# Two Decades Using Stentless Porcine Aortic Root in Right Ventricular Outflow Tract Reconstruction

Running head: RVOT Reconstruction in Adults

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**Abstract**

***Background:*** The stentless porcine aortic root prosthesis (SPAR) has been described as a suitable valve for right ventricular outflow tract reconstruction (RVOTR). Our institution began using this valve for RVOTR in 1998. Herein we report our medium to late term outcomes of the valve in the pulmonary position.

***Methods:*** A retrospective chart review was conducted of patients over 18 years old who underwent RVOTR with the SPAR between April 2000 and October 2019. Primary outcomes included survival and freedom from any valvular re-intervention. Secondary outcomes included endocarditis and conduit dysfunction obtained from routine echocardiography and/or cardiac MRI.

***Results:*** A total of 135 patients underwent RVOTR with a SPAR at a median age of 32.4 (range 18-71). 129 had previous surgery. Indications included pulmonary insufficiency (90.4%), stenosis (34.8%), endocarditis (7.4%) and carcinoid (4.4%). Median follow-up was 2.97 years (IQR 0.6-8.0). Overall survival was 93.3%, with 3 perioperative and 6 late deaths. Four (2.9%) developed endocarditis, two of which required reoperation. Progressive conduit degradation was evident at 10 years with 22.2% and 7.7% moderate stenosis and insufficiency. Eight (5.9%) re-interventions included 2 surgical replacements, 3 percutaneous replacements and 3 balloon valvuloplasties at means of 8.5, 7.4 and 2.2 years, respectively. Overall freedom from re-intervention at 1, 5, 10 years was 99.1%, 94.7% and 90.7%, respectively.

***Conclusions:*** In one of the largest single institution experiences with adults, with one of the longest follow-up periods, this usage of the SPAR demonstrates excellent mid-to-long term durability, low rates of endocarditis, and high freedom from re-intervention.

**Abstract word count: 250**

Right ventricular outflow tract (RVOT) procedures are among the most common surgical procedures performed for adults with congenital heart disease (ACHD).[1] A wide variety of pulmonary valve replacement options exist, and there is significant heterogeneity in congenital cardiac surgical program preferences. The stentless porcine aortic root (Freestyle, Medtronic Inc., Minneapolis, MN) was initially developed for aortic root replacement, but has gradually gained wider acceptance for pulmonary valve replacement (PVR) over the past two decades based on its favorable hemodynamic profile. Since 2000, we have preferentially used the Freestyle stentless porcine aortic root for PVR and RVOT reconstruction in patients 18 years and older.

Possible advantages of the stentless porcine valve include its wider size availability and maintenance of laminar flow in an orthotopic position. The primary disadvantage is the more involved surgical technique with the need to fully mobilize the main pulmonary artery and RVOT. Despite this added difficulty with surgical placement of the stentless porcine aortic root, numerous studies have demonstrated excellent short-to-medium term outcomes and rates of endocarditis ranging from 0-5%. [2-7]

In this study, we aimed to evaluate medium-to-long term outcomes including valve durability and need for re-intervention following stentless porcine PVR for older adolescent and adult patients at our institution.

## Material and Methods

*Patient Selection*

All patients 18 and older at the time of pulmonary valve replacement between April 2000 and October 2019 were retrospectively identified from hospital databases at Indiana University Methodist Hospital and Riley Hospital for Children at Indiana University Health. Patients who underwent placement of a stentless porcine aortic root in the right ventricular position were included. Selection was based on surgeon's preference and anatomical suitability and patients were not consecutive. The databases were queried for index operative details as well as follow up details including echocardiographic and cardiac magnetic resonance imaging (MRI) data, last follow up date, and death information.

Death and freedom from re-intervention were the primary endpoints. Secondary endpoints included conduit dysfunction and endocarditis. Peak and mean conduit gradients were determined by standard echocardiography. Conduit regurgitation was graded as none, trivial/trace/mild (grouped into one category), moderate and severe.

