SPVC) with its No-React anticalcification properties was developed as a potential alternative to homografts.

Methods. During a 10-month period, 8 patients underwent seven successful SPVC implantations. Median age was 9.5 days. Six conduits were less than 12 mm in diameter (range, 9 to 19 mm).

Results. The early and late survival rates were 100%. During a mean follow-up of 18 months, five conduits were replaced at 6, 10, 12, 12, and 13 months for severe obstruction. Actuarial conduit failure at 12 months was 72%. Explanted SPVCs demonstrated marked pseudointimal peel formation along the original intima with an intense granulomatous inflammatory reaction. The intimal reaction was severely fibrogenic, but calcification

was not present. For comparison, we retrospectively reviewed the cases of 23 infants receiving cryopreserved homografts during an overlapping period. Twelve patients, 6 of them neonates, were less than 90 days old. Mean homograft size was 13 mm (range, 8 to 15 mm), with nine less than 13 mm. During a mean follow-up of 26 months, six conduits were replaced at 7, 12, 12, 16, 20, and 35 months (sizes 13, 17, 14, 12, 10, and 12 mm, respectively). Only three of nine homografts less than 13 mm in size were replaced during a mean follow-up of 12 months. The overall homograft replacement rate was 17% at 22 months ($p = 0.005$) compared with the SPVC).

Conclusions. Although the SPVC appears to resist calcification, a marked foreign-body type of reaction results in pseudointimal peel formation and early conduit stenosis. In its present configuration, the SPVC is not a suitable valved conduit for use in infants. Although not ideal, the cryopreserved homograft has superior longevity to the SPVC.

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Valved conduits are frequently used to reestablish right ventricular (RV)-pulmonary artery (PA) continuity for various congenital heart defects [1, 2]. Use of RV-PA conduits, however, has been complicated by limited longevity because of the development of calcific stenosis, fibrointimal peel formation resulting in obstruction, on both [3-7]. In addition, lack of growth forces eventual reoperation. Early reintervention is particularly likely with the smaller conduits used for neonatal repairs [8]. Furthermore, the most commonly used conduit, the cryopreserved homograft, is a scarce resource, availability of small size is limited. Cryopreserved homografts often demonstrate substantial valve regurgitation early after implantation, thereby negating in some patients the benefits of having a competent valve in the pulmonary outflow. Several other types of conduits have been developed and used to reestablish RV-PA continuity. However, resistance to obstruction and long-term durability

have yet to be demonstrated with bovine jugular vein valved conduits [9, 10] or equine pericardial conduits [11].

The Shelhigh porcine-valved conduit (SPVC) was developed as an alternative to homografts, which are increasingly difficult to obtain in small sizes. The SPVC is readily available in several sizes with minimal shelf-to-operative-field preparation time. The conduit consists of a glutaraldehyde-treated porcine valve and contiguous pulmonary artery. Both a "short-sleeved" conduit and a "long-sleeved" conduit are available, the difference being a proximal pericardial tube extension in the long-sleeved conduit. Unlike other porcine valves, the valve is treated with a proprietary anticalcification process (No-React) designed to stabilize or fix the glutaraldehyde and hence prevent the development of calcification. Experience with the SPVC in neonates and infants is limited [12]. Intrigued by the described anticalcification properties and frustrated by the difficulty obtaining small-sized homografts, we began using the SPVC.

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Table 1. Demographic Data for the Two Patient Groups and One Subgroup^a

Variable	SPVC (n = 8)	Homograft (n = 23)
No. of conduits implanted	7	25
Median age (days)	9.5 (2-630)	42 (4-470)
Mean age (days)	117	94
Mean weight (kg)	4.7 (2.2-11.6)	4.9 (2.5-13.2)
Diagnosis		
Truncus	5	7
TGA or DORV	1	5
Ross-Konno	1	4
PA-VSD	1	7
Cross-clamp time (min)	126 (95-157)	118 (22-307)
CPB time (min)	201 (154-265)	271 (92-403)
Circulatory arrest	2	6
No. of patients	2	6
Duration (min)	27	42
Conduit Sizes (mm)		
8	0	2
9	2 ^b	2
10	4	2
11	1	1
12	0	4
13	0	5
>14	1	9
Mean conduit size (mm)	11	13
Subgroup With Conduits Sized 12 mm or Less		
No. of patients	6	11
Mean age (days)	21	37
Median age (days)	7.5 (5-90)	14 (2-130)
Mean weight (kg)	3.5 (2.2-6.5)	3.8 (2.5-5.4)

^a Numbers in parentheses are ranges. ^b One 9-mm conduit was removed at the time of implantation for technical reasons and was replaced with a bifurcated pulmonary homograft.

