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Aortic root replacement to treat type A aortic dissection: A comparison of midterm outcomes between composite valve grafts and porcine aortic roots

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Abstract

Background: Porcine aortic roots (PAR) have been reported in the literature with acceptable short- and long-term outcomes for the treatment of aortic root aneurysms. However, their efficacy in type A aortic dissection (TAAD) is yet to be defined.

Methods: Using data from a locally collated aortic dissection registry, we compared the outcomes in patients undergoing aortic root replacement for TAAD using either of two surgical options: (a) PAR or (b) composite valve grafts (CVG). A retrospective analysis was conducted for all procedures in the period from 2005 to 2018.

Results: A total of 252 patients underwent procedures for TAAD in the time period. Sixty-five patients had aortic root replacements (PAR n = 30, CVG n = 35). Between-group comparisons identified a younger CVG group (50.5 vs 64.5, $P < .05$) although all other covariates were comparable. Operative parameters were comparable between the two groups. The use of PAR did not significantly impact operative mortality (odds ratio [OR], 0.93; 95% confidence interval [CI], 0.22-3.61; $P = .992$), stroke (OR, 2.91, 0.25-34.09, $P = .395$), reoperation (OR, 0.91; 95% CI, 0.22-3.62; $P = .882$) or length of stay (coeff 2.33, −8.23 to 12.90; $P = .659$) compared to CVG. Five-year survival was similar between both groups (PAR 59% vs CVG 69%; $P = .153$) and reoperation was negligible. Echocardiography revealed significantly lower aortic valve gradients in the PAR group (8.69 vs 15.45mm Hg; $P < .0001$), and smaller left ventricular dimensions both at 6-week and 1-year follow-up ($P < .05$).

Conclusions: This study highlights the comparable short- and midterm outcomes of PAR in cases of TAAD, in comparison to established therapy.

KEYWORDS
aorta, great vessels

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1 | INTRODUCTION

The primary aim of surgery for acute type A aortic dissection (TAAD) is the prevention of death from aortic rupture, which is mainly accomplished by excision of the proximal intimal tear, supracoronary ascending aorta replacement, and re-establishment of dominant flow in the distal true lumen.[1-3] Ensuring a competent aortic valve is an equally vital goal of surgery, although the methods of how to address this is a matter of debate.

The decision to replace the aortic root depends on the proximal extent of the dissection flap, degree of aortic regurgitation, and the surgeon's choice. The operative strategies can be broadly divided between a conservative root repair and a complete root replacement with reimplantation of coronaries. Aortic root replacement (ARR) has most commonly involved mechanical composite valve grafts (CVG),[4] which have excellent durability but necessitate lifelong anticoagulation.

The rationale for stentless aortic valve replacement was born out of the pioneering use of homografts and pulmonary autografts over the last few decades. Acceptable valve durability and improved valve hemodynamics compared to stentless valves were important characteristics that stimulated continued uptake of stentless technology.[5,6] Stentless porcine aortic roots (PAR) also have an established role in clinical practice, although their use in TAAD is less well characterized in the literature.

This study aims to compare the outcomes between PAR and CVG in patients undergoing ARR for acute TAAD.

2 | MATERIALS AND METHODS

Perioperative data were retrospectively analyzed from a prospectively collated database at a single cardiothoracic institution between 2005 and 2018. Due to the retrospective nature of the study, the requirement for ethical approval was waivered by the Research Ethics Office at the Royal Brompton and Harefield Foundation Trust.

2.1 | Study population

In this period, a total of 252 patients underwent repair for acute TAAD. The institution operates a regional referral system from associated nearby emergency departments for cases with TAAD. The on-call cardiothoracic consultant alternates on a rota basis. The standard care is immediate transfer upon discussion with the referring physician and review of relevant imaging, followed by planning for emergent surgery.

Only patients undergoing ARR were included. Patients were subclassified as having (a) porcine ARR (PAR); or (b) CVG root replacement. The prosthesis used in the former group was the Freestyle porcine aortic root (Medtronic, Minneapolis, MN).

The primary indication for ARR was the presence of an intimal tear in the aortic root. Other indications were aortic root diameter more than 4.5 cm, known connective tissue disease, aortic valve pathology, and coronary dissection. Patients undergoing a valve-sparing root replacement or interposition graft (with or with aortic valve replacement) were excluded.