Conduit dysfunction was defined as moderate or greater insufficiency or a peak gradient >36mm Hg, consistent with moderate pulmonic stenosis based on American Heart Association guidelines.[8] Patients who underwent catheter-based intervention (balloon valvuloplasty or percutaneous valve replacement) or surgical valve replacement were considered intervened upon, and concluded in the study. In the situation of a patient undergoing replacement with another porcine aortic root, a new patient entry into the database was created. Follow-up data were gathered from the most recent clinical assessment by a member of the heart team. To minimize heterogeneity, specific time intervals were studied.

*Operative Technique*

Cardiopulmonary bypass was performed with bi-caval cannulation and mild-moderate hypothermia (32-34$^{o}$C). A transesophageal echocardiogram is performed prior to cardiopulmonary bypass to assess for a patent foramen ovale (PFO) or atrial septal defect (ASD). If no PFO/ASD is present, frequently we performed PVR without arrest at normothermia with the patient in Trendelenberg position and the aortic root vented in the event that a small shunt was missed on bubble study. For the PVR, the main pulmonary artery is incised then mobilized circumferentially to the bifurcation. The main pulmonary artery is transected and excised to the level of the infundibulum. If a transannular patch is present, we do not excise it entirely if it is not aneurysmal and include it in the proximal anastomosis. The RVOT is inspected for muscle bundles or other obstructions. The porcine aortic root is rinsed and prepared according to manufacturer instructions. We orient the porcine aortic root such that one coronary stump faces leftward and the other anteriorly. This positions one commissure directly posteriorly and midline. Typically, a small wedge is resected from the distal edge of the conduit to minimize length. (Figure 1) The distal anastomosis is constructed with a 4-0 or 5-0 polypropylene suture in continuous fashion after aligning the frenulum at the distal bifurcation with the posterior conduit commissure. If the infundibular region is aneurysmal, resection or plication is performed. Conversely, augmentation of the infundibulum with a bovine pericardial patch is used when the proximal anastomosis appears to be constricted. The proximal anastomosis is fashioned using a continuous 3-0 or 4-0 polypropylene suture. The coronary stumps of the conduit must be inspected as they frequently are not fully hemostatic and additional ties may be needed to secure them. For all conduit replacement procedures, we reconstruct the pericardium with a 0.1 mm expanded polytetrafluoroethylene patch (W. L. Gore & Associates, Flagstaff, AZ).

*Statistical Methods*

Univariate analysis was used in the full sample (n=135) to describe the population. In addition, the median length-of-stay was compared between groups undergoing isolated pulmonary valve replacement against those with concomitant procedures with the student's t-test. Kaplan-Meier (KM) survival curves were generated to provide graphical descriptions of overall survival and freedom from re-intervention.

**Results**

A total of 135 patients underwent 137 right ventricular outflow tract reconstructions with a porcine aortic root during the study period. Demographics are listed in Table 1. The median age was 32.4 years and a slight majority was male. Tetralogy of Fallot, pulmonary atresia, and pulmonary stenosis were the most common underlying primary diagnoses (Table 1). Only 6 patients had no prior sternotomy, all of whom had metastatic carcinoid syndrome with right heart dysfunction. Ten previous Ross patients underwent PVR as a replacement for the homograft implanted at the initial Ross operation. The majority (94%) of patients had previous RVOT intervention including 53 (39.2%) with a right ventricular conduit (consisting of non-valved conduits, bovine jugular venous conduit, homograft, Freestyle porcine aortic root, or a stented bioprosthesis). An additional 32 patients (23.7%) had a previous transannular patch repair.

The most common indication (90%) for PVR was insufficiency of the existing conduit or native pulmonary valve, followed by pulmonary valve or conduit stenosis and right ventricular dilation and/or dysfunction. Associated diagnoses included atrial arrhythmia, moderate or greater tricuspid insufficiency, atrial septal defect and ventricular septal defect. Notably, 10 patients had active pulmonary prosthetic endocarditis at the time of operation, with none re-infecting the new SPAR, though one died in the perioperative period (Table 2).

