Analysis of incidence and reasons for re-intervention after aortic valve replacement using the Trifecta aortic bioprosthesis

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Abstract:

Introduction:

Trifecta bioprosthesis claims favourable haemodynamic performance. However, reports of structural valve deterioration (SVD) raise concerns of its long-term durability. We assessed outcomes with the Trifecta valve over a 10-year period.

Methods:

All patients receiving Trifecta bioprostheses between October 2011 and October 2020 were included. Perioperative and survival characteristics were prospectively collated in an independent database. Re-intervention was recorded as a surrogate for SVD.

Results:

944 patients (mean age 72.82 years ± 8.13, 58% male) underwent aortic valve replacement with the Trifecta valve. At 10-years, 1.4% of patients required a redo operation, giving an overall freedom from re-intervention of 98.6%. The mean time to re-intervention was 48.87 months. Survival was 73.58% and 76.92% in patients who did not require re-intervention vs re-intervention group, respectively.

Conclusions:

In a large, single-centre cohort, the Trifecta aortic bioprosthesis had a 1.4% all-cause re-intervention rate at 10-years, with insignificant impact on survival.

Keywords:

Trifecta; Bioprosthesis; Aortic Valve Replacement; Re-Intervention; Structural Valve Deterioration.

1. Introduction:

The Trifecta aortic bioprosthesis (Abbott, St Paul, MN, USA) is heart valve made from bovine pericardial sheet mounted outside the stent frame, designed for supra-annular placement[1]. A titanium stent aims to reduce stress on the leaflets, tissue-to-tissue contact created by bovine pericardial covering reduces the risk of abrasion and structural valve deterioration (SVD), reinforced by ethanol-based anti-calcification technology, and glide technology (GT) in the second-generation valves provide handling protection[2].

This expansive design has shown to improve the opening area and haemodynamic performance at rest[3,4], during effort[5] and at a 3-year follow-up[6], making this bioprosthesis an attractive option for aortic valve replacement (AVR), especially for patients with a small aortic annulus and/or impaired left ventricular function. The Trifecta Durability Study, a global

multicentre prospective clinical study over a median 0.9 year of follow-up for 1014 patients, reported a freedom from valve explant of 99.4% at 2 years, and only 1 explant due to SVD, suggesting good durability of this device in the initial follow-up. However, designs risks and technical issues at implantation of the first-generation Trifecta valve have been reported, resulting in SVD requiring re-intervention[7]. These include deformation of the titanium stent due to poor sizing or handling at implantation, which may lead to leaflet malcoaptation in a narrow sinotubular junction anatomy and valvular incompetence[8]; oversizing, which may contribute to coronary ostial obstruction [9]; and the outer position of the rectangular pericardial sheet, which has been associated with an increased risk of coronary obstruction during valve-in-valve (ViV) transcatheter aortic valve implantation (TAVI)[10]. Recently, the Medicines and Healthcare Products Regulatory Agency reported 65 UK adverse incidents relating to the first generation Trifecta, and 5 relating to the Trifecta GT valve since 2010[11].

The aim of this study was to evaluate the perioperative patient and operative characteristics, and re-intervention rates and survival of patients undergoing surgical implantation of the Trifecta and Trifecta GT aortic bioprostheses in our centre over a 10-year period.

2. Methods

2.1 Study Design and Data Collection:

All patients who underwent surgical implantation of the Trifecta aortic bioprosthesis from October 2011 to October 2020 were consecutively included in this cross-sectional observational study. The surgical database was used to prospectively record pre- and post-operative patient data. Patient characteristics including, sex, logarithmic EuroSCORE II, underlying valve pathology and left ventricular ejection fraction (LVEF), in addition to operative characteristics including valve size, surgical priority, surgical incision, bypass time and cross-clamp time were recorded and independently verified by the hospital's audit team. The need for redo operation for non-infective reasons after Trifecta valve implantation was used as a surrogate for SVD as the primary outcome, as recently defined[12]. For the secondary outcome, survival and time to

redo operation were analysed. Perioperative patient characteristics were recorded for all patients at initial procedure and for those patients who underwent a redo operation for Trifecta valve implantation. Patients who required immediate (intraoperative or peri-operative) replacement of the prosthesis were excluded from the SVD analysis.

The study received approval from the Audit Department.

2.2 Statistical Analysis:

Statistical analysis was performed using IBM SPSS® software v26 and Microsoft Excel. A confidence interval (CI) of 95% was used and, by convention, a p-value <0.05 was deemed statistically significant. Independent samples T-tests were performed to compare the mean differences between patient characteristics, and paired sample T-tests were used to compare the mean differences in patient characteristics before and after their redo-operations. Kaplan-Meier curves for time to redo-operation from day of primary operation were constructed, and survival following initial aortic valve replacement. Differences in time were tested using the log-rank (mantel-cox) method.

