# Long-Term Survival and Freedom From Reoperation After Placement of a Pulmonary Xenograft Valved Conduit

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*Background.* **The optimal choice for pulmonary valve replacement (PVR) remains controversial. This study hypothesized that xenografts used for PVR would result in prolonged long-term survival and freedom from reoperation.**

*Methods.* **Children and adults with congenital heart disease requiring PVR using a xenograft from 1980 to 1985 were reviewed. In all cases, the xenograft valve was either sewn or manufactured into a Dacron conduit, and the conduit was sewn to the pulmonary artery bifurcation. Clinical data were analyzed, and survival and freedom from reoperation were determined using Kaplan-Meier analysis.**

*Results.* **Twenty-four patients received a xenograft for PVR at 14.6 ± 5.6 years. Conduit size ranged from 21 to 27 mm. Most patients received a Carpentier-Edwards valved conduit (n = 17), followed by a Hancock valved conduit (n = 5) and an Ionescu-Shiley valve sewn into a Dacron graft (n = 2). No perioperative deaths occurred. Reoperation was required mainly for pulmonary stenosis (72.7%), followed by pulmonary insufficiency (18.2%), or both stenosis and insufficiency (9%). Freedom from reoperation was 90%, 56%, 43%, and 14% at 10, 20, 25, and 30 years, respectively. At most recent follow-up the was only death, which was related to severe biventricular failure 25 years after conduit implant.**

*Conclusions.* **PVR using a xenograft valved conduit results in prolonged freedom from reoperation and excellent long-term survival. These data, which provide long-term follow-up information on xenograft valves after PVR.**

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Pulmonary valve replacement (PVR) using a prosthetic pulmonary valve was first reported in 1966 [1]. However, despite numerous studies demonstrating good short-term and intermediate-term results [2–4], there are limited data regarding the long-term outcomes after PVR. At an intermediate-term follow-up, only 30% of patients have required reoperation for conduit exchange [2]. Therefore, the timing when the majority of PVRs will structurally deteriorate to the point of replacement is unknown. Further, although in many cases the operative mortality rate after PVR has remained low [2, 3], the impact of PVR on long-term survival is unknown. Survival after PVR at an intermediate-term follow-up is lower than in the general population, largely because of right ventricular failure and arrhythmias [5, 6]. Whether the survival difference diverges further at long-term follow-up is unknown.

The choices available for PVR have remained largely unchanged since the 1980s. Most patients receive a homograft (pulmonary or aortic), a Contegra (Medtronic, Minneapolis, MN) unstented bovine jugular venous conduit, or a stented xenograft to reestablish right ventricular–to–pulmonary arterial continuity. Of the choices, our group has favored xenografts because they are readily available, and unlike jugular venous conduits, they have a lower risk of prosthetic valve endocarditis [7]. Additionally, xenografts primarily fail by stenosis, thereby limiting right ventricular dilation secondary to volume overload [3, 4, 8].

Between 1980 and 1985, we primarily began to use xenografts for PVR and demonstrated limited operative mortality, as well as an incremental improvement in right ventricular function [9]. As a consequence, we have continued to use xenografts for PVR and have reported recent intermediate-term outcomes [3, 4]. Because of our continued use of xenograft valve conduits for PVR, we reviewed the long-term data for xenograft pulmonary valve implants performed between 1980 and 1985.

## Patients and Methods

### *Patients' Demographics*

After Institutional Review Board approval, all patients who received a xenograft valve for PVR from 1980 to 1985

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at SUNY Upstate Medical University, in Syracuse, New York were reviewed. Preoperative demographics and outcomes were obtained through a detailed review of clinical records. Follow-up cardiac catheterizations and echocardiograms were used to quantify the peak gradient across the prosthesis, as well as the degree of pulmonary insufficiency over the follow-up period.

### *Surgical Technique*

Aortic and bicaval cannulation was used, cardiopulmonary bypass was initiated, and the patient cooled to 24°C to 32°C. The heart was arrested using crystalloid cardioplegia, and the main pulmonary artery was opened. The size of the xenograft valve was selected to be at least 2 to 4 mm larger than the normal pulmonary valve diameter on the basis of the patient's body surface area. The Hancock and Carpentier-Edwards (CE) valved conduits were preclotted using the patient's own blood, and the conduit was cut minimizing the amount of Dacron distal to the valve. The distal anastomosis was performed using a running polypropylene (Prolene, Ethicon, Somerville, NJ) suture, and the proximal portion of the conduit was tailored to create a hood that was sutured to the right ventricular outflow tract.