Table 3 lists the multitude of concomitant procedures performed in over 60% of patients. The most common concomitant procedures included pacemaker insertion/revision and RVOT revisional procedures (muscle bundle division, aneurysm plication, or infundibuloplasty with bovine pericardial hood augmentation). Utilization of a right atrial MAZE procedure increased later in the series. Tricuspid valve replacement was required in a small subset of patients. Performance of concomitant procedures was associated with a longer hospital length-of-stay ($p<0.0003$; Table 3). The most common size of porcine aortic root was 27 mm which was used in over half of the group (Figure 2). Over 90% of the group received a conduit 25 mm or larger. Interestingly, two early patients under 10 years of age received 19 mm and 21 mm porcine aortic root, and subsequently underwent re-replacement as adults, at intervals of 15 and 19 years, respectively. These were not included in the durability and re-intervention data due to age exclusions, but their second PVR procedures were.

*Survival*

Overall survival for the entire group was 93% (Table 4). Three deaths occurred in the immediate perioperative period as a result of multisystem organ failure. Three other mortalities within the first year were due to hepatic dysfunction, metastatic carcinoid tumors or unknown etiology. Overall, two of the six metastatic carcinoid tumor patients died. There were no deaths between 1 and 5 years. Three late deaths occurred (5, 7 and 11.5 years postop). The death at five years was a patient undergoing repeat PVR for porcine root endocarditis with pseudoaneurysm and died in the perioperative period, and remains unique to our experience due to the complications and mortality. The other two deaths were due to pneumoniarelated complications. None of the PVR-only patients died in the early or late period. Figure 3 displays the Kaplan-Meyer curve for overall survival, which at 1, 5, 10 and 14.5 years was 94.5%, 93.2%, 90.8% and 79.5%, respectively.

Twenty-four patients (17.7%) experienced a total of 46 complications within 90 days of operation (Table 4). Six patients required early mediastinal exploration for postoperative hemorrhage or tamponade. Six additional mediastinal complications after 30 days and included pericardial effusion and mediastinal infection. Rhythm related complications (atrial fibrillation and atrial flutter) were the most common in our series. Pulmonary complications included prolonged mechanical ventilation, pleural effusion, and pneumothorax requiring tube thoracostomy.

*Reintervention*

There were a total of 8 porcine aortic root interventions during the study period occurring at a mean interval of 5.7 years. Six patients developed stenosis requiring intervention. Three patients underwent early balloon valvuloplasty at 1, 1.8 and 4 years, but required no further intervention. Three patients underwent transcatheter pulmonary valve replacement at 5, 6.4, and 10.9 years. Four patients developed endocarditis of the porcine aortic root, and two of these required eventual surgical replacement at 5 and 12 years (with porcine aortic roots). Figure 3 displays the Kaplan-Meyer curve for porcine aortic root intervention. The freedom from re-intervention (transcatheter or surgical) at 1, 5, and 10 years was 99.1%, 94.7%, and 90.7% respectively.

*Conduit Performance*

Echocardiograms were routinely collected perioperatively and during postoperative years 1 (Early), 3-5 (Middle) and 8-10 (Late;Table 6). One echocardiogram per patient during each time period was chosen as some patients underwent multiple studies in a short time interval. Initial hemodynamics were excellent in terms of conduit gradients. 52% had no regurgitation, 24% trace, and 24% mild insufficiency in the perioperative period. As Table 6 and Figure 4 illustrate, there were progressive, linear increases without plateau in these parameters over the study period. At one year, no patients had moderate PI, and nine had moderate-or-greater PS. Two patients required balloon valvuloplasty. By the Middle interval of 3-5 years,, ten patients developed moderate-or-greater PS requiring two interventions: one balloon valvuloplasty and one transcatheter valve replacement. One patient who had undergone early balloon valvuloplasty developed moderate PI in this interval. By the late postoperative period PS increased to a median peak gradient of 27 mmHg, though carrying a low re-intervention rate and 30.7% exhibited no PI and 61.5% developed trace to mild PI. More recently, patients have been followed with cardiac MRI. Twenty–nine patients at a median 2.5 years (IQR 1.5-4.8) postoperatively had an RVEDV:LVEDV ratio of 1.2 (IQR 1.0-1.5) and a pulmonary artery regurgitation fraction of 5% or less.

*Endocarditis*

Ten patients (7.4%) underwent placement of the porcine root with active endocarditis; two patients with an infected porcine aortic root and eight with various other prostheses. None of the ten infected the new prosthesis and antibiotics were discontinued at six weeks beyond surgery. One of the ten died in the postoperative period following replacement. Of the study group, four patients (2.9%) developed endocarditis. Two patients were able to clear the bacteremia and did not require any reintervention, while the aforementioned two required replacement with a SPAR.