3. Results:

3.1 Baseline Patient Characteristics:

A total of 944 patients underwent AVR with Trifecta valves at our institution between October 2011 and October 2020, 590 (62.5%) of whom received the first-generation Trifecta valve, and 354 (37.5%) the Trifecta GT valve for their initial AVR. Of the total cohort of implanted Trifecta valves, 548 (58%) were male and 392 (42%) were female, mean age was 72.82 years ± 8.13 (range 28–91 years), and the mean logistic EuroSCORE II was 8.56 ± 7.53 (range 1.22 – 67.32). Most patients (78%) had LVEF >50% at baseline, 17% had LVEF=31-50%, 4% had LVEF=21-30% and in 1% it was <21%. The primary haemodynamic pathology warranting AVR was aortic stenosis (79%) followed by mixed pathology (16%), and finally aortic regurgitation (5%). Perioperative patient characteristics for the initial procedure are described in Table 1.

3.2 Need for Re-intervention:

Of the 944 patients, 13 (1.4%) required a redo operation after implantation of the Trifecta valves. Of the 590 (62.5%) patients who received the first-generation Trifecta, 11 (1.86%) required re-intervention compared to 2 (0.56%) of the 354 (37.5%) patients who received the Trifecta GT for the initial AVR. Collectively, 5 (38.5%) of all re-intervention patients were male and 8 (61.5%) were female, and the mean age at time of initial procedure was 63.31 years ± 8.66 (range 50 – 78 years), which was significantly lower than those who did not undergo a redo operation after Trifecta implantation (72.95 years ± 8.04), by a mean difference of 9.64 years (2.42 – 14.90, 95% CI), p = 0.002. The mean logistic EuroSCORE II prior to the initial procedure in patients who later required a redo operation was 4.02 ± 2.55 (range 1.51 – 9.46), which was significantly lower than that of patients who did not undergo a redo operation (8.62 ± 7.56, range 1.22 – 67.32), p <0.0005. All patients who required re-intervention had good LVEF >50% at baseline. The mean cross clamp time and bypass time of the initial AVR were not significantly different between patients who required re-intervention and those who did not (p = 0.297 and p = 0.2, respectively). The perioperative characteristics of patients who required a redo operation after Trifecta valve implantation are described in Table 2. Five patients required re-intervention on the same day as their initial trifecta implantation and were excluded from the analysis.

A total of 19 different implant prosthesis models were used for the initial operation, of which the first-generation TF-23A prevailed (23.31%), (*Figure 1)*. However, the implant models that most commonly required redo operation were the first-generation TF-21A and TF-23A model (30.77% each), (*Figure 2)*. The 3300TFX model was most commonly used (30.77%) as the redo Trifecta bioprosthesis. There was no significant difference in the initial prosthetic valve size between patients who did or did not require redo operation (p = 0.976), nor was there a significant difference in the mean prosthetic valve size between the initial and prosthetic valves inserted at the redo-operation (p = 0.151).

In the total cohort of implanted Trifecta valves, 7 patients (0.7%) required re-intervention due to SVD, comprising 53.85% of all re-interventions, and 6 patients (0.6%) required re-intervention

due to infection, comprising 46.15% of all re-interventions. This corresponds to a freedom from re-intervention due to SVD of 99.3%, and a freedom from re-intervention due to infection of 99.4% at 10-years. Specific to the first-generation Trifecta valve, 4 (36.4%) were due to infection, and 7 (63.6%) due to SVD. Both of the Trifecta GT valves that required reintervention were due to infection (n=2, 100%). We did not experience non-calcific leaflet tear in our SVD population which was manifested by progressive calcification and stenosis.

Most initial Trifecta implantations were performed on an elective basis (67%), and by median sternotomy (85.6%), while most redo operations were performed on an urgent basis (84.62%), followed by elective (7.69%), and emergency (7.69%).

3.3 Time to Redo Operation:

The mean time to all-cause re-intervention was 1486.46 days (48.87 months), with a 95% CI between 922.74 (30.33 months) and 2050.18 (67.40 months), (*Figure 3)*. The mean time to re-intervention due to SVD was 2088.71 days: 68.67 months (1681.57–2495.86 days, 55.28–82.06 months, 95% CI) (n = 7), (*Figure 4)*. The mean time to reintervention of the first-generation Trifecta valves was 1740 days (57.2 months), and the mean time to re-intervention for the Trifecta GT was 92 days (3.02 months).

3.4 Patient Survival:

Of the 931 patients who underwent AVR with a Trifecta valve and did not undergo re-intervention, 246 (26.42%) died during the follow up period, giving a 73.58% freedom from mortality from primo AVR. This group had a mean survival of 2500.80 (2418.91 – 2582.68, 95% CI) days or 82.22 (79.53 - 84.91, 95% CI) months.

From the 13 patients who did undergo redo operation, 3 died (23.08%) giving a 76.92% freedom from mortality for the duration of follow up. This group had a mean survival of 2700.88 (2136.30 – 3265.45, 95% CI) days or 88.80 (70.23 - 107.36, 95% CI) months.

There was no statistically significant difference in survival between patients who did require reintervention compared to those who did not require reintervention (p = 0.375), as illustrated in *Figure 5*.

4. Discussion:

In this cross-sectional observational study, we evaluated the perioperative patient characteristics, and re-intervention rates of patients who underwent AVR with the Trifecta bioprosthesis in our centre over a 10-year period.