CPB = cardiopulmonary bypass; DORV = double-outlet right ventricle; SPVC = Shelhigh porcine-valved conduit; TGA = transposition of the great arteries; PA-VSD = pulmonary atresia with ventricular septal defect.

Material and Methods

SPVC Group

During the 10-month period December 1999 through September 2000, 8 patients requiring a valved conduit for repair of congenital heart disease underwent attempted implantation of a SPVC from the right ventricle to the PA. The median age was 9.5 days; there were 6 neonates, and only 1 patient was older than 1 year. Diagnoses included truncus arteriosus in 5, transposition with ventricular septal defect and pulmonary stenosis in 1, and pulmonary atresia, plus ventricular septal defect in 1.

The patient who was more than 12 months old required conduit replacement with a 19-mm SPVC after a Ross-Konno procedure (Table 1).

Standard hypothermic cardiopulmonary bypass and blood cardioplegia were used. Closure of the ventricular septal defect was carried out using a Dacron patch. Distal conduit anastomoses were performed using a continuous running suture with 5-0 or 6-0 polypropylene (Prolene;

Ethicon, Somerville, NJ) suture. Only the short-sleeved configuration was implanted. Either a Shelhigh pericardial patch or native pericardium was used for proximal extension to the ventriculotomy. The proximal anastomosis was carried out with 5-0 polypropylene suture. Intraoperative transesophageal echocardiography was performed in all patients. Long-term aspirin therapy was prescribed for all patients postoperatively.

The SPVC has been approved for use in patients less than 4 years of age and in sizes smaller than 18 mm in the United States. Therefore, formal institutional review board approval or informed consent was not required by our review board. Approval was obtained from our institutional review board and the Food and Drug Administration for implantation of the 19-mm SPVC.

Cryopreserved Homograft Group

We retrospectively reviewed the cases of 23 patients receiving 25 cryopreserved homografts during a 42-month period (January 1998 through June 2001) overlapping the Shelhigh time period. The diagnoses included truncus arteriosus in 7, tetralogy of Fallot with pulmonary atresia in 7 (with aortopulmonary collaterals in 5, aortic and subaortic stenosis with coarctation in 4, and either double-outlet right ventricle or transposition of the great arteries plus ventricular septal defect plus pulmonary atresia in 5 (see Table 1). The median age was 42 days. Twelve patients were less than 90 days of age, and 6 were less than 1 month old. Mean homograft size was 13 mm (range, 8 to 15 mm). Eleven conduits were 12 mm or less in size; the demographic data for these patients is shown in Table 1. Two patients underwent conduit replacement with a second homograft within the period of study. Eleven aortic and 14 pulmonary homografts were used.

Identical operative techniques were used, and patients were maintained on long-term aspirin therapy. The choice of conduit during the Shelhigh experience was not randomized but was based primarily on size availability and surgeon choice. Both surgeons implanted both types of conduits.

Statistical Analyses

The time to replacement of valves was analyzed by nonparametric survival analysis. Kaplan-Meier survival and hazard analyses were determined followed by log-rank testing (Mantel-Cox) and Breslow-Gehan-Wilcoxon rank testing with Statview 4.01 software (Abacus Concepts, Inc, Berkeley, CA). A *p* value of less than or equal to 0.05 was considered significant.

Results

SPVC Group

Seven of the 8 patients receiving the SPVC underwent successful implantation. In the patient with pulmonary atresia plus ventricular septal defect and multiple aortopulmonary collaterals, the conduit was removed at the time of implantation and replaced with a bifurcated

Table 2. Follow-Up Data for the 7 Patients Having Successful Implantation With Shelhigh Porcine-Valved Conduit

Age (Days)	Diagnosis	Weight (kg)	Conduit Size (mm)	Follow-up
7	TGA+PS	3.3	10	Replaced at 12 months
7	Truncus	3.0	11	Replaced at 6 months
11	Truncus	2.2	9	Replaced at 10 months
5	Truncus	3.2	10	Replaced at 12 months
8	Truncus	2.9	10	Replaced at 13 months
90	Truncus	6.5	10	55 mm Hg gradient at 19 months
630	AS, SubAS, CoA	11.6	19	20 mm Hg gradient at 18 months