2.2 | Operative technique

All patients underwent median sternotomy for access. Cannulation strategies varied: venous cannulation of the right atrium was usually attempted. Arterial cannulation usually involved the femoral or right axillary artery cannulation. Myocardial protection was achieved with cold-blood cardioplegia solution, infused retrogradely via the coronary sinus or antegrade directly through the coronary ostia. A left ventricular vent was commonly inserted via the right superior pulmonary vein. A hypothermic circulatory arrest was used in most cases, and the arch was inspected for tears.

The goal of surgery was to resect the intimal tear, replace the ascending aorta with a prosthetic graft, and restore the anatomy of the aortic root. This study included patients in whom the aortic root or valve was deemed to be diseased beyond repair, necessitating a nonvalve sparing procedure. The majority of patients requiring ARR with biological substitutes received a Freestyle graft. Patients receiving a bioprosthetic CVG, although few, were not excluded.

Following excision of the native aortic root and sizing of the annulus, the graft (either PAR or CVG) was sewn into the aortic annulus with interrupted sutures. The method for reimplantation of the left coronary button on the Freestyle prosthesis was left to the discretion of the surgeon, either to the left or right coronary stump of the graft (the remaining stump is usually oversewn). For the right coronary button, a new ostium was fashioned on a suitable region of the graft for anastomosis.

Where appropriate, hemiarch or arch replacement with reimplantation of one- to three-branch vessels was performed based on the arch pathology. Antegrade or retrograde cerebral perfusion was used for cerebral protection during hypothermic circulatory arrest.

2.3 | Data collection

The cardiac surgical database is locally managed and centrally overseen at a national level, following national guidelines for minimal perioperative data collection, including preoperative covariates, detailed operative characteristics, and short-term postoperative outcomes. Early and midterm outcomes were assessed based on echocardiographic findings and grading of aortic regurgitation.

2.4 | Statistical analysis

Results were analyzed and presented as means and standard deviations. Preoperative covariates were assessed for normal distribution using the Shapiro-Wilk test. Between group, characteristics were assessed for statistical differences using the Student *t* test or Wilcoxon rank test for nonparametric variables. Multivariate logistic regression models were constructed to assess the influence of a variety of covariates on

short-term outcomes. Linear regression was used to assess the influence of covariates on parametric outcomes, namely hospital stay. Adjusted odds ratio (OR) with 95% confidence interval (CI) of binary outcomes were calculated. Crude survival curves were estimated using the non-parametric Kaplan-Meier method, and logrank tests were used to compare the survival distribution among groups. Cox proportional hazard regression was conducted to calculate the adjusted hazards ratio with 95% CI. Stepwise selection was performed using age, sex, chronic obstructive pulmonary disease (COPD), Euroscore, New York Heart Association class, and left ventricular (LV) function in the model. Statistical analyses were conducted using the Stata 13.0 software (Stata Corp, College Station, TX).

3 | RESULTS

During the study period, out of 252 patients, 65 patients underwent ARR, out of which 35 patients underwent root replacement with a CVG and 30 patients underwent root replacement with the Freestyle porcine root (PAR).

Preoperative characteristics are presented in Table 1. There was a significant difference in mean age between the two operative groups (CVG vs PAR: 50.5 vs 64.5 years). All other preoperative covariates (gender, diabetes, hypertension, COPD, renal failure, and Euroscore) were not significantly different. Many of the patients had hemodynamic instability preoperatively, although this was not significantly different between the CVG (82.9%) and PAR (83.3%) cohorts ($P = .889$). The degree of visceral malperfusion was also similar between the cohorts, as evidenced by preoperative lactate levels (median, interquartile range): CVG 1.4 (1.0-2.6); PAR 1.5 (1.1-3.3).