4.1 Patient Demographics:

Our single-centre sample included one of the largest recorded cohorts of 944 consecutive patients receiving the Trifecta and Trifecta GT valves in similar proportions. The mean baseline age of all patients that later required re-intervention (63.31 years ±8.66, range 50–78), was significantly lower than those who did not require redo operation (72.95 years ± 8.04), by a mean difference of 9.64 years (2.42–14.90, 95% CI), p=0.002. It is recognised that tissue valves deteriorate quicker in younger patients. Patients less than 40-years-old have shown significantly accelerated degeneration rate over 40% at 10-years, compared to 15% in patients aged 60 to 70[13]. In this case, tissue AVR may have been less successful in this group regardless of the valve used, or its performance. Nevertheless, further research is required to elucidate the true causality of this finding.

Overall, from our large sample we can infer that the patient demographics, and thus findings of this study, represent the general population of patients who undergo AVR with bio-prostheses in our region.

4.2 Trifecta Valve Haemodynamic and Durability:

The Trifecta valve has been recognised for its potential to improve haemodynamic performance compared to other similar models[7,14]. However, some reports of early SVD have raised concerns about its durability[11], which may be attributed to its design of bovine pericardial sheet mounted outside the stent frame.

A systematic review and meta-analysis of 2119 patients reporting 6-month median follow-up, comparing first-generation Trifecta valve to Magna Ease valve found that Trifecta valve had an early mean gradient that was lower by a mean difference of 4.09 (3.48 – 4.69 95% CI, $p < 0.0001$) and a greater effective orifice area (EOA) of 0.30 (0.22 – 0.38 95% CI, $p < 0.0001$). However, they found no significant difference in 30-day mortality of patients ($p = 1$). This suggests that Trifecta valve may offer some haemodynamic advantages compared to the Magna Ease valve, with no detriment in survival[15]. Further comparison from the post-market study with the Magna Ease valve showed that baseline characteristics, freedom from SVD, all-cause intervention, all-cause surgical explant, valve-related mortality, and all-cause mortality were comparable[16].

More recent evidence from a 10-year propensity-matched analysis of 2,298 patients receiving Trifecta bio-prosthesis versus 17,281 patients receiving Perimount bioprosthesis reaffirmed that Trifecta valve had superior early haemodynamic performance. However, it was limited by a rapid increase in transvalvular gradient and aortic regurgitation, resulting in a lower freedom from explant of 95.9% versus 98.7% for the Perimount valve at 5-years – further raising concerns regarding the long-term durability of the Trifecta valve[17].

While this study did not evaluate the haemodynamic performance of the Trifecta valve, it would be of clinical interest for future studies to compare the haemodynamic performance of Trifecta valve to other contemporary aortic bio-prostheses.

4.3 Re-intervention and Structural Valve Deterioration:

A redo operation for implantation of a replacement valve is regarded the surgical method of choice for patients with dysfunctional and infected valves[18]. In our cohort, 1.4% of patients required re-intervention, corresponding to a freedom from overall re-intervention of 98.6% at 10-years. Of these re-interventions, 53.85% were attributed to SVD, and 46.15% to infection, giving a 99.3% and 99.4% freedom from re-intervention due to SVD and infection at 10-years, respectively.

The rate of re-intervention in patients who received the first-generation Trifecta valve was more than double that of those who received the Trifecta GT at initial AVR, at 1.86% and 0.56%, respectively. However, with only 2 patients in the trifecta GT re-intervention group, further evidence is required make objective inferences with greater statistical robustness. Moreover, The Trifecta GT valves were naturally implanted at later dates; therefore, the reason for their lower re-intervention rate may be a reflection of the shorter duration of implantation compared to the first-generation Trifecta valves at the point of our data collection. If standardised for time, the true-reintervention rate may differ.

In our study, 5 patients required re-intervention on the same day after their initial Trifecta implantation. However, these were due to possible technical issues at the time of implantation, as opposed to defective or structurally degenerative valves. As such, these patients were not included as those requiring re-intervention in our analysis.

SVD has been recognised as a major complication after aortic valve replacement with bio-prosthesis, with significant impact on survival[19]. Risk factors that have demonstrated association with SVD include female gender, dyslipidaemia, renal failure, chronic obstructive pulmonary disease, and severe patient-prosthesis mismatch[20]. Observational evidence of 617 patients (age 76.1 ± 6.3 years, 54.8% female, follow-up 3.8 ± 2.0 years) undergoing AVR with the Mitroflow valve (Sorin, Milan, Italy) with external leaflet mounting showed an 8.4% 5-year cumulative probability of SVD[19]. A later study of the same valve found that the 4-year and 7-year SVD cumulative incidences were 15.2% and 31.0% respectively, with an associated 2-fold increase in the risk of death[20].