AS = aortic stenosis; CoA = coarctation; SubAS = subaortic stenosis; TGA+PS = transposition of the great arteries with pulmonary stenosis.

pulmonary homograft for technical reasons. The early and late survival rates were 100%. During a mean follow-up of 18 months, five conduits were replaced at 6, 11, 12, 12, and 13 months for severe obstruction with systemic or suprasystemic RV pressures. Actuarial conduit failure at 12 months was 72% (Table 2; Fig 1). The remaining infant implant has substantial conduit stenosis 19 months postoperatively with a gradient of 55 mm Hg on echocardiography and estimated RV pressures greater than 50% of systemic pressure. This patient likely will undergo replacement by 2 years after implantation. The older patient who received the 19-mm conduit has required stent placement for branch PA stenosis and has a 20-mm Hg gradient in the conduit itself (see Table 2).

The five explanted Shelhigh conduits were examined in cross sections taken above and below the valve and in longitudinal sections parallel to the long axis of the conduit at one or more levels. Paraffin sections were stained with hematoxylin and eosin, and the methenamine-silver, acid-fast, and Gram methods for organisms. The spectrum of the inflammatory changes and the accumulation of bland, acellular lumen-obstructing intimal fibrosis were remarkably similar in all cases. The reactive fibrous layer was supravalvar, valvar, and subvalvar and was most severe above the valve in four of the

five conduits (Fig 2). In some sections, valve cusps were spared or minimally involved, whereas in other sections from the same specimen, the cusps were completely encased. In every instance, the inflammatory infiltrate was concentrated in layers. The most prominent inflammation involved the original endothelial surfaces of the xenograft and was located beneath the dense fibrous layer. Loss of structural integrity in the zone of inflammation caused the specimens to "peel." The major component of the inflammation was a granulomatous reaction with scattered multinucleated giant cells of foreign body type (Fig 3). Foreign material was rarely evident in giant cells. Patches of mixed inflammation containing abundant plasma cells and lesser numbers of lymphocytes and eosinophils were seen focally beneath the intimal fibrosis. Polymorphonuclear leukocytes were rare to absent. The foreign-body reaction was less intense along the epicardial surface of the porcine component and the surfaces of the bovine pericardial sheath, which enclosed the prosthesis where it was associated with focal lysis of collagen. Reaction to sutures was minimal to absent. Fine punctate calcification was evident only near suture material, it was not seen in the zone of intimal fibrous reaction. No organisms were demonstrated.

Cryopreserved Homograft Group

During a mean follow-up of 26 months (range, 7 to 48 months), six conduits were replaced at 7, 12, 12, 16, 20, and 35 months (sizes 13, 17, 14, 12, 10, and 12 mm, respectively) primarily for conduit stenosis in 5 patients and regurgitation in 1 patient (see Fig 1). Only three of nine homografts less than 13 mm in size were replaced during the follow-up period. There was one late death at 8 months secondary to native truncal valve regurgitation and stenosis. Of the currently implanted homografts, 14 have no gradient or a mild gradient, defined as a peak gradient of less than 35 mm Hg measured by echocardiography. Six patients have a moderate gradient (35 to 55 mm Hg), and 2 patients have gradients higher than 55 mm Hg. Six patients have major branch PA stenosis. Right ventricular pressure estimates are higher than 50% of systemic in only 6 patients, with an RV pressure greater than 75% of systemic in only 1 patient. In five of these 6 patients, the elevated pressure is thought to be related to branch and peripheral PA stenosis.

The overall homograft replacement rate was 22% at 26

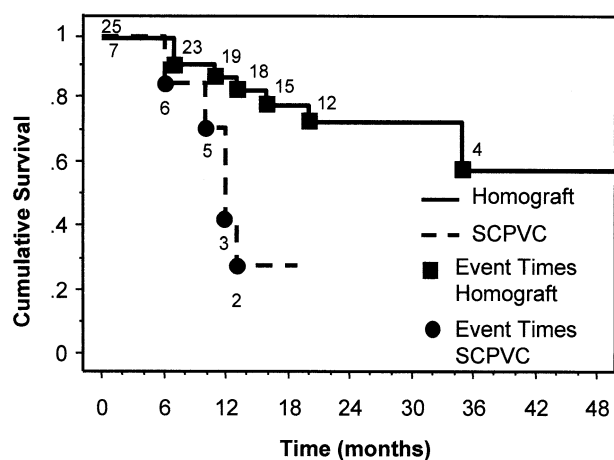


Fig 1. Actuarial survival curve demonstrating percentage free from graft failure for all conduit sizes. Number of patients at risk at each time point is shown for both groups. (SCPVC = Shelhigh porcine-valved conduit.)