TABLE 1 Preoperative patient characteristics

Covariates	Composite valve graft (n = 35)	Porcine aortic root (n = 30)	P
Age	50.5 ± 15.8	64.5 ± 12.6	.003
Female Male	8 (22.8%) 27 (77.1%)	15 (50%) 15 (50%)	.290
Connective tissue disease	6 (2.9%)	2 (6.7%)	
Hypercholesterolemia	10 (28.5%)	12 (40%)	.407
Diabetes	4 (11.4%)	4 (13.3%)	.968
Hypertension	24 (68.6%)	21 (70%)	.982
Congestive cardiac failure	5 (14.3%)	5 (16.7%)	.889
Myocardial infarction	5 (14.3%)	4 (13.3%)	.996
Acute kidney injury	2 (5.7%)	1 (3.3%)	
Chronic kidney disease	0 (0%)	0 (0%)	.990
Dialysis	1 (2.9%)	0 (0%)	
Chronic obstructive pulmonary disease	4 (11.4%)	2 (6.7%)	.948
Arrhythmia	2 (5.7%)	2 (6.7%)	.986
Previous cardiac surgery	2 (5.7%)	4 (13.3%)	.873
Smoking	18 (51.4%)	13 (43.3%)	.981
Haemodynamic instability	29 (82.9%)	25 (83.3%)	.889
Preoperative serum lactate, mmol/L[a]	1.4 (1.0-2.6)	1.5 (1.1-3.3)	.362

[a]Values are given as median (interquartile range).

3.1 | Operative characteristics

Operative characteristics are presented in Table 2. Cardiopulmonary bypass time was similar between the two groups (CVG vs PAR, 228 ± 19 vs 211 ± 34 minutes; $P = .678$), as was aortic cross-clamp time (197 ± 16 vs 210 ± 19; $P = .291$) and circulatory arrest time (19 ± 4 vs 22 ± 5; $P = .328$).

Similarly, cannulation strategy was also comparable, with n = 12 vs 9 (CVG vs PAR) receiving femoral cannulation, and n = 8 vs 10 (CVG vs PAR) receiving axillary cannulation.

Primary tears arising in the aortic sinus were identified in 28.6% of CVG patients (10/30) whilst this was found in 30% of PAR patients (9/30). The remaining patients had secondary tears of the root or had the root replaced due to the enlargement of the sinuses at the surgeon's discretion.

Of the 35 CVG patients, four received a biological valve graft conduit, with the remainder of patients in the cohort undergoing a mechanical Bentall. In the CVG group, seven patients, showing evidence of the tear extending into the coronary vessels, required concomitant coronary artery bypass grafting (in the PAR group, this occurred in five patients).

TABLE 2 Intraoperative characteristics

Intraoperative	Composite valve graft (n = 35)	Porcine aortic root (n = 30)	P
Cardiopulmonary bypass time, min	228 ± 19	211 ± 34	.678
Cross clamp time, min	197 ± 16	210 ± 19	.291
Circulatory arrest time, min	19 ± 4	22 ± 5	.328
Valve size implanted, mm	25.6 ± 2.0	26.2 ± 2.7	.390
Concomitant CABG (for evidence of coronary malperfusion)	7	5	.673
Redo sternotomy	2	5	.211
Femoral cannulation	12	9	.340
Axillary/left subclavian	8	10	.491
Hemiarch replacement	2	2	.810
Total arch replacement	3	1	.150
Primary tear in aortic sinus	10	9	.801

TABLE 3 Postoperative complications of patients in Bentall group vs porcine aortic root group

Short-term complication	Composite valve graft (n = 35)	Porcine aortic root (n = 30)
IABP	2 (5.7%)	0 (0%)
VAD	1 (2.9%)	0 (0%)
Permanent pacemaker	3 (8.6%)	1 (3.3%)
Reoperation	6 (17.1%)	4 (13.3%)
Reintubation	10 (28.6%)	3 (10%)
Sepsis	1 (2.9%)	2 (6.7%)
Wound infection	1 (2.9%)	1 (3.3%)
Pericardial effusion	1 (2.9%)	1 (3.3%)
Pleural effusion	5 (14.3%)	2 (6.7%)
New neurological deficit	2 (5.7%)	4 (13.3%)
Renal dialysis	8 (22.9%)	8 (26.7%)
Average length of stay	17.4 d	22.1 d
Death	6 (17.1%)	4 (13.3%)

Abbreviations: IABP, intra-aortic balloon pump; VAD, ventricular assist device.

Two patients in either group underwent a hemiarch replacement, whereas three patients required a total arch replacement in the CVG group, compared to none from the PAR group.

3.2 | Short-term outcomes

Postoperative characteristics are shown in Table 3. Operative deaths occurred in six of the CVG patients, compared to four of the PAR patients ($P > .05$). The most common cause of death was cardiac. Two (5.7%) patients in the CVG group and four (13.3%) patients in the PAR group had a new postoperative neurological deficit. There was no statistically significant difference between both groups.