Our data demonstrated similar, if not lower, rates of re-intervention and SVD compared to the findings of previous studies of the Trifecta valve[14,21–23]. A prospective, non-randomized, follow-up study of 710 patients (mean age 72.4 ± 9.3 years, 66.3% male) receiving the Trifecta valve showed a freedom from reoperation due to SVD at 6-years was 97.3% (95% confidence limits, 98.6-94.7)[14]. Similarly, a more recent large single-centre study of 1,953 patients

receiving the Trifecta valve found an overall freedom from re-intervention of 96.4%, and a freedom from SVD of 98.7% at 5-years[21]. Conversely, Werner P et al. reported one of the highest occurrences of SVD in their recent single-centre study of 317 patients undergoing AVR with the Trifecta valve, with 7.2% SVD at a median time to first diagnosis of 73 months, and a freedom from overall mortality at 1, 5 and 7 years of 88.7 ± 1.7%, 73.7 ± 2.6% and 64.7 ± 4.2%, respectively[23]. This was closer to the manufacturers own post-market clinical 10-year follow-up study of 710 patients, which demonstrated a 75% freedom from ViV or surgical explant due to SVD, and an 87% freedom from surgical explant due to SVD[22], which raised concerns that Trifecta valve durability decreases at intermediate to long-term follow-up, leading to considerable rates of re-intervention due to SVD. Despite conflicting evidence, our data suggests that SVD, re-intervention rates associated with the Trifecta valve are comparable to other commonly used bio-prosthesis[15,19]. Future studies should directly compare the performance of the Trifecta valve to other aortic bio-prostheses on a large scale to reinforce this evidence.

The mean time to all-cause re-intervention in our cohort was 48.87 months (30.33 – 67.40 95% CI) and the mean time to re-intervention due to SVD was 68.67 months (55.28 – 82.06, 95% CI). Since the re-intervention in the Trifecta GT valves was due to infection as opposed to SVD, the time to re-intervention was significantly shorter by a mean difference of 1648.00 days, 95% CI 177.59 – 3118.41 (54.2 months, 95% CI 3.87 – 102.52), p = 0.031. Previous studies report early explantation possibly due to imperfect sizing of the valves and technical faults at implantation[2,24], whereas the primary contributing factors for late valve dysfunction include leaflet calcification, fibrous thickening or pannus formation[14]. In our opinion, attention must be exercised to avoid over-sizing and deformation of the titanium stent during implantation, which may result in early altered haemodynamic performance and detriment to durability. Perfect implantation of the valve prosthesis should avoid patient-prosthesis mismatch, prevent coronary artery obstruction, and overall achieve successful short and long term clinical outcomes[24].

We found that the TF-21 and TF-23 valve models most commonly required re-intervention, which may be partly explained by the fact that TF-23 valve model was the most commonly used valve. Furthermore, the inherently higher-pressure gradients that smaller valves are subjected to, due to their smaller EOA may predispose these valves to earlier degeneration. Yet, the TF-19 valve, which is smaller, saw a much lower rate of re-intervention, but this can be accounted for by the considerably lower number of TF-19 valves implanted for the initial AVR. Data from the UK National Registry (N = 43,782) showed freedom from any re-intervention and mortality of 47.2% average at 10-years for the different valve models, suggesting that no single valve was notably better or worse than the others[25]. From our data, we agree that there was no single factor that determined the outcomes of different valve models.

Finally, our study recognised the temporal distribution of initial AVRs with the Trifecta valve, with periods where more valves were implanted than others. Such a phasic increase in implantation may be expected to return a consequent surge of SVD, re-intervention, and valve-related death, with different event rates recordable at different time-points – one of which the cross-sectional nature of this study gives a representation of. Moreover, this surge may present a public health challenge, especially in the older patients that this study represents. Our study showed that most redo operations were performed on an urgent basis, suggesting that re-intervention at our centre was not often planned. As such, it would be favourable to offer close follow-up of these patients with aims to recognise early SVD when patients are still asymptomatic.

4.4 Survival:

In the present cohort, we report a 10-year freedom from mortality of 73.58% in patients who did not require a redo operation, which is comparably lower than previous studies concerning the first-generation Trifecta valve[14,21,22]. Notably, the 10-year freedom from mortality of patients that did require a redo operation was similar at 76.92%. Goldman S et al. reported a freedom from valve-related mortality of 98.3% in 6-years[14], and Kilic A et al. reported a freedom from mortality of 98.6%, 94.1%, and 77.5% at 30 days, 1 year, and 5 years[21], respectively. Most

similarly, the Trifecta post-market study reported one of the lower freedoms from mortality of 70% at 10-years. Notably in our cohort, there was no statistically significant difference in mean survival following primo AVR between patients who did and did not require reintervention.

4.5 Limitations:

While our study is of major clinical relevance, it is not without its limitations. Firstly, the observational nature of data collection and analysis meant that we were unable to rule out any confounding factors, such as age and fragility. Crucially, the need for re-intervention in non-infective valves is a crude surrogate of true incidence of SVD, generating potential selection bias. Undoubtedly, the true incidence of SVD is higher than that reported as some patients with clinically insignificant SVD might not have undergone re-intervention during the period of this observational study. Secondly, our analysis of reintervention was not standardised for the number of procedures carried out at the initial AVR. The majority of patients undergoing initial AVR had an isolated implantation of the Trifecta valve; however, a proportion of our cohort underwent simultaneous operations including coronary artery bypass grafting, mitral or tricuspid valve surgery, ablation surgery, or surgery of the aorta. Moreover, 19 different valve models were implanted, of both the first- and second-generation trifecta valves, which contributes to heterogeneity in our study, potentially reflected in the reintervention rate.