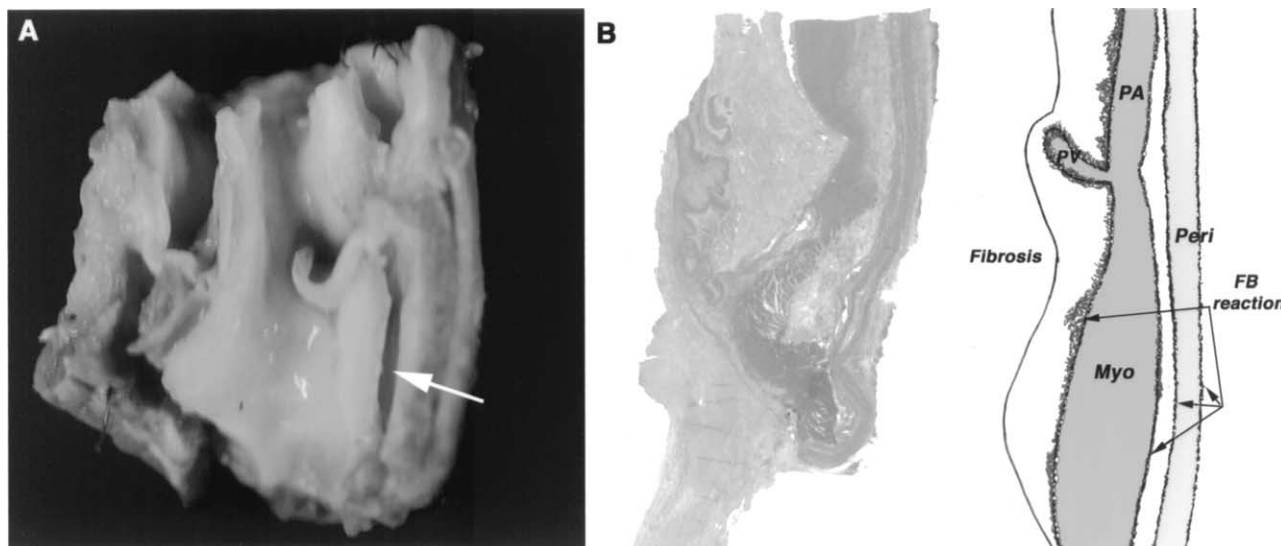


Fig 2. (A) Longitudinal hemisection of explanted Shelhigh conduit with severe supralvalvar and subvalvar intimal fibrosis. Arrow designates delamination of intimal peel from underlying porcine endocardium. (B) Low-power long-axis section through pulmonary valve of Shelhigh conduit demonstrates severe intimal fibrous plaque encasing the pulmonary valve and extending the entire length of the conduit. (FB = foreign body; Myo = myocardium; PA = pulmonary artery; Peri = pericardium; PV = pulmonary valve.)

months ($p < 0.005$ compared with the SPVC). At 12 months, the homograft replacement rate was only 16% compared with 72% for the SPVC ($p < 0.005$) (see Fig 1). Adjusting for the fact that the homograft group included some larger conduits, subset evaluation of conduits smaller than 13 mm shows an even greater discrepancy in conduit survival—94% freedom from failure for homografts versus 16.6% for the SPVC at 12 months ($p < 0.005$) (Fig 4).

Comment

The ideal valved conduit for right-sided (pulmonary) reconstruction in infants and children remains elusive [1, 4, 5]. Desired characteristics include availability, ease of implantation, and longevity. The major limitation, however, has been finite conduit longevity secondary to the development of calcific stenosis, fibrointimal peel formation or both [2, 6, 13–15]. Although results vary, early obstruction is particularly likely with the smaller conduits used for neonatal repairs. The introduction of the homograft provided great hope initially, excellent mid-term survival was demonstrated with the use of fresh homografts. The drawback is that in most countries, including the United States, fresh homografts are not available, and cryopreserved homografts have become the preponderant conduit used. However, durability and longevity of the cryopreserved homograft, although superior to the xenograft, have not approached that of the fresh homograft [16, 17]. Furthermore, the availability of small-sized homografts used for increasingly common neonatal repairs is limited. Freedom from homograft failure for cryopreserved homografts is reported as approximately 75% at 5 years and 50% at 10 years [1, 2, 4, 18]. Younger age and smaller conduit size are generally

thought to be risk factors for earlier conduit failure, although it has been reported that conduit failure is unrelated to somatic growth (unpublished observations).