3.3 | Multivariate regression analysis: short-term outcomes

Stepwise multivariate regression models were constructed to assess the effects of covariates on the main outcomes of interest, namely mortality, length of stay, reoperation, and a composite measure of complications (Table 4). Importantly, the use of PAR over CVG did not increase the risk of operative death, reoperation, composite complications, or length of hospital stay. The only covariate found to be a predictor of short-term complications was the Euroscore (OR, 0.91; 95% CI, 0.84-0.99; $P = .033$).

3.4 | Survival and reoperation

Results were available for up to 5-year follow-up for survival analysis (total follow-up time = 164 patient years). Mean follow-up time was 2.9 ± 3.9 years. Kaplan-Meier analysis (Figure 1) showed similar survival between the two surgical cohorts: PAR 59% survival (95% CI, 26-80%), CVG 69% survival (95% CI, 37-82%), logrank test $P = .158$.

The Cox proportional hazards model analysis found the Euroscore and preoperative hemodynamic instability function to be predictors of worse survival (HR, 1.03; 95% CI, 1.01-1.07; $P = .046$) and (HR, 3.74; 95% CI, 1.19-11.80; $P = .024$). After controlling for age, sex, history of renal failure, the influence of PAR on survival compared to CVG remained to be noninferior (HR, 1.05; 95% CI, 0.39-2.81; $P = .920$) (Table 5).

3.4.1 | Reintervention

Throughout the follow-up period, only one patient required reintervention on the aortic root at 3 years following the index procedure (mechanical CVG). This was due to recurrent mediastinitis resulting in a false aneurysm around the left coronary button and dehiscence of the proximal suture-line. The patient died shortly after the reintervention. No patient from the PAR required reintervention within the 5-year follow-up period.

TABLE 4 Multivariate model assessing the influence of relevant covariates on short-term outcomes

	Mortality			Length of stay			Post-op complications			Reoperation		
Covariate	OR	95% CI	P	Coeff	95% CI	P	OR	95% CI	P	OR	95% CI	P
Use of porcine aortic root	0.9	0.22-3.61	.992	2.33	−8.23 to 12.90	.659	0.57	0.20-1.66	.305	0.90	0.22-3.62	.882
Patient Age	1.01	0.94-1.09	.669	0.0081	−0.33 to 0.35	.962	0.97	0.93-1.00	.062	0.97	0.93-1.02	.204
Euroscore	1.05	0.98-1.14	.180	0.43	−0.061 to 0.923	.085	0.91	0.84-0.99	**.033**	0.97	0.91-1.03	.258
Pre-op NYHA class	0.52	0.19-1.44	.209	−3.11	−7.31 to 0.109	.143	1.12	0.72-1.71	.611	0.82	0.46-1.46	.505

Note: Statistical models used were as follows: for mortality and reoperation: binary logistic regression; for length of stay: Poisson regression; for composite complication: ordinal logistic regression. The bold values indicate statistical significance.
Abbreviations: CI, confidence interval; OR, odds ratio.

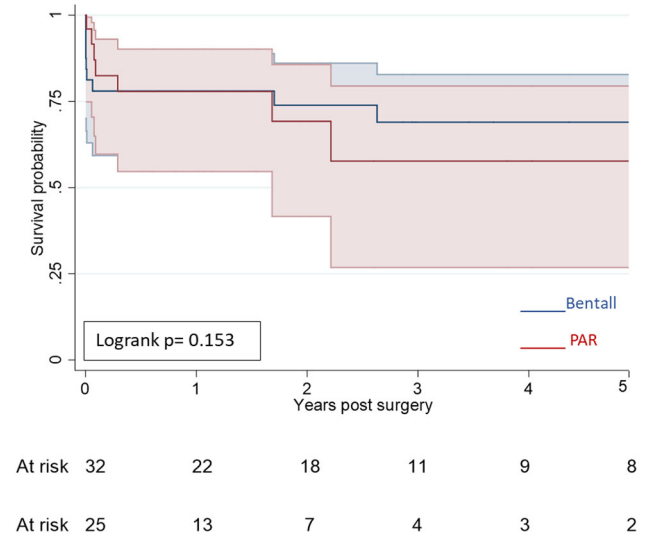


FIGURE 1 Kaplan-Meier survival analysis comparing composite valve graft with porcine aortic root replacement (PAR). PAR 5-year survival 59% (95% CI, 26-80%), Bentall 5-year survival 69% (95% CI, 37-82%). CI, confidence interval

3.5 | Echocardiographic follow-up

Follow-up echocardiography data were available for more than 85% of patients, with both 6-week and 1-year follow-up available, allowing for a comparative analysis between both time points (Figure 2 and Table 6).