In terms of follow-up, we had limited information on prosthetic size, patient-prosthesis mismatch and echocardiography including gradients and insufficiency. Furthermore, we did not have access to data from patients who may have not been referred back to our centre and may have undergone re-intervention elsewhere. Although this may have highlighted further patients at risk, we suspect this might only be the case in a very small number of patients. Finally, while our maximum follow-up duration was 10-years, the median follow-up was shorter. As such, we may expect more cases of SVD and re-intervention with time.

5. Conclusions:

The Trifecta aortic bioprosthesis claims favourable haemodynamic performance. However, reports of early valve failure have raised concerns regarding its durability. Recognising the limited value of redo intervention as a surrogate for structural valve deterioration, our data shows that the need for re-intervention for the Trifecta aortic bioprosthesis is small, with negligible impact on survival. Nevertheless, continued quality improvement for sizing and implantation of these valves should be encouraged locally, with long-term follow-up of patients to identify potential valve dysfunction early. Ultimately, further research to understand the performance of this bioprosthesis may better guide the choice of implant used in clinical practice.

6. Funding Statement:

No funding was received for this work.

7. Conflicts of Interest:

None declared.

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Legends:

Figure 1: Frequency of Initial Implant Prosthesis Models Used

Figure 2: Frequency of Initial Implant Prosthesis Models That Required Redo Operation

Figure 3: Time to All-Cause Re-intervention: Kaplan Meier Curve

Figure 4: Time to Re-intervention due to SVD: Kaplan Meier Curve

Figure 5: Survival Following Initial Aortic Valve Replacement

Table 1: Perioperative Characteristics of All Patients for Initial Procedure

Table 2: Perioperative Characteristics of Patients Who Underwent Reintervention

Figure 1: Frequency of Initial Implant Prosthesis Models Used

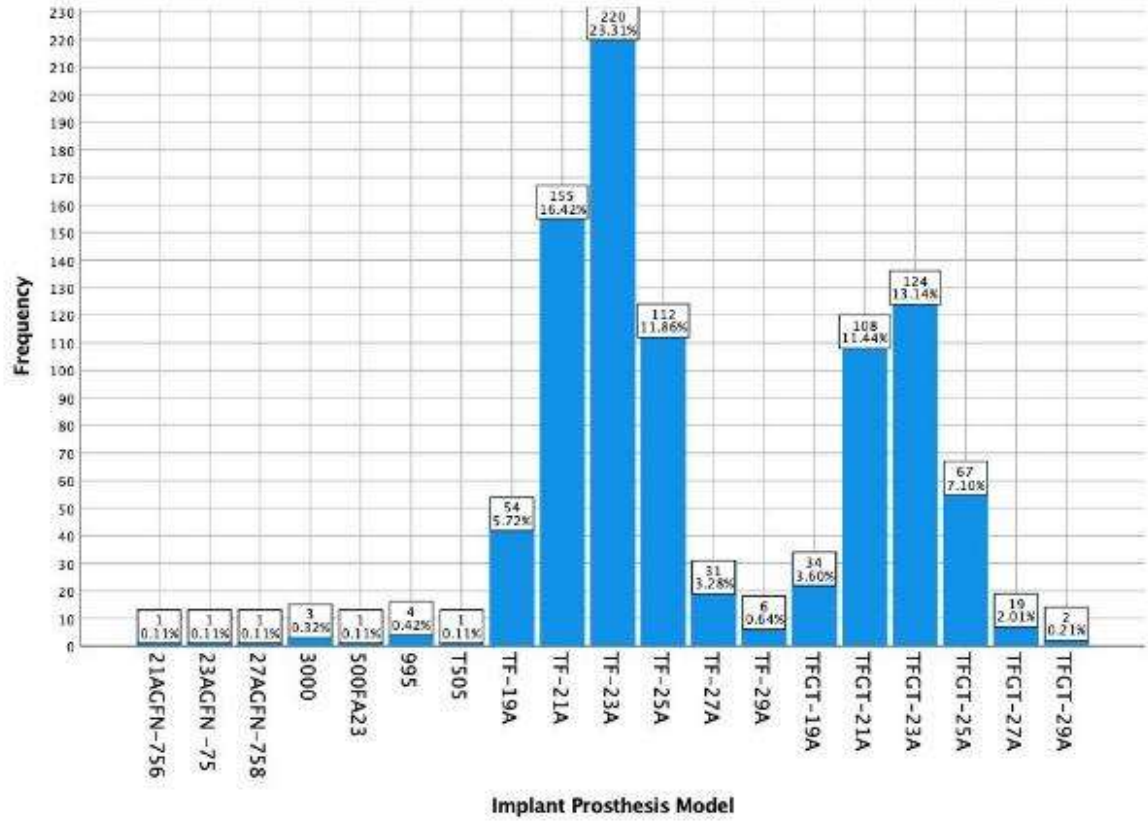
Frequency
Implant Prosthesis Model
21AGFN-756
23AGFN -75
27AGFN-758
3000
500FA23
995
T505
TF-19A
TF-21A
TF-23A
TF-25A
TF-27A
TF-29A
TFGT-19A
TFGT-21A
TFGT-23A
TFGT-25A
TFGT-27A
TFGT-29A
1 0.11%
1 0.11%
1 0.11%
3 0.32%
1 0.11%
4 0.42%
1 0.11%
54 5.72%
155 16.42%
220 23.31%
112 11.86%
31 3.28%
6 0.64%
34 3.60%
108 11.44%
124 13.14%
67 7.10%
19 2.01%
2 0.21%