Until recently, other valved conduit choices included glutaraldehyde-preserved porcine valves contained within a Dacron conduit [5, 13, 15]. Composite xenograft conduits have been shown to be prone to rapid calcification in young patients, which results in early failure. Most previous studies have shown a poorer conduit survival and earlier failure of xenografts compared with homografts [5]. This is thought to be secondary to an immune reaction or related to leakage of glutaraldehyde and subsequent deterioration of the porcine tissue and calcium deposition. Efforts to avoid this have included techniques to fix the glutaraldehyde or to detoxify the valve by washing out the glutaraldehyde [3].

The Shelhigh No-React process is a patented and proprietary technique that is a detoxification process aimed at cross-linking the glutaraldehyde to prevent leakage from the treated tissue. The No-React process is designed to prevent calcification of the valve leaflets. In fact, despite early failure of the SPVC from pseudointimal peel formation, calcification of the valve leaflets was noticeably absent in these implants that were in place for a relatively short duration. However, the thick pseudointimal peel often involved the paravalvular area and resulted in distortion of the valve and obstruction at the valve level as well.

In comparison to the reaction seen with homografts, the SPVC exhibited a polymorphous reaction including giant cells suggesting a foreign body reaction. In all specimens, there was a distinct zone between the actual conduit wall and the thick fibrointimal peel that was frankly granulomatous with large numbers of foreign body cells. The appearance was reminiscent of the