3.5.1 | Aortic valve gradient

At 6 weeks postoperatively, the PAR group had a significantly lower transvalvular peak gradient (8.69 vs 15.45; $P < .0001$) compared to the CVG group, which persisted at 1 year (7.52 vs 13.70; $P = .001$).

TABLE 5 Cox proportional hazards, influence of covariates on mid-long-term survival

Covariate	Hazard ratio	Standard error	95% confidence interval	*P*
Porcine root	0.29	0.29	0.044-1.97	.208
Mechanical valve	0.52	0.46	0.092-2.96	.462
Age	1.02	0.022	0.98-1.07	.214
Euroscore	1.03	0.023	1.01-1.07	**.046**
NYHA score	1.03	0.20	0.70-1.50	.894
Hemodynamic instability	3.74	2.19	1.19-11.80	**.024**
COPD	2.12	1.13	0.74-6.03	.159

Note: The bold values indicate statistical significance.
Abbreviations: COPD, chronic obstructive pulmonary disease; NYHA, New York Heart Association.

None of the patients in either group were found to have more than mild aortic regurgitation.

3.5.2 | Left ventricle

Patients in the PAR group demonstrated echocardiographic signs of early positive left ventricular remodeling (Table 6). At 6 weeks, left ventricular end-diastolic diameter (LVEDD) was significantly lower in the PAR group (4.64 vs 5.01 cm; $P = .039$) compared to the CVG group. By 1 year, LVEDD was not different (4.65 vs 4.94 cm; $P = .144$) although the left ventricular end-systolic diameter (LVESD) was found to be significantly smaller in the PAR group (3.04 vs 3.53 cm; $P = .024$). The overall mean net change in LVESD between 6 weeks and 1 year was also more negative in the PAR group (−0.11 vs +0.13 cm; $P = .05$). Left ventricular function at 6 weeks and 1 year was not different between the treatment groups, nor was the net change in function.

4 | DISCUSSION

In our experience, root replacement in TAAD with stentless PAR is a feasible alternative to the CVG, especially in older patients. Our decision for root replacement in TAAD was based primarily on the requirement for biological substitutes, either due to the patient's age or known contraindication to anticoagulation, as a suitable alternative to a bio-Bentall. The need for clarity on patient and procedure selection is crucial in TAAD, especially given the excellent outcomes reported by several institutions using widely varying techniques.[7]

Acute TAAD has a mortality of 50% within the first 48 hours if not operated on.[8] The choice of root replacement vs conservation varies from center to center, although certain cases render the need for root replacement in TAAD quite necessary, especially if the dissection extends to at least one sinus of Valsalva. Avoiding root replacement in such cases is associated with late dilation of the aortic sinuses and recurrence of aortic regurgitation, making the risk of reoperation unacceptably high.[9]

Root replacement using CVG has been considered the gold standard for all acute TAAD when the aortic root is dilated greater than 4.5 cm, contains an intimal tear, or if there is known connective tissue disease.[10,11] A mechanical CVG is usually offered to younger patients due to proven valve durability.[12] However, the need for surgical alternatives is important, especially in cases where anticoagulation may be contraindicated. Furthermore, the impact of anticoagulation on the prognosis of the distal aorta is important to consider and may in fact increase the incidence of false lumen patency.[13] This claim has however been refuted by other studies, finding that anticoagulation did not lead to an increased incidence of distal aortic events or impact false lumen thrombosis.[14,15] The present study has demonstrated that the performance of ARRs using porcine stentless aortic roots (PAR) have comparable short and midterm outcomes to CVG and can be safely used for the management of TAAD.