Figure 2: Frequency of Initial Implant Prosthesis Models That Required Redo Operation

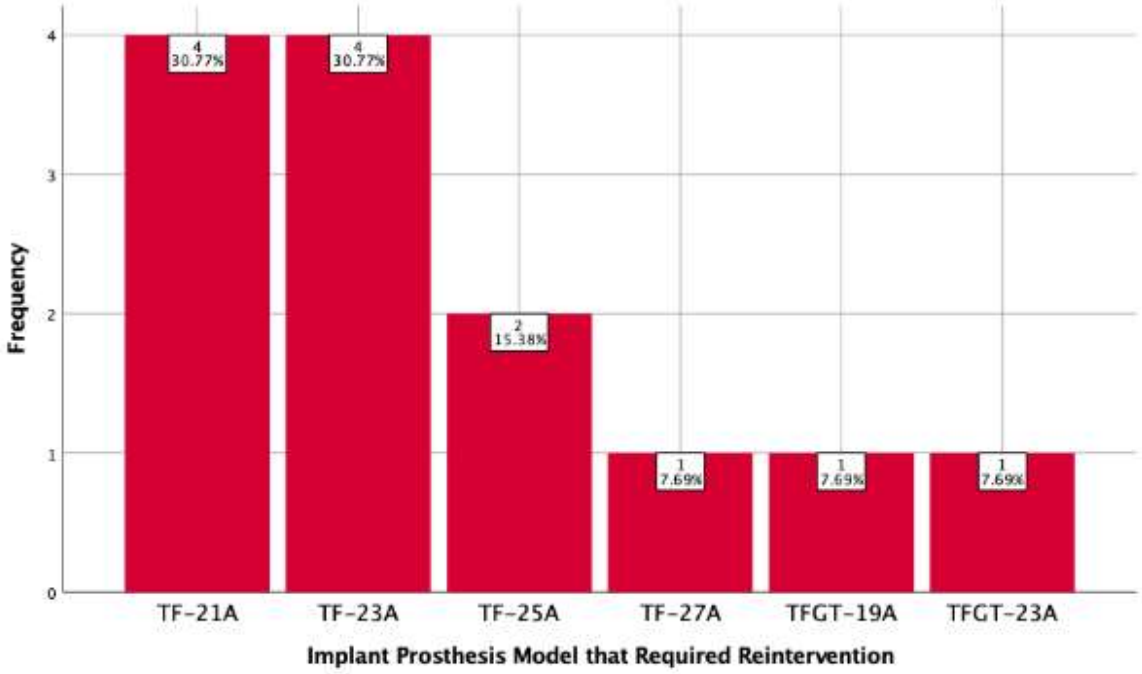

Figure 3: Time to All-Cause Re-intervention: Kaplan Meier Curve

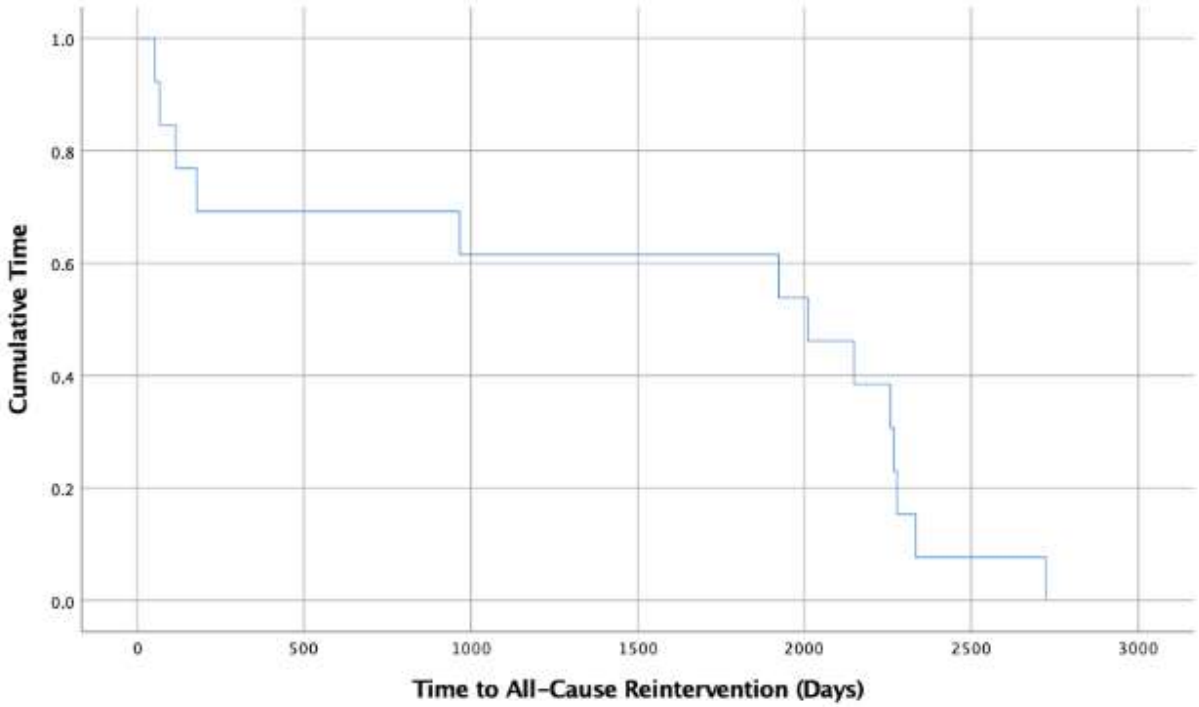

Figure 4: Time to Re-intervention due to SVD: Kaplan Meier Curve

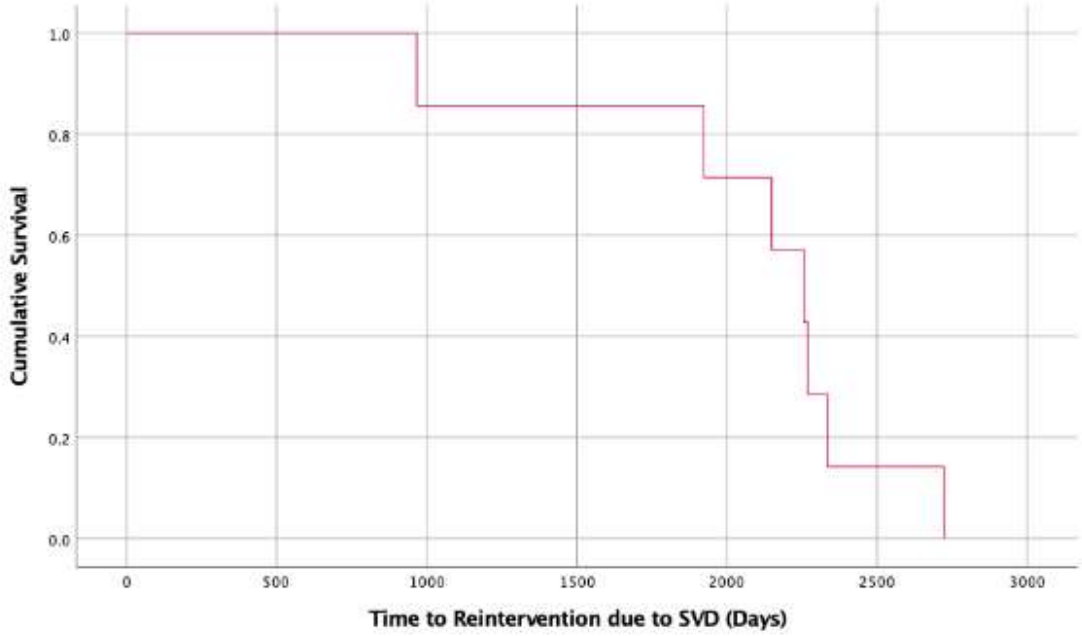

Figure 5: Survival Following Initial Aortic Valve Replacement

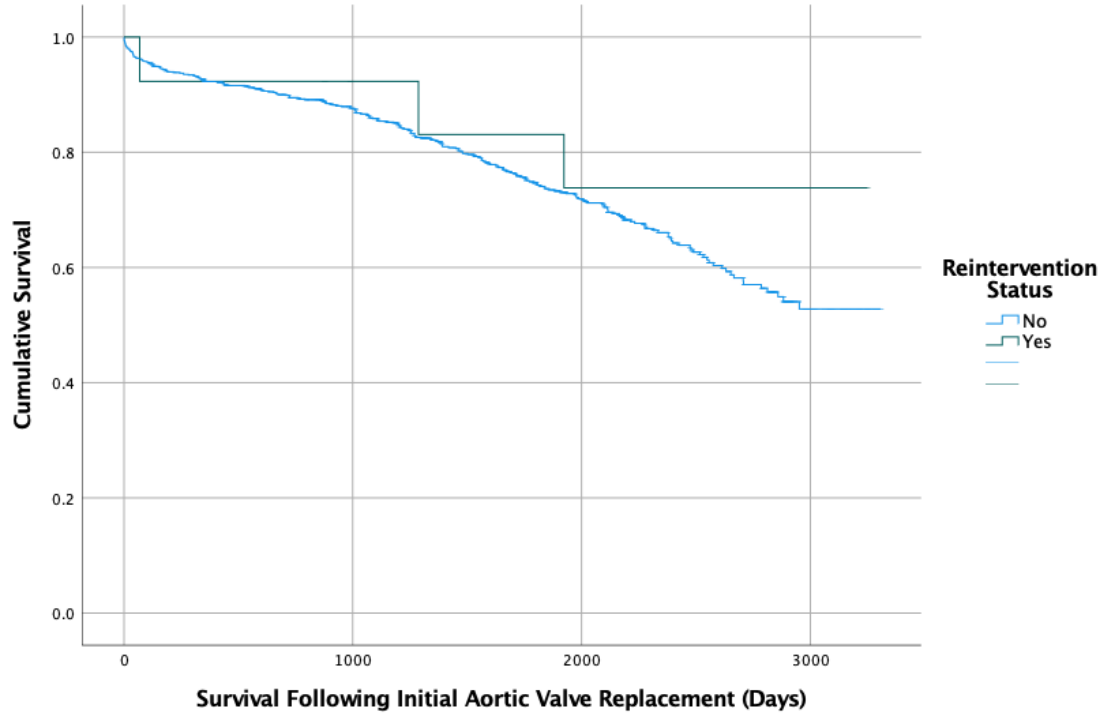

Table 1: Perioperative Characteristics of All Patients for Initial Procedure

Mean Age, years ± SD (range)	72.82 ± 8.13 (28 – 91)
<65	141 (15%)
≥65	803 (85%)
Gender	
Male	548 (58%)
Female	396 (42%)
Mean LogEuroSCORE II ± SD (range)	8.56 ± 7.53 (1.22–67.32)
Valve prior to procedure	
Native Valve	920 (97%)
Biological Valve	20 (2.6%)
Mechanical Valve	4 (0.4%)
Haemodynamic Pathology*	
Stenosis	729 (79%)
Regurgitation	50 (5%)
Mixed	145 (16%)
Degree of Aortic Stenosis**	
Mild	20 (3%)
Moderate	130 (20%)
Severe	495 (77%)
Surgery Priority	
Elective	629 (67%)
Urgent	310 (32.5%)
Emergency	5 (0.5%)
Left Ventricular Function (LVEF)	
Good (>50%)	736 (78%)
Moderate (31-50%)	158 (17%)