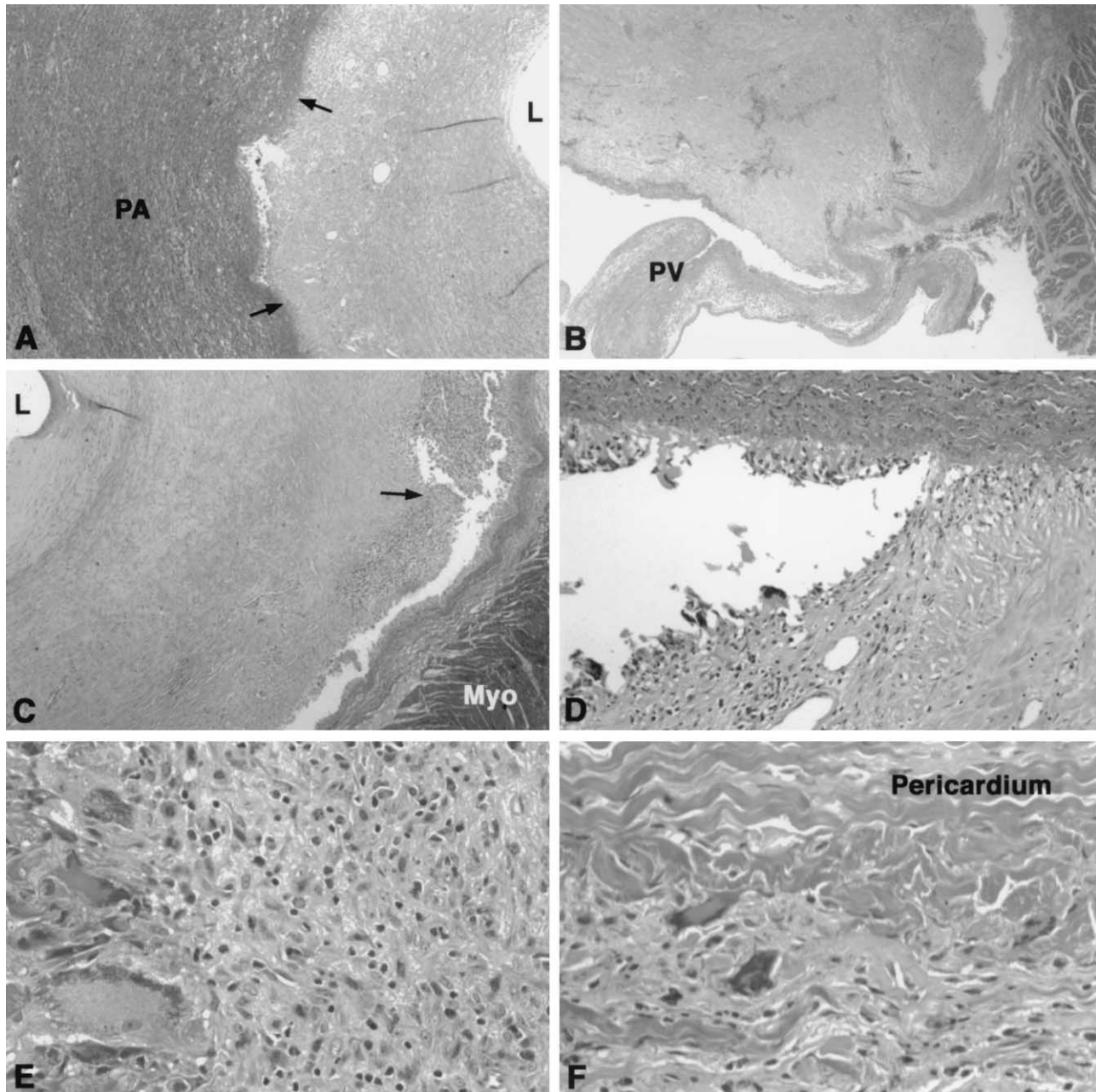


Fig 3. (A) Supravalvar bland, fibrous plaque with zone of foreign body reaction (arrows) and lumen (L) of pulmonary artery (PA) ($\times 60$). (B) Supravalvar fibrous plaque attached to relatively unaltered pulmonary valve (PV). Foreign body reaction is noted in areas where plaque is separating from valve ($\times 60$). (C) Subvalvular fibrosis with zone of foreign body reaction adjacent to original endocardium (arrow) ($\times 100$). (D) Delamination of fibrous plaque at zone of intimal foreign body reaction in PA of conduit. Note the multinucleated giant cells ($\times 160$). (E) Foreign body giant cells are accompanied by plasma cells, which infiltrate beneath the fibrous plaque. (F) Bovine pericardial collagen shows evidence of lysis with scattered foreign body giant cells. (Myo = myocardium.) ($\times 160$.) (A)–(F) Hematoxylin and eosin stain.

marked pseudointimal peel that has been well characterized in Dacron conduits. A less intense granulomatous reaction was also observed along surfaces of other components of the mixed xenograft. We interpret this reaction as mainly foreign body reaction, which involved the lumen and valve by eliciting massive intimal fibrosis but probably did not affect performance of other graft components. We discounted infection for lack of clinical and

morphological evidence. Foci of plasma cell-rich polymorphous inflammation suggest the possibility that an immune reaction to the xenograft protein also played a role in prosthesis failure.

Separate evaluation of explanted conduits by Shelhigh suggested bacterial endocarditis as the cause of the failed conduit in at least one instance. Our evaluation including cultures and bacterial and fungal stains failed to demon-

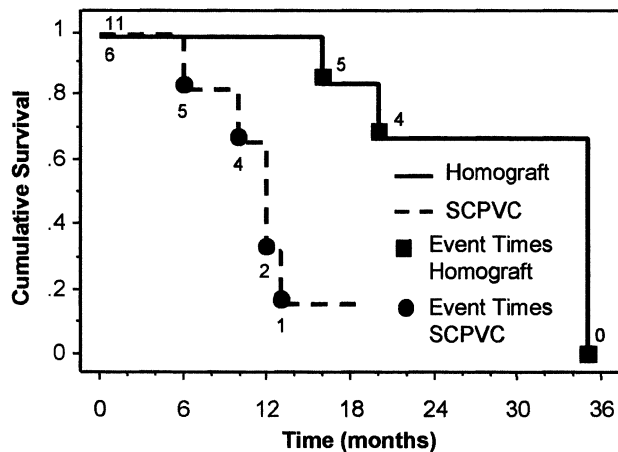


Fig 4. Actuarial survival curve demonstrating percentage free from graft failure for conduits 12 mm or less in size. Number of patients at risk at each time point is shown for both groups. (SCPVC = Shelhigh porcine-valved conduit.)