## Comment

This study represents the largest and among the longest follow up single center experience with right ventricular outflow tract reconstruction using the porcine aortic root in patients 18 years of age. This nearly twenty-year experience provides insight into the intermediate-to-late term outcomes of the use of the porcine aortic root in the pulmonary position with favorable durability and patient outcomes.

The first porcine aortic root PVR procedures were performed at our institution in 1998 and 2000 for adult usage, however, these occurred sporadically. The porcine aortic root became increasingly utilized after 2003 and we now perform 10-15 porcine aortic root PVR procedures annually, almost exclusively in adult patients. This trend of increased and preferred usage has decreased the median follow up and accordingly, comparison with our bioprosthetic valve replacement options was not possible. The authors recognize that the increased recent usage has decreased the study's median time points, however the large population with data extending beyond five and ten years provide insight into the true durability of the conduit.

*Survival*

Overall survival in this series was excellent and comparable to other published reports.[2,9-11] However, there is considerable variability in patient cohorts, number of patients studied, and length of follow-up across studies. In a similar study to our own, Dunne et al. retrospectively reviewed all porcine aortic root PVRs in 114 patients with congenital heart disease at a single institution with a median age of 21 years, and reported a survival rate of 91% at 10 years and overall.[7] In a study comparing several different bioprosthetic valves in the pulmonary position (n=181), including the porcine aortic root (n=23), Lee et al reported an overall survival of 93.7% at 10 years.[12] Our study supports the literature which demonstrates that the porcine aortic root is a safe option for surgical PVR with excellent rates of survival approaching long-term periods of follow-up.

*Reintervention*

Perhaps the most remarkable finding of the present study is the low rate of re-intervention. At 1, 5, and 10 years, the freedom from re-intervention was 99.1%, 94.7% and 90.7%, respectively. Other studies report similar rates of freedom from re-intervention at 5 years: 95.5% (Hawkins et al), 93.2% (Kuo et al), and 85% (Dunne et al).[2,4,7] However, the results of our study dramatically diverge from the literature at 10 years with rates of freedom from re-intervention dropping to 71% (Dunne et al), 48.4% (Kuo et al), and 31.2% (Lee et al).[4,7,12] One possible explanation for this difference is patient age at the time of operation. While the median age of the above studies ranged from 12.2 to 21 years, the median age of our patients was 32.4 years, with the youngest patient being 18 years of age. Our study did not include metrics of body size, and correlating conduit and patient size may be of future interest.

*Structural Valve Degeneration*

We observed progressive, linear changes in conduit stenosis and regurgitation throughout the study period without an obvious plateau. However, the rate of re-intervention did not seem to correlate yet with these patterns. Similar to our results, other studies have demonstrated low early rates of structural valve degeneration which tend to increase over time.[7, 10, 11, 15] Dunne et al reported that at 18 months follow-up only 3.5% of patients had signs of moderate pulmonary stenosis and/or regurgitation.[7] By 5 and 10 years, only 82% and 61% of patients were free from significant valve degeneration, respectively.[7,15] Of the patients with structural valve degeneration, half were attributed to pulmonary stenosis, 12.5% to pulmonary regurgitation, and 16.7% to both.[7,15] Other recent single institution reports have found that the porcine aortic root compares comparably favorably with pulmonary homografts in terms of conduit durability at up to 10 years of follow-up.[5,6] What remains to be seen is whether the trajectory of conduit dysfunction changes over time and whether patients will face an increasing likelihood of conduit re-intervention. The early cardiac MRI data for more recent patients in this study indicate favorable conduit performance with positive RV remodeling, although more longitudinal follow-up for more patients is necessary. Regardless, with an adequately sized porcine aortic root (e.g., >23 mm), transcatheter pulmonary valve replacement should remain a viable option for these patients especially since the porcine aortic root is resistant to late dilatation.