For the Ionescu-Shiley valves, the main pulmonary artery was opened, the posterior one-half of the valve was sutured in place using a running Prolene suture. An appropriately sized Dacron graft was then used to augment and provide an oval roof to the pulmonary artery over the valve, and it was sutured in place using a running Prolene suture. The proximal portion of the Dacron graft was then used to establish ventricular pulmonary arterial continuity using a running Prolene suture.

### *Statistics*

Variables are reported as mean ± standard deviation and as a percentage for noncontinuous variables. Variables were evaluated for homogeneity of variances ensuring normality and were then compared using one-way analysis of variance (ANOVA). Comparisons made between categorical variables were done using Pearson's $\chi^2$ analysis and Fisher's exact tests where appropriate. Freedom from reoperation and survival calculations were performed using Kaplan-Meier analysis. Statistical significance was determined if the $p$ value was $<0.05$. All statistics were completed using GraphPad Prism software (GraphPad Software, Inc, La Jolla, CA).

## Results

Twenty-four patients received a PVR using a xenograft valve. Most patients received valve conduits (CE, 17; Hancock, 5). Two patients received an Ionescu-Shiley valve augmented with a Dacron conduit (Fig 1). The fundamental diagnosis for most (20 of 24) patients was tetralogy of Fallot (Table 1). For all patients, the PVR was a reoperation. Previous procedures included Blalock-Taussig and Waterson shunts (n = 7), a right ventricular outflow tract transannular patch (n = 7), and previous

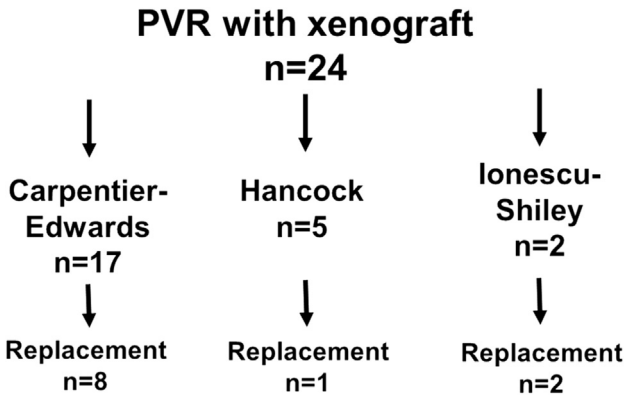


*Fig 1. Flow chart of the different xenograft pulmonary valve replacements (PVR) and their outcome.*

PVR using a prosthetic pulmonary valve (n = 10). Valve sizes at the time of implant ranged between 21 and 27 mm, and the most common implant was a 25-mm valve (Table 2). No operative deaths occurred.

Follow-up was available for 92% (22 of 24) of patients at 23.8 ± 9.0 years, for a total follow-up of 552 patient-years. Two patients were referred from outside institutions, and although they were discharged from the hospital, follow-up could not be determined. In addition, 4 patients had only early follow-up of 5, 8, 10, and 12 years after valve replacement and subsequently moved. Survival for the entire group was 93% at 30 years, with one death related to severe biventricular failure at 25 years after conduit implant (Fig 2).

For most patients, significant valve dysfunction did not occur within the first 10 years after valve implant. Three patients developed early valve dysfunction requiring valve replacement before 10 years. All were younger than 7 years old at the time of PVR and received valves smaller than 23 mm. Over the follow-up period, there were 14 valve replacements in 12 patients, primarily for pulmonary stenosis (72.7%), followed by pulmonary insufficiency (18.2%), or both stenosis and insufficiency (9%) (Fig 3). There were no differences in the method of failure by valve type. Two patients required catheter-based reintervention, both at 15 years after implant. In both cases, balloon dilation of the valve only was preformed because of early calcification of the valve leaflets, thereby limiting leaflet mobility and resulting in valve stenosis. One patient had only minimal improvement and required reoperation the following year. The other patient had a dramatic decrease in degree of stenosis, decreasing the gradient by more than 50 mm Hg. At current follow-up, that valve has not been replaced and has a gradient of 35 mm Hg. In both cases the valve, and not the conduit, was dilated. Rates of freedom from reoperation were 90%, 56%, 43%, and 14% at 10, 20, 25, and 30 years, respectively (Fig 4). Variations among valve types at 20 years demonstrated no significant differences (53.5% for CE vs. 55% for Hancock vs. 55% for Ionescu-Shiley; $p = 0.6$). At most recent follow-up, 6 patients (5 with CE valves