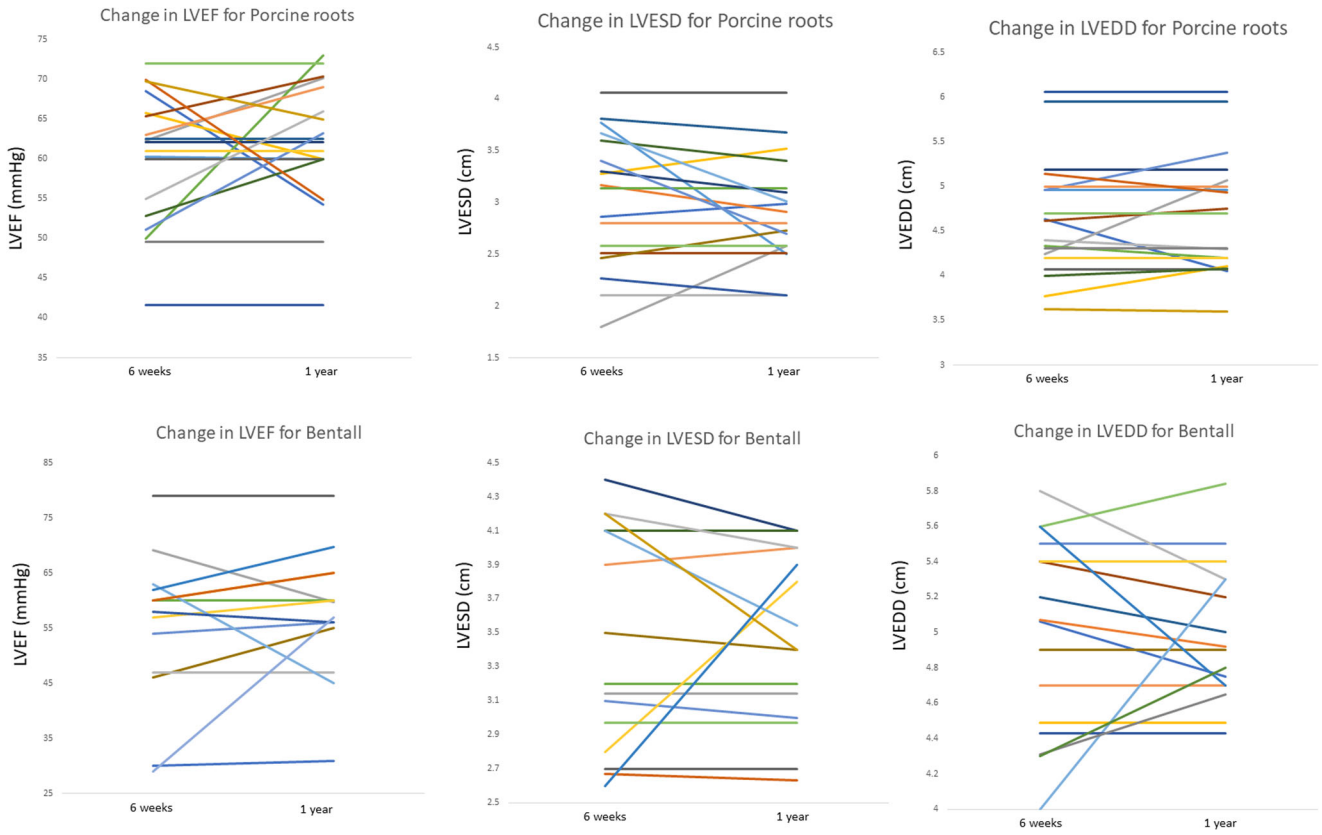


FIGURE 2 Plots displaying changes in echocardiographic data for patients between 6-week and 1-year follow-up following Porcine aortic root replacement (A-C) and composite valve graft (D-F) for type A aortic dissection. LVEDD, left ventricular end-diastolic diameter; LVESD, left ventricular end-systolic diameter; LVEF, left ventricular ejection fraction

The Freestyle bioprosthesis (Medtronic, Minneapolis, MN) is a complete porcine aortic root with ligated coronary arteries and a thin skirt over the porcine septal muscle bar. Their design have very comparable advantages to stented bioprosthetic valves, including suitable durability in the elderly population whilst making anticoagulation redundant.[16] Furthermore, stentless valve technology has long been shown to offer superior hemodynamic performance when compared to stented counterparts.[5,17] Flow patterns are remarkably similar to normal native aortic valves.[18] Echocardiographic studies have demonstrated lower mean aortic valve gradient