*Endocarditis*

Other studies also report very low rates of stentless porcine aortic root endocarditis, with incidences ranging from 0% to 5.4%.[7,11-14] Multiple series report using the stentless porcine aortic root in aortic valve or aortic root endocarditis, but to our knowledge, this series represents the first reporting for of the use of this conduit in active RVOT endocarditis. Our study rates of endocarditis in the present study are comparable to contemporary RVOTR studies, but when considering the usage in active endocarditis without subsequent reinfection, these results are very favorable. It is unclear why the porcine aortic root is associated with a comparatively low rate of endocarditis, but we hypothesize that orthotopic positioning of the conduit facilitates more laminar flow than stented bioprostheses.

*Study Limitations*

Our study is inherently limited by its design as a retrospective, single-institution study. Nearly all operations were performed, at least in part, by a single surgeon which may limit the generalizability of this study to other institutions. Patient management spanned over a 19-year period, and era effects may not have been fully characterized. Certain aspects of the surgical procedures (e.g., cardiopulmonary bypass variables) and follow-up data (e.g., cardiac MRI) were not consistently available across the study period. There was no direct comparison with other bioprosthetic valves.

*Conclusion*

Pulmonary valve replacement using the porcine aortic root in adults can be performed safely and effectively with excellent mid-to-long term durability, low rates of endocarditis, and high freedom from re-intervention. Should re-intervention be required, the porcine aortic root can usually accommodate percutaneous valve replacement. Future multi-institutional studies may be necessary to effectively compare various prosthetic PVR options and longitudinal follow-up will be important for understanding the natural history of the porcine aortic root in the pulmonary position.

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**Table 1.** Patient Demographics (N=135).

| Demographic | N (%) |
|---|---|
| Age at implant, years | |
| Median | 32.4 |
| Range | 18-71 |
| Sex | |
| Male | 70 (51.8%) |
| Female | 65 (48.2%) |
| Follow-up (years) | |
| Median, IQR | 2.97 (0.6-8.0) |
| Range | 0-14.5 |
| Primary Diagnosis | |
| Tetralogy of Fallot | 66 (48.9%) |
| Pulmonary atresia | 25 (18.5%) |
| Pulmonary stenosis | 11 (8.1%) |
| Aortic stenosis status post Ross procedure | 10 (7.4%) |
| Double-outlet right ventricle | 6 (4.4%) |
| Carcinoid syndrome | 6 (4.4%) |
| Truncus Arteriosus | 5 (3.7%) |
| Transposition of the great arteries | 4 (3.0%) |
| Absent pulmonary valve | 2 (1.5%) |
| Prior Sternotomy | 129 (95.6%) |
| Prior RVOT Interventions | 127 (94.0%) |
| RVPA Conduit | 53 (39.2%) |
| Non-valved conduit | 16 (11.8%) |
| Monocusp repair | 11 (8.1%) |
| Homograft | 10 (7.4%) |
| Other PVR | 10 (7.4%) |
| Bovine jugular venous conduit | 6 (4.4%) |
| Other Tetralogy repair | 38 (26.6%) |
| Transannular patch | 32 (23.7%) |
| Surgical valvotomy | 12 (8.8%) |
| Rastelli procedure | 8 (5.9%) |

IQR, interquartile range; RVOT, right ventricular outflow tract.

**Table 2.** Pulmonary valve replacement indications.

| **Operative Indications** | **N (%)** |
|---|---|
| Pulmonary/conduit insufficiency | 122 (90.4) |
| Pulmonary/conduit stenosis | 47 (34.8) |
| RV dilatation/dysfunction | 32 (23.7) |
| Endocarditis | 10 (7.4) |
| Carcinoid syndrome | 6 (4.4) |
| Additional Diagnoses | |
| ASD/PFO | 10 (7.4) |
| Atrial arrhythmia | 19 (14.1) |
| Moderate or severe tricuspid insufficiency | 14 (10.4) |
| Ventricular septal defect | 5 (3.7) |

ASD, atrial septal defect; PFO, patent foramen ovale.