Poor (21-30%)	40 (4%)
Very Poor (<21%)	10 (1%)
Mean Valve Size ± SD, mm (range)	23 ± 2 (19–29)
Surgical Incision***	
Median Sternotomy	760 (85.6%)
Median Re-sternotomy	33 (4%)
MIS (J-shaped Sternotomy)	84 (9%)
MIS (Short Right Anterior Thoracotomy)	3 (0.3%)
MIS (Short Lateral Anterior Thoracotomy)	1 (0.1%)
MIS (Superior Median Sternotomy)	13 (1%)
Mean Bypass Time, minutes ± SD (range)****	120.57 ± 51.73 (42–699)
Mean Cross Clamp Time, minutes ± SD (range)*****	90.58 ± 32.51 (19–245)

Comments:
*Haemodynamic Pathology data missing for 20 patients; N = 924
**Degree of Aortic Stenosis data missing for 299 patients; N = 645
***Surgical Incision data missing for 50 patients; N = 894
****Mean Bypass Time data missing for 89 patients; N = 885

*****Mean Cross Clamp Time data missing for 58 patients; N = 886

Table 2: Perioperative Characteristics of Patients Who Underwent Reintervention

Mean Age, years ± SD (range)	63.31 ± 8.66 (50 – 78)
<65	7 (53.8%)
≥65	6 (46.2%)
Gender	
Male	5 (38.5%)
Female	8 (61.5%)
Mean LogEuroSCORE II ± SD (range) at Initial Procedure	4.02 ± 2.55 (1.51 – 9.46)