TABLE 6 Echocardiographic outcomes following aortic root replacement for type A aortic dissection at 6 wk and 1 y, and average change between the earlier and later follow-up time

	Aortic valve PG, mm Hg	LVEF (%)	LVESD, cm	LVEDD, cm
6 wk				
Porcine root	8.69 ± 2.89	60.15 ± 8.18	3.18 ± 0.89	4.64 ± 0.66
Composite valve graft	15.45 ± 5.51	55.30 ± 13.66	3.11 ± 1.13	5.01 ± 0.55
P	**<.0001**	.894	.578	**.039**
1 y				
Porcine root	7.52 ± 3.63	62.39 ± 7.76	3.04 ± 0.79	4.65 ± 0.64
Composite valve graft	13.70 ± 6.78	56.43 ± 10.98	3.53 ± 0.80	4.94 ± 1.07
P	**.001**	.673	**.024**	.144
Change				
Porcine root	−0.98 ± 5.59	+1.68 ± 8.83	−0.11 ± 0.42	+0.04 ± 0.28
Composite valve graft	+0.87 ± 4.33	+1.90 ± 9.48	+0.13 ± 0.67	+0.01 ± 0.42
P	.163	.472	**.050**	.614

Note: The bold values indicate statistical significance.
Abbreviations: LVEDD, left ventricular end-diastolic diameter; LVEF, left ventricular ejection fraction; LVESD, left ventricular end-systolic diameter; PG, peak gradient.

and improved left ventricular mass regression at 6 months postoperatively.[19] This is supported by our data (Table 4) which demonstrates that the improved valve hemodynamic profile and consequent positive LV remodeling is achievable in emergency TAAD cases, with results potentially evident by 6-week follow-up.

In the literature, evidence for the use of PAR in patients with TAAD has been sporadic. Smith et al[20] demonstrated the use of the Medtronic Freestyle bioprosthesis in TAAD with satisfactory early and midterm outcomes in 24 patients, although this was not compared with a valid control. Similarly, larger centers have reported the use of porcine stentless aortic roots as the biological conduit of choice in TAAD with good results.[21,22] Despite this, there is limited evidence comparing the use of porcine stentless aortic bioprosthesis with alternative root surgery in TAAD.

The use of PAR in nonenlarged aortic roots also has demonstrable benefit, particularly to mitigate patient-prosthesis mismatch in patients undergoing aortic valve replacement with a small annulus.[23] Similarly, the need to replace a nonenlarged root in TAAD is not infrequent, as tears may extend into a nondilated sinus, highlighting a potential advantage of PAR. Despite these advantages, the use of PAR remains limited compared to the uptake of biological CVG. The choice for PAR, a more technically demanding procedure compared to CVG, relies significantly on an intact aortic annulus, the assessment for which occurs intraoperatively. Although the overarching practice in our institution is to choose PAR for patients requiring biological substitutes, the final decision intraoperatively hinges on surgeon preference, which introduces subjectivity in the present analysis: patients with more unfavorable anatomy may be selected to undergo root replacement with CVG. The risk of bias should, therefore, raise caution when interpreting the results.

4.1 | Strengths and limitations

The present study is the first to assimilate clinical data in TAAD directly comparing the use of PAR to best practice. Our analysis included survival, as well as echocardiographic data at separate time points. However, the retrospective design and small sample size (n = 30 in PAR group; n = 35 in CVG group) renders this analysis relatively underpowered. As our follow-up time was limited to 5 years, valve durability, especially of PAR could not be adequately analyzed, which may have important relevance beyond 10 years, including the incidence of structural valve degeneration and the need for reintervention. Future studies would benefit from long-term echocardiographic and outcome analysis as well as the effect of either treatment on the prognosis of the distal aorta and the need for intervention on the descending portion.

5 | CONCLUSION

Our data illustrate that the use of PAR, such as the Freestyle, can be used to replace the diseased aortic root at the time of repair of TAAD with acceptable intra- and postoperative mortality and morbidity. Midterm survival is satisfactory echocardiographic outcomes that are more favorable than CVG in the early phase. Especially in the elderly population, PAR can be considered as a first-line option when indicated. More studies are required to confirm the durability, freedom from structural valve degeneration, and long-term clinical outcomes of this group of patients.

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