**Table 3.** Concomitant Procedures

| | |
|---|---|
| None | 51 (37.7) |
| At least one | 84 (63.3) |
| 1 | 46 (34.0) |
| 2 | 21 (15.5) |
| 3 or more | 17 (11.1) |
| Pacemaker-related | 21 (15.6) |
| RVOT revision | 25 (18.5) |
| RVMB division | 11 (8.1) |
| Infundibular patch revision | 7 (5.2) |
| Right ventriculoplasty | 6 (4.4) |
| Aneurysm plication | 3 (2.2) |
| Infundibulopasty | 2 (1.5) |
| MAZE procedure | 17 (12.6) |
| ASD/PFO closure | 15 (11.1) |
| Tricuspid repair/replacement | 13 (9.6) |
| Pulmonary artery patch angioplasty | 12 (8.9) |
| Aortic valve/root procedures | 11 (8.1) |
| Right atrioplasty | 7 (5.2) |
| VSD closure | 5 (3.7) |
| Pulmonary artery stent removal | 5 (3.7) |
| Coronary artery bypass | 3 (2.2) |
| Ascending aorta replacement | 3 (2.2) |
| Warden procedure | 1 (0.7) |
| SVC reconstruction | 1 (0.7) |
| Median Length-of-stay (days) | 7.3 (0-31) |
| LOS, PVR only | 5 (IQR 4-6) |
| LOS, concomitant procedures | 7 (IQR 5-10) |

ASD, atrial septal defect; IQR, interquartile; LOS, length-of-stay; PFO, patent foramen ovale; RVMB, right ventricular muscle bundle; SVC, superior vena cava; VSD, ventricular septal defect.

**Table 4.** Survival and complications.

| | |
|---|---|
| Survivors, n (%) | 126 (93.3) |
| Carcinoid survival | 4 (66.7) |
| Total Deaths | 9 (6.7) |
| Early (<30 days) | 3 (2.2) |
| <1 year carcinoid death | 2 (1.5) |
| Intermediate (30 days-5 years) | 3(2.2) |
| Late (>5 years) | 3 (2.2) |
| Total Early Complications | 46 (34.1) |
| Rhythm disturbance | 11 (8.1) |
| Pulmonary (prolonged ventilation, effusion, pneumothorax) | 7 (5.2) |
| Mediastinal | |
| Early (<30 days, hemorrhage, tamponade) | 6 (4.4) |
| Delayed (>30 days, effusion, mediastinal infection) | 6 (4.4) |
| Others (vocal cord paralysis, pancreatitis, right heart failure, decubitus ulcer, opiate intoxication) | 6 (4.4) |
| Multisystem organ failure | 5 (3.7) |
| Renal Failure | 5 (3.7) |

IQR, interquartile range; PVR, pulmonary valve replacement.

**Table 5.** Pulmonary valve re-interventions.

| **Re-intervention** | **N (%)** | **Median Interval (years)** |
|---|---|---|
| Total re-interventions | 8 (5.9) | 5.0 (IQR 3.4-7.5) |
| Balloon valvuloplasty | 3 (2.2) | 1.9 (IQR1.4-2.9) |
| Percutaneous replacement | 3 (2.2) | 6.4 (IQR 5.7-7.9) |
| Surgical replacement | 2 (1.5) | 8.5 (IQR 6.8-10.3) |

IQR, interquartile range

**Table 6.** Echocardiographic follow-up.

| **Period** | **Perioperative** | **Early** | **Middle** | **Late** |
|---|---|---|---|---|
| Number of studies | 104 | 77 | 58 | 44 |
| Median time (IQR) | 13 days (3-39) | 1.1 years (0.8-1.5) | 3.6 years (3.0-4.9) | 9.1 years (7.4-10.5) |
| Median peak gradient (mmHg) | 16.0 (IQR 12.0-22.7) | 20.0 (IQR 16.0-29.8) | 22.5 (IQR 18.0-32.0) | 27.0 (IQR 17.0-35.5) |
| Median mean gradient (mmHg) | 7.5 (IQR 6.0-11.0) | 14.5 (IQR 9.7-20.0) | 10.9 (IQR 8.8-15.8) | 12.3 (IQR 7.8-21.4) |
| Moderate PS (>36mmHg peak) | 2 (2.4%) | 8 (11.8%) | 8 (17.8%) | 8 (22.2%) |
| Moderate PI | 1 (1.8%) | 0 (0%) | 1 (2.1%) | 2 (7.7%) |
| Re-interventions (%) | 0 | 2 (2.5) | 3 (5.1) | 2 (4.5) |

IQR, interquartile range; PI, pulmonary insufficiency; PS, pulmonary stenosis.