strate any evidence of infection in our portion of the specimen. In addition, none of the patients exhibited any clinical evidence of ongoing infection. None of the patients receiving homografts during this same period exhibited signs of infection, nor did any of the explanted homografts show infection. It is likely that if subclinical bacterial contamination was present, it represents contamination of the SPVC itself prior to implantation. Two explanted SPVCs from an institution in Ireland demonstrated *Mycobacterium* on acid-fast staining, and in one case, cultures grew *Mycobacterium*. On the basis of the location of the staining and the subclinical nature of the contamination, it was concluded that the conduits were contaminated prior to implantation. In all, four SPVCs were explanted and evaluated by the Irish group within a year of implantation and demonstrated similar findings of granulomatous inflammation, but minimal calcification (Michael McDermott: Personal communication). We retrospectively performed acid-fast staining of our conduits and were unable to demonstrate any evidence of mycobacterial contamination.

Experience with the SPVC is limited, especially in neonates and infants. Marianeschi and colleagues [12] reported their experience with the SPVC in 25 patients. Only 5 patients were infants, and none were less than 6 months of age. Also, only four conduits were less than 13 mm in size. There were at least three early conduit failures, one at 5 months.

Recent experience with newly developed porcine xenograft conduits such as the TissueMed conduit have also demonstrated poor longevity compared with homografts because of the development of early stenosis. Levine and associates [3] reported early conduit failure secondary to stenosis in 8 of 9 patients by 12 months after implantation of a TissueMed porcine-valved conduit. At explantation, fibrous tissue was identified at anastomotic suture lines. In contrast, none of 12 homografts implanted during the same period developed signs of

obstruction by 12 months. The experience with the TissueMed porcine valve is nearly identical to our experience with the SPVC.

The SPVC has certain properties that may be advantageous, such as the ability to readily stock small sizes and a quick shelf-to-operative-field time. Overall, the SPVC has the consistency and handling characteristics of an aortic homograft rather than a pulmonary homograft in that it is stiffer and bulkier than a pulmonary homograft. Theoretically, this may make it less susceptible to distortion or compression. However, suture drag is considerable, and use of a telescoping technique or anastomosing to very friable thin vessels such as during unifocalization procedures is difficult.

The Shelhigh company has recommended that interrupted sutures or an everting running suture be used for the distal anastomosis to avoid exposing the lumen to any suture material. We used a typical running polypropylene suture identical to the technique used successfully with the homografts. As we did not see the same degree of distal obstruction and peel formation in the homografts, it is unlikely that the suturing technique was the cause of the impressive circumferential pseudointimal peel formation seen with the SPVC. Furthermore, unless the conduits themselves were contaminated, it is statistically improbable that all of the SPVC patients had infection as the cause of early peel formation, whereas none of the homografts recipients did. As mentioned previously, none of the patients had clinical symptoms or laboratory or microscopic features consistent with infection.

Although the SPVC appears to resist calcification, substantial pseudointimal peel formation caused by what appears to be a foreign body reaction leads to marked early conduit stenosis. In its present configuration, the SPVC is not a suitable valved conduit for neonates and infants. Although not ideal, the cryopreserved homograft has better longevity than the SPVC. Despite their limitations, cryopreserved homografts remain the most reliable valved conduit available for establishment of RV-PA continuity. Although the SPVC tends to show early development of stenosis, characterized by pseudointimal peel formation, the valve itself appears to resist calcification and maintain early competency. Currently, we cannot recommend the Shelhigh No-React porcine-valved conduit in infants less than 6 months of age or in sizes smaller than 13 mm.

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DISCUSSION

DR JOHN W. BROWN (Indianapolis, IN): I compliment Dr Pearl and his colleagues for an excellent presentation and thank them for providing me with a copy of the manuscript prior to their presentation. They have brought our attention to the fact that the Shelhigh porcine-valved conduit is not suitable for neonates and infants. The marked pseudointimal peel formation is reminiscent of the problems seen with the Dacron valved conduit that we used in the 1970s and early 1980s before homografts were available in the United States.

Doctor Pearl points out that the cryopreserved pulmonary homograft, the most widely used right ventricular-pulmonary artery conduit in the United States, is superior to the Shelhigh conduit, but their experience with the pulmonary homograft is far from ideal. Fourteen of the 25 homografts either have failed or have gradients in excess of 35 mm Hg by 24 months postoperatively. The results with the Shelhigh conduit and the pulmonary homograft point out the need for a better right ventricular-pulmonary artery conduit in children, particularly neonates and small infants.