Mean LogEuroSCORE II ± SD (range) at Redo procedure*	24.61 ± 18.31 (2.08 – 67.32)
Valve prior to initial procedure	
Native Valve	12 (92.3%)
Biological Valve	0 (0%)
Mechanical Valve	1 (7.7%)
Redo Priority	
Elective	1 (7.7%)
Urgent	11 (84.6%)
Emergency	1 (7.7%)
Haemodynamic Pathology Prior to Initial procedure**	
Stenosis	8 (66.67%)
Regurgitation	1 (8.33%)
Mixed	3 (25.00%)
Degree of Aortic Stenosis***	
Mild	0 (0%)
Moderate	5 (62.5%)
Severe	3 (37.5%)
Left Ventricular Function (LVEF)	
Good (>50%)	13 (100%)
Moderate (31-50%)	0 (0%)
Poor (21-30%)	0 (0%)
Very Poor (<21%)	0 (0%)
Mean Valve Size ± SD, mm (range) of Initial procedure	22.69 ± 2.14 (19 – 27)
Mean Valve Size ± SD, mm (range) of redo procedure	21.46 ± 2.18 (19 – 27)
Mean Bypass Time, minutes ± SD (range) at initial procedure	102.31 ± 31.01 (57 – 168)
Mean Cross Clamp Time, minutes ± SD at initial procedure (range)	81.23 ± 27.12 (36 – 139)

Comments:
*Redo Log EuroSCORE data missing for 1 patients; N = 12
**Haemodynamic Pathology Prior to Initial procedure data missing for 1 patients; N = 12
***Degree of aortic stenosis data missing for 5 patients; N = 8