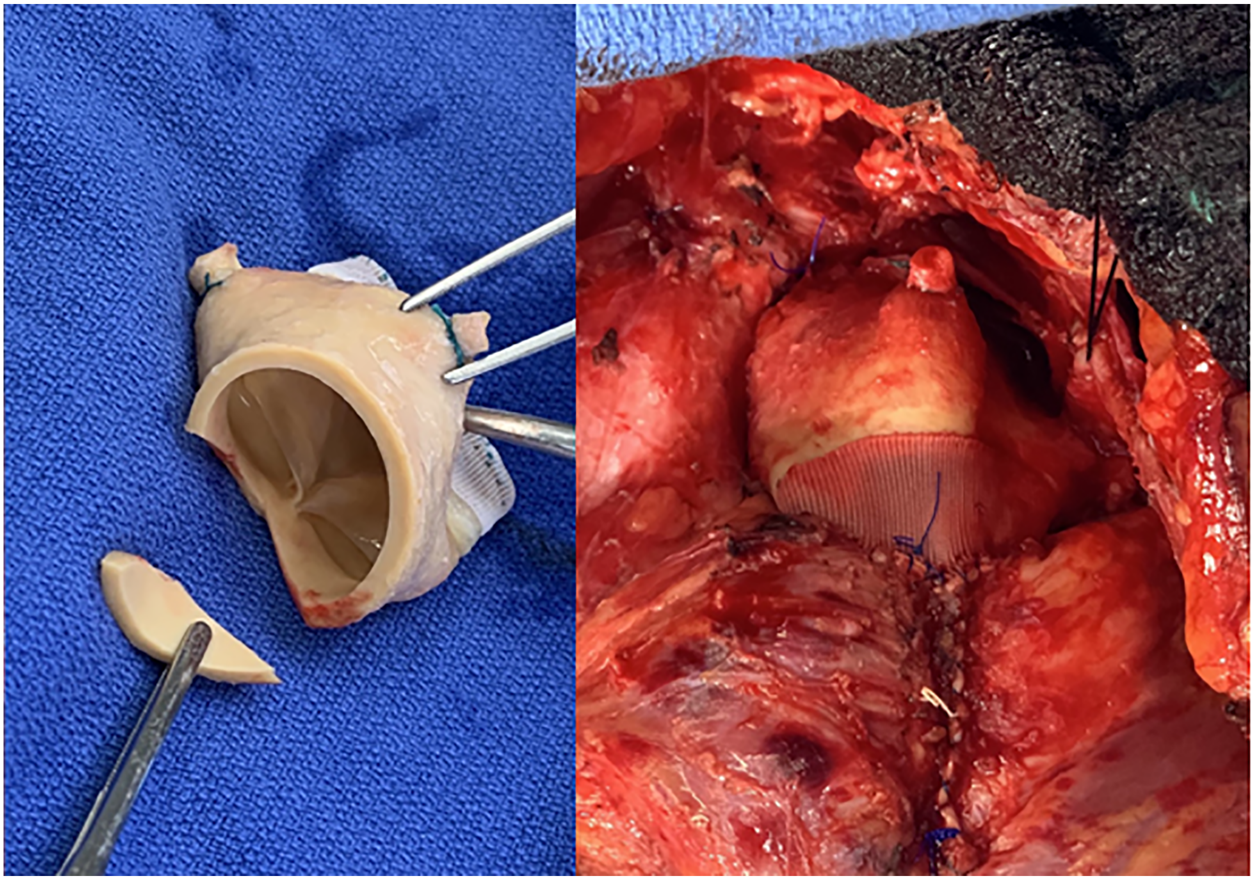
**Figure Legends**

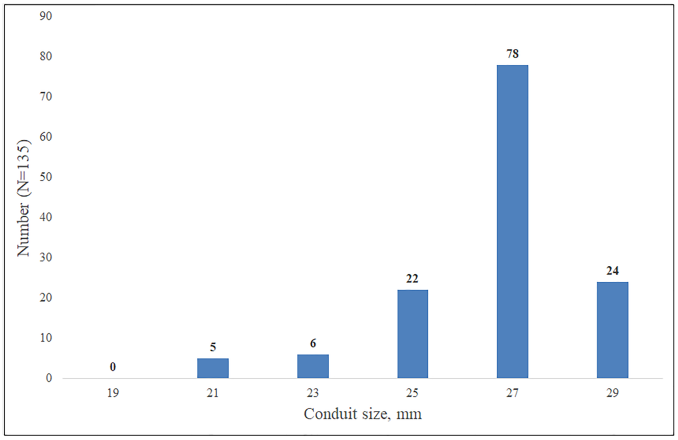
**Figure 1.** (Left) The porcine aortic root with small wedge excision above the posterior commissure. (Right) Orthotopic positioning of the porcine aortic root aligns the coronary stumps anteriorly and leftward. An infundibuloplasty was performed inferior to the conduit.

**Figure 2.** Porcine aortic root available sizes and usage within the study population. N=135

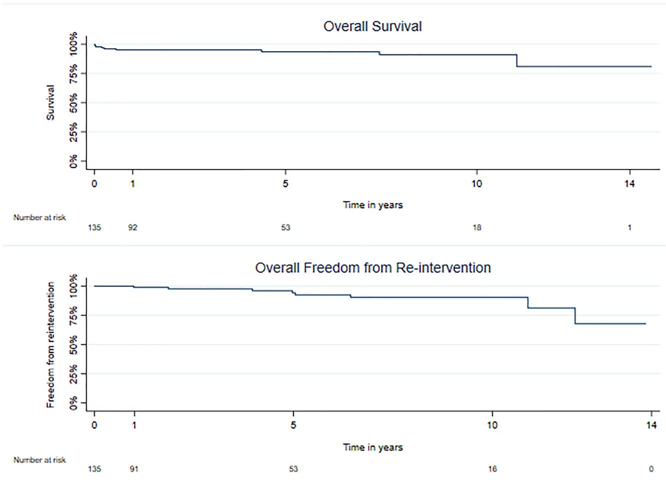
**Figure 3.** (Top) Overall survival for all adult patients with the porcine aortic root in pulmonary position. Survival at 1, 5, 10, and 14.5 years was 94.5%, 93.2%, 90.8% and 79.5%. (Bottom) Overall freedom from re-intervention (balloon valvuloplasty, transcatheter or open surgical replacement) for all adult patients with the porcine aortic root in pulmonary position**.