There may be some light at the end of this clinical tunnel. My colleagues and I have been interested in extracardiac conduits for more than 25 years. It appears that the bovine jugular venous valved conduit, which is now undergoing clinical investigation in the United States in ten centers, and the more than 1,100 conduits implanted in Europe do not show signs of this kind of obstruction. We have had the opportunity to implant 15 of these bovine jugular venous valved conduits over the last 2½ years and have not seen this type of obstruction.

In addition, it is hopeful that the SynerGraft technology that CryoLife is proposing may possibly make a difference. Dr Pearl, do you think the SynerGraft technology will improve the durability of pulmonary homografts?

Do you think that anticoagulation of these tissue conduits, that is, the Shelhigh conduits, would have prevented the-thick neointimal peel?

One thing you did not mention in the manuscript or the presentation is the presence of regurgitation during the time that these Shelhigh conduits were in place. It appears that

regurgitation is also an important mechanism of failure. What are your thoughts on this matter?

DR ROBERTO M. DIDONATO (Rome, Italy): Doctor Pearl, I congratulate you on your very nice presentation and the outstanding results achieved by your group. However, I am puzzled by your findings on the basis of which you draw negative conclusions about the suitability of the Shelhigh pulmonary conduit as a good alternative to homografts. Our experience is quite different.

Between 1998 and 2001, my colleagues and I implanted a total of 37 conduits in 33 patients. The median age was 8.1 months and the median weight 5.2 kg. The procedures performed included 28 repairs and five palliative reconstructions of the right ventricular outflow tract. The hospital mortality rate of 16% was fairly high, but none of the hospital deaths were related to the conduit. Eight of the 28 survivors, required replacement. The patient indications for conduit replacement were outgrowth in 5 patients pseudoaneurysm in 1, vegetation from prior endocarditis on a homograft in 1 and mechanical obstruction, a technical problem in 1. Freedom from explantation was about 80% at 10 months and 50% at 20 and 30 months.

Typically, a Shelhigh pulmonary conduit explanted 15 months after operation is soft; and there is no calcification. The pulmonary wall, the cusps, and the subvalvular apparatus are completely clean. In particular, pseudointimal formation has not been noted, at least to the extent you found. Histologically, there is no evidence of infiltration or calcification.

In conclusion, on the basis of our experience, we believe that the Shelhigh pulmonary conduit is a good alternative to a homograft. I am not sure how to explain the disparity in results between our series and yours. Do you think that a randomized and possibly multicenter, study looking at a larger patient population and covering a longer follow-up might better elucidate the performance of this conduit?

DR PEARL: I thank the discussants for their very insightful comments. In response to Dr Brown's remarks, in reference to

anticoagulation, we have stuck with a policy of using aspirin for recipients of both homografts and Shelhigh conduits.

In regard to the SynerGraft technology, I am a little bit skeptical that it will make a huge difference in terms of homograft viability. I guess it has yet to be shown whether homografts will repopulate with host cells, but it will be interesting to see the results as that study comes along.

I did not discuss regurgitation. We have found, and I think others have reported this, too, that the homografts become regurgitant fairly early after implantation, which usually is not too big an issue. However, the point of putting in a valved conduit is to have a competent valve. The Shelhigh conduits did seem to have more valvar competence early and less regurgitation in one short experience them.

In regard to the Italian experience, I was able to review the initial publication and was struck by the fact that even though it was commented that this was a suitable conduit for neonates

and infants, the median age was older than 8 months, and as best I could tell, there were very few true neonates in that study.

In addition, it was hard to tell which patients required explantation. I do not know whether it was the younger patients. I have no idea why our conduits look so different from those explanted by others. After talking with others in the United States who have used the Shelhigh conduits, I have concluded that most people have stopped using them because they do not seem to hold up and become obstructive quite a bit earlier than other types of conduits.

I think it would be difficult with the current technology to do a randomized study. I have a hard time choosing to implant a small Shelhigh conduit again. The large Shelhigh conduit was used in a patient who had rejected two homografts, and that 19-mm Shelhigh conduit has lasted longer than either of the homografts.

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Peter C. Pairolero, MD
Chairman
The American Board of Thoracic Surgery

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Jeffrey M. Pearl, David S. Cooper, Kevin E. Bove and Peter B. Manning
Ann Thorac Surg 2002;74:542-549

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