** Freedom from re-intervention at 1, 5, and 10 years was 99.1%, 94.7%, and 90.7%.

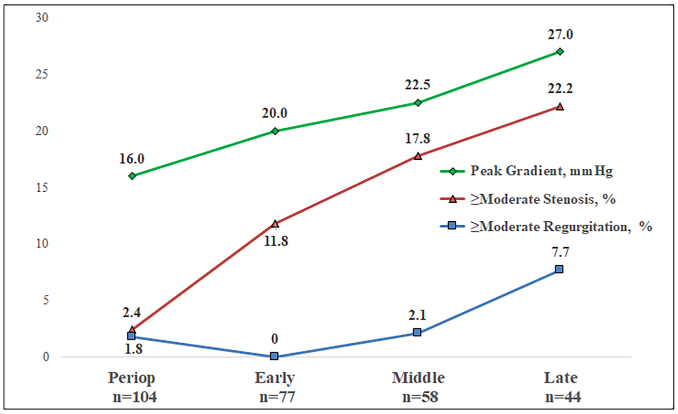
**Figure 4.** Echocardiographic data perioperatively and at Early, Middle and Late intervals. Peak conduit gradients of >36mm Hg represent moderate stenosis.





90
80
70
60
50
40
30
20
10
0
Number (N=135)
0
5
6
22
78
24
19
21
23
25
27
29
Conduit size, mm


Overall Survival
Survival
0%
25%
50%
75%
100%
0
1
5
10
14
Time in years
Number at risk
135
92
53
18
1
Overall Freedom from Re-intervention
Freedom from reintervention
0%
25%
50%
75%
100%
0
1
5
10
14
Time in years
Number at risk
135
91
53
16
0



30
25
20
15
10
5
0
27.0
22.5
20.0
16.0
22.2
17.8
11.8
2.4
1.8
0
2.1
7.7
Peak Gradient, mmHg
≥Moderate Stenosis, %
≥Moderate Regurgitation, %
Periop
n=104
Early
n=77
Middle
n=58
Late
n=44